

Table 14.1.1.1: Overall subject accounting

Category	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=139)
Subjects enrolled [1]	N (%)	-	-	-	139 (100)
Screen failure	N (%)	-	-	-	19 (13.7)
Subjects randomized	N (%)	58 (100)	37 (100)	25 (100)	120 (100)
Center 01	N (%)	23 (39.7)	16 (43.2)	7 (28.0)	46 (38.3)
Center 02	N (%)	10 (17.2)	8 (21.6)	3 (12.0)	21 (17.5)
Center 04	N (%)	0	0	1 (4.0)	1 (0.8)
Center 06	N (%)	7 (12.1)	4 (10.8)	4 (16.0)	15 (12.5)
Center 07	N (%)	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Center 08	N (%)	4 (6.9)	2 (5.4)	2 (8.0)	8 (6.7)
Center 09	N (%)	6 (10.3)	4 (10.8)	4 (16.0)	14 (11.7)
Center 11	N (%)	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Center 12	N (%)	1 (1.7)	0	0	1 (0.8)
Center 13	N (%)	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Subjects in Safety Set [2]	N (%)	58 (100)	37 (100)	25 (100)	120 (100)
Subjects in Full Analysis Set [3]	N (%)	47 (81.0)	27 (73.0)	24 (96.0)	98 (81.7)

SC = Standard Care

[1] Enrolled Set = all subjects enrolled into the study, i.e. gave their Informed Consent

[2] Safety Set = all randomized subjects who received surgery with sequestrectomy for tissue explants

[3] Full Analysis Set = all subjects randomized who underwent surgery with at least one primary efficacy assessment after surgery/implantation

Table 14.1.1.2: Subjects disposition - safety set

Category	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
VISIT 1	N (%)	58 (100)	37 (100)	25 (100)	120 (100)
VISIT 2A	N (%)	57 (98.3)	37 (100)	24 (96.0)	118 (98.3)
VISIT 2B	N (%)	58 (100)	37 (100)	25 (100)	120 (100)
VISIT 3A	N (%)	50 (86.2)	28 (75.7)	0	78 (65.0)
VISIT 3B	N (%)	48 (82.8)	28 (75.7)	0	76 (63.3)
VISIT 4	N (%)	47 (81.0)	27 (73.0)	24 (96.0)	98 (81.7)
VISIT 5	N (%)	46 (79.3)	27 (73.0)	23 (92.0)	96 (80.0)
VISIT 6	N (%)	46 (79.3)	26 (70.3)	23 (92.0)	95 (79.2)
VISIT 7	N (%)	46 (79.3)	26 (70.3)	21 (84.0)	93 (77.5)
VISIT 8	N (%)	44 (75.9)	26 (70.3)	22 (88.0)	92 (76.7)
VISIT 9	N (%)	43 (74.1)	26 (70.3)	21 (84.0)	90 (75.0)
VISIT 10	N (%)	41 (70.7)	26 (70.3)	22 (88.0)	89 (74.2)
VISIT 11	N (%)	41 (70.7)	27 (73.0)	22 (88.0)	90 (75.0)
UNSCHEDULED	N (%)	24 (41.4)	13 (35.1)	5 (20.0)	42 (35.0)
Subjects who discontinued the study prematurely (and reason)	N (%)	17 (29.3)	11 (29.7)	4 (16.0)	32 (26.7)
within 90 days after sequestrectomy (before Visit 3b/Visit 5*)	N (%)	10 (17.2)	9 (24.3)	2 (8.0)	21 (17.5)
after 90 days after sequestrectomy (after Visit 3b/Visit 5*)	N (%)	7 (12.1)	2 (5.4)	2 (8.0)	11 (9.2)
Inclusion/Exclusion criteria not met	N (%)	3 (5.2)	3 (8.1)	1 (4.0)	7 (5.8)
Lack of compliance	N (%)	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Loss of interest for participation	N (%)	1 (1.7)	0	0	1 (0.8)
Other reason: COVID-INFECTION / NO FINAL VISIT /LFU	N (%)	0	0	1 (4.0)	1 (0.8)
Other reason: Insecurity after introperative complication.	N (%)	1 (1.7)	0	0	1 (0.8)
Other reason: MRSA contamination, nose	N (%)	1 (1.7)	0	0	1 (0.8)
Other reason: Pat moved to Styria, doesn't want to participate in V11 in Innsbruck	N (%)	1 (1.7)	0	0	1 (0.8)
Other reason: Patient Decision	N (%)	0	1 (2.7)	0	1 (0.8)
Other reason: Subject doesn't want to take risk for another surgical treatment due to currently good health status	N (%)	0	1 (2.7)	0	1 (0.8)
Other reason: Time consuming work as farmer	N (%)	0	1 (2.7)	0	1 (0.8)
Other reason: lost to follow-up	N (%)	1 (1.7)	0	0	1 (0.8)
Other reason: lost to follow-up at V11	N (%)	1 (1.7)	0	0	1 (0.8)
Withdrawal of clinical trial subject's consent	N (%)	5 (8.6)	4 (10.8)	1 (4.0)	10 (8.3)

SC = Standard Care

*90 days after sequestrectomy is Visit 3b for patients of the NDplus and NDbasic group and Visit 5 for patients of the SC group.

Visit 11 = End of Trial

Table 14.1.2.1: Demographics - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Sex					
Male	N (%)	31 (53.4)	23 (62.2)	18 (72.0)	72 (60.0)
Female	N (%)	27 (46.6)	14 (37.8)	7 (28.0)	48 (40.0)
Age [years]					
	N with data	58	37	25	120
	Mean	42.5	40.4	41.7	41.7
	SD	10.26	11.35	10.15	10.54
	Min	21	22	25	21
	25% quantile	33.0	29.0	35.0	32.0
	Median	45.5	45.0	41.0	44.5
	75% quantile	51.0	50.0	50.0	50.5
	Max	59	58	58	59
Weight [kg] at Visit 2a (Baseline)					
	N with data	53	34	24	111
	N missing	5	3	1	9
	Mean	77.4	79.8	80.9	78.9
	SD	14.45	12.55	13.07	13.56
	Min	50	58	49	49
	25% quantile	67.0	71.0	72.5	70.0
	Median	75.0	78.0	82.0	78.0
	75% quantile	86.0	90.0	85.5	87.0
	Max	115	109	110	115
Height [cm] at Visit 2a (Baseline)					
	N with data	53	35	24	112
	N missing	5	2	1	8
	Mean	176.4	177.9	177.0	177.0
	SD	9.73	9.73	9.51	9.62
	Min	158	157	158	157
	25% quantile	169.0	170.0	171.0	170.0
	Median	176.0	178.0	178.5	177.5
	75% quantile	184.0	188.0	185.0	185.0
	Max	198	193	191	198

SC = Standard Care

BMI = Body Mass Index

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Table 14.1.2.1: Demographics - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
BMI [kg/m**2] at Visit 2a (Baseline)					
	N with data	53	34	24	111
	N missing	5	3	1	9
	Mean	24.7	25.1	25.9	25.1
	SD	3.10	2.84	4.24	3.31
	Min	18	19	19	18
	25% quantile	22.9	23.0	23.6	22.9
	Median	24.9	25.2	25.1	24.9
	75% quantile	26.9	27.7	28.7	27.2
	Max	33	30	35	35
Race					
White	N (%)	58 (100)	37 (100)	25 (100)	120 (100)
American Indian or Alaska Native	N (%)	0	0	0	0
Asian	N (%)	0	0	0	0
Native Hawaiian or Other Pacific Islander	N (%)	0	0	0	0
Black or African American	N (%)	0	0	0	0
Other	N (%)	0	0	0	0
Ethnic group: Hispanic or Latino?					
No	N (%)	57 (98.3)	37 (100)	25 (100)	119 (99.2)
Yes	N (%)	1 (1.7)	0	0	1 (0.8)

SC = Standard Care

BMI = Body Mass Index

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Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Baseline					
Tobacco use					
No	N (%)	36 (62.1)	24 (64.9)	16 (64.0)	76 (63.3)
Yes	N (%)	22 (37.9)	12 (32.4)	9 (36.0)	43 (35.8)
Missing	N (%)	0	1 (2.7)	0	1 (0.8)
Number of cigarettes per day					
	N with data	21	11	9	41
	Mean	13.0	10.2	11.9	12.0
	SD	5.82	5.69	5.04	5.62
	Min	3	2	5	2
	25% quantile	10.0	6.0	10.0	8.0
	Median	12.0	10.0	10.0	10.0
	75% quantile	20.0	12.0	15.0	19.0
	Max	20	20	20	20
Number of pipes per day					
	N with data	1	-	-	1
	Mean	1.0	-	-	1.0
	SD	-	-	-	-
	Min	1	-	-	1
	25% quantile	1.0	-	-	1.0
	Median	1.0	-	-	1.0
	75% quantile	1.0	-	-	1.0
	Max	1	-	-	1
Number of other tobacco substances per day					
	N with data	-	1	-	1
	Mean	-	1.0	-	1.0
	SD	-	-	-	-
	Min	-	1	-	1
	25% quantile	-	1.0	-	1.0
	Median	-	1.0	-	1.0
	75% quantile	-	1.0	-	1.0
	Max	-	1	-	1

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

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Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 3a*					
Tobacco use					
No	N (%)	31 (53.4)	18 (48.6)	0	49 (40.8)
Yes	N (%)	19 (32.8)	10 (27.0)	0	29 (24.2)
Missing	N (%)	8 (13.8)	9 (24.3)	25 (100)	42 (35.0)
Number of cigarettes per day					
	N with data	19	9	-	28
	Mean	13.7	9.8	-	12.5
	SD	5.62	5.91	-	5.91
	Min	3	2	-	2
	25% quantile	10.0	5.0	-	10.0
	Median	12.0	10.0	-	10.0
	75% quantile	20.0	15.0	-	17.5
	Max	25	20	-	25
Number of other tobacco substances per day					
	N with data	-	1	-	1
	Mean	-	1.0	-	1.0
	SD	-	-	-	-
	Min	-	1	-	1
	25% quantile	-	1.0	-	1.0
	Median	-	1.0	-	1.0
	75% quantile	-	1.0	-	1.0
	Max	-	1	-	1

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

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Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 4					
Tobacco use					
No	N (%)	31 (53.4)	18 (48.6)	16 (64.0)	65 (54.2)
Yes	N (%)	15 (25.9)	9 (24.3)	8 (32.0)	32 (26.7)
Missing	N (%)	12 (20.7)	10 (27.0)	1 (4.0)	23 (19.2)
Number of cigarettes per day					
	N with data	15	8	8	31
	Mean	13.6	9.9	10.9	11.9
	SD	5.67	4.94	4.29	5.27
	Min	4	2	5	2
	25% quantile	10.0	6.0	9.0	10.0
	Median	10.0	10.0	10.0	10.0
	75% quantile	20.0	15.0	12.5	15.0
	Max	20	15	19	20
Number of other tobacco substances per day					
	N with data	-	1	-	1
	Mean	-	1.0	-	1.0
	SD	-	-	-	-
	Min	-	1	-	1
	25% quantile	-	1.0	-	1.0
	Median	-	1.0	-	1.0
	75% quantile	-	1.0	-	1.0
	Max	-	1	-	1

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

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Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 5					
Tobacco use					
No	N (%)	30 (51.7)	19 (51.4)	15 (60.0)	64 (53.3)
Yes	N (%)	16 (27.6)	8 (21.6)	8 (32.0)	32 (26.7)
Missing	N (%)	12 (20.7)	10 (27.0)	2 (8.0)	24 (20.0)
Number of cigarettes per day					
	N with data	16	8	8	32
	Mean	13.9	10.9	9.9	12.1
	SD	6.05	5.36	4.76	5.71
	Min	4	5	4	4
	25% quantile	10.0	6.0	6.0	7.5
	Median	12.5	10.0	10.0	10.0
	75% quantile	20.0	15.0	12.5	19.0
	Max	20	20	18	20

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

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Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 6					
Tobacco use					
No	N (%)	31 (53.4)	18 (48.6)	14 (56.0)	63 (52.5)
Yes	N (%)	15 (25.9)	8 (21.6)	9 (36.0)	32 (26.7)
Missing	N (%)	12 (20.7)	11 (29.7)	2 (8.0)	25 (20.8)
Number of cigarettes per day					
	N with data	15	8	9	32
	Mean	11.5	12.1	8.1	10.7
	SD	5.25	5.62	4.46	5.24
	Min	3	6	3	3
	25% quantile	10.0	8.0	4.0	7.0
	Median	10.0	10.0	10.0	10.0
	75% quantile	15.0	17.5	10.0	14.0
	Max	20	20	15	20

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

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Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 7					
Tobacco use					
No	N (%)	30 (51.7)	17 (45.9)	14 (56.0)	61 (50.8)
Yes	N (%)	16 (27.6)	9 (24.3)	7 (28.0)	32 (26.7)
Missing	N (%)	12 (20.7)	11 (29.7)	4 (16.0)	27 (22.5)
Number of cigarettes per day					
	N with data	16	9	7	32
	Mean	11.9	10.8	9.1	11.0
	SD	5.74	5.02	6.89	5.73
	Min	1	5	3	1
	25% quantile	10.0	6.0	4.0	7.0
	Median	10.0	10.0	10.0	10.0
	75% quantile	17.5	15.0	10.0	15.0
	Max	20	20	23	23

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

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Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 8					
Tobacco use					
No	N (%)	30 (51.7)	18 (48.6)	14 (56.0)	62 (51.7)
Yes	N (%)	13 (22.4)	8 (21.6)	8 (32.0)	29 (24.2)
Missing	N (%)	15 (25.9)	11 (29.7)	3 (12.0)	29 (24.2)
Number of cigarettes per day					
	N with data	13	8	8	29
	Mean	14.5	7.5	8.6	10.9
	SD	5.36	4.17	6.32	6.11
	Min	8	1	4	1
	25% quantile	10.0	5.5	4.0	7.0
	Median	10.0	6.5	7.0	10.0
	75% quantile	20.0	10.0	10.0	15.0
	Max	20	15	23	23

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

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Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 9					
Tobacco use					
No	N (%)	32 (55.2)	18 (48.6)	14 (56.0)	64 (53.3)
Yes	N (%)	11 (19.0)	8 (21.6)	7 (28.0)	26 (21.7)
Missing	N (%)	15 (25.9)	11 (29.7)	4 (16.0)	30 (25.0)
Number of cigarettes per day					
	N with data	11	8	7	26
	Mean	14.5	9.0	9.9	11.6
	SD	5.30	3.25	6.49	5.58
	Min	8	5	4	4
	25% quantile	10.0	6.0	4.0	8.0
	Median	12.0	10.0	8.0	10.0
	75% quantile	20.0	10.0	12.0	15.0
	Max	20	15	23	23

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

Clinipace: 14DEC21 / 7:38 / demo2.lst / demo2.sas

Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 10					
Tobacco use					
No	N (%)	30 (51.7)	18 (48.6)	14 (56.0)	62 (51.7)
Yes	N (%)	11 (19.0)	8 (21.6)	8 (32.0)	27 (22.5)
Missing	N (%)	17 (29.3)	11 (29.7)	3 (12.0)	31 (25.8)
Number of cigarettes per day					
	N with data	11	8	8	27
	Mean	13.7	9.5	9.9	11.3
	SD	6.17	3.02	6.73	5.78
	Min	5	5	4	4
	25% quantile	8.0	8.0	4.0	8.0
	Median	10.0	10.0	9.0	10.0
	75% quantile	20.0	10.0	13.0	16.0
	Max	20	15	23	23

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

Clinipace: 14DEC21 / 7:38 / demo2.lst / demo2.sas

Table 14.1.2.2: Tobacco Use - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
End of Trial					
Tobacco use					
No	N (%)	29 (50.0)	20 (54.1)	14 (56.0)	63 (52.5)
Yes	N (%)	12 (20.7)	7 (18.9)	7 (28.0)	26 (21.7)
Missing	N (%)	17 (29.3)	10 (27.0)	4 (16.0)	31 (25.8)
Number of cigarettes per day					
	N with data	12	7	7	26
	Mean	12.8	10.1	10.0	11.3
	SD	6.15	3.89	7.14	5.86
	Min	3	5	4	3
	25% quantile	9.0	6.0	4.0	6.0
	Median	11.0	10.0	8.0	10.0
	75% quantile	20.0	15.0	16.0	15.0
	Max	20	15	23	23

SC = Standard Care

* Visit 3a applicable for subjects in NDplus and NDbasic only.

Clinipace: 14DEC21 / 7:38 / demo2.lst / demo2.sas

Table 14.1.2.3: Employment during healthy status - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Work Status					
Working fulltime	N (%)	42 (72.4)	28 (75.7)	17 (68.0)	87 (72.5)
Working part-time	N (%)	11 (19.0)	7 (18.9)	5 (20.0)	23 (19.2)
Unemployed	N (%)	3 (5.2)	0	2 (8.0)	5 (4.2)
Not employed (e.g. homemaker, student)	N (%)	2 (3.4)	2 (5.4)	1 (4.0)	5 (4.2)
Retired	N (%)	0	0	0	0

Table 14.1.2.4: Anamnesis - location and presence of adjacent degenerated disc - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Type of degenerative lumbar disc disease					
Presence of adjacent degenerative disc	N (%)	11 (19.0)	10 (27.0)	2 (8.0)	23 (19.2)
Absence of adjacent degenerative disc	N (%)	47 (81.0)	27 (73.0)	23 (92.0)	97 (80.8)
Location1 (herniated disc, HD+ADD patients)					
	N (%)	58 (100)	37 (100)	25 (100)	120 (100)
between vertebra L2 and L3	N (%)	1 (1.7)	1 (2.7)	0	2 (1.7)
between vertebra L3 and L4	N (%)	4 (6.9)	0	4 (16.0)	8 (6.7)
between vertebra L4 and L5	N (%)	20 (34.5)	13 (35.1)	6 (24.0)	39 (32.5)
between vertebra L5 and S1	N (%)	33 (56.9)	23 (62.2)	15 (60.0)	71 (59.2)
Location 1 and 2 (herniated and adjacent disc, ADD patients)					
	N (%)	11 (100)	10 (100)	2 (100)	23 (100)
between L4/L5 and L3/L4	N (%)	2 (18.2)	2 (20.0)	0	4 (17.4)
between L4/L5 and L5/S1	N (%)	2 (18.2)	0	0	2 (8.7)
between L5/S1 and L4/L5	N (%)	7 (63.6)	7 (70.0)	2 (100)	16 (69.6)
missing	N (%)	0	1 (10.0)	0	1 (4.3)
Time since start of complaint (days)					
	N with data	46	25	25	96
	N missing	12	12	0	24
	Mean	97.5	130.3	125.6	113.3
	SD	96.12	150.80	198.03	142.36
	Min	6	6	3	3
	Q1	22.0	46.0	13.0	22.5
	Median	66.0	98.0	61.0	68.5
	Q3	145.0	134.0	185.0	149.5
	Max	381	589	955	955

Table 14.1.2.5: Relevant medical history during the last year - safety set

Primary System Organ Class Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Subjects with relevant medical history during the last year	30 (51.7)	18 (48.6)	9 (36.0)	57 (47.5)
Cardiac disorders	3 (5.2)	0	0	3 (2.5)
Arrhythmia	1 (1.7)	0	0	1 (0.8)
Coronary artery disease	1 (1.7)	0	0	1 (0.8)
Tachycardia	1 (1.7)	0	0	1 (0.8)
Congenital, familial and genetic disorders	0	1 (2.7)	0	1 (0.8)
Urea cycle disorder	0	1 (2.7)	0	1 (0.8)
Endocrine disorders	6 (10.3)	4 (10.8)	1 (4.0)	11 (9.2)
Hypothyroidism	6 (10.3)	4 (10.8)	1 (4.0)	11 (9.2)
Gastrointestinal disorders	3 (5.2)	0	0	3 (2.5)
Dyspepsia	1 (1.7)	0	0	1 (0.8)
Large intestine polyp	1 (1.7)	0	0	1 (0.8)
Nausea	1 (1.7)	0	0	1 (0.8)
Immune system disorders	3 (5.2)	5 (13.5)	0	8 (6.7)
Drug hypersensitivity	1 (1.7)	1 (2.7)	0	2 (1.7)
Food allergy	1 (1.7)	0	0	1 (0.8)
Seasonal allergy	1 (1.7)	4 (10.8)	0	5 (4.2)
Infections and infestations	2 (3.4)	2 (5.4)	0	4 (3.3)
Appendicitis	0	1 (2.7)	0	1 (0.8)
Conjunctivitis	0	1 (2.7)	0	1 (0.8)
Pharyngitis	1 (1.7)	0	0	1 (0.8)
Pneumonia	1 (1.7)	0	0	1 (0.8)
Metabolism and nutrition disorders	2 (3.4)	3 (8.1)	0	5 (4.2)
Fructose intolerance	0	1 (2.7)	0	1 (0.8)
Hypercholesterolaemia	2 (3.4)	1 (2.7)	0	3 (2.5)
Lipid metabolism disorder	0	1 (2.7)	0	1 (0.8)
Musculoskeletal and connective tissue disorders	1 (1.7)	1 (2.7)	2 (8.0)	4 (3.3)
Back pain	1 (1.7)	0	1 (4.0)	2 (1.7)
Fibromyalgia	0	0	1 (4.0)	1 (0.8)
Osteoarthritis	0	1 (2.7)	0	1 (0.8)

SC = Standard Care

Table 14.1.2.5: Relevant medical history during the last year - safety set

Primary System Organ Class Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Nervous system disorders	1 (1.7)	3 (8.1)	2 (8.0)	6 (5.0)
Headache	0	1 (2.7)	0	1 (0.8)
Migraine	1 (1.7)	1 (2.7)	0	2 (1.7)
Neuralgia	0	0	1 (4.0)	1 (0.8)
Sciatica	0	1 (2.7)	1 (4.0)	2 (1.7)
Psychiatric disorders	5 (8.6)	2 (5.4)	5 (20.0)	12 (10.0)
Anxiety	0	1 (2.7)	0	1 (0.8)
Anxiety disorder	1 (1.7)	0	0	1 (0.8)
Claustrophobia	1 (1.7)	0	0	1 (0.8)
Depression	3 (5.2)	1 (2.7)	4 (16.0)	8 (6.7)
Insomnia	0	0	1 (4.0)	1 (0.8)
Sleep disorder	0	0	1 (4.0)	1 (0.8)
Reproductive system and breast disorders	1 (1.7)	0	1 (4.0)	2 (1.7)
Gynaecomastia	1 (1.7)	0	0	1 (0.8)
Menopausal symptoms	0	0	1 (4.0)	1 (0.8)
Respiratory, thoracic and mediastinal disorders	5 (8.6)	2 (5.4)	1 (4.0)	8 (6.7)
Asthma	5 (8.6)	1 (2.7)	1 (4.0)	7 (5.8)
Respiratory disorder	0	1 (2.7)	0	1 (0.8)
Social circumstances	1 (1.7)	0	0	1 (0.8)
Postmenopause	1 (1.7)	0	0	1 (0.8)
Surgical and medical procedures	3 (5.2)	0	1 (4.0)	4 (3.3)
Nerve block	0	0	1 (4.0)	1 (0.8)
Sterilisation	1 (1.7)	0	0	1 (0.8)
Thyroidectomy	1 (1.7)	0	0	1 (0.8)
Tooth extraction	1 (1.7)	0	0	1 (0.8)
Vascular disorders	11 (19.0)	3 (8.1)	4 (16.0)	18 (15.0)
Arteriosclerosis	1 (1.7)	0	0	1 (0.8)
Hypertension	11 (19.0)	3 (8.1)	4 (16.0)	18 (15.0)

Table 14.1.2.6: Relevant surgical history (except lumbar spinal history) - safety set

Primary System Organ Class Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Subjects with relevant surgical history (except lumbar spinal history) during the last year	6 (10.3)	3 (8.1)	4 (16.0)	13 (10.8)
Injury, poisoning and procedural complications	0	0	1 (4.0)	1 (0.8)
Jaw fracture	0	0	1 (4.0)	1 (0.8)
Investigations	1 (1.7)	0	1 (4.0)	2 (1.7)
Arthroscopy	0	0	1 (4.0)	1 (0.8)
Laparoscopy	1 (1.7)	0	0	1 (0.8)
Musculoskeletal and connective tissue disorders	0	1 (2.7)	0	1 (0.8)
Rotator cuff syndrome	0	1 (2.7)	0	1 (0.8)
Surgical and medical procedures	5 (8.6)	2 (5.4)	2 (8.0)	9 (7.5)
Abscess drainage	1 (1.7)	0	0	1 (0.8)
Appendicectomy	0	1 (2.7)	0	1 (0.8)
Cholecystectomy	0	1 (2.7)	0	1 (0.8)
Dental implantation	1 (1.7)	0	1 (4.0)	2 (1.7)
Infiltration anaesthesia	0	0	1 (4.0)	1 (0.8)
Mastectomy	1 (1.7)	0	0	1 (0.8)
Meniscus operation	1 (1.7)	0	0	1 (0.8)
Polypectomy	1 (1.7)	0	0	1 (0.8)

Table 14.1.3.1: Feasibility of surgery and tissue explant (Visit 2b) - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Was practicability of surgical instruments acceptable?					
No	N (%)	0	0	0	0
Yes	N (%)	58 (100)	37 (100)	25 (100)	120 (100)
Amount of tissue (g)					
	N with data	57	36	25	118
	N missing	1	1	0	2
	Mean	1.7434	2.0401	1.9311	1.8737
	SD	1.43100	1.50317	1.03508	1.37597
	Min	0.043	0.361	0.001	0.001
	25% quantile	0.7200	1.0080	1.1410	0.9060
	Median	1.4440	1.3405	1.9760	1.5970
	75% quantile	2.5240	2.4380	2.3400	2.5130
	Max	7.541	6.820	4.330	7.541
Type of anulus defect [1]					
Number of patients in phase II	N (%)	46 (100)	25 (100)	25 (100)	96 (100)
Slit	N (%)	24 (52.2)	8 (32.0)	12 (48.0)	44 (45.8)
Torn	N (%)	10 (21.7)	5 (20.0)	5 (20.0)	20 (20.8)
Total defect (hole)	N (%)	11 (23.9)	10 (40.0)	8 (32.0)	29 (30.2)
NA	N (%)	1 (2.2)	1 (4.0)	0	2 (2.1)
UNK	N (%)	0	1 (4.0)	0	1 (1.0)
Size of anulus defect [1]					
Number of patients in phase II	N (%)	46 (100)	25 (100)	25 (100)	96 (100)
0 to 3 mm	N (%)	22 (47.8)	10 (40.0)	11 (44.0)	43 (44.8)
3 to 6 mm	N (%)	20 (43.5)	9 (36.0)	11 (44.0)	40 (41.7)
> 6 mm	N (%)	4 (8.7)	5 (20.0)	3 (12.0)	12 (12.5)
NA	N (%)	0	0	0	0
UNK	N (%)	0	1 (4.0)	0	1 (1.0)
Description of removed sequester/tissue*					
Tight fitting sequester	N (%)	12 (20.7)	11 (29.7)	9 (36.0)	32 (26.7)
Loose sequester	N (%)	37 (63.8)	20 (54.1)	8 (32.0)	65 (54.2)
Fibrousness tissue	N (%)	7 (12.1)	3 (8.1)	4 (16.0)	14 (11.7)
Compact tissue	N (%)	24 (41.4)	13 (35.1)	9 (36.0)	46 (38.3)
Other	N (%)	0	1 (2.7)	1 (4.0)	2 (1.7)

SC = Standard Care

[1] Information was only captured in phase II of the study

NA = Not applicable, UNK = Unknown

* Multiple entries possible

Table 14.1.3.1: Feasibility of surgery and tissue explant (Visit 2b) - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Length of procedure (min)					
	N with data	58	37	25	120
	Mean	63.0	59.9	70.3	63.5
	SD	25.22	27.65	35.53	28.37
	Min	26	15	33	15
	25% quantile	48.0	40.0	49.0	45.0
	Median	60.0	50.0	63.0	60.0
	75% quantile	70.0	73.0	77.0	75.0
	Max	157	140	209	209
Postoperative length of hospitalization (days)					
	N with data	57	37	25	119
	N missing	1	0	0	1
	Mean	8.4	7.0	7.6	7.8
	SD	2.91	2.15	2.55	2.67
	Min	5	4	4	4
	25% quantile	7.0	5.0	6.0	6.0
	Median	8.0	7.0	7.0	7.0
	75% quantile	9.0	8.0	9.0	9.0
	Max	21	14	14	21

SC = Standard Care

[1] Information was only captured in phase II of the study

NA = Not applicable, UNK = Unknown

* Multiple entries possible

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Table 14.1.3.2: Feasibility of transplantation (Visit 3b) - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	Overall (N=95)
Number of patients with ADD				
Treated only in herniated disc	N (%)	0	1 (2.7)	1 (1.1)
Treated in both discs	N (%)	11 (19.0)	9 (24.3)	20 (21.1)
Length of procedure (min) for ADD patients				
	N with data	9	5	14
	N missing	2	5	7
	Mean	31.6	21.4	27.9
	SD	15.27	4.62	13.25
	Min	16	15	15
	25% quantile	25.0	18.0	22.0
	Median	26.0	24.0	25.0
	75% quantile	35.0	25.0	30.0
	Max	69	25	69
Length of procedure (min) for HD patients				
	N with data	38	22	60
	N missing	9	5	14
	Mean	21.0	23.3	21.9
	SD	11.58	13.05	12.08
	Min	10	10	10
	25% quantile	15.0	15.0	15.0
	Median	17.5	19.5	18.0
	75% quantile	22.0	28.0	24.0
	Max	60	70	70

Only subjects who received surgical transplant/implant are included.

HD = absence of adjacent degenerated disc, ADD = presence of adjacent degenerated disc

Table 14.1.3.2: Feasibility of transplantation (Visit 3b) - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	Overall (N=95)
Volume of injection (mL) herniated disc (HD and ADD patients)				
	N with data	47	27	74
	Mean	1.39	1.28	1.35
	SD	0.466	0.425	0.452
	Min	0.5	0	0
	25% quantile	1.00	1.00	1.00
	Median	1.30	1.20	1.20
	75% quantile	1.50	1.50	1.50
	Max	2.5	2.1	2.5
Volume of injection (mL) adjacent disc (ADD patients)				
	N with data	8	5	13
	Mean	1.38	1.12	1.28
	SD	0.580	0.084	0.464
	Min	0.5	1.0	0.5
	25% quantile	1.00	1.10	1.00
	Median	1.35	1.10	1.20
	75% quantile	1.75	1.20	1.50
	Max	2.3	1.2	2.3
Application pressure herniated disc (HD and ADD patients)				
Low	N (%)	9 (15.5)	3 (8.1)	12 (12.6)
Normal	N (%)	26 (44.8)	16 (43.2)	42 (44.2)
High	N (%)	12 (20.7)	6 (16.2)	18 (18.9)
Unknown	N (%)	0	1 (2.7)	1 (1.1)
Missing	N (%)	0	1 (2.7)	1 (1.1)
Application pressure adjacent disc (ADD patients)				
Low	N (%)	1 (1.7)	1 (2.7)	2 (2.1)
Normal	N (%)	6 (10.3)	2 (5.4)	8 (8.4)
High	N (%)	1 (1.7)	2 (5.4)	3 (3.2)
Unknown	N (%)	0	0	0
Missing	N (%)	0	0	0

Only subjects who received surgical transplant/implant are included.

HD = absence of adjacent degenerated disc, ADD = presence of adjacent degenerated disc

Table 14.1.3.2: Feasibility of transplantation (Visit 3b) - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	Overall (N=95)
Postoperative length of hospitalization (days)				
	N with data	46	27	73
	N missing	12	10	22
	Mean	3.2	3.1	3.2
	SD	0.85	1.15	0.97
	Min	1	1	1
	25% quantile	3.0	2.0	3.0
	Median	3.0	3.0	3.0
	75% quantile	4.0	4.0	4.0
	Max	6	5	6

Only subjects who received surgical transplant/implant are included.

HD = absence of adjacent degenerated disc, ADD = presence of adjacent degenerated disc

Table 14.1.3.3: Fluoroscopy at surgical transplant/implant (Visit 3b) - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	Overall (N=95)
Total radiation dose (cGy cm ²) for herniated disc (HD patients)				
	N with data	34	18	52
	N missing	4	4	8
	Mean	520.16	301.82	444.58
	SD	1171.673	213.545	956.293
	Min	61.3	83.0	61.3
	25% quantile	147.70	157.96	153.44
	Median	232.89	226.10	230.66
	75% quantile	443.60	423.40	426.18
	Max	6976.0	888.5	6976.0
for herniated and adjacent disc (ADD patients)				
	N with data	6	4	10
	N missing	3	1	4
	Mean	443.32	468.24	453.28
	SD	230.099	120.271	185.477
	Min	160.0	378.9	160.0
	25% quantile	246.45	383.25	378.88
	Median	425.93	427.90	425.93
	75% quantile	621.85	553.22	621.85
	Max	779.8	638.3	779.8
Total time (sec) for herniated disc (HD patients)				
	N with data	34	20	54
	N missing	4	2	6
	Mean	33.5	39.6	35.7
	SD	23.33	37.43	29.15
	Min	6	8	6
	25% quantile	21.0	20.0	21.0
	Median	24.5	29.5	26.0
	75% quantile	39.0	38.5	39.0
	Max	125	182	182

Table 14.1.3.3: Fluoroscopy at surgical transplant/implant (Visit 3b) - safety set

Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	Overall (N=95)
for herniated and adjacent disc (ADD patients)				
	N with data	6	3	9
	N missing	3	2	5
	Mean	69.7	50.0	63.1
	SD	48.32	19.08	40.58
	Min	14	38	14
	25% quantile	33.0	38.0	38.0
	Median	66.5	40.0	52.0
	75% quantile	88.0	72.0	81.0
	Max	150	72	150

Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Subjects with previous medication	51 (87.9)	33 (89.2)	21 (84.0)	105 (87.5)
Agents acting on the renin-angiotensin system	5 (8.6)	3 (8.1)	2 (8.0)	10 (8.3)
Candesartan	0	0	1 (4.0)	1 (0.8)
Diovan amlo	0	1 (2.7)	0	1 (0.8)
Enalapril	0	1 (2.7)	0	1 (0.8)
Enalapril maleate	1 (1.7)	0	0	1 (0.8)
Ramipril	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
All other non-therapeutic products	1 (1.7)	0	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Analgesics	6 (10.3)	6 (16.2)	3 (12.0)	15 (12.5)
Acetylsalicylic acid	3 (5.2)	0	0	3 (2.5)
Hydromorphone hydrochloride	1 (1.7)	0	0	1 (0.8)
Metamizole	0	2 (5.4)	0	2 (1.7)
Metamizole sodium	1 (1.7)	2 (5.4)	1 (4.0)	4 (3.3)
Oxycodone hydrochloride	1 (1.7)	0	0	1 (0.8)
Paracetamol	1 (1.7)	2 (5.4)	0	3 (2.5)
Targin	0	1 (2.7)	0	1 (0.8)
Tramadol hydrochloride	0	1 (2.7)	0	1 (0.8)
Venlafaxine hydrochloride	0	1 (2.7)	1 (4.0)	2 (1.7)
Verapamil	0	0	1 (4.0)	1 (0.8)
Anti-acne preparations	2 (3.4)	1 (2.7)	0	3 (2.5)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Anti-parkinson drugs	0	0	1 (4.0)	1 (0.8)
Pramipexole dihydrochloride	0	0	1 (4.0)	1 (0.8)
Antianemic preparations	1 (1.7)	1 (2.7)	0	2 (1.7)
Keltican	0	1 (2.7)	0	1 (0.8)
Vitamin b nos	1 (1.7)	0	0	1 (0.8)

SC = Standard Care

Medications coded according to WHO Drug Dictionary version WHODD 01-SEP-16 V3.

Preferred terms may belong to different ATC levels.

Note: medications are classified as previous if the start and stop date is before the date of the sequestrectomy/tissue explant.

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Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Antibacterials for systemic use	0	2 (5.4)	0	2 (1.7)
Ciprofloxacin	0	1 (2.7)	0	1 (0.8)
Fusafungine	0	1 (2.7)	0	1 (0.8)
Antibiotics and chemotherapeutics for dermatological use	0	1 (2.7)	0	1 (0.8)
Ciprofloxacin	0	1 (2.7)	0	1 (0.8)
Antidiarrheals, intestinal antiinflammatory/antiinfective agents	0	1 (2.7)	0	1 (0.8)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Antiemetics and antinauseants	4 (6.9)	0	0	4 (3.3)
Dimenhydrinate	3 (5.2)	0	0	3 (2.5)
Ondansetron	1 (1.7)	0	0	1 (0.8)
Antiepileptics	2 (3.4)	0	0	2 (1.7)
Diazepam	1 (1.7)	0	0	1 (0.8)
Lorazepam	1 (1.7)	0	0	1 (0.8)
Antifungals for dermatological use	1 (1.7)	0	0	1 (0.8)
Econazole	1 (1.7)	0	0	1 (0.8)
Antigout preparations	0	1 (2.7)	0	1 (0.8)
Allopurinol	0	1 (2.7)	0	1 (0.8)
Antihistamines for systemic use	5 (8.6)	1 (2.7)	2 (8.0)	8 (6.7)
Cetirizine hydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Dimenhydrinate	3 (5.2)	0	0	3 (2.5)
Doxylamine succinate	0	0	1 (4.0)	1 (0.8)
Ebastine	0	1 (2.7)	0	1 (0.8)
Levocetirizine dihydrochloride	1 (1.7)	0	0	1 (0.8)
Antiinflammatory and antirheumatic products	4 (6.9)	9 (24.3)	1 (4.0)	14 (11.7)
Diclofenac	1 (1.7)	2 (5.4)	0	3 (2.5)
Diclofenac sodium	1 (1.7)	4 (10.8)	0	5 (4.2)
Ibuprofen	2 (3.4)	3 (8.1)	1 (4.0)	6 (5.0)
Mefenamic acid	0	1 (2.7)	0	1 (0.8)
Naproxen	0	3 (8.1)	0	3 (2.5)

SC = Standard Care

Medications coded according to WHO Drug Dictionary version WHODD 01-SEP-16 V3.

Preferred terms may belong to different ATC levels.

Note: medications are classified as previous if the start and stop date is before the date of the sequestrectomy/tissue explant.

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Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Antimycotics for systemic use	1 (1.7)	0	0	1 (0.8)
Itraconazole	1 (1.7)	0	0	1 (0.8)
Antipruritics, incl. antihistamines, anesthetics, etc.	1 (1.7)	0	1 (4.0)	2 (1.7)
Doxepin	1 (1.7)	0	1 (4.0)	2 (1.7)
Antithrombotic agents	37 (63.8)	22 (59.5)	13 (52.0)	72 (60.0)
Acetylsalicylic acid	3 (5.2)	0	0	3 (2.5)
Certoparin sodium	9 (15.5)	7 (18.9)	5 (20.0)	21 (17.5)
Dalteparin sodium	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Enoxaparin sodium	26 (44.8)	12 (32.4)	6 (24.0)	44 (36.7)
Fondaparinux sodium	0	1 (2.7)	0	1 (0.8)
Nadroparin calcium	0	1 (2.7)	0	1 (0.8)
Prasugrel hydrochloride	1 (1.7)	0	0	1 (0.8)
Beta blocking agents	9 (15.5)	2 (5.4)	1 (4.0)	12 (10.0)
Bisoprolol	3 (5.2)	0	1 (4.0)	4 (3.3)
Bisoprolol fumarate	1 (1.7)	0	0	1 (0.8)
Metoprolol	2 (3.4)	0	0	2 (1.7)
Metoprolol succinate	1 (1.7)	0	0	1 (0.8)
Nebivolol	0	2 (5.4)	0	2 (1.7)
Nebivolol hydrochloride	1 (1.7)	0	0	1 (0.8)
Sotalol hydrochloride	1 (1.7)	0	0	1 (0.8)
Bile and liver therapy	1 (1.7)	1 (2.7)	0	2 (1.7)
Lactulose	1 (1.7)	1 (2.7)	0	2 (1.7)
Blood substitutes and perfusion solutions	2 (3.4)	0	1 (4.0)	3 (2.5)
Potassium	1 (1.7)	0	1 (4.0)	2 (1.7)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Calcium channel blockers	0	0	2 (8.0)	2 (1.7)
Amlodipine	0	0	1 (4.0)	1 (0.8)
Verapamil	0	0	1 (4.0)	1 (0.8)

SC = Standard Care

Medications coded according to WHO Drug Dictionary version WHODD 01-SEP-16 V3.

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Clinipace: 14DEC21 / 7:38 / demo81.lst / demo8.sas

Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Cardiac therapy	2 (3.4)	3 (8.1)	1 (4.0)	6 (5.0)
Ibuprofen	2 (3.4)	3 (8.1)	1 (4.0)	6 (5.0)
Corticosteroids for systemic use	2 (3.4)	2 (5.4)	0	4 (3.3)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Corticosteroids, dermatological preparations	2 (3.4)	2 (5.4)	0	4 (3.3)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Cough and cold preparations	1 (1.7)	0	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Drugs for acid related disorders	37 (63.8)	21 (56.8)	17 (68.0)	75 (62.5)
Famotidine	0	1 (2.7)	0	1 (0.8)
Magnesium oxide	1 (1.7)	0	0	1 (0.8)
Omeprazole	1 (1.7)	0	1 (4.0)	2 (1.7)
Pantoprazole	1 (1.7)	0	0	1 (0.8)
Pantoprazole sodium sesquihydrate	35 (60.3)	21 (56.8)	16 (64.0)	72 (60.0)
Ranitidine hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Drugs for constipation	5 (8.6)	1 (2.7)	0	6 (5.0)
Lactulose	1 (1.7)	1 (2.7)	0	2 (1.7)
Magnesium oxide	1 (1.7)	0	0	1 (0.8)
Osmotically acting laxatives	1 (1.7)	0	0	1 (0.8)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Sodium picosulfate	1 (1.7)	0	0	1 (0.8)
Drugs for functional gastrointestinal disorders	1 (1.7)	0	1 (4.0)	2 (1.7)
Metoclopramide	0	0	1 (4.0)	1 (0.8)
Simeticone	1 (1.7)	0	0	1 (0.8)

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Clinipace: 14DEC21 / 7:38 / demo81.lst / demo8.sas

Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Drugs for obstructive airway diseases	6 (10.3)	1 (2.7)	1 (4.0)	8 (6.7)
Budesonide w/formoterol fumarate	4 (6.9)	0	0	4 (3.3)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Fenoterol hydrobromide	0	0	1 (4.0)	1 (0.8)
Ectoparasitocides, incl. scabicides, insecticides and repellents	1 (1.7)	0	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Emollients and protectives	1 (1.7)	0	0	1 (0.8)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Gynecological antiinfectives and antiseptics	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Ciprofloxacin	0	1 (2.7)	0	1 (0.8)
Econazole	1 (1.7)	0	0	1 (0.8)
Potassium	1 (1.7)	0	1 (4.0)	2 (1.7)
Homeopathic preparation	3 (5.2)	0	1 (4.0)	4 (3.3)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Potassium	1 (1.7)	0	1 (4.0)	2 (1.7)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Lipid modifying agents	2 (3.4)	3 (8.1)	0	5 (4.2)
Atorvastatin	0	1 (2.7)	0	1 (0.8)
Omega-3-acid ethyl ester	0	1 (2.7)	0	1 (0.8)
Simvastatin	2 (3.4)	2 (5.4)	0	4 (3.3)
Medicated dressings	1 (1.7)	0	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Mineral supplements	3 (5.2)	0	1 (4.0)	4 (3.3)
Magnesium oxide	1 (1.7)	0	0	1 (0.8)
Potassium	1 (1.7)	0	1 (4.0)	2 (1.7)
Sodium chloride	1 (1.7)	0	0	1 (0.8)

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Clinipace: 14DEC21 / 7:38 / demo81.lst / demo8.sas

Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Muscle relaxants	3 (5.2)	2 (5.4)	2 (8.0)	7 (5.8)
Diazepam	1 (1.7)	0	0	1 (0.8)
Methocarbamol	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Tetrazepam	0	1 (2.7)	0	1 (0.8)
Tolperisone	0	0	1 (4.0)	1 (0.8)
Nasal preparations	2 (3.4)	3 (8.1)	0	5 (4.2)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Fusafungine	0	1 (2.7)	0	1 (0.8)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Ophthalmological and otological preparations	2 (3.4)	3 (8.1)	0	5 (4.2)
Ciprofloxacin	0	1 (2.7)	0	1 (0.8)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Ophthalmologicals	7 (12.1)	9 (24.3)	1 (4.0)	17 (14.2)
Cetirizine hydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Ciprofloxacin	0	1 (2.7)	0	1 (0.8)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Diclofenac	1 (1.7)	2 (5.4)	0	3 (2.5)
Diclofenac sodium	1 (1.7)	4 (10.8)	0	5 (4.2)
Naproxen	0	3 (8.1)	0	3 (2.5)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Potassium	1 (1.7)	0	1 (4.0)	2 (1.7)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Other dermatological preparations	2 (3.4)	5 (13.5)	0	7 (5.8)
Diclofenac	1 (1.7)	2 (5.4)	0	3 (2.5)
Diclofenac sodium	1 (1.7)	4 (10.8)	0	5 (4.2)

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Clinipace: 14DEC21 / 7:38 / demo81.lst / demo8.sas

Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Other gynecologicals	2 (3.4)	6 (16.2)	2 (8.0)	10 (8.3)
Fenoterol hydrobromide	0	0	1 (4.0)	1 (0.8)
Ibuprofen	2 (3.4)	3 (8.1)	1 (4.0)	6 (5.0)
Naproxen	0	3 (8.1)	0	3 (2.5)
Other nervous system drugs	3 (5.2)	1 (2.7)	0	4 (3.3)
Dimenhydrinate	3 (5.2)	0	0	3 (2.5)
Targin	0	1 (2.7)	0	1 (0.8)
Other respiratory system products	2 (3.4)	1 (2.7)	0	3 (2.5)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Otologicals	3 (5.2)	3 (8.1)	0	6 (5.0)
Ciprofloxacin	0	1 (2.7)	0	1 (0.8)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Preparations for treatment of wounds and ulcers	1 (1.7)	0	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Psychoanaleptics	5 (8.6)	1 (2.7)	4 (16.0)	10 (8.3)
Citalopram	1 (1.7)	0	0	1 (0.8)
Doxepin	1 (1.7)	0	1 (4.0)	2 (1.7)
Escitalopram	1 (1.7)	0	1 (4.0)	2 (1.7)
Fluoxetine hydrochloride	1 (1.7)	0	0	1 (0.8)
Mirtazapine	1 (1.7)	0	1 (4.0)	2 (1.7)
Paroxetine	1 (1.7)	0	0	1 (0.8)
Sertraline	1 (1.7)	0	1 (4.0)	2 (1.7)
Trazodone hydrochloride	0	0	1 (4.0)	1 (0.8)
Venlafaxine hydrochloride	0	1 (2.7)	1 (4.0)	2 (1.7)

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Clinipace: 14DEC21 / 7:38 / demo81.lst / demo8.sas

Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Psycholeptics	11 (19.0)	5 (13.5)	3 (12.0)	19 (15.8)
Alprazolam	1 (1.7)	0	0	1 (0.8)
Brotizolam	5 (8.6)	5 (13.5)	1 (4.0)	11 (9.2)
Diazepam	1 (1.7)	0	0	1 (0.8)
Doxepin	1 (1.7)	0	1 (4.0)	2 (1.7)
Doxylamine succinate	0	0	1 (4.0)	1 (0.8)
Lorazepam	1 (1.7)	0	0	1 (0.8)
Lormetazepam	1 (1.7)	0	0	1 (0.8)
Zolpidem	1 (1.7)	0	0	1 (0.8)
Zolpidem tartrate	1 (1.7)	0	0	1 (0.8)
Zopiclone	0	0	1 (4.0)	1 (0.8)
Sex hormones and modulators of the genital system	1 (1.7)	2 (5.4)	1 (4.0)	4 (3.3)
Desogestrel	0	1 (2.7)	0	1 (0.8)
Eugynon	0	1 (2.7)	0	1 (0.8)
Kliogest	0	0	1 (4.0)	1 (0.8)
Marvelon	1 (1.7)	0	0	1 (0.8)
Stomatological preparations	8 (13.8)	8 (21.6)	1 (4.0)	17 (14.2)
Acetylsalicylic acid	3 (5.2)	0	0	3 (2.5)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Diclofenac	1 (1.7)	2 (5.4)	0	3 (2.5)
Diclofenac sodium	1 (1.7)	4 (10.8)	0	5 (4.2)
Naproxen	0	3 (8.1)	0	3 (2.5)
Potassium	1 (1.7)	0	1 (4.0)	2 (1.7)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Sodium chloride	1 (1.7)	0	0	1 (0.8)
Throat preparations	4 (6.9)	7 (18.9)	1 (4.0)	12 (10.0)
Diclofenac	1 (1.7)	2 (5.4)	0	3 (2.5)
Diclofenac sodium	1 (1.7)	4 (10.8)	0	5 (4.2)
Fusafungine	0	1 (2.7)	0	1 (0.8)
Ibuprofen	2 (3.4)	3 (8.1)	1 (4.0)	6 (5.0)

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Clinipace: 14DEC21 / 7:38 / demo81.lst / demo8.sas

Table 14.1.4.1: Previous medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Thyroid therapy	5 (8.6)	4 (10.8)	1 (4.0)	10 (8.3)
Levothyroxine sodium	5 (8.6)	4 (10.8)	1 (4.0)	10 (8.3)
Topical products for joint and muscular pain	7 (12.1)	9 (24.3)	1 (4.0)	17 (14.2)
Acetylsalicylic acid	3 (5.2)	0	0	3 (2.5)
Diclofenac	1 (1.7)	2 (5.4)	0	3 (2.5)
Diclofenac sodium	1 (1.7)	4 (10.8)	0	5 (4.2)
Ibuprofen	2 (3.4)	3 (8.1)	1 (4.0)	6 (5.0)
Naproxen	0	3 (8.1)	0	3 (2.5)
Tolperisone	0	0	1 (4.0)	1 (0.8)
Vasoprotectives	2 (3.4)	2 (5.4)	0	4 (3.3)
Dexamethasone	2 (3.4)	1 (2.7)	0	3 (2.5)
Prednisolone	0	1 (2.7)	0	1 (0.8)
Vitamins	1 (1.7)	0	0	1 (0.8)
Vitamin b nos	1 (1.7)	0	0	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Subjects with concomitant medication	58 (100)	37 (100)	25 (100)	120 (100)
Agents acting on the renin-angiotensin system	9 (15.5)	4 (10.8)	3 (12.0)	16 (13.3)
Blopress plus	0	1 (2.7)	0	1 (0.8)
Candesartan	1 (1.7)	0	1 (4.0)	2 (1.7)
Candesartan cilexetil	1 (1.7)	0	0	1 (0.8)
Diovan amlo	0	1 (2.7)	0	1 (0.8)
Enalapril	0	1 (2.7)	0	1 (0.8)
Enalapril maleate	1 (1.7)	1 (2.7)	0	2 (1.7)
Enalapril w/lercanidipine	0	1 (2.7)	0	1 (0.8)
Olmesartan medoxomil	1 (1.7)	0	0	1 (0.8)
Ramipril	6 (10.3)	1 (2.7)	2 (8.0)	9 (7.5)
Valsartan	1 (1.7)	0	0	1 (0.8)
Zaneril	0	1 (2.7)	0	1 (0.8)
All other non-therapeutic products	4 (6.9)	0	1 (4.0)	5 (4.2)
Ascorbic acid	1 (1.7)	0	0	1 (0.8)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Penicillin nos	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
All other therapeutic products	7 (12.1)	2 (5.4)	1 (4.0)	10 (8.3)
Acetylcysteine	2 (3.4)	1 (2.7)	0	3 (2.5)
Ascorbic acid	1 (1.7)	0	0	1 (0.8)
Atropine	0	0	1 (4.0)	1 (0.8)
Homeopathic preparation (90113701001)	1 (1.7)	0	0	1 (0.8)
Homeopathics nos	1 (1.7)	0	0	1 (0.8)
Oxygen	1 (1.7)	1 (2.7)	0	2 (1.7)
Potassium iodide	1 (1.7)	0	0	1 (0.8)
Allergens	0	0	1 (4.0)	1 (0.8)
Allergens, insect venom	0	0	1 (4.0)	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Analgesics	28 (48.3)	15 (40.5)	12 (48.0)	55 (45.8)
Acetylsalicylic acid	8 (13.8)	2 (5.4)	1 (4.0)	11 (9.2)
Amitriptyline hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Biogesic	1 (1.7)	1 (2.7)	0	2 (1.7)
Clonidine hydrochloride	0	0	1 (4.0)	1 (0.8)
Dihydrocodeine	1 (1.7)	0	1 (4.0)	2 (1.7)
Fentanyl	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Gabapentin	2 (3.4)	0	0	2 (1.7)
Grippostad c	0	0	1 (4.0)	1 (0.8)
Hydromorphone hydrochloride	1 (1.7)	0	0	1 (0.8)
Influbene	1 (1.7)	0	0	1 (0.8)
Metamizole	3 (5.2)	2 (5.4)	2 (8.0)	7 (5.8)
Metamizole sodium	9 (15.5)	6 (16.2)	3 (12.0)	18 (15.0)
Morphine	1 (1.7)	0	0	1 (0.8)
Morphine sulfate	0	0	1 (4.0)	1 (0.8)
Neo citran	4 (6.9)	1 (2.7)	0	5 (4.2)
Oxycodone hydrochloride	1 (1.7)	0	0	1 (0.8)
Paracetamol	10 (17.2)	2 (5.4)	6 (24.0)	18 (15.0)
Piritramide	3 (5.2)	0	2 (8.0)	5 (4.2)
Pregabalin	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Rizatriptan	1 (1.7)	0	0	1 (0.8)
Sumatriptan	1 (1.7)	0	0	1 (0.8)
Targin	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Thomapyrin n	0	1 (2.7)	0	1 (0.8)
Topiramate	1 (1.7)	0	0	1 (0.8)
Tramadol	0	1 (2.7)	0	1 (0.8)
Tramadol hydrochloride	1 (1.7)	2 (5.4)	0	3 (2.5)
Valoron n	2 (3.4)	1 (2.7)	0	3 (2.5)
Venlafaxine hydrochloride	0	1 (2.7)	1 (4.0)	2 (1.7)
Verapamil	0	0	1 (4.0)	1 (0.8)
Anesthetics	7 (12.1)	5 (13.5)	4 (16.0)	16 (13.3)
Bupivacaine	1 (1.7)	0	0	1 (0.8)
Bupivacaine hydrochloride	4 (6.9)	2 (5.4)	1 (4.0)	7 (5.8)
Cepacol anesthetic	1 (1.7)	0	1 (4.0)	2 (1.7)
Desflurane	2 (3.4)	1 (2.7)	0	3 (2.5)
Fentanyl	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Isoflurane	1 (1.7)	0	0	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)
Mepivacaine hydrochloride	2 (3.4)	0	1 (4.0)	3 (2.5)
Prilocaine hydrochloride	0	0	1 (4.0)	1 (0.8)
Propofol	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Remifentanyl	1 (1.7)	0	2 (8.0)	3 (2.5)
Ropivacaine hydrochloride	0	0	1 (4.0)	1 (0.8)
Sevoflurane	1 (1.7)	0	0	1 (0.8)
Anti-acne preparations	12 (20.7)	8 (21.6)	4 (16.0)	24 (20.0)
Azithromycin	3 (5.2)	1 (2.7)	0	4 (3.3)
Clindamycin	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Clindamycin hydrochloride	2 (3.4)	1 (2.7)	0	3 (2.5)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone palmitate	0	0	2 (8.0)	2 (1.7)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Dimeticone	0	1 (2.7)	0	1 (0.8)
Doxycycline	1 (1.7)	1 (2.7)	0	2 (1.7)
Anti-parkinson drugs	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Madopar	1 (1.7)	0	0	1 (0.8)
Orphenadrine hydrochloride	0	1 (2.7)	0	1 (0.8)
Pramipexole dihydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Ropinirole hydrochloride	1 (1.7)	0	0	1 (0.8)
Antianemic preparations	3 (5.2)	2 (5.4)	1 (4.0)	6 (5.0)
Ascorbic acid w/biotin/colecalciferol/docosah	0	0	1 (4.0)	1 (0.8)
Ferrous glycine sulfate	1 (1.7)	0	0	1 (0.8)
Folic acid	2 (3.4)	0	0	2 (1.7)
Keltican	0	2 (5.4)	0	2 (1.7)
Vitamin b12 nos	1 (1.7)	0	0	1 (0.8)
Antibacterials for systemic use	56 (96.6)	33 (89.2)	24 (96.0)	113 (94.2)
Amoxi-clavulanico	0	2 (5.4)	0	2 (1.7)
Amoxicillin	2 (3.4)	0	1 (4.0)	3 (2.5)
Amoxicillin trihydrate	1 (1.7)	0	0	1 (0.8)
Amoxicillin w/clavulanate potassium	0	1 (2.7)	0	1 (0.8)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Augmentin	0	0	1 (4.0)	1 (0.8)
Azithromycin	3 (5.2)	1 (2.7)	0	4 (3.3)
Bactrim	2 (3.4)	0	0	2 (1.7)
Beta-lactam antibacterials, penicillins	0	1 (2.7)	1 (4.0)	2 (1.7)
Cefalexin	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Cefazolin	10 (17.2)	6 (16.2)	7 (28.0)	23 (19.2)
Cefazolin sodium	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Cefpodoxime proxetil	1 (1.7)	0	0	1 (0.8)
Ceftriaxone sodium	2 (3.4)	0	1 (4.0)	3 (2.5)
Cefuroxime	38 (65.5)	18 (48.6)	14 (56.0)	70 (58.3)
Cefuroxime sodium	4 (6.9)	7 (18.9)	0	11 (9.2)
Ciprofloxacin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Clindamycin	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Clindamycin hydrochloride	2 (3.4)	1 (2.7)	0	3 (2.5)
Doxycycline	1 (1.7)	1 (2.7)	0	2 (1.7)
Fosfomycin	0	1 (2.7)	0	1 (0.8)
Fusafungine	0	1 (2.7)	0	1 (0.8)
Gentamicin sulfate	0	1 (2.7)	0	1 (0.8)
Josamycin	1 (1.7)	1 (2.7)	0	2 (1.7)
Levofloxacin	2 (3.4)	0	0	2 (1.7)
Metronidazole	2 (3.4)	0	0	2 (1.7)
Nitrofurantoin	1 (1.7)	0	0	1 (0.8)
Norfloxacin	1 (1.7)	0	0	1 (0.8)
Penicillin nos	1 (1.7)	0	0	1 (0.8)
Phenoxyethylpenicillin	2 (3.4)	0	0	2 (1.7)
Roxithromycin	1 (1.7)	0	0	1 (0.8)
Spektramox	5 (8.6)	2 (5.4)	0	7 (5.8)
Trimethoprim	1 (1.7)	0	0	1 (0.8)
Unacid	1 (1.7)	0	1 (4.0)	2 (1.7)
Vancomycin	0	1 (2.7)	0	1 (0.8)
Antibiotics and chemotherapeutics for dermatological use	8 (13.8)	8 (21.6)	3 (12.0)	19 (15.8)
Aciclovir	2 (3.4)	0	0	2 (1.7)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Ciprofloxacin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Doxycycline	1 (1.7)	1 (2.7)	0	2 (1.7)
Gentamicin sulfate	0	1 (2.7)	0	1 (0.8)
Metronidazole	2 (3.4)	0	0	2 (1.7)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Norfloxacin	1 (1.7)	0	0	1 (0.8)
Ophthalmo-framkyoin	0	2 (5.4)	0	2 (1.7)
Rifampicin	0	1 (2.7)	0	1 (0.8)
Antidiarrheals, intestinal antiinflammatory/antiinfective agents	5 (8.6)	5 (13.5)	5 (20.0)	15 (12.5)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Enterococcus faecalis	0	0	1 (4.0)	1 (0.8)
Lactobacillus acidophilus	0	1 (2.7)	0	1 (0.8)
Loperamide hydrochloride	0	1 (2.7)	0	1 (0.8)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Prednisone	0	1 (2.7)	0	1 (0.8)
Prosymbioflor	0	0	1 (4.0)	1 (0.8)
Vancomycin	0	1 (2.7)	0	1 (0.8)
Antiemetics and antinauseants	9 (15.5)	1 (2.7)	3 (12.0)	13 (10.8)
Dimenhydrinate	3 (5.2)	0	1 (4.0)	4 (3.3)
Granisetron	1 (1.7)	0	0	1 (0.8)
Granisetron hydrochloride	0	0	1 (4.0)	1 (0.8)
Neurobion	1 (1.7)	0	0	1 (0.8)
Ondansetron	5 (8.6)	1 (2.7)	2 (8.0)	8 (6.7)
Antiepileptics	9 (15.5)	1 (2.7)	3 (12.0)	13 (10.8)
Clobazam	1 (1.7)	0	0	1 (0.8)
Diazepam	1 (1.7)	1 (2.7)	0	2 (1.7)
Gabapentin	2 (3.4)	0	0	2 (1.7)
Lamotrigine	2 (3.4)	0	0	2 (1.7)
Lorazepam	2 (3.4)	0	1 (4.0)	3 (2.5)
Pregabalin	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Topiramate	1 (1.7)	0	0	1 (0.8)
Antifungals for dermatological use	3 (5.2)	4 (10.8)	2 (8.0)	9 (7.5)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Clotrimazole	1 (1.7)	1 (2.7)	0	2 (1.7)

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Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Antigout preparations	0	1 (2.7)	0	1 (0.8)
Allopurinol	0	1 (2.7)	0	1 (0.8)
Antihistamines for systemic use	7 (12.1)	4 (10.8)	6 (24.0)	17 (14.2)
Cetirizine	0	0	1 (4.0)	1 (0.8)
Cetirizine hydrochloride	2 (3.4)	0	1 (4.0)	3 (2.5)
Desloratadine	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Dimenhydrinate	3 (5.2)	0	1 (4.0)	4 (3.3)
Dimetindene maleate	0	0	2 (8.0)	2 (1.7)
Doxylamine succinate	0	0	1 (4.0)	1 (0.8)
Ebastine	0	1 (2.7)	0	1 (0.8)
Levocetirizine dihydrochloride	1 (1.7)	0	0	1 (0.8)
Loratadine	0	2 (5.4)	1 (4.0)	3 (2.5)
Antihypertensives	0	0	1 (4.0)	1 (0.8)
Clonidine hydrochloride	0	0	1 (4.0)	1 (0.8)
Urapidil	0	0	1 (4.0)	1 (0.8)
Antiinflammatory and antirheumatic products	26 (44.8)	17 (45.9)	14 (56.0)	57 (47.5)
Antiinflammatory/antirheumatic agen/90068101/	1 (1.7)	0	0	1 (0.8)
B-voltaren	0	0	1 (4.0)	1 (0.8)
Benzzydamine hydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Celecoxib	0	1 (2.7)	0	1 (0.8)
Co-advil	1 (1.7)	0	0	1 (0.8)
Dexibuprofen	6 (10.3)	7 (18.9)	3 (12.0)	16 (13.3)
Diclofenac	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
Diclofenac resinate	1 (1.7)	0	0	1 (0.8)
Diclofenac sodium	3 (5.2)	3 (8.1)	2 (8.0)	8 (6.7)
Etoricoxib	2 (3.4)	0	0	2 (1.7)
Ibuprofen	12 (20.7)	8 (21.6)	9 (36.0)	29 (24.2)
Mefenamic acid	1 (1.7)	3 (8.1)	0	4 (3.3)
Meloxicam	1 (1.7)	0	0	1 (0.8)
Mucopolysaccharide polysulfuric acid ester	0	1 (2.7)	0	1 (0.8)
Naproxen	6 (10.3)	2 (5.4)	1 (4.0)	9 (7.5)
Parecoxib	1 (1.7)	0	0	1 (0.8)
Vimovo	1 (1.7)	0	0	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Antimycobacterials	2 (3.4)	4 (10.8)	2 (8.0)	8 (6.7)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Rifampicin	0	1 (2.7)	0	1 (0.8)
Antimycotics for systemic use	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Antineoplastic agents	1 (1.7)	1 (2.7)	0	2 (1.7)
Celecoxib	0	1 (2.7)	0	1 (0.8)
Methotrexate	1 (1.7)	0	0	1 (0.8)
Antiprotozoals	3 (5.2)	1 (2.7)	0	4 (3.3)
Clotrimazole	1 (1.7)	1 (2.7)	0	2 (1.7)
Metronidazole	2 (3.4)	0	0	2 (1.7)
Antipruritics, incl. antihistamines, anesthetics, etc.	3 (5.2)	2 (5.4)	3 (12.0)	8 (6.7)
Dimetindene maleate	0	0	2 (8.0)	2 (1.7)
Doxepin	1 (1.7)	0	1 (4.0)	2 (1.7)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)
Antiseptics and disinfectants	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Cetylpyridinium chloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Povidone-iodine	0	1 (2.7)	0	1 (0.8)
Antithrombotic agents	52 (89.7)	37 (100)	23 (92.0)	112 (93.3)
Acetylsalicylic acid	8 (13.8)	2 (5.4)	1 (4.0)	11 (9.2)
Certoparin sodium	17 (29.3)	11 (29.7)	10 (40.0)	38 (31.7)
Dabigatran etexilate mesilate	0	1 (2.7)	0	1 (0.8)
Dalteparin sodium	3 (5.2)	1 (2.7)	2 (8.0)	6 (5.0)
Edoxaban tosilate	0	0	1 (4.0)	1 (0.8)
Enoxaparin	1 (1.7)	0	0	1 (0.8)
Enoxaparin sodium	37 (63.8)	23 (62.2)	10 (40.0)	70 (58.3)
Fondaparinux sodium	0	1 (2.7)	0	1 (0.8)
Heparin	0	1 (2.7)	0	1 (0.8)
Mucopolysaccharide polysulfuric acid ester	0	1 (2.7)	0	1 (0.8)
Nadroparin calcium	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Phenprocoumon	1 (1.7)	0	0	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Tinzaparin sodium	0	0	1 (4.0)	1 (0.8)
Antivirals for systemic use	2 (3.4)	0	0	2 (1.7)
Aciclovir	2 (3.4)	0	0	2 (1.7)
Brivudine	1 (1.7)	0	0	1 (0.8)
Beta blocking agents	12 (20.7)	4 (10.8)	2 (8.0)	18 (15.0)
Bisoprolol	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Bisoprolol fumarate	1 (1.7)	0	0	1 (0.8)
Carvedilol	0	1 (2.7)	0	1 (0.8)
Metoprolol	5 (8.6)	0	0	5 (4.2)
Metoprolol succinate	1 (1.7)	0	0	1 (0.8)
Nebivolol	0	2 (5.4)	0	2 (1.7)
Nebivolol hydrochloride	1 (1.7)	0	0	1 (0.8)
Sotalol hydrochloride	1 (1.7)	0	0	1 (0.8)
Bile and liver therapy	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Lactulose	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Blood substitutes and perfusion solutions	6 (10.3)	1 (2.7)	2 (8.0)	9 (7.5)
Cetylpyridinium chloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Compound sodium chloride	2 (3.4)	0	0	2 (1.7)
Electrolyte solutions	2 (3.4)	0	1 (4.0)	3 (2.5)
Haemofiltrationsloesung hf 24	1 (1.7)	0	1 (4.0)	2 (1.7)
Ionosteril	1 (1.7)	1 (2.7)	0	2 (1.7)
Potassium	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Travad phosphate	1 (1.7)	0	0	1 (0.8)
Calcium channel blockers	3 (5.2)	2 (5.4)	3 (12.0)	8 (6.7)
Amlodipine	3 (5.2)	1 (2.7)	2 (8.0)	6 (5.0)
Lercanidipine	0	1 (2.7)	0	1 (0.8)
Verapamil	0	0	1 (4.0)	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Cardiac therapy	12 (20.7)	12 (32.4)	10 (40.0)	34 (28.3)
Akrinor	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Atropine	0	0	1 (4.0)	1 (0.8)
Cafedrine	2 (3.4)	0	0	2 (1.7)
Etilefrine hydrochloride	0	1 (2.7)	0	1 (0.8)
Ibuprofen	12 (20.7)	8 (21.6)	9 (36.0)	29 (24.2)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)
Norepinephrine	0	0	2 (8.0)	2 (1.7)
Contrast media	1 (1.7)	0	1 (4.0)	2 (1.7)
Iohexol	1 (1.7)	0	0	1 (0.8)
Iopamidol	0	0	1 (4.0)	1 (0.8)
Corticosteroids for systemic use	13 (22.4)	7 (18.9)	5 (20.0)	25 (20.8)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Cortisone acetate	1 (1.7)	0	0	1 (0.8)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone palmitate	0	0	2 (8.0)	2 (1.7)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Diprosan	1 (1.7)	0	0	1 (0.8)
Mykoproct n	1 (1.7)	0	0	1 (0.8)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Prednisolone acetate	1 (1.7)	0	0	1 (0.8)
Prednisolone sodium succinate	1 (1.7)	0	0	1 (0.8)
Prednisone	0	1 (2.7)	0	1 (0.8)
Triamcinolone	2 (3.4)	2 (5.4)	0	4 (3.3)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Corticosteroids, dermatological preparations	14 (24.1)	8 (21.6)	4 (16.0)	26 (21.7)
Aureodelf	1 (1.7)	0	0	1 (0.8)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Diprosan	1 (1.7)	0	0	1 (0.8)
Methylprednisolone aceponate	0	1 (2.7)	0	1 (0.8)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Prednisolone acetate	1 (1.7)	0	0	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Prednisolone sodium succinate	1 (1.7)	0	0	1 (0.8)
Triamcinolone	2 (3.4)	2 (5.4)	0	4 (3.3)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Cough and cold preparations	6 (10.3)	2 (5.4)	1 (4.0)	9 (7.5)
Acetylcysteine	2 (3.4)	1 (2.7)	0	3 (2.5)
Ambroxol	0	0	1 (4.0)	1 (0.8)
Ambroxol hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Cineole	1 (1.7)	0	0	1 (0.8)
Guaifenesin	1 (1.7)	0	0	1 (0.8)
Mucolytics	1 (1.7)	0	0	1 (0.8)
Potassium iodide	1 (1.7)	0	0	1 (0.8)
Sinupret	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Vicks medinaït	1 (1.7)	0	0	1 (0.8)
Diagnostic agents	2 (3.4)	0	0	2 (1.7)
Folic acid	2 (3.4)	0	0	2 (1.7)
Diuretics	1 (1.7)	0	0	1 (0.8)
Hydrochlorothiazide	1 (1.7)	0	0	1 (0.8)
Drugs for acid related disorders	51 (87.9)	30 (81.1)	20 (80.0)	101 (84.2)
Esomeprazole	0	1 (2.7)	0	1 (0.8)
Magaldrate	1 (1.7)	0	0	1 (0.8)
Magnesium oxide	1 (1.7)	0	0	1 (0.8)
Omeprazole	1 (1.7)	0	2 (8.0)	3 (2.5)
Pantoprazole	2 (3.4)	0	0	2 (1.7)
Pantoprazole sodium sesquihydrate	49 (84.5)	30 (81.1)	19 (76.0)	98 (81.7)
Pylera	1 (1.7)	0	0	1 (0.8)
Ranitidine hydrochloride	0	1 (2.7)	0	1 (0.8)
Sucralfate	1 (1.7)	0	0	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Drugs for constipation	10 (17.2)	1 (2.7)	3 (12.0)	14 (11.7)
Bisacodyl	1 (1.7)	0	0	1 (0.8)
Klysma salinisch	1 (1.7)	0	0	1 (0.8)
Lactulose	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Magnesium oxide	1 (1.7)	0	0	1 (0.8)
Movicol	0	0	1 (4.0)	1 (0.8)
Osmotically acting laxatives	3 (5.2)	0	1 (4.0)	4 (3.3)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Sodium picosulfate	1 (1.7)	0	0	1 (0.8)
Travad phosphate	1 (1.7)	0	0	1 (0.8)
Drugs for functional gastrointestinal disorders	5 (8.6)	4 (10.8)	3 (12.0)	12 (10.0)
Atropine	0	0	1 (4.0)	1 (0.8)
Dexpanthenol	1 (1.7)	0	0	1 (0.8)
Dimeticone	0	1 (2.7)	0	1 (0.8)
Hyoscine butylbromide	2 (3.4)	2 (5.4)	1 (4.0)	5 (4.2)
Metoclopramide	0	1 (2.7)	2 (8.0)	3 (2.5)
Metoclopramide hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Simeticone	0	1 (2.7)	0	1 (0.8)
Tropium chloride	1 (1.7)	0	0	1 (0.8)
Drugs for obstructive airway diseases	13 (22.4)	8 (21.6)	4 (16.0)	25 (20.8)
Bekform	0	1 (2.7)	0	1 (0.8)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Budesonide w/formoterol fumarate	4 (6.9)	0	0	4 (3.3)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Fenoterol hydrobromide	0	0	1 (4.0)	1 (0.8)
Seretide	1 (1.7)	0	0	1 (0.8)
Triamcinolone	2 (3.4)	2 (5.4)	0	4 (3.3)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Drugs used in diabetes	0	1 (2.7)	1 (4.0)	2 (1.7)
Exenatide	0	0	1 (4.0)	1 (0.8)
Insulin aspart	0	1 (2.7)	0	1 (0.8)
Insulin degludec	0	1 (2.7)	0	1 (0.8)
Insulin glargine	0	1 (2.7)	0	1 (0.8)
Metformin	0	0	1 (4.0)	1 (0.8)

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Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Ectoparasiticides, incl. scabicides, insecticides and repellents	2 (3.4)	1 (2.7)	0	3 (2.5)
Dimeticone	0	1 (2.7)	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Emollients and protectives	3 (5.2)	2 (5.4)	0	5 (4.2)
Dimeticone	0	1 (2.7)	0	1 (0.8)
Mucopolysaccharide polysulfuric acid ester	0	1 (2.7)	0	1 (0.8)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Soft paraffin and fat products	1 (1.7)	0	0	1 (0.8)
Zinc oxide	1 (1.7)	0	0	1 (0.8)
Gynecological antiinfectives and antiseptics	9 (15.5)	8 (21.6)	4 (16.0)	21 (17.5)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Ascorbic acid	1 (1.7)	0	0	1 (0.8)
Ciprofloxacin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Clindamycin	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Clindamycin hydrochloride	2 (3.4)	1 (2.7)	0	3 (2.5)
Clotrimazole	1 (1.7)	1 (2.7)	0	2 (1.7)
Metronidazole	2 (3.4)	0	0	2 (1.7)
Potassium	1 (1.7)	0	0	1 (0.8)
Povidone-iodine	0	1 (2.7)	0	1 (0.8)
Homeopathic preparation	6 (10.3)	2 (5.4)	1 (4.0)	9 (7.5)
Ascorbic acid	1 (1.7)	0	0	1 (0.8)
Cortisone acetate	1 (1.7)	0	0	1 (0.8)
Homeopathic preparation (90113701001)	1 (1.7)	0	0	1 (0.8)
Homeopathics nos	1 (1.7)	0	0	1 (0.8)
Hypericum perforatum	0	2 (5.4)	0	2 (1.7)
Melatonin	0	0	1 (4.0)	1 (0.8)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Potassium	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)

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Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Immune sera and immunoglobulins	0	0	1 (4.0)	1 (0.8)
Immunoglobulin human anti-tetanus	0	0	1 (4.0)	1 (0.8)
Immunosuppressants	2 (3.4)	0	0	2 (1.7)
Azathioprine	1 (1.7)	0	0	1 (0.8)
Methotrexate	1 (1.7)	0	0	1 (0.8)
Lipid modifying agents	4 (6.9)	5 (13.5)	1 (4.0)	10 (8.3)
Atorvastatin	3 (5.2)	3 (8.1)	1 (4.0)	7 (5.8)
Omega-3-acid ethyl ester	0	1 (2.7)	0	1 (0.8)
Simvastatin	2 (3.4)	3 (8.1)	0	5 (4.2)
Medicated dressings	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
Cetylpyridinium chloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Povidone-iodine	0	1 (2.7)	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Zinc oxide	1 (1.7)	0	0	1 (0.8)
Mineral supplements	5 (8.6)	2 (5.4)	0	7 (5.8)
Magnesium	2 (3.4)	1 (2.7)	0	3 (2.5)
Magnesium oxide	1 (1.7)	0	0	1 (0.8)
Magnosolv	0	1 (2.7)	0	1 (0.8)
Potassium	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Muscle relaxants	10 (17.2)	9 (24.3)	3 (12.0)	22 (18.3)
Cisatracurium	1 (1.7)	0	1 (4.0)	2 (1.7)
Diazepam	1 (1.7)	1 (2.7)	0	2 (1.7)
Methocarbamol	4 (6.9)	2 (5.4)	1 (4.0)	7 (5.8)
Neodolpasse	0	3 (8.1)	0	3 (2.5)
Rocuronium	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Tetrazepam	0	2 (5.4)	0	2 (1.7)
Tizanidine hydrochloride	4 (6.9)	3 (8.1)	0	7 (5.8)
Tolperisone	0	0	1 (4.0)	1 (0.8)
Tolperisone hydrochloride	1 (1.7)	0	0	1 (0.8)

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Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Nasal preparations	19 (32.8)	10 (27.0)	6 (24.0)	35 (29.2)
Acetylcysteine	2 (3.4)	1 (2.7)	0	3 (2.5)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Compound sodium chloride	2 (3.4)	0	0	2 (1.7)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone palmitate	0	0	2 (8.0)	2 (1.7)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Dexpanthenol	1 (1.7)	0	0	1 (0.8)
Fusafungine	0	1 (2.7)	0	1 (0.8)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Naphazoline hydrochloride	2 (3.4)	0	0	2 (1.7)
Nasic	0	1 (2.7)	0	1 (0.8)
Oxymetazoline hydrochloride	0	0	1 (4.0)	1 (0.8)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Triamcinolone	2 (3.4)	2 (5.4)	0	4 (3.3)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Xylometazoline hydrochloride	2 (3.4)	1 (2.7)	0	3 (2.5)
Ophthalmological and otological preparations	14 (24.1)	6 (16.2)	4 (16.0)	24 (20.0)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Ciprofloxacin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone palmitate	0	0	2 (8.0)	2 (1.7)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Gentamicin sulfate	0	1 (2.7)	0	1 (0.8)
Levofloxacin	2 (3.4)	0	0	2 (1.7)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Prednisolone acetate	1 (1.7)	0	0	1 (0.8)
Prednisolone sodium succinate	1 (1.7)	0	0	1 (0.8)
Ophthalmologicals	48 (82.8)	29 (78.4)	18 (72.0)	95 (79.2)
Acetylcysteine	2 (3.4)	1 (2.7)	0	3 (2.5)
Aciclovir	2 (3.4)	0	0	2 (1.7)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Ascorbic acid	1 (1.7)	0	0	1 (0.8)
Atropine	0	0	1 (4.0)	1 (0.8)
Azithromycin	3 (5.2)	1 (2.7)	0	4 (3.3)

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Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Bibrocathol	0	0	1 (4.0)	1 (0.8)
Bupivacaine	1 (1.7)	0	0	1 (0.8)
Bupivacaine hydrochloride	4 (6.9)	2 (5.4)	1 (4.0)	7 (5.8)
Cefuroxime	38 (65.5)	18 (48.6)	14 (56.0)	70 (58.3)
Cefuroxime sodium	4 (6.9)	7 (18.9)	0	11 (9.2)
Cetirizine	0	0	1 (4.0)	1 (0.8)
Cetirizine hydrochloride	2 (3.4)	0	1 (4.0)	3 (2.5)
Cetylpyridinium chloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Ciprofloxacin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Clonidine hydrochloride	0	0	1 (4.0)	1 (0.8)
Clotrimazole	1 (1.7)	1 (2.7)	0	2 (1.7)
Cortisone acetate	1 (1.7)	0	0	1 (0.8)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone palmitate	0	0	2 (8.0)	2 (1.7)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Dexpanthenol	1 (1.7)	0	0	1 (0.8)
Diclofenac	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
Diclofenac resinate	1 (1.7)	0	0	1 (0.8)
Diclofenac sodium	3 (5.2)	3 (8.1)	2 (8.0)	8 (6.7)
Dimeticone	0	1 (2.7)	0	1 (0.8)
Gentamicin sulfate	0	1 (2.7)	0	1 (0.8)
Heparin	0	1 (2.7)	0	1 (0.8)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Levofloxacin	2 (3.4)	0	0	2 (1.7)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)
Meloxicam	1 (1.7)	0	0	1 (0.8)
Mucopolysaccharide polysulfuric acid ester	0	1 (2.7)	0	1 (0.8)
Naphazoline hydrochloride	2 (3.4)	0	0	2 (1.7)
Naproxen	6 (10.3)	2 (5.4)	1 (4.0)	9 (7.5)
Nasic	0	1 (2.7)	0	1 (0.8)
Norfloxacin	1 (1.7)	0	0	1 (0.8)
Ophthalmolmo-framykoin	0	2 (5.4)	0	2 (1.7)
Oxymetazoline hydrochloride	0	0	1 (4.0)	1 (0.8)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Polyvinyl alcohol	1 (1.7)	0	0	1 (0.8)
Potassium	1 (1.7)	0	0	1 (0.8)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Potassium iodide	1 (1.7)	0	0	1 (0.8)
Povidone-iodine	0	1 (2.7)	0	1 (0.8)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Prednisolone acetate	1 (1.7)	0	0	1 (0.8)
Prednisolone sodium succinate	1 (1.7)	0	0	1 (0.8)
Prednisone	0	1 (2.7)	0	1 (0.8)
Rifampicin	0	1 (2.7)	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Triamcinolone	2 (3.4)	2 (5.4)	0	4 (3.3)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Vancomycin	0	1 (2.7)	0	1 (0.8)
Xylometazoline hydrochloride	2 (3.4)	1 (2.7)	0	3 (2.5)
Other alimentary tract and metabolism products	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Acetylcysteine	2 (3.4)	1 (2.7)	0	3 (2.5)
Escherichia coli	0	0	1 (4.0)	1 (0.8)
Other dermatological preparations	10 (17.2)	7 (18.9)	5 (20.0)	22 (18.3)
Ascorbic acid	1 (1.7)	0	0	1 (0.8)
Compound sodium chloride	2 (3.4)	0	0	2 (1.7)
Diclofenac	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
Diclofenac sodium	3 (5.2)	3 (8.1)	2 (8.0)	8 (6.7)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Oxygen	1 (1.7)	1 (2.7)	0	2 (1.7)
Oxymetazoline hydrochloride	0	0	1 (4.0)	1 (0.8)
Polidocanol	0	1 (2.7)	0	1 (0.8)
Povidone-iodine	0	1 (2.7)	0	1 (0.8)
Sucralfate	1 (1.7)	0	0	1 (0.8)
Other drugs for disorders of the musculo-skeletal system	0	1 (2.7)	1 (4.0)	2 (1.7)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Mucopolysaccharide polysulfuric acid ester	0	1 (2.7)	0	1 (0.8)

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Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Other gynecologicals	18 (31.0)	10 (27.0)	12 (48.0)	40 (33.3)
Benzylamine hydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Fenoterol hydrobromide	0	0	1 (4.0)	1 (0.8)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Ibuprofen	12 (20.7)	8 (21.6)	9 (36.0)	29 (24.2)
Lactobacillus acidophilus	0	1 (2.7)	0	1 (0.8)
Methotrexate	1 (1.7)	0	0	1 (0.8)
Naproxen	6 (10.3)	2 (5.4)	1 (4.0)	9 (7.5)
Other nervous system drugs	6 (10.3)	1 (2.7)	1 (4.0)	8 (6.7)
Dimenhydrinate	3 (5.2)	0	1 (4.0)	4 (3.3)
Gabapentin	2 (3.4)	0	0	2 (1.7)
Pyridostigmine	1 (1.7)	0	0	1 (0.8)
Targin	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Other respiratory system products	7 (12.1)	5 (13.5)	3 (12.0)	15 (12.5)
Ambroxol	0	0	1 (4.0)	1 (0.8)
Ambroxol hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Oxygen	1 (1.7)	1 (2.7)	0	2 (1.7)
Otologicals	16 (27.6)	8 (21.6)	4 (16.0)	28 (23.3)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Ciprofloxacin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Clotrimazole	1 (1.7)	1 (2.7)	0	2 (1.7)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone palmitate	0	0	2 (8.0)	2 (1.7)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Gentamicin sulfate	0	1 (2.7)	0	1 (0.8)
Levofloxacin	2 (3.4)	0	0	2 (1.7)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)
Paraffin, liquid	1 (1.7)	0	0	1 (0.8)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Prednisolone acetate	1 (1.7)	0	0	1 (0.8)
Prednisolone sodium succinate	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)

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Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Preparations for treatment of wounds and ulcers	3 (5.2)	0	1 (4.0)	4 (3.3)
Dexpanthenol	1 (1.7)	0	0	1 (0.8)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Panthenol	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Psychoanaleptics	9 (15.5)	4 (10.8)	6 (24.0)	19 (15.8)
Amitriptyline hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Citalopram	1 (1.7)	0	0	1 (0.8)
Clonidine hydrochloride	0	0	1 (4.0)	1 (0.8)
Doxepin	1 (1.7)	0	1 (4.0)	2 (1.7)
Escitalopram	2 (3.4)	0	1 (4.0)	3 (2.5)
Fluoxetine hydrochloride	2 (3.4)	0	0	2 (1.7)
Mirtazapine	2 (3.4)	0	2 (8.0)	4 (3.3)
Modafinil	0	0	1 (4.0)	1 (0.8)
Opipramol	1 (1.7)	0	1 (4.0)	2 (1.7)
Paroxetine	1 (1.7)	0	0	1 (0.8)
Sertraline	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Tianeptine sodium	0	1 (2.7)	0	1 (0.8)
Trazodone hydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Trimipramine	0	0	1 (4.0)	1 (0.8)
Venlafaxine hydrochloride	0	1 (2.7)	1 (4.0)	2 (1.7)
Psycholeptics	27 (46.6)	15 (40.5)	10 (40.0)	52 (43.3)
Bromazepam	1 (1.7)	0	0	1 (0.8)
Brotizolam	14 (24.1)	11 (29.7)	4 (16.0)	29 (24.2)
Clobazam	1 (1.7)	0	0	1 (0.8)
Clorazepate dipotassium	2 (3.4)	0	0	2 (1.7)
Diazepam	1 (1.7)	1 (2.7)	0	2 (1.7)
Doxepin	1 (1.7)	0	1 (4.0)	2 (1.7)
Doxylamine succinate	0	0	1 (4.0)	1 (0.8)
Lorazepam	2 (3.4)	0	1 (4.0)	3 (2.5)
Lormetazepam	2 (3.4)	0	1 (4.0)	3 (2.5)
Melatonin	0	0	1 (4.0)	1 (0.8)
Midazolam	4 (6.9)	3 (8.1)	2 (8.0)	9 (7.5)
Oxazepam	1 (1.7)	0	0	1 (0.8)
Pregabalin	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Prothipendyl hydrochloride	1 (1.7)	0	0	1 (0.8)

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Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Quetiapine fumarate	0	1 (2.7)	1 (4.0)	2 (1.7)
Zolpidem	3 (5.2)	0	1 (4.0)	4 (3.3)
Zolpidem tartrate	2 (3.4)	0	0	2 (1.7)
Zopiclone	0	0	1 (4.0)	1 (0.8)
Sex hormones and modulators of the genital system	1 (1.7)	2 (5.4)	1 (4.0)	4 (3.3)
Desogestrel	0	1 (2.7)	0	1 (0.8)
Eugynon	0	1 (2.7)	0	1 (0.8)
Kliogest	0	0	1 (4.0)	1 (0.8)
Marvelon	1 (1.7)	0	0	1 (0.8)
Stomatological preparations	30 (51.7)	15 (40.5)	10 (40.0)	55 (45.8)
Acetylsalicylic acid	8 (13.8)	2 (5.4)	1 (4.0)	11 (9.2)
Benzydamine hydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Cepacol anesthetic	1 (1.7)	0	1 (4.0)	2 (1.7)
Cetylpyridinium chloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Clotrimazole	1 (1.7)	1 (2.7)	0	2 (1.7)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone palmitate	0	0	2 (8.0)	2 (1.7)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Diclofenac	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
Diclofenac sodium	3 (5.2)	3 (8.1)	2 (8.0)	8 (6.7)
Dimeticone	0	1 (2.7)	0	1 (0.8)
Doxycycline	1 (1.7)	1 (2.7)	0	2 (1.7)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)
Metronidazole	2 (3.4)	0	0	2 (1.7)
Mykoproct n	1 (1.7)	0	0	1 (0.8)
Naproxen	6 (10.3)	2 (5.4)	1 (4.0)	9 (7.5)
Oxygen	1 (1.7)	1 (2.7)	0	2 (1.7)
Potassium	1 (1.7)	0	0	1 (0.8)
Povidone-iodine	0	1 (2.7)	0	1 (0.8)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Prednisolone acetate	1 (1.7)	0	0	1 (0.8)
Sodium chloride	2 (3.4)	0	0	2 (1.7)
Sucralfate	1 (1.7)	0	0	1 (0.8)
Triamcinolone	2 (3.4)	2 (5.4)	0	4 (3.3)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Throat preparations	19 (32.8)	17 (45.9)	15 (60.0)	51 (42.5)
Ambroxol	0	0	1 (4.0)	1 (0.8)
Ambroxol hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Benzylamine hydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Cepacol anesthetic	1 (1.7)	0	1 (4.0)	2 (1.7)
Cetylpyridinium chloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Diclofenac	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
Diclofenac sodium	3 (5.2)	3 (8.1)	2 (8.0)	8 (6.7)
Fusafungine	0	1 (2.7)	0	1 (0.8)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Ibuprofen	12 (20.7)	8 (21.6)	9 (36.0)	29 (24.2)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)
Ophthalmic-framylkoin	0	2 (5.4)	0	2 (1.7)
Povidone-iodine	0	1 (2.7)	0	1 (0.8)
Thyroid therapy	9 (15.5)	4 (10.8)	3 (12.0)	16 (13.3)
Levothyroxine sodium	8 (13.8)	4 (10.8)	3 (12.0)	15 (12.5)
Novothyral	1 (1.7)	0	0	1 (0.8)
Potassium iodide	1 (1.7)	0	0	1 (0.8)
Topical products for joint and muscular pain	29 (50.0)	16 (43.2)	13 (52.0)	58 (48.3)
Acetylsalicylic acid	8 (13.8)	2 (5.4)	1 (4.0)	11 (9.2)
Benzylamine hydrochloride	1 (1.7)	0	1 (4.0)	2 (1.7)
Dexibuprofen	6 (10.3)	7 (18.9)	3 (12.0)	16 (13.3)
Diclofenac	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
Diclofenac resinate	1 (1.7)	0	0	1 (0.8)
Diclofenac sodium	3 (5.2)	3 (8.1)	2 (8.0)	8 (6.7)
Folic acid	2 (3.4)	0	0	2 (1.7)
Ibuprofen	12 (20.7)	8 (21.6)	9 (36.0)	29 (24.2)
Meloxicam	1 (1.7)	0	0	1 (0.8)
Naproxen	6 (10.3)	2 (5.4)	1 (4.0)	9 (7.5)
Tolperisone	0	0	1 (4.0)	1 (0.8)
Tolperisone hydrochloride	1 (1.7)	0	0	1 (0.8)

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Note: medications are classified as concomitant if the start and stop date is after the date of the sequestrectomy/tissue explant.

Clinipace: 14DEC21 / 7:38 / demo82.lst / demo8.sas

Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Unspecified herbal and traditional medicine	3 (5.2)	6 (16.2)	2 (8.0)	11 (9.2)
Ginkgo biloba leaf	1 (1.7)	0	0	1 (0.8)
Harpagophytum procumbens root	0	1 (2.7)	0	1 (0.8)
Hypericum perforatum	0	2 (5.4)	0	2 (1.7)
Iberogast	0	1 (2.7)	1 (4.0)	2 (1.7)
Quercus spp. bark extract	0	1 (2.7)	0	1 (0.8)
Sinupret	0	1 (2.7)	1 (4.0)	2 (1.7)
Thymus vulgaris fluid extract	1 (1.7)	0	0	1 (0.8)
Unspecified herbal and traditional medicine (90116001001)	1 (1.7)	0	0	1 (0.8)
Valeriana officinalis root	1 (1.7)	0	0	1 (0.8)
Urologicals	4 (6.9)	4 (10.8)	2 (8.0)	10 (8.3)
Escherichia coli	0	0	1 (4.0)	1 (0.8)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)
Tamsulosin	1 (1.7)	2 (5.4)	0	3 (2.5)
Tropium chloride	1 (1.7)	0	0	1 (0.8)
Vaccines	1 (1.7)	1 (2.7)	0	2 (1.7)
Hepatitis a vaccine	1 (1.7)	0	0	1 (0.8)
Influenza vaccine	1 (1.7)	0	0	1 (0.8)
Other viral vaccines (90125501001)	0	1 (2.7)	0	1 (0.8)
Pneumococcal vaccine	1 (1.7)	0	0	1 (0.8)
Varicella zoster vaccine	1 (1.7)	0	0	1 (0.8)
Vasoprotectives	15 (25.9)	9 (24.3)	8 (32.0)	32 (26.7)
Antibiotics	2 (3.4)	3 (8.1)	2 (8.0)	7 (5.8)
Betamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Capiven	0	1 (2.7)	0	1 (0.8)
Dexamethasone	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Dexamethasone palmitate	0	0	2 (8.0)	2 (1.7)
Dexamethasone sodium phosphate	1 (1.7)	1 (2.7)	0	2 (1.7)
Escherichia coli	0	0	1 (4.0)	1 (0.8)
Heparin	0	1 (2.7)	0	1 (0.8)
Hyaluronic acid	0	0	1 (4.0)	1 (0.8)
Lidocaine	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine hydrochloride	0	2 (5.4)	0	2 (1.7)

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Table 14.1.4.2: Concomitant medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Mucopolysaccharide polysulfuric acid ester	0	1 (2.7)	0	1 (0.8)
Mykoproct n	1 (1.7)	0	0	1 (0.8)
Polidocanol	0	1 (2.7)	0	1 (0.8)
Prednisolone	3 (5.2)	0	2 (8.0)	5 (4.2)
Prednisolone acetate	1 (1.7)	0	0	1 (0.8)
Prednisolone sodium succinate	1 (1.7)	0	0	1 (0.8)
Scheriproct	0	1 (2.7)	0	1 (0.8)
Triamcinolone	2 (3.4)	2 (5.4)	0	4 (3.3)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Vitamins	6 (10.3)	2 (5.4)	3 (12.0)	11 (9.2)
Ascorbic acid	1 (1.7)	0	0	1 (0.8)
Colecalciferol	3 (5.2)	1 (2.7)	0	4 (3.3)
Dexpanthenol	1 (1.7)	0	0	1 (0.8)
Multivitamins, plain	0	0	1 (4.0)	1 (0.8)
Neurobion	1 (1.7)	0	0	1 (0.8)
Panthenol	1 (1.7)	0	0	1 (0.8)
Trineurin	0	1 (2.7)	0	1 (0.8)
Vitamedin intravenous	1 (1.7)	0	1 (4.0)	2 (1.7)
Vitamin d nos	1 (1.7)	0	1 (4.0)	2 (1.7)

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Table 14.1.4.3: Previous pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Subjects with previous pain medication	45 (77.6)	29 (78.4)	22 (88.0)	96 (80.0)
Analgesics	30 (51.7)	16 (43.2)	12 (48.0)	58 (48.3)
Flupirtine maleate	0	0	1 (4.0)	1 (0.8)
Hydromorphone hydrochloride	1 (1.7)	0	0	1 (0.8)
Metamizole	3 (5.2)	1 (2.7)	2 (8.0)	6 (5.0)
Metamizole sodium	17 (29.3)	11 (29.7)	5 (20.0)	33 (27.5)
Morphine sulfate	3 (5.2)	0	0	3 (2.5)
Oxycodone hydrochloride	10 (17.2)	7 (18.9)	3 (12.0)	20 (16.7)
Paracetamol	6 (10.3)	5 (13.5)	2 (8.0)	13 (10.8)
Piritramide	4 (6.9)	4 (10.8)	1 (4.0)	9 (7.5)
Pregabalin	3 (5.2)	0	1 (4.0)	4 (3.3)
Tapentadol hydrochloride	2 (3.4)	0	0	2 (1.7)
Targin	2 (3.4)	2 (5.4)	2 (8.0)	6 (5.0)
Tramadol	1 (1.7)	0	0	1 (0.8)
Tramadol hydrochloride	5 (8.6)	1 (2.7)	1 (4.0)	7 (5.8)
Valoron n	8 (13.8)	3 (8.1)	1 (4.0)	12 (10.0)
Anti-acne preparations	1 (1.7)	0	1 (4.0)	2 (1.7)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Antiepileptics	3 (5.2)	0	1 (4.0)	4 (3.3)
Pregabalin	3 (5.2)	0	1 (4.0)	4 (3.3)
Antiinflammatory and antirheumatic products	34 (58.6)	23 (62.2)	17 (68.0)	74 (61.7)
Celecoxib	1 (1.7)	0	0	1 (0.8)
Dexibuprofen	6 (10.3)	6 (16.2)	4 (16.0)	16 (13.3)
Dexketoprofen	1 (1.7)	0	0	1 (0.8)
Diclofenac	4 (6.9)	2 (5.4)	0	6 (5.0)
Diclofenac resinate	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Diclofenac sodium	3 (5.2)	3 (8.1)	0	6 (5.0)
Etoricoxib	1 (1.7)	0	1 (4.0)	2 (1.7)
Ibuprofen	19 (32.8)	11 (29.7)	9 (36.0)	39 (32.5)
Ibuprofen lysinate	1 (1.7)	0	0	1 (0.8)
Mefenamic acid	0	1 (2.7)	1 (4.0)	2 (1.7)
Naproxen	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)

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Note: medications are classified as previous if the start and stop date is before the date of the sequestrectomy/tissue explant.

Clinipace: 14DEC21 / 7:38 / demo83.lst / demo8.sas

Table 14.1.4.3: Previous pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Antineoplastic agents	1 (1.7)	0	0	1 (0.8)
Celecoxib	1 (1.7)	0	0	1 (0.8)
Cardiac therapy	20 (34.5)	11 (29.7)	9 (36.0)	40 (33.3)
Ibuprofen	19 (32.8)	11 (29.7)	9 (36.0)	39 (32.5)
Ibuprofen lysinate	1 (1.7)	0	0	1 (0.8)
Corticosteroids for systemic use	2 (3.4)	0	1 (4.0)	3 (2.5)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Triamcinolone	1 (1.7)	0	0	1 (0.8)
Corticosteroids, dermatological preparations	2 (3.4)	0	1 (4.0)	3 (2.5)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Triamcinolone	1 (1.7)	0	0	1 (0.8)
Drugs for acid related disorders	2 (3.4)	0	0	2 (1.7)
Pantoprazole sodium sesquihydrate	2 (3.4)	0	0	2 (1.7)
Drugs for functional gastrointestinal disorders	0	0	1 (4.0)	1 (0.8)
Metoclopramide hydrochloride	0	0	1 (4.0)	1 (0.8)
Drugs for obstructive airway diseases	2 (3.4)	0	1 (4.0)	3 (2.5)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Triamcinolone	1 (1.7)	0	0	1 (0.8)
Muscle relaxants	11 (19.0)	6 (16.2)	6 (24.0)	23 (19.2)
Methocarbamol	8 (13.8)	5 (13.5)	5 (20.0)	18 (15.0)
Neodolpasse	0	0	1 (4.0)	1 (0.8)
Tizanidine hydrochloride	3 (5.2)	1 (2.7)	0	4 (3.3)
Nasal preparations	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Triamcinolone	1 (1.7)	0	0	1 (0.8)

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Clinipace: 14DEC21 / 7:38 / demo83.lst / demo8.sas

Table 14.1.4.3: Previous pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Ophthalmological and otological preparations	1 (1.7)	0	1 (4.0)	2 (1.7)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Ophthalmologicals	12 (20.7)	10 (27.0)	3 (12.0)	25 (20.8)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Diclofenac	4 (6.9)	2 (5.4)	0	6 (5.0)
Diclofenac resinate	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Diclofenac sodium	3 (5.2)	3 (8.1)	0	6 (5.0)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Naproxen	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Triamcinolone	1 (1.7)	0	0	1 (0.8)
Other dermatological preparations	7 (12.1)	6 (16.2)	0	13 (10.8)
Diclofenac	4 (6.9)	2 (5.4)	0	6 (5.0)
Diclofenac sodium	3 (5.2)	3 (8.1)	0	6 (5.0)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Other drugs for disorders of the musculo-skeletal system	0	1 (2.7)	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Other gynecologicals	23 (39.7)	13 (35.1)	10 (40.0)	46 (38.3)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Ibuprofen	19 (32.8)	11 (29.7)	9 (36.0)	39 (32.5)
Ibuprofen lysinate	1 (1.7)	0	0	1 (0.8)
Naproxen	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Other nervous system drugs	2 (3.4)	2 (5.4)	2 (8.0)	6 (5.0)
Targin	2 (3.4)	2 (5.4)	2 (8.0)	6 (5.0)
Other respiratory system products	1 (1.7)	0	1 (4.0)	2 (1.7)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Otologicals	1 (1.7)	0	1 (4.0)	2 (1.7)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)

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Clinipace: 14DEC21 / 7:38 / demo83.lst / demo8.sas

Table 14.1.4.3: Previous pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Preparations for treatment of wounds and ulcers	0	1 (2.7)	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Psycholeptics	3 (5.2)	0	1 (4.0)	4 (3.3)
Pregabalin	3 (5.2)	0	1 (4.0)	4 (3.3)
Stomatological preparations	11 (19.0)	7 (18.9)	2 (8.0)	20 (16.7)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Diclofenac	4 (6.9)	2 (5.4)	0	6 (5.0)
Diclofenac sodium	3 (5.2)	3 (8.1)	0	6 (5.0)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Naproxen	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Triamcinolone	1 (1.7)	0	0	1 (0.8)
Throat preparations	23 (39.7)	16 (43.2)	9 (36.0)	48 (40.0)
Diclofenac	4 (6.9)	2 (5.4)	0	6 (5.0)
Diclofenac sodium	3 (5.2)	3 (8.1)	0	6 (5.0)
Ibuprofen	19 (32.8)	11 (29.7)	9 (36.0)	39 (32.5)
Topical products for joint and muscular pain	33 (56.9)	22 (59.5)	15 (60.0)	70 (58.3)
Dexibuprofen	6 (10.3)	6 (16.2)	4 (16.0)	16 (13.3)
Dexketoprofen	1 (1.7)	0	0	1 (0.8)
Diclofenac	4 (6.9)	2 (5.4)	0	6 (5.0)
Diclofenac resinate	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Diclofenac sodium	3 (5.2)	3 (8.1)	0	6 (5.0)
Dolobene	1 (1.7)	0	0	1 (0.8)
Ibuprofen	19 (32.8)	11 (29.7)	9 (36.0)	39 (32.5)
Ibuprofen lysinate	1 (1.7)	0	0	1 (0.8)
Naproxen	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Urologicals	0	1 (2.7)	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)

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Clinipace: 14DEC21 / 7:38 / demo83.lst / demo8.sas

Table 14.1.4.3: Previous pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Vasoprotectives	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Dexamethasone	1 (1.7)	0	1 (4.0)	2 (1.7)
Dolobene	1 (1.7)	0	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Triamcinolone	1 (1.7)	0	0	1 (0.8)

SC = Standard Care

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Table 14.1.4.4: Previous opioid pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Subjects with previous opioid pain medication	23 (39.7)	14 (37.8)	6 (24.0)	43 (35.8)
Analgesics	23 (39.7)	14 (37.8)	6 (24.0)	43 (35.8)
Hydromorphone hydrochloride	1 (1.7)	0	0	1 (0.8)
Morphine sulfate	3 (5.2)	0	0	3 (2.5)
Oxycodone hydrochloride	10 (17.2)	7 (18.9)	3 (12.0)	20 (16.7)
Piritramide	4 (6.9)	4 (10.8)	1 (4.0)	9 (7.5)
Tapentadol hydrochloride	2 (3.4)	0	0	2 (1.7)
Targin	2 (3.4)	2 (5.4)	2 (8.0)	6 (5.0)
Tramadol	1 (1.7)	0	0	1 (0.8)
Tramadol hydrochloride	5 (8.6)	1 (2.7)	1 (4.0)	7 (5.8)
Valoron n	8 (13.8)	3 (8.1)	1 (4.0)	12 (10.0)

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Table 14.1.4.5: Concomitant pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Subjects with concomitant pain medication	55 (94.8)	34 (91.9)	24 (96.0)	113 (94.2)
All other therapeutic products	0	1 (2.7)	0	1 (0.8)
Naloxone w/tilidine	0	1 (2.7)	0	1 (0.8)
Analgesics	47 (81.0)	32 (86.5)	22 (88.0)	101 (84.2)
Acetylsalicylic acid	1 (1.7)	0	0	1 (0.8)
Amitriptyline hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Buprenorphine	1 (1.7)	0	0	1 (0.8)
Duloxetine	1 (1.7)	0	0	1 (0.8)
Flupirtine maleate	0	1 (2.7)	1 (4.0)	2 (1.7)
Gabapentin	0	1 (2.7)	1 (4.0)	2 (1.7)
Hydromorphone hydrochloride	2 (3.4)	0	0	2 (1.7)
Metamizole	8 (13.8)	3 (8.1)	5 (20.0)	16 (13.3)
Metamizole sodium	28 (48.3)	23 (62.2)	12 (48.0)	63 (52.5)
Morphine hydrochloride	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Morphine sulfate	4 (6.9)	0	1 (4.0)	5 (4.2)
Naloxone w/tilidine	0	1 (2.7)	0	1 (0.8)
Oxycodone hydrochloride	11 (19.0)	8 (21.6)	4 (16.0)	23 (19.2)
Panadeine co	1 (1.7)	0	0	1 (0.8)
Paracetamol	22 (37.9)	10 (27.0)	8 (32.0)	40 (33.3)
Piritramide	13 (22.4)	6 (16.2)	8 (32.0)	27 (22.5)
Pregabalin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Tapentadol hydrochloride	2 (3.4)	0	0	2 (1.7)
Targin	1 (1.7)	0	4 (16.0)	5 (4.2)
Thomapyrin n	0	2 (5.4)	0	2 (1.7)
Tilidine	0	0	1 (4.0)	1 (0.8)
Tramadol	2 (3.4)	0	1 (4.0)	3 (2.5)
Tramadol hydrochloride	6 (10.3)	4 (10.8)	1 (4.0)	11 (9.2)
Valoron n	13 (22.4)	6 (16.2)	4 (16.0)	23 (19.2)
Anesthetics	5 (8.6)	1 (2.7)	0	6 (5.0)
Bupivacaine hydrochloride	2 (3.4)	1 (2.7)	0	3 (2.5)
Lidocaine	1 (1.7)	0	0	1 (0.8)
Ropivacaine	2 (3.4)	0	0	2 (1.7)

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Table 14.1.4.5: Concomitant pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Anti-acne preparations	3 (5.2)	1 (2.7)	2 (8.0)	6 (5.0)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Methylprednisolone	1 (1.7)	0	0	1 (0.8)
Antiepileptics	3 (5.2)	2 (5.4)	2 (8.0)	7 (5.8)
Gabapentin	0	1 (2.7)	1 (4.0)	2 (1.7)
Pregabalin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Antiinflammatory and antirheumatic products	43 (74.1)	30 (81.1)	19 (76.0)	92 (76.7)
Celecoxib	1 (1.7)	0	0	1 (0.8)
Dexibuprofen	17 (29.3)	11 (29.7)	5 (20.0)	33 (27.5)
Dexketoprofen	2 (3.4)	0	0	2 (1.7)
Diclofenac	3 (5.2)	4 (10.8)	5 (20.0)	12 (10.0)
Diclofenac resinate	1 (1.7)	2 (5.4)	1 (4.0)	4 (3.3)
Diclofenac sodium	3 (5.2)	5 (13.5)	0	8 (6.7)
Etoricoxib	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Ibuprofen	21 (36.2)	13 (35.1)	9 (36.0)	43 (35.8)
Mefenamic acid	0	1 (2.7)	1 (4.0)	2 (1.7)
Naproxen	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Vimovo	1 (1.7)	0	0	1 (0.8)
Antineoplastic agents	1 (1.7)	0	0	1 (0.8)
Celecoxib	1 (1.7)	0	0	1 (0.8)
Antipruritics, incl. antihistamines, anesthetics, etc.	1 (1.7)	0	0	1 (0.8)
Lidocaine	1 (1.7)	0	0	1 (0.8)
Antithrombotic agents	1 (1.7)	0	0	1 (0.8)
Acetylsalicylic acid	1 (1.7)	0	0	1 (0.8)
Cardiac therapy	21 (36.2)	13 (35.1)	9 (36.0)	43 (35.8)
Ibuprofen	21 (36.2)	13 (35.1)	9 (36.0)	43 (35.8)
Lidocaine	1 (1.7)	0	0	1 (0.8)

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Table 14.1.4.5: Concomitant pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Corticosteroids for systemic use	6 (10.3)	2 (5.4)	2 (8.0)	10 (8.3)
Cortisone acetate	0	1 (2.7)	0	1 (0.8)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Methylprednisolone	1 (1.7)	0	0	1 (0.8)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	0	5 (4.2)
Corticosteroids, dermatological preparations	6 (10.3)	1 (2.7)	2 (8.0)	9 (7.5)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Methylprednisolone	1 (1.7)	0	0	1 (0.8)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	0	5 (4.2)
Cough and cold preparations	1 (1.7)	0	0	1 (0.8)
Carbocisteine	1 (1.7)	0	0	1 (0.8)
Drugs for acid related disorders	2 (3.4)	0	1 (4.0)	3 (2.5)
Pantoprazole sodium sesquihydrate	2 (3.4)	0	1 (4.0)	3 (2.5)
Drugs for functional gastrointestinal disorders	0	0	1 (4.0)	1 (0.8)
Metoclopramide hydrochloride	0	0	1 (4.0)	1 (0.8)
Drugs for obstructive airway diseases	6 (10.3)	1 (2.7)	2 (8.0)	9 (7.5)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	0	5 (4.2)
Homeopathic preparation	1 (1.7)	1 (2.7)	0	2 (1.7)
Cortisone acetate	0	1 (2.7)	0	1 (0.8)
Toxicodendron pubescens	1 (1.7)	0	0	1 (0.8)
Muscle relaxants	13 (22.4)	11 (29.7)	9 (36.0)	33 (27.5)
Methocarbamol	8 (13.8)	7 (18.9)	8 (32.0)	23 (19.2)
Neodolpasse	1 (1.7)	1 (2.7)	0	2 (1.7)
Tetrazepam	1 (1.7)	1 (2.7)	0	2 (1.7)
Tizanidine hydrochloride	4 (6.9)	2 (5.4)	1 (4.0)	7 (5.8)

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Clinipace: 14DEC21 / 7:39 / demo84.lst / demo8.sas

Table 14.1.4.5: Concomitant pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Nasal preparations	6 (10.3)	2 (5.4)	2 (8.0)	10 (8.3)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	0	5 (4.2)
Ophthalmological and otological preparations	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Ophthalmologicals	15 (25.9)	12 (32.4)	8 (32.0)	35 (29.2)
Bupivacaine hydrochloride	2 (3.4)	1 (2.7)	0	3 (2.5)
Cortisone acetate	0	1 (2.7)	0	1 (0.8)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Diclofenac	3 (5.2)	4 (10.8)	5 (20.0)	12 (10.0)
Diclofenac resinate	1 (1.7)	2 (5.4)	1 (4.0)	4 (3.3)
Diclofenac sodium	3 (5.2)	5 (13.5)	0	8 (6.7)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Lidocaine	1 (1.7)	0	0	1 (0.8)
Methylprednisolone	1 (1.7)	0	0	1 (0.8)
Naproxen	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	0	5 (4.2)
Other dermatological preparations	6 (10.3)	9 (24.3)	5 (20.0)	20 (16.7)
Diclofenac	3 (5.2)	4 (10.8)	5 (20.0)	12 (10.0)
Diclofenac sodium	3 (5.2)	5 (13.5)	0	8 (6.7)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Other drugs for disorders of the musculo-skeletal system	0	1 (2.7)	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Other gynecologicals	25 (43.1)	14 (37.8)	11 (44.0)	50 (41.7)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Ibuprofen	21 (36.2)	13 (35.1)	9 (36.0)	43 (35.8)
Naproxen	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)

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Clinipace: 14DEC21 / 7:39 / demo84.lst / demo8.sas

Page 4 of 6

-continued on next page-

Table 14.1.4.5: Concomitant pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Other nervous system drugs	2 (3.4)	1 (2.7)	4 (16.0)	7 (5.8)
Buprenorphine	1 (1.7)	0	0	1 (0.8)
Gabapentin	0	1 (2.7)	1 (4.0)	2 (1.7)
Targin	1 (1.7)	0	4 (16.0)	5 (4.2)
Other respiratory system products	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Otologicals	3 (5.2)	1 (2.7)	2 (8.0)	6 (5.0)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Lidocaine	1 (1.7)	0	0	1 (0.8)
Preparations for treatment of wounds and ulcers	0	1 (2.7)	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Psychoanaleptics	1 (1.7)	1 (2.7)	0	2 (1.7)
Amitriptyline hydrochloride	1 (1.7)	1 (2.7)	0	2 (1.7)
Duloxetine	1 (1.7)	0	0	1 (0.8)
Psycholeptics	4 (6.9)	1 (2.7)	1 (4.0)	6 (5.0)
Duloxetine	1 (1.7)	0	0	1 (0.8)
Pregabalin	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Stomatological preparations	15 (25.9)	11 (29.7)	8 (32.0)	34 (28.3)
Acetylsalicylic acid	1 (1.7)	0	0	1 (0.8)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Diclofenac	3 (5.2)	4 (10.8)	5 (20.0)	12 (10.0)
Diclofenac sodium	3 (5.2)	5 (13.5)	0	8 (6.7)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Lidocaine	1 (1.7)	0	0	1 (0.8)
Naproxen	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	0	5 (4.2)

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Table 14.1.4.5: Concomitant pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Throat preparations	26 (44.8)	20 (54.1)	12 (48.0)	58 (48.3)
Diclofenac	3 (5.2)	4 (10.8)	5 (20.0)	12 (10.0)
Diclofenac sodium	3 (5.2)	5 (13.5)	0	8 (6.7)
Ibuprofen	21 (36.2)	13 (35.1)	9 (36.0)	43 (35.8)
Lidocaine	1 (1.7)	0	0	1 (0.8)
Topical products for joint and muscular pain	42 (72.4)	29 (78.4)	18 (72.0)	89 (74.2)
Acetylsalicylic acid	1 (1.7)	0	0	1 (0.8)
Dexibuprofen	17 (29.3)	11 (29.7)	5 (20.0)	33 (27.5)
Dexketoprofen	2 (3.4)	0	0	2 (1.7)
Diclofenac	3 (5.2)	4 (10.8)	5 (20.0)	12 (10.0)
Diclofenac resinate	1 (1.7)	2 (5.4)	1 (4.0)	4 (3.3)
Diclofenac sodium	3 (5.2)	5 (13.5)	0	8 (6.7)
Ibuprofen	21 (36.2)	13 (35.1)	9 (36.0)	43 (35.8)
Naproxen	4 (6.9)	1 (2.7)	2 (8.0)	7 (5.8)
Unspecified herbal and traditional medicine	1 (1.7)	0	0	1 (0.8)
Toxicodendron pubescens	1 (1.7)	0	0	1 (0.8)
Urologicals	2 (3.4)	1 (2.7)	0	3 (2.5)
Duloxetine	1 (1.7)	0	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Lidocaine	1 (1.7)	0	0	1 (0.8)
Vasoprotectives	6 (10.3)	2 (5.4)	2 (8.0)	10 (8.3)
Dexamethasone	2 (3.4)	0	2 (8.0)	4 (3.3)
Dexamethasone sodium phosphate	0	1 (2.7)	0	1 (0.8)
Hyaluronate sodium	0	1 (2.7)	0	1 (0.8)
Lidocaine	1 (1.7)	0	0	1 (0.8)
Triamcinolone acetonide	4 (6.9)	1 (2.7)	0	5 (4.2)
Vitamins	0	2 (5.4)	0	2 (1.7)
Vitamedin intravenous	0	2 (5.4)	0	2 (1.7)

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Table 14.1.4.6: Concomitant opioid pain medications - safety set

ATC Level Preferred Term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Subjects with concomitant opioid pain medication	34 (58.6)	22 (59.5)	18 (72.0)	74 (61.7)
Analgesics	34 (58.6)	22 (59.5)	18 (72.0)	74 (61.7)
Buprenorphine	1 (1.7)	0	0	1 (0.8)
Hydromorphone hydrochloride	2 (3.4)	0	0	2 (1.7)
Morphine hydrochloride	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Morphine sulfate	4 (6.9)	0	1 (4.0)	5 (4.2)
Naloxone w/tilidine	0	1 (2.7)	0	1 (0.8)
Oxycodone hydrochloride	11 (19.0)	8 (21.6)	4 (16.0)	23 (19.2)
Panadeine co	1 (1.7)	0	0	1 (0.8)
Piritramide	13 (22.4)	6 (16.2)	8 (32.0)	27 (22.5)
Tapentadol hydrochloride	2 (3.4)	0	0	2 (1.7)
Targin	1 (1.7)	0	4 (16.0)	5 (4.2)
Tilidine	0	0	1 (4.0)	1 (0.8)
Tramadol	2 (3.4)	0	1 (4.0)	3 (2.5)
Tramadol hydrochloride	6 (10.3)	4 (10.8)	1 (4.0)	11 (9.2)
Valoron n	13 (22.4)	6 (16.2)	4 (16.0)	23 (19.2)

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Table 14.2.1.1.1: Frequency on ODI Section 1 (Pain Intensity) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
I have no pain at the moment	0	0	1 (4.2)	1 (1.0)
The pain is very mild at the moment	5 (10.6)	1 (3.7)	1 (4.2)	7 (7.1)
The pain is moderate at the moment	21 (44.7)	8 (29.6)	10 (41.7)	39 (39.8)
The pain is fairly severe at the moment	16 (34.0)	9 (33.3)	6 (25.0)	31 (31.6)
The pain is very severe at the moment	5 (10.6)	8 (29.6)	4 (16.7)	17 (17.3)
The pain is the worst imaginable at the moment	0	1 (3.7)	2 (8.3)	3 (3.1)
Missing	0	0	0	0
Visit 3a*				
I have no pain at the moment	19 (40.4)	15 (55.6)	-	34 (34.7)
The pain is very mild at the moment	16 (34.0)	6 (22.2)	-	22 (22.4)
The pain is moderate at the moment	12 (25.5)	5 (18.5)	-	17 (17.3)
The pain is fairly severe at the moment	0	1 (3.7)	-	1 (1.0)
The pain is very severe at the moment	0	0	-	0
The pain is the worst imaginable at the moment	0	0	-	0
Missing	0	0	-	0
Visit 4				
I have no pain at the moment	12 (25.5)	11 (40.7)	5 (20.8)	28 (28.6)
The pain is very mild at the moment	20 (42.6)	6 (22.2)	7 (29.2)	33 (33.7)
The pain is moderate at the moment	12 (25.5)	9 (33.3)	12 (50.0)	33 (33.7)
The pain is fairly severe at the moment	1 (2.1)	1 (3.7)	0	2 (2.0)
The pain is very severe at the moment	1 (2.1)	0	0	1 (1.0)
The pain is the worst imaginable at the moment	0	0	0	0
Missing	1 (2.1)	0	0	1 (1.0)
Visit 5				
I have no pain at the moment	17 (36.2)	13 (48.1)	8 (33.3)	38 (38.8)
The pain is very mild at the moment	18 (38.3)	8 (29.6)	6 (25.0)	32 (32.7)
The pain is moderate at the moment	8 (17.0)	4 (14.8)	8 (33.3)	20 (20.4)
The pain is fairly severe at the moment	2 (4.3)	1 (3.7)	0	3 (3.1)
The pain is very severe at the moment	0	1 (3.7)	1 (4.2)	2 (2.0)
The pain is the worst imaginable at the moment	0	0	0	0
Missing	2 (4.3)	0	1 (4.2)	3 (3.1)

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:39 / odifrq01.lst / odifrq.sas

Table 14.2.1.1.1: Frequency on ODI Section 1 (Pain Intensity) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
I have no pain at the moment	17 (36.2)	13 (48.1)	9 (37.5)	39 (39.8)
The pain is very mild at the moment	18 (38.3)	8 (29.6)	8 (33.3)	34 (34.7)
The pain is moderate at the moment	10 (21.3)	4 (14.8)	6 (25.0)	20 (20.4)
The pain is fairly severe at the moment	1 (2.1)	1 (3.7)	0	2 (2.0)
The pain is very severe at the moment	0	0	0	0
The pain is the worst imaginable at the moment	0	0	0	0
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Visit 7				
I have no pain at the moment	22 (46.8)	10 (37.0)	8 (33.3)	40 (40.8)
The pain is very mild at the moment	13 (27.7)	11 (40.7)	7 (29.2)	31 (31.6)
The pain is moderate at the moment	10 (21.3)	3 (11.1)	4 (16.7)	17 (17.3)
The pain is fairly severe at the moment	0	2 (7.4)	1 (4.2)	3 (3.1)
The pain is very severe at the moment	1 (2.1)	0	0	1 (1.0)
The pain is the worst imaginable at the moment	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Visit 8				
I have no pain at the moment	15 (31.9)	15 (55.6)	9 (37.5)	39 (39.8)
The pain is very mild at the moment	17 (36.2)	7 (25.9)	7 (29.2)	31 (31.6)
The pain is moderate at the moment	8 (17.0)	2 (7.4)	5 (20.8)	15 (15.3)
The pain is fairly severe at the moment	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
The pain is very severe at the moment	1 (2.1)	1 (3.7)	0	2 (2.0)
The pain is the worst imaginable at the moment	0	0	0	0
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Visit 9				
I have no pain at the moment	18 (38.3)	12 (44.4)	5 (20.8)	35 (35.7)
The pain is very mild at the moment	9 (19.1)	4 (14.8)	5 (20.8)	18 (18.4)
The pain is moderate at the moment	9 (19.1)	8 (29.6)	9 (37.5)	26 (26.5)
The pain is fairly severe at the moment	2 (4.3)	0	2 (8.3)	4 (4.1)
The pain is very severe at the moment	3 (6.4)	2 (7.4)	0	5 (5.1)
The pain is the worst imaginable at the moment	0	0	0	0
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:39 / odifrq01.lst / odifrq.sas

Table 14.2.1.1.1: Frequency on ODI Section 1 (Pain Intensity) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
I have no pain at the moment	13 (27.7)	9 (33.3)	6 (25.0)	28 (28.6)
The pain is very mild at the moment	13 (27.7)	5 (18.5)	4 (16.7)	22 (22.4)
The pain is moderate at the moment	10 (21.3)	9 (33.3)	6 (25.0)	25 (25.5)
The pain is fairly severe at the moment	3 (6.4)	3 (11.1)	5 (20.8)	11 (11.2)
The pain is very severe at the moment	2 (4.3)	0	1 (4.2)	3 (3.1)
The pain is the worst imaginable at the moment	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
End of Trial				
I have no pain at the moment	18 (38.3)	13 (48.1)	7 (29.2)	38 (38.8)
The pain is very mild at the moment	13 (27.7)	6 (22.2)	6 (25.0)	25 (25.5)
The pain is moderate at the moment	9 (19.1)	5 (18.5)	8 (33.3)	22 (22.4)
The pain is fairly severe at the moment	0	1 (3.7)	0	1 (1.0)
The pain is very severe at the moment	1 (2.1)	1 (3.7)	0	2 (2.0)
The pain is the worst imaginable at the moment	0	0	0	0
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

Table 14.2.1.1.2: Frequency on ODI Section 2 (Personal Care) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
I can look after myself normally without causing extra pain	10 (21.3)	2 (7.4)	4 (16.7)	16 (16.3)
I can look after myself normally but it causes extra pain	19 (40.4)	13 (48.1)	10 (41.7)	42 (42.9)
It is painful to look after myself and I am slow and careful	15 (31.9)	11 (40.7)	8 (33.3)	34 (34.7)
I need some help but can manage most of my personal care	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
I need help every day in most aspects of self-care	1 (2.1)	0	1 (4.2)	2 (2.0)
I do not get dressed, wash with difficulty and stay in bed	0	0	0	0
Missing	0	0	0	0
Visit 3a*				
I can look after myself normally without causing extra pain	36 (76.6)	25 (92.6)	-	61 (62.2)
I can look after myself normally but it causes extra pain	9 (19.1)	2 (7.4)	-	11 (11.2)
It is painful to look after myself and I am slow and careful	2 (4.3)	0	-	2 (2.0)
I need some help but can manage most of my personal care	0	0	-	0
I need help every day in most aspects of self-care	0	0	-	0
I do not get dressed, wash with difficulty and stay in bed	0	0	-	0
Missing	0	0	-	0
Visit 4				
I can look after myself normally without causing extra pain	41 (87.2)	22 (81.5)	18 (75.0)	81 (82.7)
I can look after myself normally but it causes extra pain	5 (10.6)	4 (14.8)	3 (12.5)	12 (12.2)
It is painful to look after myself and I am slow and careful	0	1 (3.7)	3 (12.5)	4 (4.1)
I need some help but can manage most of my personal care	0	0	0	0
I need help every day in most aspects of self-care	0	0	0	0
I do not get dressed, wash with difficulty and stay in bed	0	0	0	0
Missing	1 (2.1)	0	0	1 (1.0)
Visit 5				
I can look after myself normally without causing extra pain	40 (85.1)	25 (92.6)	18 (75.0)	83 (84.7)
I can look after myself normally but it causes extra pain	4 (8.5)	0	3 (12.5)	7 (7.1)
It is painful to look after myself and I am slow and careful	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
I need some help but can manage most of my personal care	0	0	1 (4.2)	1 (1.0)
I need help every day in most aspects of self-care	0	0	0	0
I do not get dressed, wash with difficulty and stay in bed	0	0	0	0
Missing	2 (4.3)	0	1 (4.2)	3 (3.1)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq02.lst / odifrq.sas

Table 14.2.1.1.2: Frequency on ODI Section 2 (Personal Care) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects							
	NDplus (N=47)		NDbasic (N=27)		SC (N=24)		Overall (N=98)	
Visit 6								
I can look after myself normally without causing extra pain	41	(87.2)	23	(85.2)	22	(91.7)	86	(87.8)
I can look after myself normally but it causes extra pain	3	(6.4)	2	(7.4)	1	(4.2)	6	(6.1)
It is painful to look after myself and I am slow and careful	2	(4.3)	1	(3.7)	0		3	(3.1)
I need some help but can manage most of my personal care	0		0		0		0	
I need help every day in most aspects of self-care	0		0		0		0	
I do not get dressed, wash with difficulty and stay in bed	0		0		0		0	
Missing	1	(2.1)	1	(3.7)	1	(4.2)	3	(3.1)
Visit 7								
I can look after myself normally without causing extra pain	42	(89.4)	24	(88.9)	17	(70.8)	83	(84.7)
I can look after myself normally but it causes extra pain	3	(6.4)	1	(3.7)	2	(8.3)	6	(6.1)
It is painful to look after myself and I am slow and careful	1	(2.1)	1	(3.7)	1	(4.2)	3	(3.1)
I need some help but can manage most of my personal care	0		0		0		0	
I need help every day in most aspects of self-care	0		0		0		0	
I do not get dressed, wash with difficulty and stay in bed	0		0		0		0	
Missing	1	(2.1)	1	(3.7)	4	(16.7)	6	(6.1)
Visit 8								
I can look after myself normally without causing extra pain	40	(85.1)	23	(85.2)	19	(79.2)	82	(83.7)
I can look after myself normally but it causes extra pain	3	(6.4)	2	(7.4)	1	(4.2)	6	(6.1)
It is painful to look after myself and I am slow and careful	0		0		2	(8.3)	2	(2.0)
I need some help but can manage most of my personal care	1	(2.1)	1	(3.7)	0		2	(2.0)
I need help every day in most aspects of self-care	0		0		0		0	
I do not get dressed, wash with difficulty and stay in bed	0		0		0		0	
Missing	3	(6.4)	1	(3.7)	2	(8.3)	6	(6.1)
Visit 9								
I can look after myself normally without causing extra pain	34	(72.3)	20	(74.1)	19	(79.2)	73	(74.5)
I can look after myself normally but it causes extra pain	5	(10.6)	4	(14.8)	0		9	(9.2)
It is painful to look after myself and I am slow and careful	2	(4.3)	1	(3.7)	2	(8.3)	5	(5.1)
I need some help but can manage most of my personal care	0		1	(3.7)	0		1	(1.0)
I need help every day in most aspects of self-care	0		0		0		0	
I do not get dressed, wash with difficulty and stay in bed	0		0		0		0	
Missing	6	(12.8)	1	(3.7)	3	(12.5)	10	(10.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq02.lst / odifrq.sas

Table 14.2.1.1.2: Frequency on ODI Section 2 (Personal Care) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
I can look after myself normally without causing extra pain	35 (74.5)	21 (77.8)	15 (62.5)	71 (72.4)
I can look after myself normally but it causes extra pain	3 (6.4)	3 (11.1)	6 (25.0)	12 (12.2)
It is painful to look after myself and I am slow and careful	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
I need some help but can manage most of my personal care	2 (4.3)	0	0	2 (2.0)
I need help every day in most aspects of self-care	0	0	0	0
I do not get dressed, wash with difficulty and stay in bed	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
End of Trial				
I can look after myself normally without causing extra pain	36 (76.6)	24 (88.9)	16 (66.7)	76 (77.6)
I can look after myself normally but it causes extra pain	4 (8.5)	0	4 (16.7)	8 (8.2)
It is painful to look after myself and I am slow and careful	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
I need some help but can manage most of my personal care	0	1 (3.7)	0	1 (1.0)
I need help every day in most aspects of self-care	0	0	0	0
I do not get dressed, wash with difficulty and stay in bed	0	0	0	0
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq02.lst / odifrq.sas

Table 14.2.1.1.3: Frequency on ODI Section 3 (Lifting) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
I can lift heavy weights without extra pain	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
I can lift heavy weights but it gives me extra pain	7 (14.9)	1 (3.7)	6 (25.0)	14 (14.3)
Pain prevents me lifting heavy weights off the floor but I can manage	11 (23.4)	6 (22.2)	1 (4.2)	18 (18.4)
Pain prevents me lifting heavy weights but I can manage light to medium weights	15 (31.9)	15 (55.6)	7 (29.2)	37 (37.8)
I can only lift very light weights	9 (19.1)	3 (11.1)	7 (29.2)	19 (19.4)
I cannot lift or carry anything	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Missing	0	0	1 (4.2)	1 (1.0)
Visit 3a*				
I can lift heavy weights without extra pain	9 (19.1)	6 (22.2)	-	15 (15.3)
I can lift heavy weights but it gives me extra pain	13 (27.7)	8 (29.6)	-	21 (21.4)
Pain prevents me lifting heavy weights off the floor but I can manage	8 (17.0)	6 (22.2)	-	14 (14.3)
Pain prevents me lifting heavy weights but I can manage light to medium weights	8 (17.0)	3 (11.1)	-	11 (11.2)
I can only lift very light weights	8 (17.0)	4 (14.8)	-	12 (12.2)
I cannot lift or carry anything	0	0	-	0
Missing	1 (2.1)	0	-	1 (1.0)
Visit 4				
I can lift heavy weights without extra pain	17 (36.2)	8 (29.6)	3 (12.5)	28 (28.6)
I can lift heavy weights but it gives me extra pain	18 (38.3)	13 (48.1)	8 (33.3)	39 (39.8)
Pain prevents me lifting heavy weights off the floor but I can manage	5 (10.6)	2 (7.4)	3 (12.5)	10 (10.2)
Pain prevents me lifting heavy weights but I can manage light to medium weights	4 (8.5)	2 (7.4)	6 (25.0)	12 (12.2)
I can only lift very light weights	2 (4.3)	1 (3.7)	4 (16.7)	7 (7.1)
I cannot lift or carry anything	0	0	0	0
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
Visit 5				
I can lift heavy weights without extra pain	14 (29.8)	12 (44.4)	4 (16.7)	30 (30.6)
I can lift heavy weights but it gives me extra pain	21 (44.7)	7 (25.9)	6 (25.0)	34 (34.7)
Pain prevents me lifting heavy weights off the floor but I can manage	7 (14.9)	1 (3.7)	6 (25.0)	14 (14.3)
Pain prevents me lifting heavy weights but I can manage light to medium weights	3 (6.4)	5 (18.5)	3 (12.5)	11 (11.2)
I can only lift very light weights	0	2 (7.4)	4 (16.7)	6 (6.1)
I cannot lift or carry anything	0	0	0	0
Missing	2 (4.3)	0	1 (4.2)	3 (3.1)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq03.lst / odifrq.sas

Table 14.2.1.1.3: Frequency on ODI Section 3 (Lifting) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
I can lift heavy weights without extra pain	22 (46.8)	14 (51.9)	9 (37.5)	45 (45.9)
I can lift heavy weights but it gives me extra pain	15 (31.9)	9 (33.3)	4 (16.7)	28 (28.6)
Pain prevents me lifting heavy weights off the floor but I can manage	5 (10.6)	2 (7.4)	5 (20.8)	12 (12.2)
Pain prevents me lifting heavy weights but I can manage light to medium weights	2 (4.3)	1 (3.7)	3 (12.5)	6 (6.1)
I can only lift very light weights	2 (4.3)	0	1 (4.2)	3 (3.1)
I cannot lift or carry anything	0	0	0	0
Missing	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Visit 7				
I can lift heavy weights without extra pain	18 (38.3)	12 (44.4)	8 (33.3)	38 (38.8)
I can lift heavy weights but it gives me extra pain	16 (34.0)	9 (33.3)	8 (33.3)	33 (33.7)
Pain prevents me lifting heavy weights off the floor but I can manage	4 (8.5)	3 (11.1)	3 (12.5)	10 (10.2)
Pain prevents me lifting heavy weights but I can manage light to medium weights	6 (12.8)	2 (7.4)	1 (4.2)	9 (9.2)
I can only lift very light weights	1 (2.1)	0	0	1 (1.0)
I cannot lift or carry anything	0	0	0	0
Missing	2 (4.3)	1 (3.7)	4 (16.7)	7 (7.1)
Visit 8				
I can lift heavy weights without extra pain	17 (36.2)	17 (63.0)	11 (45.8)	45 (45.9)
I can lift heavy weights but it gives me extra pain	17 (36.2)	3 (11.1)	5 (20.8)	25 (25.5)
Pain prevents me lifting heavy weights off the floor but I can manage	3 (6.4)	4 (14.8)	4 (16.7)	11 (11.2)
Pain prevents me lifting heavy weights but I can manage light to medium weights	4 (8.5)	0	2 (8.3)	6 (6.1)
I can only lift very light weights	3 (6.4)	1 (3.7)	0	4 (4.1)
I cannot lift or carry anything	0	0	0	0
Missing	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Visit 9				
I can lift heavy weights without extra pain	12 (25.5)	13 (48.1)	8 (33.3)	33 (33.7)
I can lift heavy weights but it gives me extra pain	20 (42.6)	7 (25.9)	6 (25.0)	33 (33.7)
Pain prevents me lifting heavy weights off the floor but I can manage	3 (6.4)	3 (11.1)	4 (16.7)	10 (10.2)
Pain prevents me lifting heavy weights but I can manage light to medium weights	4 (8.5)	2 (7.4)	1 (4.2)	7 (7.1)
I can only lift very light weights	2 (4.3)	1 (3.7)	2 (8.3)	5 (5.1)
I cannot lift or carry anything	0	0	0	0
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq03.lst / odifrq.sas

Table 14.2.1.1.3: Frequency on ODI Section 3 (Lifting) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
I can lift heavy weights without extra pain	13 (27.7)	13 (48.1)	8 (33.3)	34 (34.7)
I can lift heavy weights but it gives me extra pain	15 (31.9)	4 (14.8)	7 (29.2)	26 (26.5)
Pain prevents me lifting heavy weights off the floor but I can manage	5 (10.6)	4 (14.8)	4 (16.7)	13 (13.3)
Pain prevents me lifting heavy weights but I can manage light to medium weights	6 (12.8)	5 (18.5)	2 (8.3)	13 (13.3)
I can only lift very light weights	2 (4.3)	0	1 (4.2)	3 (3.1)
I cannot lift or carry anything	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
End of Trial				
I can lift heavy weights without extra pain	17 (36.2)	14 (51.9)	9 (37.5)	40 (40.8)
I can lift heavy weights but it gives me extra pain	12 (25.5)	6 (22.2)	7 (29.2)	25 (25.5)
Pain prevents me lifting heavy weights off the floor but I can manage	7 (14.9)	3 (11.1)	4 (16.7)	14 (14.3)
Pain prevents me lifting heavy weights but I can manage light to medium weights	4 (8.5)	2 (7.4)	1 (4.2)	7 (7.1)
I can only lift very light weights	1 (2.1)	1 (3.7)	0	2 (2.0)
I cannot lift or carry anything	0	0	0	0
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq03.lst / odifrq.sas

Table 14.2.1.1.4: Frequency on ODI Section 4 (Walking) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
Pain does not prevent me walking any distance	10 (21.3)	6 (22.2)	8 (33.3)	24 (24.5)
Pain prevents me from walking more than 1-2 km	19 (40.4)	7 (25.9)	4 (16.7)	30 (30.6)
Pain prevents me from walking more than 0.5 km	7 (14.9)	9 (33.3)	5 (20.8)	21 (21.4)
Pain prevents me from walking more than 100 m	7 (14.9)	4 (14.8)	4 (16.7)	15 (15.3)
I can only walk using a stick or crutches	2 (4.3)	0	0	2 (2.0)
I am in bed most of the time and requiring assistance getting to the bathroom	1 (2.1)	1 (3.7)	3 (12.5)	5 (5.1)
Missing	1 (2.1)	0	0	1 (1.0)
Visit 3a*				
Pain does not prevent me walking any distance	32 (68.1)	23 (85.2)	-	55 (56.1)
Pain prevents me from walking more than 1-2 km	13 (27.7)	4 (14.8)	-	17 (17.3)
Pain prevents me from walking more than 0.5 km	2 (4.3)	0	-	2 (2.0)
Pain prevents me from walking more than 100 m	0	0	-	0
I can only walk using a stick or crutches	0	0	-	0
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	-	0
Missing	0	0	-	0
Visit 4				
Pain does not prevent me walking any distance	33 (70.2)	20 (74.1)	20 (83.3)	73 (74.5)
Pain prevents me from walking more than 1-2 km	12 (25.5)	5 (18.5)	4 (16.7)	21 (21.4)
Pain prevents me from walking more than 0.5 km	1 (2.1)	1 (3.7)	0	2 (2.0)
Pain prevents me from walking more than 100 m	0	0	0	0
I can only walk using a stick or crutches	0	0	0	0
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	0	0
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
Visit 5				
Pain does not prevent me walking any distance	35 (74.5)	23 (85.2)	18 (75.0)	76 (77.6)
Pain prevents me from walking more than 1-2 km	9 (19.1)	3 (11.1)	4 (16.7)	16 (16.3)
Pain prevents me from walking more than 0.5 km	0	1 (3.7)	0	1 (1.0)
Pain prevents me from walking more than 100 m	0	0	1 (4.2)	1 (1.0)
I can only walk using a stick or crutches	0	0	0	0
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	0	0
Missing	3 (6.4)	0	1 (4.2)	4 (4.1)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.4: Frequency on ODI Section 4 (Walking) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
Pain does not prevent me walking any distance	37 (78.7)	22 (81.5)	20 (83.3)	79 (80.6)
Pain prevents me from walking more than 1-2 km	9 (19.1)	3 (11.1)	3 (12.5)	15 (15.3)
Pain prevents me from walking more than 0.5 km	0	0	0	0
Pain prevents me from walking more than 100 m	0	1 (3.7)	0	1 (1.0)
I can only walk using a stick or crutches	0	0	0	0
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	0	0
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Visit 7				
Pain does not prevent me walking any distance	38 (80.9)	24 (88.9)	18 (75.0)	80 (81.6)
Pain prevents me from walking more than 1-2 km	7 (14.9)	0	2 (8.3)	9 (9.2)
Pain prevents me from walking more than 0.5 km	1 (2.1)	2 (7.4)	0	3 (3.1)
Pain prevents me from walking more than 100 m	0	0	0	0
I can only walk using a stick or crutches	0	0	0	0
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Visit 8				
Pain does not prevent me walking any distance	39 (83.0)	24 (88.9)	20 (83.3)	83 (84.7)
Pain prevents me from walking more than 1-2 km	4 (8.5)	0	2 (8.3)	6 (6.1)
Pain prevents me from walking more than 0.5 km	0	2 (7.4)	0	2 (2.0)
Pain prevents me from walking more than 100 m	0	0	0	0
I can only walk using a stick or crutches	0	0	0	0
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	0	0
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
Visit 9				
Pain does not prevent me walking any distance	36 (76.6)	20 (74.1)	19 (79.2)	75 (76.5)
Pain prevents me from walking more than 1-2 km	5 (10.6)	4 (14.8)	2 (8.3)	11 (11.2)
Pain prevents me from walking more than 0.5 km	1 (2.1)	2 (7.4)	0	3 (3.1)
Pain prevents me from walking more than 100 m	0	0	0	0
I can only walk using a stick or crutches	0	0	0	0
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	0	0
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.4: Frequency on ODI Section 4 (Walking) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
Pain does not prevent me walking any distance	32 (68.1)	22 (81.5)	18 (75.0)	72 (73.5)
Pain prevents me from walking more than 1-2 km	7 (14.9)	1 (3.7)	4 (16.7)	12 (12.2)
Pain prevents me from walking more than 0.5 km	1 (2.1)	3 (11.1)	0	4 (4.1)
Pain prevents me from walking more than 100 m	0	0	0	0
I can only walk using a stick or crutches	1 (2.1)	0	0	1 (1.0)
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
End of Trial				
Pain does not prevent me walking any distance	37 (78.7)	21 (77.8)	20 (83.3)	78 (79.6)
Pain prevents me from walking more than 1-2 km	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
Pain prevents me from walking more than 0.5 km	1 (2.1)	2 (7.4)	0	3 (3.1)
Pain prevents me from walking more than 100 m	0	0	0	0
I can only walk using a stick or crutches	0	0	0	0
I am in bed most of the time and requiring assistance getting to the bathroom	0	0	0	0
Missing	6 (12.8)	2 (7.4)	3 (12.5)	11 (11.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.5: Frequency on ODI Section 5 (Sitting) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
I can sit in any chair as long as I like	4 (8.5)	1 (3.7)	1 (4.2)	6 (6.1)
I can only sit in my favorite chair as long as I like	2 (4.3)	3 (11.1)	1 (4.2)	6 (6.1)
Pain prevents me sitting more than one hour	16 (34.0)	6 (22.2)	9 (37.5)	31 (31.6)
Pain prevents me from sitting more than 30 minutes	12 (25.5)	7 (25.9)	7 (29.2)	26 (26.5)
Pain prevents me from sitting more than 10 minutes	8 (17.0)	7 (25.9)	2 (8.3)	17 (17.3)
Pain prevents me from sitting at all	4 (8.5)	2 (7.4)	4 (16.7)	10 (10.2)
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
Visit 3a*				
I can sit in any chair as long as I like	9 (19.1)	10 (37.0)	-	19 (19.4)
I can only sit in my favorite chair as long as I like	13 (27.7)	6 (22.2)	-	19 (19.4)
Pain prevents me sitting more than one hour	19 (40.4)	10 (37.0)	-	29 (29.6)
Pain prevents me from sitting more than 30 minutes	6 (12.8)	1 (3.7)	-	7 (7.1)
Pain prevents me from sitting more than 10 minutes	0	0	-	0
Pain prevents me from sitting at all	0	0	-	0
Missing	0	0	-	0
Visit 4				
I can sit in any chair as long as I like	13 (27.7)	11 (40.7)	5 (20.8)	29 (29.6)
I can only sit in my favorite chair as long as I like	18 (38.3)	2 (7.4)	3 (12.5)	23 (23.5)
Pain prevents me sitting more than one hour	10 (21.3)	11 (40.7)	16 (66.7)	37 (37.8)
Pain prevents me from sitting more than 30 minutes	5 (10.6)	2 (7.4)	0	7 (7.1)
Pain prevents me from sitting more than 10 minutes	0	0	0	0
Pain prevents me from sitting at all	0	0	0	0
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
Visit 5				
I can sit in any chair as long as I like	21 (44.7)	12 (44.4)	10 (41.7)	43 (43.9)
I can only sit in my favorite chair as long as I like	10 (21.3)	7 (25.9)	2 (8.3)	19 (19.4)
Pain prevents me sitting more than one hour	10 (21.3)	7 (25.9)	10 (41.7)	27 (27.6)
Pain prevents me from sitting more than 30 minutes	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Pain prevents me from sitting more than 10 minutes	0	0	0	0
Pain prevents me from sitting at all	0	0	0	0
Missing	3 (6.4)	0	1 (4.2)	4 (4.1)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.5: Frequency on ODI Section 5 (Sitting) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
I can sit in any chair as long as I like	18 (38.3)	13 (48.1)	11 (45.8)	42 (42.9)
I can only sit in my favorite chair as long as I like	14 (29.8)	5 (18.5)	5 (20.8)	24 (24.5)
Pain prevents me sitting more than one hour	13 (27.7)	8 (29.6)	7 (29.2)	28 (28.6)
Pain prevents me from sitting more than 30 minutes	1 (2.1)	0	0	1 (1.0)
Pain prevents me from sitting more than 10 minutes	0	0	0	0
Pain prevents me from sitting at all	0	0	0	0
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Visit 7				
I can sit in any chair as long as I like	20 (42.6)	13 (48.1)	10 (41.7)	43 (43.9)
I can only sit in my favorite chair as long as I like	16 (34.0)	6 (22.2)	4 (16.7)	26 (26.5)
Pain prevents me sitting more than one hour	8 (17.0)	5 (18.5)	5 (20.8)	18 (18.4)
Pain prevents me from sitting more than 30 minutes	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)
Pain prevents me from sitting more than 10 minutes	0	0	0	0
Pain prevents me from sitting at all	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Visit 8				
I can sit in any chair as long as I like	20 (42.6)	14 (51.9)	12 (50.0)	46 (46.9)
I can only sit in my favorite chair as long as I like	14 (29.8)	8 (29.6)	3 (12.5)	25 (25.5)
Pain prevents me sitting more than one hour	8 (17.0)	3 (11.1)	6 (25.0)	17 (17.3)
Pain prevents me from sitting more than 30 minutes	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Pain prevents me from sitting more than 10 minutes	0	0	0	0
Pain prevents me from sitting at all	0	0	0	0
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
Visit 9				
I can sit in any chair as long as I like	14 (29.8)	12 (44.4)	10 (41.7)	36 (36.7)
I can only sit in my favorite chair as long as I like	18 (38.3)	6 (22.2)	6 (25.0)	30 (30.6)
Pain prevents me sitting more than one hour	8 (17.0)	6 (22.2)	4 (16.7)	18 (18.4)
Pain prevents me from sitting more than 30 minutes	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Pain prevents me from sitting more than 10 minutes	0	1 (3.7)	0	1 (1.0)
Pain prevents me from sitting at all	0	0	0	0
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.5: Frequency on ODI Section 5 (Sitting) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
I can sit in any chair as long as I like	14 (29.8)	9 (33.3)	8 (33.3)	31 (31.6)
I can only sit in my favorite chair as long as I like	14 (29.8)	8 (29.6)	3 (12.5)	25 (25.5)
Pain prevents me sitting more than one hour	8 (17.0)	7 (25.9)	10 (41.7)	25 (25.5)
Pain prevents me from sitting more than 30 minutes	4 (8.5)	2 (7.4)	1 (4.2)	7 (7.1)
Pain prevents me from sitting more than 10 minutes	1 (2.1)	0	0	1 (1.0)
Pain prevents me from sitting at all	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
End of Trial				
I can sit in any chair as long as I like	18 (38.3)	12 (44.4)	11 (45.8)	41 (41.8)
I can only sit in my favorite chair as long as I like	17 (36.2)	4 (14.8)	4 (16.7)	25 (25.5)
Pain prevents me sitting more than one hour	5 (10.6)	8 (29.6)	5 (20.8)	18 (18.4)
Pain prevents me from sitting more than 30 minutes	0	1 (3.7)	1 (4.2)	2 (2.0)
Pain prevents me from sitting more than 10 minutes	1 (2.1)	0	0	1 (1.0)
Pain prevents me from sitting at all	0	0	0	0
Missing	6 (12.8)	2 (7.4)	3 (12.5)	11 (11.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.6: Frequency on ODI Section 6 (Standing) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
I can stand as long as I want without extra pain	3 (6.4)	0	4 (16.7)	7 (7.1)
I can stand as long as I want but it gives me extra pain	4 (8.5)	2 (7.4)	3 (12.5)	9 (9.2)
Pain prevents me from standing for more than 1 hour	11 (23.4)	9 (33.3)	8 (33.3)	28 (28.6)
Pain prevents me from standing for more than 30 minutes	9 (19.1)	5 (18.5)	3 (12.5)	17 (17.3)
Pain prevents me from standing for more than 10 minutes	16 (34.0)	8 (29.6)	2 (8.3)	26 (26.5)
Pain prevents me from standing at all	3 (6.4)	2 (7.4)	4 (16.7)	9 (9.2)
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
Visit 3a*				
I can stand as long as I want without extra pain	11 (23.4)	13 (48.1)	-	24 (24.5)
I can stand as long as I want but it gives me extra pain	22 (46.8)	9 (33.3)	-	31 (31.6)
Pain prevents me from standing for more than 1 hour	11 (23.4)	3 (11.1)	-	14 (14.3)
Pain prevents me from standing for more than 30 minutes	1 (2.1)	2 (7.4)	-	3 (3.1)
Pain prevents me from standing for more than 10 minutes	2 (4.3)	0	-	2 (2.0)
Pain prevents me from standing at all	0	0	-	0
Missing	0	0	-	0
Visit 4				
I can stand as long as I want without extra pain	19 (40.4)	15 (55.6)	10 (41.7)	44 (44.9)
I can stand as long as I want but it gives me extra pain	18 (38.3)	6 (22.2)	6 (25.0)	30 (30.6)
Pain prevents me from standing for more than 1 hour	7 (14.9)	3 (11.1)	3 (12.5)	13 (13.3)
Pain prevents me from standing for more than 30 minutes	2 (4.3)	1 (3.7)	5 (20.8)	8 (8.2)
Pain prevents me from standing for more than 10 minutes	0	0	0	0
Pain prevents me from standing at all	0	0	0	0
Missing	1 (2.1)	2 (7.4)	0	3 (3.1)
Visit 5				
I can stand as long as I want without extra pain	20 (42.6)	19 (70.4)	11 (45.8)	50 (51.0)
I can stand as long as I want but it gives me extra pain	15 (31.9)	5 (18.5)	8 (33.3)	28 (28.6)
Pain prevents me from standing for more than 1 hour	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Pain prevents me from standing for more than 30 minutes	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
Pain prevents me from standing for more than 10 minutes	3 (6.4)	0	0	3 (3.1)
Pain prevents me from standing at all	0	0	0	0
Missing	3 (6.4)	0	1 (4.2)	4 (4.1)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.6: Frequency on ODI Section 6 (Standing) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
I can stand as long as I want without extra pain	25 (53.2)	14 (51.9)	13 (54.2)	52 (53.1)
I can stand as long as I want but it gives me extra pain	14 (29.8)	7 (25.9)	7 (29.2)	28 (28.6)
Pain prevents me from standing for more than 1 hour	6 (12.8)	3 (11.1)	2 (8.3)	11 (11.2)
Pain prevents me from standing for more than 30 minutes	0	2 (7.4)	1 (4.2)	3 (3.1)
Pain prevents me from standing for more than 10 minutes	1 (2.1)	0	0	1 (1.0)
Pain prevents me from standing at all	0	0	0	0
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Visit 7				
I can stand as long as I want without extra pain	25 (53.2)	13 (48.1)	9 (37.5)	47 (48.0)
I can stand as long as I want but it gives me extra pain	11 (23.4)	8 (29.6)	7 (29.2)	26 (26.5)
Pain prevents me from standing for more than 1 hour	6 (12.8)	2 (7.4)	2 (8.3)	10 (10.2)
Pain prevents me from standing for more than 30 minutes	3 (6.4)	3 (11.1)	1 (4.2)	7 (7.1)
Pain prevents me from standing for more than 10 minutes	1 (2.1)	0	1 (4.2)	2 (2.0)
Pain prevents me from standing at all	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Visit 8				
I can stand as long as I want without extra pain	23 (48.9)	14 (51.9)	14 (58.3)	51 (52.0)
I can stand as long as I want but it gives me extra pain	12 (25.5)	10 (37.0)	5 (20.8)	27 (27.6)
Pain prevents me from standing for more than 1 hour	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Pain prevents me from standing for more than 30 minutes	2 (4.3)	0	1 (4.2)	3 (3.1)
Pain prevents me from standing for more than 10 minutes	0	1 (3.7)	0	1 (1.0)
Pain prevents me from standing at all	0	0	0	0
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
Visit 9				
I can stand as long as I want without extra pain	22 (46.8)	12 (44.4)	11 (45.8)	45 (45.9)
I can stand as long as I want but it gives me extra pain	12 (25.5)	7 (25.9)	7 (29.2)	26 (26.5)
Pain prevents me from standing for more than 1 hour	5 (10.6)	3 (11.1)	1 (4.2)	9 (9.2)
Pain prevents me from standing for more than 30 minutes	1 (2.1)	3 (11.1)	2 (8.3)	6 (6.1)
Pain prevents me from standing for more than 10 minutes	2 (4.3)	1 (3.7)	0	3 (3.1)
Pain prevents me from standing at all	0	0	0	0
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.6: Frequency on ODI Section 6 (Standing) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
I can stand as long as I want without extra pain	17 (36.2)	12 (44.4)	12 (50.0)	41 (41.8)
I can stand as long as I want but it gives me extra pain	12 (25.5)	9 (33.3)	4 (16.7)	25 (25.5)
Pain prevents me from standing for more than 1 hour	6 (12.8)	3 (11.1)	3 (12.5)	12 (12.2)
Pain prevents me from standing for more than 30 minutes	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
Pain prevents me from standing for more than 10 minutes	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Pain prevents me from standing at all	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
End of Trial				
I can stand as long as I want without extra pain	18 (38.3)	15 (55.6)	13 (54.2)	46 (46.9)
I can stand as long as I want but it gives me extra pain	12 (25.5)	7 (25.9)	4 (16.7)	23 (23.5)
Pain prevents me from standing for more than 1 hour	8 (17.0)	2 (7.4)	1 (4.2)	11 (11.2)
Pain prevents me from standing for more than 30 minutes	2 (4.3)	0	0	2 (2.0)
Pain prevents me from standing for more than 10 minutes	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Pain prevents me from standing at all	0	0	0	0
Missing	6 (12.8)	2 (7.4)	4 (16.7)	12 (12.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.7: Frequency on ODI Section 7 (Sleeping) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
My sleep is never disturbed by pain	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
My sleep is occasionally disturbed by pain	21 (44.7)	9 (33.3)	10 (41.7)	40 (40.8)
Because of pain I have less than 6 hours sleep	13 (27.7)	11 (40.7)	4 (16.7)	28 (28.6)
Because of pain I have less than 4 hours sleep	8 (17.0)	4 (14.8)	9 (37.5)	21 (21.4)
Because of pain I have less than 2 hours sleep	2 (4.3)	1 (3.7)	0	3 (3.1)
Pain prevents me from sleeping at all	0	0	0	0
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
Visit 3a*				
My sleep is never disturbed by pain	28 (59.6)	17 (63.0)	-	45 (45.9)
My sleep is occasionally disturbed by pain	17 (36.2)	9 (33.3)	-	26 (26.5)
Because of pain I have less than 6 hours sleep	2 (4.3)	1 (3.7)	-	3 (3.1)
Because of pain I have less than 4 hours sleep	0	0	-	0
Because of pain I have less than 2 hours sleep	0	0	-	0
Pain prevents me from sleeping at all	0	0	-	0
Missing	0	0	-	0
Visit 4				
My sleep is never disturbed by pain	29 (61.7)	14 (51.9)	12 (50.0)	55 (56.1)
My sleep is occasionally disturbed by pain	15 (31.9)	9 (33.3)	11 (45.8)	35 (35.7)
Because of pain I have less than 6 hours sleep	1 (2.1)	0	1 (4.2)	2 (2.0)
Because of pain I have less than 4 hours sleep	0	2 (7.4)	0	2 (2.0)
Because of pain I have less than 2 hours sleep	0	0	0	0
Pain prevents me from sleeping at all	1 (2.1)	0	0	1 (1.0)
Missing	1 (2.1)	2 (7.4)	0	3 (3.1)
Visit 5				
My sleep is never disturbed by pain	24 (51.1)	18 (66.7)	14 (58.3)	56 (57.1)
My sleep is occasionally disturbed by pain	19 (40.4)	7 (25.9)	8 (33.3)	34 (34.7)
Because of pain I have less than 6 hours sleep	1 (2.1)	0	0	1 (1.0)
Because of pain I have less than 4 hours sleep	0	2 (7.4)	0	2 (2.0)
Because of pain I have less than 2 hours sleep	0	0	1 (4.2)	1 (1.0)
Pain prevents me from sleeping at all	0	0	0	0
Missing	3 (6.4)	0	1 (4.2)	4 (4.1)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Table 14.2.1.1.7: Frequency on ODI Section 7 (Sleeping) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
My sleep is never disturbed by pain	30 (63.8)	16 (59.3)	14 (58.3)	60 (61.2)
My sleep is occasionally disturbed by pain	12 (25.5)	9 (33.3)	8 (33.3)	29 (29.6)
Because of pain I have less than 6 hours sleep	2 (4.3)	1 (3.7)	0	3 (3.1)
Because of pain I have less than 4 hours sleep	1 (2.1)	0	1 (4.2)	2 (2.0)
Because of pain I have less than 2 hours sleep	0	0	0	0
Pain prevents me from sleeping at all	0	0	0	0
Missing	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Visit 7				
My sleep is never disturbed by pain	25 (53.2)	15 (55.6)	15 (62.5)	55 (56.1)
My sleep is occasionally disturbed by pain	19 (40.4)	10 (37.0)	4 (16.7)	33 (33.7)
Because of pain I have less than 6 hours sleep	1 (2.1)	1 (3.7)	0	2 (2.0)
Because of pain I have less than 4 hours sleep	1 (2.1)	0	0	1 (1.0)
Because of pain I have less than 2 hours sleep	0	0	0	0
Pain prevents me from sleeping at all	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Visit 8				
My sleep is never disturbed by pain	25 (53.2)	16 (59.3)	12 (50.0)	53 (54.1)
My sleep is occasionally disturbed by pain	16 (34.0)	8 (29.6)	9 (37.5)	33 (33.7)
Because of pain I have less than 6 hours sleep	1 (2.1)	1 (3.7)	0	2 (2.0)
Because of pain I have less than 4 hours sleep	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Because of pain I have less than 2 hours sleep	0	0	0	0
Pain prevents me from sleeping at all	0	0	0	0
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
Visit 9				
My sleep is never disturbed by pain	24 (51.1)	13 (48.1)	14 (58.3)	51 (52.0)
My sleep is occasionally disturbed by pain	12 (25.5)	8 (29.6)	6 (25.0)	26 (26.5)
Because of pain I have less than 6 hours sleep	4 (8.5)	3 (11.1)	1 (4.2)	8 (8.2)
Because of pain I have less than 4 hours sleep	2 (4.3)	2 (7.4)	0	4 (4.1)
Because of pain I have less than 2 hours sleep	0	0	0	0
Pain prevents me from sleeping at all	0	0	0	0
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.7: Frequency on ODI Section 7 (Sleeping) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
My sleep is never disturbed by pain	20 (42.6)	10 (37.0)	11 (45.8)	41 (41.8)
My sleep is occasionally disturbed by pain	17 (36.2)	11 (40.7)	8 (33.3)	36 (36.7)
Because of pain I have less than 6 hours sleep	2 (4.3)	4 (14.8)	2 (8.3)	8 (8.2)
Because of pain I have less than 4 hours sleep	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Because of pain I have less than 2 hours sleep	1 (2.1)	0	0	1 (1.0)
Pain prevents me from sleeping at all	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
End of Trial				
My sleep is never disturbed by pain	21 (44.7)	12 (44.4)	14 (58.3)	47 (48.0)
My sleep is occasionally disturbed by pain	17 (36.2)	11 (40.7)	7 (29.2)	35 (35.7)
Because of pain I have less than 6 hours sleep	2 (4.3)	0	0	2 (2.0)
Because of pain I have less than 4 hours sleep	1 (2.1)	1 (3.7)	0	2 (2.0)
Because of pain I have less than 2 hours sleep	0	0	0	0
Pain prevents me from sleeping at all	0	0	0	0
Missing	6 (12.8)	3 (11.1)	3 (12.5)	12 (12.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.8: Frequency on ODI Section 8 (Sexual Life) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
My sex life is normal and causes no extra pain	9 (19.1)	2 (7.4)	2 (8.3)	13 (13.3)
My sex life is normal but causes some extra pain	10 (21.3)	4 (14.8)	5 (20.8)	19 (19.4)
My sex life is nearly normal but is very painful	5 (10.6)	7 (25.9)	0	12 (12.2)
My sex life is severely restricted by pain	5 (10.6)	6 (22.2)	6 (25.0)	17 (17.3)
My sex life is nearly absent because of pain	7 (14.9)	6 (22.2)	6 (25.0)	19 (19.4)
Pain prevents any sex life at all	7 (14.9)	2 (7.4)	4 (16.7)	13 (13.3)
Missing	4 (8.5)	0	1 (4.2)	5 (5.1)
Visit 3a*				
My sex life is normal and causes no extra pain	32 (68.1)	19 (70.4)	-	51 (52.0)
My sex life is normal but causes some extra pain	8 (17.0)	6 (22.2)	-	14 (14.3)
My sex life is nearly normal but is very painful	0	0	-	0
My sex life is severely restricted by pain	3 (6.4)	0	-	3 (3.1)
My sex life is nearly absent because of pain	1 (2.1)	0	-	1 (1.0)
Pain prevents any sex life at all	0	0	-	0
Missing	3 (6.4)	2 (7.4)	-	5 (5.1)
Visit 4				
My sex life is normal and causes no extra pain	36 (76.6)	20 (74.1)	11 (45.8)	67 (68.4)
My sex life is normal but causes some extra pain	6 (12.8)	5 (18.5)	3 (12.5)	14 (14.3)
My sex life is nearly normal but is very painful	1 (2.1)	0	1 (4.2)	2 (2.0)
My sex life is severely restricted by pain	0	0	4 (16.7)	4 (4.1)
My sex life is nearly absent because of pain	0	1 (3.7)	1 (4.2)	2 (2.0)
Pain prevents any sex life at all	0	0	0	0
Missing	4 (8.5)	1 (3.7)	4 (16.7)	9 (9.2)
Visit 5				
My sex life is normal and causes no extra pain	32 (68.1)	20 (74.1)	18 (75.0)	70 (71.4)
My sex life is normal but causes some extra pain	5 (10.6)	5 (18.5)	2 (8.3)	12 (12.2)
My sex life is nearly normal but is very painful	1 (2.1)	0	0	1 (1.0)
My sex life is severely restricted by pain	0	0	0	0
My sex life is nearly absent because of pain	0	0	0	0
Pain prevents any sex life at all	1 (2.1)	0	0	1 (1.0)
Missing	8 (17.0)	2 (7.4)	4 (16.7)	14 (14.3)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.8: Frequency on ODI Section 8 (Sexual Life) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
My sex life is normal and causes no extra pain	35 (74.5)	21 (77.8)	17 (70.8)	73 (74.5)
My sex life is normal but causes some extra pain	5 (10.6)	4 (14.8)	1 (4.2)	10 (10.2)
My sex life is nearly normal but is very painful	1 (2.1)	0	2 (8.3)	3 (3.1)
My sex life is severely restricted by pain	0	0	0	0
My sex life is nearly absent because of pain	0	0	0	0
Pain prevents any sex life at all	0	0	0	0
Missing	6 (12.8)	2 (7.4)	4 (16.7)	12 (12.2)
Visit 7				
My sex life is normal and causes no extra pain	39 (83.0)	24 (88.9)	17 (70.8)	80 (81.6)
My sex life is normal but causes some extra pain	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
My sex life is nearly normal but is very painful	0	1 (3.7)	0	1 (1.0)
My sex life is severely restricted by pain	1 (2.1)	0	1 (4.2)	2 (2.0)
My sex life is nearly absent because of pain	0	0	0	0
Pain prevents any sex life at all	0	0	0	0
Missing	4 (8.5)	1 (3.7)	5 (20.8)	10 (10.2)
Visit 8				
My sex life is normal and causes no extra pain	34 (72.3)	22 (81.5)	17 (70.8)	73 (74.5)
My sex life is normal but causes some extra pain	3 (6.4)	2 (7.4)	4 (16.7)	9 (9.2)
My sex life is nearly normal but is very painful	1 (2.1)	1 (3.7)	0	2 (2.0)
My sex life is severely restricted by pain	2 (4.3)	1 (3.7)	0	3 (3.1)
My sex life is nearly absent because of pain	0	0	0	0
Pain prevents any sex life at all	0	0	0	0
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
Visit 9				
My sex life is normal and causes no extra pain	30 (63.8)	19 (70.4)	17 (70.8)	66 (67.3)
My sex life is normal but causes some extra pain	5 (10.6)	6 (22.2)	2 (8.3)	13 (13.3)
My sex life is nearly normal but is very painful	0	0	0	0
My sex life is severely restricted by pain	0	0	0	0
My sex life is nearly absent because of pain	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Pain prevents any sex life at all	1 (2.1)	0	0	1 (1.0)
Missing	10 (21.3)	1 (3.7)	4 (16.7)	15 (15.3)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.8: Frequency on ODI Section 8 (Sexual Life) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
My sex life is normal and causes no extra pain	26 (55.3)	21 (77.8)	15 (62.5)	62 (63.3)
My sex life is normal but causes some extra pain	10 (21.3)	3 (11.1)	4 (16.7)	17 (17.3)
My sex life is nearly normal but is very painful	0	1 (3.7)	2 (8.3)	3 (3.1)
My sex life is severely restricted by pain	0	1 (3.7)	0	1 (1.0)
My sex life is nearly absent because of pain	1 (2.1)	0	0	1 (1.0)
Pain prevents any sex life at all	0	0	0	0
Missing	10 (21.3)	1 (3.7)	3 (12.5)	14 (14.3)
End of Trial				
My sex life is normal and causes no extra pain	28 (59.6)	22 (81.5)	16 (66.7)	66 (67.3)
My sex life is normal but causes some extra pain	4 (8.5)	3 (11.1)	4 (16.7)	11 (11.2)
My sex life is nearly normal but is very painful	0	0	0	0
My sex life is severely restricted by pain	1 (2.1)	1 (3.7)	0	2 (2.0)
My sex life is nearly absent because of pain	0	0	0	0
Pain prevents any sex life at all	1 (2.1)	0	0	1 (1.0)
Missing	13 (27.7)	1 (3.7)	4 (16.7)	18 (18.4)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq08.lst / odifrq.sas

Table 14.2.1.1.9: Frequency on ODI Section 9 (Social Life) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
My social life is normal and gives me no extra pain	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
My social life is normal but increases the degree of pain	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
Pain has no significant effect on my social life apart from limiting interests	9 (19.1)	11 (40.7)	7 (29.2)	27 (27.6)
Pain has restricted my social life and I do not go out as often	21 (44.7)	4 (14.8)	7 (29.2)	32 (32.7)
Pain has restricted my social life to my home	7 (14.9)	8 (29.6)	5 (20.8)	20 (20.4)
I have no social life because of pain	0	1 (3.7)	2 (8.3)	3 (3.1)
Missing	1 (2.1)	0	0	1 (1.0)
Visit 3a*				
My social life is normal and gives me no extra pain	26 (55.3)	18 (66.7)	-	44 (44.9)
My social life is normal but increases the degree of pain	6 (12.8)	1 (3.7)	-	7 (7.1)
Pain has no significant effect on my social life apart from limiting interests	13 (27.7)	6 (22.2)	-	19 (19.4)
Pain has restricted my social life and I do not go out as often	2 (4.3)	2 (7.4)	-	4 (4.1)
Pain has restricted my social life to my home	0	0	-	0
I have no social life because of pain	0	0	-	0
Missing	0	0	-	0
Visit 4				
My social life is normal and gives me no extra pain	38 (80.9)	18 (66.7)	12 (50.0)	68 (69.4)
My social life is normal but increases the degree of pain	3 (6.4)	4 (14.8)	1 (4.2)	8 (8.2)
Pain has no significant effect on my social life apart from limiting interests	3 (6.4)	4 (14.8)	5 (20.8)	12 (12.2)
Pain has restricted my social life and I do not go out as often	2 (4.3)	0	4 (16.7)	6 (6.1)
Pain has restricted my social life to my home	0	0	2 (8.3)	2 (2.0)
I have no social life because of pain	0	0	0	0
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
Visit 5				
My social life is normal and gives me no extra pain	35 (74.5)	23 (85.2)	15 (62.5)	73 (74.5)
My social life is normal but increases the degree of pain	1 (2.1)	0	1 (4.2)	2 (2.0)
Pain has no significant effect on my social life apart from limiting interests	3 (6.4)	4 (14.8)	5 (20.8)	12 (12.2)
Pain has restricted my social life and I do not go out as often	4 (8.5)	0	2 (8.3)	6 (6.1)
Pain has restricted my social life to my home	0	0	0	0
I have no social life because of pain	0	0	0	0
Missing	4 (8.5)	0	1 (4.2)	5 (5.1)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.9: Frequency on ODI Section 9 (Social Life) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
My social life is normal and gives me no extra pain	36 (76.6)	24 (88.9)	17 (70.8)	77 (78.6)
My social life is normal but increases the degree of pain	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Pain has no significant effect on my social life apart from limiting interests	5 (10.6)	0	4 (16.7)	9 (9.2)
Pain has restricted my social life and I do not go out as often	1 (2.1)	1 (3.7)	0	2 (2.0)
Pain has restricted my social life to my home	0	0	1 (4.2)	1 (1.0)
I have no social life because of pain	0	0	0	0
Missing	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Visit 7				
My social life is normal and gives me no extra pain	38 (80.9)	22 (81.5)	17 (70.8)	77 (78.6)
My social life is normal but increases the degree of pain	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Pain has no significant effect on my social life apart from limiting interests	6 (12.8)	2 (7.4)	1 (4.2)	9 (9.2)
Pain has restricted my social life and I do not go out as often	1 (2.1)	1 (3.7)	0	2 (2.0)
Pain has restricted my social life to my home	0	0	1 (4.2)	1 (1.0)
I have no social life because of pain	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Visit 8				
My social life is normal and gives me no extra pain	36 (76.6)	24 (88.9)	17 (70.8)	77 (78.6)
My social life is normal but increases the degree of pain	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Pain has no significant effect on my social life apart from limiting interests	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Pain has restricted my social life and I do not go out as often	3 (6.4)	0	1 (4.2)	4 (4.1)
Pain has restricted my social life to my home	0	0	0	0
I have no social life because of pain	0	0	0	0
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
Visit 9				
My social life is normal and gives me no extra pain	31 (66.0)	19 (70.4)	16 (66.7)	66 (67.3)
My social life is normal but increases the degree of pain	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
Pain has no significant effect on my social life apart from limiting interests	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
Pain has restricted my social life and I do not go out as often	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Pain has restricted my social life to my home	0	0	0	0
I have no social life because of pain	0	0	0	0
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq09.lst / odifrq.sas

Table 14.2.1.1.9: Frequency on ODI Section 9 (Social Life) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
My social life is normal and gives me no extra pain	29 (61.7)	20 (74.1)	14 (58.3)	63 (64.3)
My social life is normal but increases the degree of pain	2 (4.3)	0	2 (8.3)	4 (4.1)
Pain has no significant effect on my social life apart from limiting interests	5 (10.6)	4 (14.8)	4 (16.7)	13 (13.3)
Pain has restricted my social life and I do not go out as often	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Pain has restricted my social life to my home	2 (4.3)	0	0	2 (2.0)
I have no social life because of pain	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
End of Trial				
My social life is normal and gives me no extra pain	33 (70.2)	21 (77.8)	17 (70.8)	71 (72.4)
My social life is normal but increases the degree of pain	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Pain has no significant effect on my social life apart from limiting interests	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Pain has restricted my social life and I do not go out as often	0	2 (7.4)	1 (4.2)	3 (3.1)
Pain has restricted my social life to my home	1 (2.1)	0	0	1 (1.0)
I have no social life because of pain	0	0	0	0
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Table 14.2.1.1.10: Frequency on ODI Section 10 (Traveling) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
I can travel anywhere without pain	5 (10.6)	3 (11.1)	3 (12.5)	11 (11.2)
I can travel anywhere but it gives me extra pain	7 (14.9)	8 (29.6)	3 (12.5)	18 (18.4)
Pain is bad but I manage journeys over two hours	11 (23.4)	5 (18.5)	4 (16.7)	20 (20.4)
Pain restricts me to journeys of less than one hour	8 (17.0)	2 (7.4)	5 (20.8)	15 (15.3)
Pain restricts me to short necessary journeys under 30 minutes	9 (19.1)	2 (7.4)	2 (8.3)	13 (13.3)
Pain prevents me from travelling except to receive treatment	5 (10.6)	7 (25.9)	7 (29.2)	19 (19.4)
Missing	2 (4.3)	0	0	2 (2.0)
Visit 3a*				
I can travel anywhere without pain	21 (44.7)	16 (59.3)	-	37 (37.8)
I can travel anywhere but it gives me extra pain	17 (36.2)	10 (37.0)	-	27 (27.6)
Pain is bad but I manage journeys over two hours	7 (14.9)	0	-	7 (7.1)
Pain restricts me to journeys of less than one hour	1 (2.1)	1 (3.7)	-	2 (2.0)
Pain restricts me to short necessary journeys under 30 minutes	1 (2.1)	0	-	1 (1.0)
Pain prevents me from travelling except to receive treatment	0	0	-	0
Missing	0	0	-	0
Visit 4				
I can travel anywhere without pain	28 (59.6)	20 (74.1)	9 (37.5)	57 (58.2)
I can travel anywhere but it gives me extra pain	15 (31.9)	5 (18.5)	11 (45.8)	31 (31.6)
Pain is bad but I manage journeys over two hours	0	1 (3.7)	2 (8.3)	3 (3.1)
Pain restricts me to journeys of less than one hour	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Pain restricts me to short necessary journeys under 30 minutes	0	0	0	0
Pain prevents me from travelling except to receive treatment	1 (2.1)	0	0	1 (1.0)
Missing	2 (4.3)	0	0	2 (2.0)
Visit 5				
I can travel anywhere without pain	29 (61.7)	21 (77.8)	12 (50.0)	62 (63.3)
I can travel anywhere but it gives me extra pain	10 (21.3)	3 (11.1)	8 (33.3)	21 (21.4)
Pain is bad but I manage journeys over two hours	1 (2.1)	2 (7.4)	3 (12.5)	6 (6.1)
Pain restricts me to journeys of less than one hour	1 (2.1)	1 (3.7)	0	2 (2.0)
Pain restricts me to short necessary journeys under 30 minutes	0	0	0	0
Pain prevents me from travelling except to receive treatment	1 (2.1)	0	0	1 (1.0)
Missing	5 (10.6)	0	1 (4.2)	6 (6.1)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq10.lst / odifrq.sas

Table 14.2.1.1.10: Frequency on ODI Section 10 (Traveling) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
I can travel anywhere without pain	36 (76.6)	19 (70.4)	15 (62.5)	70 (71.4)
I can travel anywhere but it gives me extra pain	4 (8.5)	5 (18.5)	7 (29.2)	16 (16.3)
Pain is bad but I manage journeys over two hours	4 (8.5)	1 (3.7)	1 (4.2)	6 (6.1)
Pain restricts me to journeys of less than one hour	0	1 (3.7)	0	1 (1.0)
Pain restricts me to short necessary journeys under 30 minutes	1 (2.1)	0	0	1 (1.0)
Pain prevents me from travelling except to receive treatment	0	0	0	0
Missing	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Visit 7				
I can travel anywhere without pain	36 (76.6)	19 (70.4)	15 (62.5)	70 (71.4)
I can travel anywhere but it gives me extra pain	6 (12.8)	5 (18.5)	4 (16.7)	15 (15.3)
Pain is bad but I manage journeys over two hours	2 (4.3)	0	1 (4.2)	3 (3.1)
Pain restricts me to journeys of less than one hour	2 (4.3)	2 (7.4)	0	4 (4.1)
Pain restricts me to short necessary journeys under 30 minutes	0	0	0	0
Pain prevents me from travelling except to receive treatment	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Visit 8				
I can travel anywhere without pain	30 (63.8)	22 (81.5)	14 (58.3)	66 (67.3)
I can travel anywhere but it gives me extra pain	9 (19.1)	2 (7.4)	8 (33.3)	19 (19.4)
Pain is bad but I manage journeys over two hours	2 (4.3)	0	0	2 (2.0)
Pain restricts me to journeys of less than one hour	2 (4.3)	2 (7.4)	0	4 (4.1)
Pain restricts me to short necessary journeys under 30 minutes	0	0	0	0
Pain prevents me from travelling except to receive treatment	0	0	0	0
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
Visit 9				
I can travel anywhere without pain	27 (57.4)	16 (59.3)	16 (66.7)	59 (60.2)
I can travel anywhere but it gives me extra pain	11 (23.4)	7 (25.9)	3 (12.5)	21 (21.4)
Pain is bad but I manage journeys over two hours	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Pain restricts me to journeys of less than one hour	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Pain restricts me to short necessary journeys under 30 minutes	0	0	0	0
Pain prevents me from travelling except to receive treatment	0	0	0	0
Missing	6 (12.8)	2 (7.4)	3 (12.5)	11 (11.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.1.1.10: Frequency on ODI Section 10 (Traveling) and changes from Baseline (Visit 2a) - full analysis set

Visit	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
I can travel anywhere without pain	26 (55.3)	17 (63.0)	12 (50.0)	55 (56.1)
I can travel anywhere but it gives me extra pain	12 (25.5)	5 (18.5)	5 (20.8)	22 (22.4)
Pain is bad but I manage journeys over two hours	1 (2.1)	3 (11.1)	4 (16.7)	8 (8.2)
Pain restricts me to journeys of less than one hour	1 (2.1)	1 (3.7)	0	2 (2.0)
Pain restricts me to short necessary journeys under 30 minutes	0	0	0	0
Pain prevents me from travelling except to receive treatment	0	0	0	0
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
End of Trial				
I can travel anywhere without pain	30 (63.8)	21 (77.8)	13 (54.2)	64 (65.3)
I can travel anywhere but it gives me extra pain	9 (19.1)	2 (7.4)	7 (29.2)	18 (18.4)
Pain is bad but I manage journeys over two hours	0	1 (3.7)	0	1 (1.0)
Pain restricts me to journeys of less than one hour	1 (2.1)	2 (7.4)	0	3 (3.1)
Pain restricts me to short necessary journeys under 30 minutes	0	0	0	0
Pain prevents me from travelling except to receive treatment	0	0	0	0
Missing	7 (14.9)	1 (3.7)	4 (16.7)	12 (12.2)

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odifrq10.lst / odifrq.sas

Table 14.2.1.2.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Total ODI Score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	Mean	44.2	48.4	48.0			
	SD	17.52	15.24	22.18			
	Min	4	20	2			
	25% quantile	33.3	38.0	32.0			
	Median	44.0	44.0	44.3			
	75% quantile	56.0	60.0	63.0			
	Max	82	80	90			
Visit 3a							
	N with data	47	27	0	47	27	0
	N missing	0	0	24	0	0	24
	Mean	17.1	12.6	-	-27.2	-35.8	-
	SD	12.70	10.25	-	19.99	16.22	-
	Min	0	0	-	-78	-76	-
	25% quantile	4.4	2.0	-	-38.0	-46.0	-
	Median	16.0	10.0	-	-28.0	-34.0	-
	75% quantile	26.0	22.0	-	-10.0	-26.0	-
	Max	46	36	-	2	-10	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	12.2	12.1	20.3	-31.7	-36.3	-27.6
	SD	10.49	12.51	13.62	19.20	19.36	20.94
	Min	0	0	0	-82	-76	-82
	25% quantile	4.0	2.0	9.0	-42.0	-52.0	-43.2
	Median	10.0	6.0	19.0	-31.0	-36.0	-23.2
	75% quantile	16.0	20.0	30.0	-18.0	-24.0	-15.0
	Max	46	44	48	0	4	6

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odil.lst / odi.sas

Table 14.2.1.2.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Total ODI Score (continued)							
Visit 5							
	N with data	45	27	23	45	27	23
	N missing	2	0	1	2	0	1
	Mean	11.8	10.3	15.1	-32.4	-38.1	-32.0
	SD	12.76	13.37	13.11	21.14	18.27	22.17
	Min	0	0	0	-80	-74	-82
	25% quantile	2.0	0	4.0	-42.0	-54.0	-48.0
	Median	8.0	4.0	10.0	-34.0	-36.0	-32.0
	75% quantile	16.0	12.0	24.4	-22.0	-28.0	-18.0
	Max	54	46	46	27	6	14
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	10.3	8.8	10.9	-33.6	-40.7	-36.3
	SD	11.96	10.45	10.41	19.64	18.42	22.86
	Min	0	0	0	-82	-72	-82
	25% quantile	0	0	2.0	-42.0	-56.0	-50.0
	Median	6.0	3.0	8.9	-33.0	-40.0	-38.0
	75% quantile	16.0	16.0	18.0	-17.3	-28.0	-22.0
	Max	53	38	38	-4	-2	6
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	10.3	9.8	10.2	-33.7	-39.6	-33.8
	SD	11.38	11.37	12.18	19.91	19.20	24.63
	Min	0	0	0	-82	-78	-82
	25% quantile	2.0	0	1.0	-42.0	-50.0	-52.0
	Median	8.0	7.0	6.0	-34.6	-38.0	-32.0
	75% quantile	14.0	12.0	16.0	-18.0	-26.0	-15.0
	Max	44	42	48	4	-6	16

SC = Standard Care; ODI = Oswestry Disability Index
 * Visit 3a only applicable for patients in NDplus or NDbasic group
 Clinipace: 14DEC21 / 7:39 / odil.lst / odi.sas

Table 14.2.1.2.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Total ODI Score (continued)							
Visit 8							
	N with data	44	26	22	44	26	22
	N missing	3	1	2	3	1	2
	Mean	11.3	8.2	10.1	-32.4	-41.3	-36.7
	SD	13.21	12.77	10.83	20.00	19.22	22.46
	Min	0	0	0	-82	-78	-82
	25% quantile	2.0	0	0	-44.0	-54.0	-52.0
	Median	7.0	3.0	6.0	-30.0	-39.0	-38.0
	75% quantile	14.0	10.0	18.0	-17.0	-32.0	-24.0
	Max	56	50	34	16	10	0
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	12.9	13.5	12.0	-30.6	-36.0	-32.7
	SD	15.32	17.14	13.51	20.86	21.76	21.72
	Min	0	0	0	-78	-78	-80
	25% quantile	2.0	0	2.0	-44.0	-46.0	-40.7
	Median	8.0	5.3	8.0	-31.0	-35.0	-32.0
	75% quantile	18.0	22.0	16.0	-13.3	-26.0	-22.0
	Max	60	62	54	16	22	4
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	15.1	13.9	15.7	-28.3	-35.6	-31.1
	SD	16.58	14.61	14.92	23.70	20.80	23.08
	Min	0	0	0	-78	-76	-80
	25% quantile	2.0	2.0	2.0	-40.0	-56.0	-48.0
	Median	8.0	9.0	12.0	-26.0	-32.0	-30.8
	75% quantile	26.0	22.0	30.0	-12.0	-22.0	-12.7
	Max	74	42	42	28	4	6

SC = Standard Care; ODI = Oswestry Disability Index
 * Visit 3a only applicable for patients in NDplus or NDbasic group
 Clinipace: 14DEC21 / 7:39 / odil.lst / odi.sas

Table 14.2.1.2.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Total ODI Score (continued)							
End of Trial							
	N with data	41	26	21	41	26	21
	N missing	6	1	3	6	1	3
	Mean	11.2	10.4	10.1	-32.6	-39.1	-34.6
	SD	13.02	13.95	10.29	21.69	20.54	21.33
	Min	0	0	0	-80	-76	-82
	25% quantile	2.0	0	2.0	-45.6	-54.0	-46.0
	Median	8.0	4.0	8.0	-34.0	-39.0	-34.0
	75% quantile	17.8	12.0	16.0	-16.0	-26.0	-20.0
	Max	64	48	38	10	8	-2

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Table 14.2.1.2.2: Differences in changes of ODI total scores between treatment groups - full analysis set

Visit Number	NDplus-SC			NDbasic-SC			NDplus-NDbasic			
	Point estimate [1]	95% CI [1]		Point estimate [1]	95% CI [1]		Point estimate [1]	95% CI [1]		
Changes from visit 2A	VISIT 3A						10.00	0.00 -	18.00	
	VISIT 4	-5.56	-14.00 -	6.00	-10.21	-21.78 -	2.00	6.00	-4.00 -	16.00
	VISIT 5	0.00	-11.43 -	10.00	-6.00	-18.00 -	6.00	6.00	-4.00 -	16.00
	VISIT 6	4.00	-8.00 -	14.00	-4.00	-17.56 -	8.00	8.00	-2.00 -	18.00
	VISIT 7	0.00	-12.00 -	12.67	-6.00	-20.00 -	8.00	6.00	-4.00 -	16.00
	VISIT 8	4.56	-7.33 -	16.00	-5.78	-18.00 -	8.00	8.76	0.00 -	18.44
	VISIT 9	2.00	-10.00 -	14.00	-4.00	-16.00 -	8.00	6.00	-4.00 -	16.86
	VISIT 10	2.00	-10.00 -	14.67	-6.00	-19.33 -	9.56	6.69	-4.00 -	20.00
	END OF TRIAL	2.00	-10.00 -	12.44	-6.00	-18.00 -	6.67	8.00	-3.78 -	18.44
Changes from visit 3A	VISIT 4						-2.33	-8.00 -	0.22	
	VISIT 5						-3.78	-6.50 -	0.00	
	VISIT 6						-1.11	-6.00 -	4.00	
	VISIT 7						-2.00	-6.67 -	2.00	
	VISIT 8						-0.89	-6.00 -	4.00	
	VISIT 9						-2.00	-8.00 -	2.44	
	VISIT 10						-1.89	-8.00 -	4.00	
	END OF TRIAL						-2.00	-8.00 -	4.00	

SC = Standard Care; ODI = Oswestry Disability Index

[1] Hodges-Lehmann confidence interval

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odidiff1.lst / odidiff.sas

Table 14.2.1.3.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) separately for HD and ADD patients - full analysis set

Indication	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
HD							
Baseline (Visit 2a)							
	N with data	38	22	22			
	Mean	43.2	47.7	48.1			
	SD	18.29	15.46	22.79			
	Min	4	20	2			
	25% quantile	33.3	38.0	32.0			
	Median	42.0	43.0	44.3			
	75% quantile	52.0	58.0	66.0			
	Max	82	80	90			
Visit 3a							
	N with data	38	22	0	38	22	0
	N missing	0	0	22	0	0	22
	Mean	16.6	13.6	-	-26.5	-34.1	-
	SD	12.63	10.52	-	21.26	16.43	-
	Min	0	0	-	-78	-76	-
	25% quantile	4.4	4.0	-	-38.0	-44.0	-
	Median	15.0	11.6	-	-26.0	-32.0	-
	75% quantile	26.0	22.0	-	-10.0	-22.0	-
	Max	46	36	-	2	-10	-
Visit 4							
	N with data	38	22	22	38	22	22
	Mean	12.7	11.5	20.5	-30.5	-36.2	-27.6
	SD	11.10	11.63	14.23	19.86	19.32	21.49
	Min	0	0	0	-82	-76	-82
	25% quantile	4.0	2.0	8.0	-38.0	-52.0	-44.4
	Median	11.0	6.0	20.0	-30.0	-35.4	-23.2
	75% quantile	16.0	20.0	30.0	-16.0	-24.0	-16.0
	Max	46	44	48	0	4	6

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odi2.lst / odi.sas

Table 14.2.1.3.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) separately for HD and ADD patients - full analysis set

Indication	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
HD (continued)							
Visit 5	N with data	36	22	21	36	22	21
	N missing	2	0	1	2	0	1
	Mean	9.6	11.0	15.7	-33.4	-36.6	-31.5
	SD	8.93	13.95	13.51	20.18	19.18	22.40
	Min	0	0	0	-80	-74	-82
	25% quantile	2.4	2.0	6.0	-41.3	-54.0	-40.0
	Median	7.3	5.0	10.0	-33.7	-33.0	-32.0
	75% quantile	14.8	12.0	24.4	-20.0	-26.9	-18.0
	Max	38	46	46	-2	6	14
Visit 6	N with data	38	21	21	38	21	21
	N missing	0	1	1	0	1	1
	Mean	9.7	8.4	11.2	-33.5	-40.5	-36.1
	SD	12.03	10.92	10.57	21.11	17.76	22.94
	Min	0	0	0	-82	-72	-82
	25% quantile	0	0	2.0	-43.1	-54.0	-49.1
	Median	5.2	2.0	8.9	-33.0	-40.0	-38.0
	75% quantile	14.0	14.0	18.0	-16.0	-30.0	-24.0
	Max	53	38	38	-4	-2	6
Visit 7	N with data	38	21	18	38	21	18
	N missing	0	1	4	0	1	4
	Mean	9.4	9.5	10.4	-33.7	-39.5	-33.4
	SD	10.84	11.66	12.50	21.14	20.17	24.79
	Min	0	0	0	-82	-78	-82
	25% quantile	2.0	0	2.0	-43.1	-46.9	-50.0
	Median	6.0	6.0	6.0	-34.6	-38.0	-32.0
	75% quantile	14.0	12.0	14.0	-17.8	-22.0	-16.0
	Max	44	42	48	4	-6	16

SC = Standard Care; ODI = Oswestry Disability Index
 * Visit 3a only applicable for patients in NDplus or NDbasic group
 Clinipace: 14DEC21 / 7:39 / odi2.lst / odi.sas

Table 14.2.1.3.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) separately for HD and ADD patients - full analysis set

Indication	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
HD (continued)							
Visit 8							
	N with data	36	21	20	36	21	20
	N missing	2	1	2	2	1	2
	Mean	10.6	8.5	10.2	-32.1	-40.5	-36.7
	SD	12.72	13.70	11.00	21.10	20.27	22.40
	Min	0	0	0	-82	-78	-82
	25% quantile	2.0	0	0	-41.0	-54.0	-51.0
	Median	7.0	2.0	6.0	-30.0	-36.0	-38.0
	75% quantile	14.0	10.0	17.0	-17.0	-32.0	-24.0
	Max	56	50	34	16	10	0
Visit 9							
	N with data	35	21	19	35	21	19
	N missing	3	1	3	3	1	3
	Mean	11.8	13.4	12.4	-31.1	-35.6	-32.1
	SD	14.70	18.17	13.92	21.78	23.60	21.61
	Min	0	0	0	-78	-78	-80
	25% quantile	2.0	0	2.0	-44.0	-46.0	-40.7
	Median	6.7	4.0	8.0	-32.0	-38.0	-32.0
	75% quantile	16.0	22.0	20.0	-13.3	-20.0	-22.0
	Max	60	62	54	16	22	4
Visit 10							
	N with data	34	21	20	34	21	20
	N missing	4	1	2	4	1	2
	Mean	14.6	14.6	16.8	-28.1	-34.4	-30.1
	SD	16.87	14.69	15.17	24.62	21.58	23.23
	Min	0	0	0	-78	-76	-80
	25% quantile	2.0	2.0	2.0	-40.0	-46.0	-45.0
	Median	8.0	12.0	15.0	-26.8	-32.0	-30.8
	75% quantile	22.0	22.0	31.0	-12.0	-22.0	-10.7
	Max	74	42	42	28	4	6

SC = Standard Care; ODI = Oswestry Disability Index
 * Visit 3a only applicable for patients in NDplus or NDbasic group
 Clinipace: 14DEC21 / 7:39 / odi2.lst / odi.sas

Table 14.2.1.3.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) separately for HD and ADD patients - full analysis set

Indication Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
HD (continued)							
End of Trial							
	N with data	33	21	19	33	21	19
	N missing	5	1	3	5	1	3
	Mean	9.4	11.7	10.6	-33.4	-37.3	-33.9
	SD	10.00	15.10	10.56	21.41	21.49	21.46
	Min	0	0	0	-80	-76	-82
	25% quantile	2.0	0	2.0	-45.6	-46.0	-46.0
	Median	6.0	4.0	8.0	-34.0	-38.0	-34.0
	75% quantile	13.3	12.0	16.0	-16.0	-26.0	-18.0
	Max	46	48	38	6	8	-2
ADD							
Baseline (Visit 2a)							
	N with data	9	5	2			
	Mean	48.7	51.6	46.0			
	SD	13.78	15.45	19.80			
	Min	24	34	32			
	25% quantile	50.0	36.0	32.0			
	Median	54.0	58.0	46.0			
	75% quantile	56.0	64.0	60.0			
	Max	62	66	60			
Visit 3a							
	N with data	9	5	0	9	5	0
	N missing	0	0	2	0	0	2
	Mean	18.9	8.4	-	-29.8	-43.2	-
	SD	13.61	8.65	-	14.01	14.46	-
	Min	0	0	-	-56	-64	-
	25% quantile	14.0	2.0	-	-34.0	-48.0	-
	Median	22.0	8.0	-	-32.0	-44.0	-
	75% quantile	22.2	10.0	-	-26.0	-34.0	-
	Max	42	22	-	-8	-26	-

SC = Standard Care; ODI = Oswestry Disability Index

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / odi2.lst / odi.sas

Table 14.2.1.3.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) separately for HD and ADD patients - full analysis set

Indication	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
ADD (continued)							
Visit 4	N with data	8	5	2	8	5	2
	N missing	1	0	0	1	0	0
	Mean	10.3	14.7	18.0	-37.5	-36.9	-28.0
	SD	7.13	17.20	0	15.45	21.85	19.80
	Min	0	0	18	-56	-64	-42
	25% quantile	5.0	0	18.0	-46.0	-50.0	-42.0
	Median	9.0	8.0	18.0	-43.0	-36.0	-28.0
	75% quantile	17.0	27.5	18.0	-29.0	-28.0	-14.0
	Max	20	38	18	-8	-7	-14
Visit 5	N with data	9	5	2	9	5	2
	Mean	20.3	6.8	9.0	-28.3	-44.8	-37.0
	SD	21.04	11.01	7.07	25.57	13.08	26.87
	Min	0	0	4	-56	-64	-56
	25% quantile	2.0	0	4.0	-42.0	-52.0	-56.0
	Median	18.0	2.0	9.0	-38.0	-40.0	-37.0
	75% quantile	32.0	6.0	14.0	-22.0	-36.0	-18.0
	Max	54	26	14	27	-32	-18
Visit 6	N with data	8	5	2	8	5	2
	N missing	1	0	0	1	0	0
	Mean	13.3	10.4	8.0	-34.4	-41.2	-38.0
	SD	11.90	9.10	11.31	11.08	23.31	31.11
	Min	0	0	0	-56	-64	-60
	25% quantile	2.2	2.0	0	-39.0	-56.0	-60.0
	Median	13.0	12.0	8.0	-33.0	-54.0	-38.0
	75% quantile	22.0	18.0	16.0	-28.0	-16.0	-16.0
	Max	32	20	16	-20	-16	-16

SC = Standard Care; ODI = Oswestry Disability Index
 * Visit 3a only applicable for patients in NDplus or NDbasic group
 Clinipace: 14DEC21 / 7:39 / odi2.lst / odi.sas

Table 14.2.1.3.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) separately for HD and ADD patients - full analysis set

Indication	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
ADD (continued)							
Visit 7	N with data	8	5	2	8	5	2
	N missing	1	0	0	1	0	0
	Mean	14.3	11.2	9.0	-33.5	-40.4	-37.0
	SD	13.79	11.19	12.73	13.60	16.46	32.53
	Min	0	0	0	-56	-64	-60
	25% quantile	4.0	8.0	0	-41.0	-50.0	-60.0
	Median	12.0	8.0	9.0	-35.0	-36.0	-37.0
	75% quantile	20.0	10.0	18.0	-23.0	-26.0	-14.0
	Max	42	30	18	-14	-26	-14
Visit 8	N with data	8	5	2	8	5	2
	N missing	1	0	0	1	0	0
	Mean	14.3	6.8	9.0	-33.5	-44.8	-37.0
	SD	15.84	8.79	12.73	15.15	15.34	32.53
	Min	0	0	0	-54	-64	-60
	25% quantile	3.0	2.0	0	-47.0	-56.0	-60.0
	Median	8.0	4.0	9.0	-32.0	-44.0	-37.0
	75% quantile	23.0	6.0	18.0	-21.0	-32.0	-14.0
	Max	46	22	18	-14	-28	-14
Visit 9	N with data	7	5	2	7	5	2
	N missing	2	0	0	2	0	0
	Mean	18.5	14.0	8.0	-28.3	-37.6	-38.0
	SD	18.29	13.64	11.31	16.62	13.07	31.11
	Min	0	2	0	-56	-60	-60
	25% quantile	0	4.0	0	-40.0	-36.0	-60.0
	Median	15.6	8.0	8.0	-26.0	-34.0	-38.0
	75% quantile	28.0	22.0	16.0	-10.0	-32.0	-16.0
	Max	52	34	16	-8	-26	-16

SC = Standard Care; ODI = Oswestry Disability Index
 * Visit 3a only applicable for patients in NDplus or NDbasic group
 Clinipace: 14DEC21 / 7:39 / odi2.lst / odi.sas

Table 14.2.1.3.1: Summary of ODI total score and changes in ODI total score from Baseline (Visit 2a) separately for HD and ADD patients - full analysis set

Indication	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
ADD (continued)							
Visit 10	N with data	7	5	2	7	5	2
	N missing	2	0	0	2	0	0
	Mean	17.6	11.2	5.0	-29.3	-40.4	-41.0
	SD	16.14	15.66	7.07	20.26	18.46	26.87
	Min	0	0	0	-56	-64	-60
	25% quantile	0	2.0	0	-46.0	-56.0	-60.0
	Median	16.0	4.0	5.0	-26.0	-32.0	-41.0
	75% quantile	31.1	12.0	10.0	-12.0	-28.0	-22.0
	Max	42	38	10	2	-22	-22
End of Trial							
	N with data	8	5	2	8	5	2
	N missing	1	0	0	1	0	0
	Mean	18.5	4.8	5.0	-29.2	-46.8	-41.0
	SD	20.87	5.22	7.07	24.01	15.40	26.87
	Min	0	0	0	-60	-64	-60
	25% quantile	1.0	0	0	-46.0	-54.0	-60.0
	Median	20.0	4.0	5.0	-32.0	-54.0	-41.0
	75% quantile	21.1	8.0	10.0	-13.9	-36.0	-22.0
	Max	64	12	10	10	-26	-22

SC = Standard Care; ODI = Oswestry Disability Index
 * Visit 3a only applicable for patients in NDplus or NDbasic group
 Clinipace: 14DEC21 / 7:39 / odi2.lst / odi.sas

Table 14.2.1.3.2: Differences in changes of ODI total scores between treatment groups separately for HD and ADD patients - full analysis set

Type	Visit Number	NDplus-SC		NDbasic-SC		NDplus-NDbasic			
		Point estimate [1]	95% CI [1]	Point estimate [1]	95% CI [1]	Point estimate [1]	95% CI [1]		
Changes from visit 2A	Absence of adjacent degenerative disc	VISIT 3A	-	-	-	-	8.33	-1.14 - 20.00	
		VISIT 4	-4.00	-13.78 - 8.00	-11.44	-22.00 - 2.00	6.86	-2.00 - 18.00	
		VISIT 5	0.00	-12.22 - 10.44	-5.56	-18.00 - 8.00	4.00	-7.14 - 16.00	
		VISIT 6	4.00	-10.00 - 16.00	-4.00	-18.00 - 8.00	8.00	-2.00 - 20.00	
		VISIT 7	0.00	-13.11 - 14.00	-6.00	-22.00 - 8.67	6.00	-4.00 - 18.00	
		VISIT 8	6.00	-7.33 - 16.67	-4.00	-18.00 - 8.00	8.00	-2.00 - 20.00	
		VISIT 9	2.00	-10.00 - 14.00	-4.00	-18.00 - 10.00	6.00	-7.11 - 18.00	
		VISIT 10	2.00	-12.00 - 15.78	-5.65	-21.33 - 10.00	6.00	-6.00 - 20.00	
		END OF TRIAL	0.44	-11.56 - 12.00	-4.00	-18.00 - 10.00	5.56	-7.56 - 18.00	
		Presence of adjacent degenerative disc	VISIT 3A	-	-	-	-	14.00	-7.78 - 34.00
			VISIT 4	-7.00	-42.00 - 34.00	-11.00	-50.00 - 35.50	-0.75	-29.50 - 28.00
			VISIT 5	7.00	-38.00 - 83.11	-11.00	-46.00 - 24.00	12.00	-10.00 - 44.00
			VISIT 6	0.22	-40.00 - 40.44	0.00	-48.00 - 44.00	13.00	-20.00 - 34.00
			VISIT 7	2.00	-42.00 - 46.00	-8.00	-50.00 - 34.00	7.00	-14.00 - 30.00
			VISIT 8	3.00	-40.00 - 46.00	-9.00	-50.00 - 32.00	11.00	-14.00 - 38.00
			VISIT 9	6.78	-40.00 - 51.56	-5.00	-44.00 - 34.00	8.00	-14.00 - 28.00
			VISIT 10	12.00	-34.00 - 62.00	-2.00	-42.00 - 38.00	10.00	-20.00 - 39.11
END OF TRIAL	12.11		-38.00 - 70.00	-4.00	-42.00 - 34.00	19.00	-8.00 - 52.22		
Changes from visit 3A	Absence of adjacent degenerative disc		VISIT 4					-2.00	-6.00 - 2.00
		VISIT 5					-4.00	-8.00 - 0.00	
		VISIT 6					0.00	-5.78 - 4.00	
		VISIT 7					-0.22	-6.00 - 4.00	
		VISIT 8					-0.22	-6.00 - 6.00	
		VISIT 9					-2.00	-10.00 - 4.00	
		VISIT 10					-0.89	-8.00 - 5.56	
		END OF TRIAL					-2.00	-8.00 - 4.00	

SC = Standard Care; ODI = Oswestry Disability Index
 [1] Hodges-Lehmann confidence interval
 Clinipace: 14DEC21 / 7:39 / odidiff2.lst / odidiff.sas

Table 14.2.1.3.2: Differences in changes of ODI total scores between treatment groups separately for HD and ADD patients - full analysis set

Type	Visit Number	NDplus-SC		NDbasic-SC		NDplus-NDbasic	
		Point estimate [1]	95% CI [1]	Point estimate [1]	95% CI [1]	Point estimate [1]	95% CI [1]
Changes from visit 3A Presence of adjacent degenerative disc	VISIT 4					-12.00	-33.50 - 2.00
	VISIT 5					-0.22	-10.00 - 26.00
	VISIT 6					-7.00	-21.56 - 8.00
	VISIT 7					-6.22	-16.00 - 2.00
	VISIT 8					0.00	-12.00 - 12.00
	VISIT 9					-4.00	-12.00 - 8.00
	VISIT 10					0.00	-16.00 - 16.89
	END OF TRIAL					4.89	-22.00 - 16.22

Table 14.2.1.4: Ancova of changes in ODI total scores from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 4	71					
NDplus		-31.6	-7.05	3.18	-2.22	0.0303
NDbasic		-35.0	-10.44	3.66	-2.85	0.0060
SC		-24.6	0.00			
ADD			0.05	4.45	0.01	0.9917
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			1.05	3.26	0.32	0.7474
size of annulus defect > 6 mm			11.73	5.59	2.10	0.0401
ODI total score at Baseline			-0.82	0.07	-11.19	<.0001
Number of cigarettes on baseline			-0.02	0.23	-0.07	0.9438
Age			0.23	0.16	1.41	0.1638
Pfarrmann score at Baseline			2.56	2.75	0.93	0.3569
Amount of tissue			-1.77	1.12	-1.58	0.1185
Pain score as assessed on VAS at Baseline			1.13	0.53	2.14	0.0365

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

ODI = Oswestry Disability Index

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.1.4: Ancova of changes in ODI total scores from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 5	69					
NDplus		-29.4	-0.77	3.42	-0.23	0.8225
NDbasic		-36.0	-7.40	3.87	-1.91	0.0610
SC		-28.6	0.00			
ADD			1.72	4.56	0.38	0.7081
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			3.68	3.45	1.06	0.2916
size of annulus defect > 6 mm			15.97	5.93	2.70	0.0092
ODI total score at Baseline			-0.81	0.08	-10.40	<.0001
Number of cigarettes on baseline			0.08	0.25	0.32	0.7474
Age			0.32	0.17	1.89	0.0632
Pfarrmann score at Baseline			1.33	2.79	0.48	0.6359
Amount of tissue			-2.36	1.21	-1.95	0.0558
Pain score as assessed on VAS at Baseline			1.24	0.55	2.24	0.0289

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

ODI = Oswestry Disability Index

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.1.4: Ancova of changes in ODI total scores from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 6	69					
NDplus		-27.6	3.81	2.92	1.30	0.1976
NDbasic		-36.1	-4.64	3.42	-1.36	0.1803
SC		-31.4	0.00			
ADD			4.47	4.03	1.11	0.2718
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			6.86	3.00	2.28	0.0261
size of annulus defect > 6 mm			19.28	5.15	3.75	0.0004
ODI total score at Baseline			-0.87	0.07	-12.88	<.0001
Number of cigarettes on baseline			0.14	0.21	0.67	0.5064
Age			0.41	0.15	2.81	0.0068
Pfarrmann score at Baseline			2.21	2.54	0.87	0.3897
Amount of tissue			-2.55	1.02	-2.51	0.0149
Pain score as assessed on VAS at Baseline			0.83	0.49	1.70	0.0944

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

ODI = Oswestry Disability Index

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Clinipace: 14DEC21 / 7:39 / odianc.lst / odianc.sas

Table 14.2.1.4: Ancova of changes in ODI total scores from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 7	66					
NDplus		-27.7	3.05	2.95	1.03	0.3062
NDbasic		-35.7	-4.94	3.39	-1.46	0.1506
SC		-30.8	0.00			
ADD			4.57	3.87	1.18	0.2433
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			3.97	2.96	1.34	0.1848
size of annulus defect > 6 mm			20.14	4.98	4.05	0.0002
ODI total score at Baseline			-0.93	0.07	-13.80	<.0001
Number of cigarettes on baseline			0.17	0.22	0.77	0.4427
Age			0.33	0.14	2.32	0.0241
Pfarrmann score at Baseline			2.91	2.43	1.19	0.2378
Amount of tissue			-2.83	0.98	-2.90	0.0053
Pain score as assessed on VAS at Baseline			1.24	0.48	2.58	0.0128

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

ODI = Oswestry Disability Index

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Clinipace: 14DEC21 / 7:39 / odianc.lst / odianc.sas

Table 14.2.1.4: Ancova of changes in ODI total scores from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 8	67					
NDplus		-27.4	5.10	2.85	1.79	0.0788
NDbasic		-35.2	-2.68	3.28	-0.82	0.4161
SC		-32.5	0.00			
ADD			6.04	3.86	1.57	0.1232
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			5.27	2.88	1.83	0.0724
size of annulus defect > 6 mm			15.66	4.93	3.18	0.0024
ODI total score at Baseline			-0.83	0.06	-12.97	<.0001
Number of cigarettes on baseline			-0.21	0.21	-0.99	0.3282
Age			0.38	0.14	2.69	0.0093
Pfarrmann score at Baseline			5.16	2.41	2.14	0.0368
Amount of tissue			-2.19	0.98	-2.23	0.0299
Pain score as assessed on VAS at Baseline			1.49	0.47	3.18	0.0024

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

ODI = Oswestry Disability Index

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Clinipace: 14DEC21 / 7:39 / odianc.lst / odianc.sas

Table 14.2.1.4: Ancova of changes in ODI total scores from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 9	65					
NDplus		-23.2	4.83	3.65	1.32	0.1911
NDbasic		-30.7	-2.64	4.20	-0.63	0.5321
SC		-28.0	0.00			
ADD			8.66	4.99	1.73	0.0886
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			6.29	3.71	1.69	0.0961
size of annulus defect > 6 mm			18.84	6.22	3.03	0.0038
ODI total score at Baseline			-0.78	0.08	-9.21	<.0001
Number of cigarettes on baseline			0.01	0.28	0.05	0.9631
Age			0.63	0.18	3.55	0.0008
Pfarrmann score at Baseline			5.51	3.17	1.74	0.0882
Amount of tissue			-2.63	1.22	-2.15	0.0359
Pain score as assessed on VAS at Baseline			1.90	0.62	3.07	0.0034

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

ODI = Oswestry Disability Index

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Clinipace: 14DEC21 / 7:39 / odianc.lst / odianc.sas

Table 14.2.1.4: Ancova of changes in ODI total scores from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 10	65					
NDplus		-23.5	5.01	3.97	1.26	0.2124
NDbasic		-30.5	-1.95	4.53	-0.43	0.6693
SC		-28.5	0.00			
ADD			3.14	5.47	0.57	0.5680
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			7.11	4.03	1.76	0.0839
size of annulus defect > 6 mm			16.97	6.83	2.49	0.0161
ODI total score at Baseline			-0.84	0.09	-9.41	<.0001
Number of cigarettes on baseline			-0.03	0.31	-0.08	0.9334
Age			0.60	0.19	3.10	0.0031
Pfarrmann score at Baseline			7.34	3.47	2.12	0.0389
Amount of tissue			-2.63	1.36	-1.93	0.0590
Pain score as assessed on VAS at Baseline			2.34	0.68	3.45	0.0011

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

ODI = Oswestry Disability Index

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Clinipace: 14DEC21 / 7:39 / odianc.lst / odianc.sas

Table 14.2.1.4: Ancova of changes in ODI total scores from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
End of Trial	64					
NDplus		-27.8	4.17	3.51	1.19	0.2400
NDbasic		-32.0	-0.09	3.96	-0.02	0.9826
SC		-32.0	0.00			
ADD			6.28	4.62	1.36	0.1797
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			7.69	3.56	2.16	0.0354
size of annulus defect > 6 mm			17.05	5.89	2.90	0.0055
ODI total score at Baseline			-0.88	0.08	-10.89	<.0001
Number of cigarettes on baseline			-0.12	0.26	-0.46	0.6470
Age			0.49	0.17	2.90	0.0054
Pfarrmann score at Baseline			3.55	3.11	1.14	0.2587
Amount of tissue			-1.89	1.16	-1.63	0.1087
Pain score as assessed on VAS at Baseline			0.86	0.61	1.42	0.1627

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

ODI = Oswestry Disability Index

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.2.1: Summary of subject's pain assessment and changes in subject's pain assessment from Baseline (Visit 2a) - full analysis set

Parameter	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Pain in the Back (cm)							
Baseline (Visit 2a)							
	N with data	44	24	23			
	N missing	3	3	1			
	Mean	3.1	3.9	3.5			
	SD	2.78	2.80	2.69			
	Min	0	0	0			
	25% quantile	0.7	1.8	1.5			
	Median	2.3	3.6	3.1			
	75% quantile	5.5	6.7	5.7			
	Max	9	9	8			
Visit 3a							
	N with data	45	26	0	42	23	0
	N missing	2	1	24	5	4	24
	Mean	1.2	0.9	-	-2.0	-3.2	-
	SD	1.53	0.84	-	2.39	2.64	-
	Min	0	0	-	-7	-9	-
	25% quantile	0.2	0.1	-	-3.7	-5.2	-
	Median	0.8	0.5	-	-1.6	-2.2	-
	75% quantile	1.5	1.3	-	0	-1.0	-
	Max	9	3	-	2	1	-
Visit 4							
	N with data	45	25	22	42	23	21
	N missing	2	2	2	5	4	3
	Mean	1.4	1.0	1.7	-1.7	-3.1	-1.9
	SD	1.55	1.44	1.83	2.71	2.56	3.68
	Min	0	0	0	-7	-8	-7
	25% quantile	0.3	0	0.3	-2.6	-4.3	-4.8
	Median	1.0	0.2	1.0	-1.1	-2.6	-2.8
	75% quantile	1.6	1.5	2.6	0	-1.1	0.1
	Max	8	5	6	6	0	6

Table 14.2.2.1: Summary of subject's pain assessment and changes in subject's pain assessment from Baseline (Visit 2a) - full analysis set

Parameter Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Pain in the Back (cm) (continued)							
Visit 5							
	N with data	45	27	23	42	24	22
	N missing	2	0	1	5	3	2
	Mean	1.2	1.0	1.7	-1.9	-2.9	-2.0
	SD	1.65	1.58	1.80	2.44	2.65	3.05
	Min	0	0	0	-7	-8	-8
	25% quantile	0.2	0	0.2	-3.1	-4.8	-4.5
	Median	0.6	0.3	1.3	-1.4	-2.3	-2.1
	75% quantile	1.6	1.8	2.5	0	-1.1	1.0
	Max	8	6	7	2	2	2
Visit 6							
	N with data	44	26	23	41	23	22
	N missing	3	1	1	6	4	2
	Mean	1.4	1.0	1.2	-1.7	-3.0	-2.4
	SD	1.82	1.47	1.28	3.09	3.07	2.73
	Min	0	0	0	-7	-8	-8
	25% quantile	0.3	0.1	0.2	-3.6	-5.8	-4.7
	Median	0.8	0.7	0.9	-1.0	-3.0	-2.0
	75% quantile	1.8	1.3	2.2	0	-0.9	-0.1
	Max	8	7	5	6	3	1
Visit 7							
	N with data	44	26	20	42	23	19
	N missing	3	1	4	5	4	5
	Mean	1.2	1.1	1.7	-1.9	-2.9	-1.9
	SD	1.04	1.41	1.93	2.62	2.84	2.68
	Min	0	0	0	-7	-9	-7
	25% quantile	0.4	0.1	0.3	-3.1	-4.4	-4.1
	Median	0.9	0.6	0.7	-1.6	-2.2	-1.4
	75% quantile	1.7	1.3	2.7	0.2	-1.1	0.1
	Max	4	6	6	3	2	3

Table 14.2.2.1: Summary of subject's pain assessment and changes in subject's pain assessment from Baseline (Visit 2a) - full analysis set

Parameter	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Pain in the Back (cm) (continued)							
Visit 8	N with data	41	25	21	39	22	20
	N missing	6	2	3	8	5	4
	Mean	1.5	1.3	1.7	-1.5	-2.5	-2.2
	SD	1.62	2.14	1.86	2.81	3.58	1.94
	Min	0	0	0	-7	-9	-6
	25% quantile	0.2	0	0.2	-3.7	-4.9	-3.4
	Median	1.1	0.7	1.6	-1.1	-2.2	-1.8
	75% quantile	1.9	1.5	2.4	0.1	-0.3	-0.7
	Max	6	8	6	5	6	1
End of Trial							
	N with data	39	24	20	37	21	19
	N missing	8	3	4	10	6	5
	Mean	1.3	2.1	1.3	-1.2	-1.4	-2.3
	SD	1.62	2.59	1.61	2.96	3.42	2.87
	Min	0	0	0	-8	-8	-7
	25% quantile	0.3	0.2	0.2	-2.4	-4.0	-4.5
	Median	0.5	1.2	0.4	-0.8	-1.2	-1.7
	75% quantile	1.9	3.1	2.1	0.5	0.5	-0.2
	Max	8	9	5	7	3	4

Table 14.2.2.1: Summary of subject's pain assessment and changes in subject's pain assessment from Baseline (Visit 2a) - full analysis set

Parameter Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Affected Leg							
Baseline (Visit 2a)							
	N with data	44	24	23			
	N missing	3	3	1			
	Mean	5.2	5.8	6.1			
	SD	2.48	2.84	2.46			
	Min	0	0	0			
	25% quantile	3.6	3.8	5.0			
	Median	5.2	6.7	6.9			
	75% quantile	7.7	7.4	7.9			
	Max	9	10	9			
Visit 3a							
	N with data	44	26	0	41	23	0
	N missing	3	1	24	6	4	24
	Mean	0.9	0.9	-	-4.3	-4.7	-
	SD	1.29	1.16	-	2.67	2.82	-
	Min	0	0	-	-9	-9	-
	25% quantile	0.1	0.1	-	-7.0	-6.8	-
	Median	0.3	0.5	-	-4.7	-5.1	-
	75% quantile	1.1	1.2	-	-2.5	-2.1	-
	Max	5	4	-	1	1	-
Visit 4							
	N with data	46	26	22	43	23	21
	N missing	1	1	2	4	4	3
	Mean	1.0	1.5	1.4	-4.2	-4.1	-4.5
	SD	1.69	2.09	1.74	2.93	2.50	2.49
	Min	0	0	0	-9	-9	-9
	25% quantile	0.1	0	0.1	-6.4	-6.5	-5.9
	Median	0.3	0.4	0.6	-4.6	-3.5	-4.6
	75% quantile	1.1	2.6	2.0	-2.1	-2.2	-2.7
	Max	9	7	6	5	0	0

Table 14.2.2.1: Summary of subject's pain assessment and changes in subject's pain assessment from Baseline (Visit 2a) - full analysis set

Parameter Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Affected Leg (continued)							
Visit 5							
	N with data	46	27	23	43	24	22
	N missing	1	0	1	4	3	2
	Mean	1.0	0.8	1.0	-4.2	-4.9	-5.2
	SD	1.61	1.39	1.92	2.89	2.79	2.83
	Min	0	0	0	-9	-9	-9
	25% quantile	0.1	0	0	-6.4	-6.7	-7.5
	Median	0.3	0.2	0.4	-4.4	-5.4	-5.6
	75% quantile	1.0	0.9	0.9	-2.6	-2.5	-4.1
	Max	7	6	9	3	0	1
Visit 6							
	N with data	44	26	23	41	23	22
	N missing	3	1	1	6	4	2
	Mean	0.8	1.3	0.8	-4.2	-4.7	-5.3
	SD	1.65	2.17	1.22	2.86	3.30	2.58
	Min	0	0	0	-9	-10	-9
	25% quantile	0	0.1	0.2	-6.6	-6.7	-6.9
	Median	0.2	0.3	0.3	-4.1	-5.1	-5.7
	75% quantile	0.6	1.1	0.8	-2.6	-2.1	-3.4
	Max	7	8	5	2	3	0
Visit 7							
	N with data	43	26	20	41	23	19
	N missing	4	1	4	6	4	5
	Mean	0.8	1.4	0.7	-4.2	-4.5	-5.2
	SD	1.37	2.09	1.56	2.71	3.41	2.77
	Min	0	0	0	-9	-9	-9
	25% quantile	0.2	0.1	0	-6.0	-6.6	-7.5
	Median	0.3	0.5	0.2	-4.6	-5.1	-5.4
	75% quantile	0.9	1.9	0.5	-2.7	-2.2	-3.6
	Max	8	8	7	4	4	0

Table 14.2.2.1: Summary of subject's pain assessment and changes in subject's pain assessment from Baseline (Visit 2a) - full analysis set

Parameter Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Affected Leg (continued)							
Visit 8							
	N with data	41	24	21	39	22	20
	N missing	6	3	3	8	5	4
	Mean	1.1	1.1	1.1	-4.1	-4.7	-4.9
	SD	1.81	2.38	1.53	3.06	3.45	2.65
	Min	0	0	0	-9	-10	-9
	25% quantile	0.1	0.1	0.2	-7.0	-6.7	-6.8
	Median	0.3	0.2	0.4	-4.2	-5.4	-5.5
	75% quantile	1.2	0.9	1.4	-1.6	-3.5	-2.5
	Max	7	9	5	3	5	0
End of Trial							
	N with data	38	23	21	36	21	20
	N missing	9	4	3	11	6	4
	Mean	0.9	1.4	1.0	-4.3	-4.2	-4.9
	SD	1.29	2.55	1.75	2.81	3.81	2.48
	Min	0	0	0	-9	-10	-9
	25% quantile	0.1	0.1	0.2	-6.7	-6.7	-6.7
	Median	0.3	0.2	0.2	-4.4	-5.0	-5.3
	75% quantile	1.6	2.3	0.9	-2.5	-3.1	-3.4
	Max	6	9	7	2	4	0

Table 14.2.2.2: Differences in changes of subject's pain assessment from Baseline (Visit 2a) between treatment groups - full analysis set

Visit Number	Point estimate [1]	NDplus-SC		Point estimate [1]	NDbasic-SC		Point estimate [1]	NDplus-NDbasic	
		95% CI [1]			95% CI [1]			95% CI [1]	
Changes from visit 2A	Pain in the Back (cm)	VISIT 3A	-	-	1.20	-0.10 - 2.60			
		VISIT 4	0.35	-1.40 - 2.50	-0.90	-3.10 - 1.20	1.20	0.10 - 2.40	
		VISIT 5	0.10	-1.40 - 1.70	-1.00	-2.60 - 1.00	1.05	-0.20 - 2.20	
		VISIT 6	0.60	-0.80 - 2.10	-0.80	-2.40 - 1.30	1.20	-0.20 - 2.80	
		VISIT 7	0.00	-1.50 - 1.50	-1.00	-2.80 - 0.80	1.10	-0.40 - 2.50	
		VISIT 8	0.70	-0.60 - 1.90	-0.40	-2.20 - 1.40	1.10	-0.40 - 2.60	
		END OF TRIAL	1.10	-0.30 - 2.60	0.90	-1.10 - 3.20	0.20	-1.70 - 1.80	
	Pain in the Affected Leg	VISIT 3A	-	-	0.40	-1.10 - 1.90			
		VISIT 4	0.30	-1.30 - 1.80	0.50	-1.10 - 2.10	-0.20	-1.60 - 1.30	
		VISIT 5	1.10	-0.50 - 2.60	0.40	-1.20 - 2.20	0.60	-1.00 - 2.00	
		VISIT 6	1.10	-0.30 - 2.60	0.30	-1.20 - 2.20	0.60	-1.20 - 2.10	
		VISIT 7	1.00	-0.50 - 2.60	0.50	-1.40 - 2.50	0.60	-1.00 - 2.00	
		VISIT 8	0.80	-0.90 - 2.60	0.15	-1.90 - 1.70	0.85	-1.10 - 2.60	
		END OF TRIAL	0.60	-1.00 - 2.20	0.20	-1.60 - 2.30	0.20	-1.60 - 2.00	

SC = Standard Care

[1] Hodges-Lehmann confidence interval

Clinipace: 14DEC21 / 7:39 / pvasdiff.lst / pvasdiff.sas

Table 14.2.2.2: Differences in changes of subject's pain assessment from Baseline (Visit 2a) between treatment groups - full analysis set

		Visit Number	NDplus-SC		NDbasic-SC		NDplus-NDbasic	
			Point estimate [1]	95% CI [1]	Point estimate [1]	95% CI [1]	Point estimate [1]	95% CI [1]
Changes from visit 3A	Pain in the Back (cm)	VISIT 4					0.10	-0.30 - 0.60
		VISIT 5					0.10	-0.60 - 0.60
		VISIT 6					0.10	-0.40 - 0.60
		VISIT 7					0.00	-0.50 - 0.50
		VISIT 8					0.00	-0.50 - 0.70
		END OF TRIAL						-0.40
	Pain in the Affected Leg	VISIT 4					0.00	-0.40 - 0.30
		VISIT 5					0.20	-0.10 - 0.70
		VISIT 6					-0.00	-0.80 - 0.40
		VISIT 7					-0.10	-0.60 - 0.30
		VISIT 8					0.00	-0.30 - 0.70
		END OF TRIAL					0.00	-0.40 - 0.60

SC = Standard Care

[1] Hodges-Lehmann confidence interval

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Table 14.2.3.1: Summary of neurological examination for items assessed on both sides (Jenny Scale) - full analysis set

Jenny Scale items	Left			Right		
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Baseline						
Motor deficits [1]						
5	37 (78.7)	19 (70.4)	20 (83.3)	38 (80.9)	22 (81.5)	19 (79.2)
4	8 (17.0)	5 (18.5)	3 (12.5)	7 (14.9)	3 (11.1)	4 (16.7)
3	2 (4.3)	2 (7.4)	1 (4.2)	2 (4.3)	2 (7.4)	0
2	0	1 (3.7)	0	0	0	1 (4.2)
1	0	0	0	0	0	0
0	0	0	0	0	0	0
Sensory deficits [2]						
None	15 (31.9)	5 (18.5)	10 (41.7)	15 (31.9)	5 (18.5)	10 (41.7)
Partial	10 (21.3)	12 (44.4)	5 (20.8)	21 (44.7)	7 (25.9)	9 (37.5)
Complete	1 (2.1)	3 (11.1)	0	0	1 (3.7)	0
Quality [3]						
None	13 (27.7)	4 (14.8)	9 (37.5)	13 (27.7)	4 (14.8)	9 (37.5)
Intermittent	1 (2.1)	1 (3.7)	1 (4.2)	5 (10.6)	1 (3.7)	6 (25.0)
Always	10 (21.3)	14 (51.9)	4 (16.7)	16 (34.0)	7 (25.9)	4 (16.7)
Ankle reflex						
Exaggerated	1 (2.1)	0	0	1 (2.1)	0	0
Normal	30 (63.8)	18 (66.7)	14 (58.3)	25 (53.2)	22 (81.5)	14 (58.3)
Reduced	8 (17.0)	4 (14.8)	8 (33.3)	11 (23.4)	4 (14.8)	6 (25.0)
Absent	7 (14.9)	5 (18.5)	2 (8.3)	10 (21.3)	1 (3.7)	4 (16.7)
Quadriceps reflex						
Exaggerated	1 (2.1)	0	0	1 (2.1)	0	0
Normal	33 (70.2)	21 (77.8)	23 (95.8)	34 (72.3)	22 (81.5)	21 (87.5)
Reduced	9 (19.1)	3 (11.1)	1 (4.2)	7 (14.9)	3 (11.1)	2 (8.3)
Absent	3 (6.4)	3 (11.1)	0	4 (8.5)	2 (7.4)	1 (4.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] The smallest value over all assessed flexors (ankle, hip) and extensors (ankle, knee, big toe) at a visit was taken into consideration

[2] The worst outcome of sensory deficit over all assessed locations was taken into consideration

[3] The worst outcome in each category (tingle, numb, hypersensitive) was taken into consideration

Table 14.2.3.1: Summary of neurological examination for items assessed on both sides (Jenny Scale) - full analysis set

Jenny Scale items	Left			Right		
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 3a*						
Motor deficits [1]						
5	43 (91.5)	22 (81.5)		45 (95.7)	25 (92.6)	
4	1 (2.1)	3 (11.1)		0	2 (7.4)	
3	2 (4.3)	2 (7.4)		1 (2.1)	0	
2	0	0		0	0	
1	0	0		0	0	
0	0	0		0	0	
Sensory deficits [2]						
None	27 (57.4)	14 (51.9)		27 (57.4)	14 (51.9)	
Partial	5 (10.6)	9 (33.3)		12 (25.5)	3 (11.1)	
Complete	0	0		0	0	
Quality [3]						
None	23 (48.9)	12 (44.4)		22 (46.8)	12 (44.4)	
Intermittent	2 (4.3)	4 (14.8)		9 (19.1)	2 (7.4)	
Always	4 (8.5)	5 (18.5)		5 (10.6)	2 (7.4)	
Ankle reflex						
Exaggerated	2 (4.3)	0		2 (4.3)	0	
Normal	34 (72.3)	20 (74.1)		29 (61.7)	19 (70.4)	
Reduced	5 (10.6)	4 (14.8)		8 (17.0)	6 (22.2)	
Absent	5 (10.6)	2 (7.4)		7 (14.9)	1 (3.7)	
Quadriceps reflex						
Exaggerated	3 (6.4)	0		2 (4.3)	0	
Normal	37 (78.7)	20 (74.1)		38 (80.9)	20 (74.1)	
Reduced	3 (6.4)	5 (18.5)		5 (10.6)	5 (18.5)	
Absent	3 (6.4)	1 (3.7)		1 (2.1)	1 (3.7)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] The smallest value over all assessed flexors (ankle, hip) and extensors (ankle, knee, big toe) at a visit was taken into consideration

[2] The worst outcome of sensory deficit over all assessed locations was taken into consideration

[3] The worst outcome in each category (tingle, numb, hypersensitive) was taken into consideration

Table 14.2.3.1: Summary of neurological examination for items assessed on both sides (Jenny Scale) - full analysis set

Jenny Scale items	Left			Right		
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 4						
Motor deficits [1]						
5	44 (93.6)	23 (85.2)	21 (87.5)	45 (95.7)	26 (96.3)	21 (87.5)
4	1 (2.1)	3 (11.1)	3 (12.5)	1 (2.1)	1 (3.7)	2 (8.3)
3	1 (2.1)	1 (3.7)	0	0	0	0
2	0	0	0	0	0	1 (4.2)
1	0	0	0	0	0	0
0	0	0	0	0	0	0
Sensory deficits [2]						
None	30 (63.8)	16 (59.3)	18 (75.0)	30 (63.8)	16 (59.3)	18 (75.0)
Partial	5 (10.6)	8 (29.6)	3 (12.5)	10 (21.3)	3 (11.1)	3 (12.5)
Complete	0	0	0	0	0	0
Quality [3]						
None	24 (51.1)	14 (51.9)	18 (75.0)	24 (51.1)	14 (51.9)	18 (75.0)
Intermittent	2 (4.3)	2 (7.4)	0	4 (8.5)	2 (7.4)	1 (4.2)
Always	4 (8.5)	5 (18.5)	3 (12.5)	5 (10.6)	1 (3.7)	2 (8.3)
Ankle reflex						
Exaggerated	0	0	0	0	0	0
Normal	34 (72.3)	20 (74.1)	18 (75.0)	30 (63.8)	20 (74.1)	17 (70.8)
Reduced	8 (17.0)	5 (18.5)	2 (8.3)	10 (21.3)	6 (22.2)	4 (16.7)
Absent	4 (8.5)	2 (7.4)	4 (16.7)	6 (12.8)	1 (3.7)	3 (12.5)
Quadriceps reflex						
Exaggerated	1 (2.1)	1 (3.7)	0	0	0	0
Normal	37 (78.7)	21 (77.8)	23 (95.8)	39 (83.0)	21 (77.8)	20 (83.3)
Reduced	6 (12.8)	3 (11.1)	1 (4.2)	5 (10.6)	4 (14.8)	3 (12.5)
Absent	2 (4.3)	2 (7.4)	0	2 (4.3)	2 (7.4)	1 (4.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] The smallest value over all assessed flexors (ankle, hip) and extensors (ankle, knee, big toe) at a visit was taken into consideration

[2] The worst outcome of sensory deficit over all assessed locations was taken into consideration

[3] The worst outcome in each category (tingle, numb, hypersensitive) was taken into consideration

Table 14.2.3.1: Summary of neurological examination for items assessed on both sides (Jenny Scale) - full analysis set

Jenny Scale items	Left			Right		
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 5						
Motor deficits [1]						
5	44 (93.6)	25 (92.6)	21 (87.5)	45 (95.7)	26 (96.3)	19 (79.2)
4	2 (4.3)	1 (3.7)	1 (4.2)	1 (2.1)	1 (3.7)	2 (8.3)
3	0	1 (3.7)	0	0	0	0
2	0	0	0	0	0	1 (4.2)
1	0	0	0	0	0	0
0	0	0	0	0	0	0
Sensory deficits [2]						
None	26 (55.3)	15 (55.6)	15 (62.5)	26 (55.3)	15 (55.6)	15 (62.5)
Partial	7 (14.9)	9 (33.3)	2 (8.3)	13 (27.7)	2 (7.4)	4 (16.7)
Complete	0	0	1 (4.2)	0	1 (3.7)	0
Quality [3]						
None	26 (55.3)	13 (48.1)	16 (66.7)	26 (55.3)	13 (48.1)	16 (66.7)
Intermittent	0	4 (14.8)	0	4 (8.5)	0	4 (16.7)
Always	6 (12.8)	5 (18.5)	2 (8.3)	7 (14.9)	3 (11.1)	0
Ankle reflex						
Exaggerated	0	0	0	0	0	0
Normal	34 (72.3)	21 (77.8)	17 (70.8)	32 (68.1)	20 (74.1)	16 (66.7)
Reduced	9 (19.1)	4 (14.8)	2 (8.3)	9 (19.1)	4 (14.8)	3 (12.5)
Absent	3 (6.4)	2 (7.4)	2 (8.3)	5 (10.6)	3 (11.1)	2 (8.3)
Quadriceps reflex						
Exaggerated	0	0	0	0	0	0
Normal	38 (80.9)	23 (85.2)	20 (83.3)	39 (83.0)	20 (74.1)	18 (75.0)
Reduced	6 (12.8)	3 (11.1)	1 (4.2)	6 (12.8)	5 (18.5)	2 (8.3)
Absent	1 (2.1)	1 (3.7)	0	1 (2.1)	2 (7.4)	1 (4.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] The smallest value over all assessed flexors (ankle, hip) and extensors (ankle, knee, big toe) at a visit was taken into consideration

[2] The worst outcome of sensory deficit over all assessed locations was taken into consideration

[3] The worst outcome in each category (tingle, numb, hypersensitive) was taken into consideration

Table 14.2.3.1: Summary of neurological examination for items assessed on both sides (Jenny Scale) - full analysis set

Jenny Scale items	Left			Right		
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 6						
Motor deficits [1]						
5	42 (89.4)	22 (81.5)	23 (95.8)	43 (91.5)	26 (96.3)	20 (83.3)
4	3 (6.4)	4 (14.8)	0	2 (4.3)	0	2 (8.3)
3	0	0	0	0	0	1 (4.2)
2	0	0	0	0	0	0
1	0	0	0	0	0	0
0	0	0	0	0	0	0
Sensory deficits [2]						
None	28 (59.6)	16 (59.3)	20 (83.3)	28 (59.6)	16 (59.3)	20 (83.3)
Partial	5 (10.6)	6 (22.2)	1 (4.2)	11 (23.4)	3 (11.1)	1 (4.2)
Complete	0	0	1 (4.2)	0	1 (3.7)	0
Quality [3]						
None	29 (61.7)	16 (59.3)	19 (79.2)	29 (61.7)	16 (59.3)	19 (79.2)
Intermittent	0	2 (7.4)	1 (4.2)	2 (4.3)	1 (3.7)	1 (4.2)
Always	5 (10.6)	4 (14.8)	1 (4.2)	7 (14.9)	3 (11.1)	1 (4.2)
Ankle reflex						
Exaggerated	0	0	0	0	0	0
Normal	31 (66.0)	15 (55.6)	17 (70.8)	28 (59.6)	13 (48.1)	16 (66.7)
Reduced	12 (25.5)	6 (22.2)	4 (16.7)	11 (23.4)	5 (18.5)	5 (20.8)
Absent	2 (4.3)	4 (14.8)	2 (8.3)	6 (12.8)	7 (25.9)	2 (8.3)
Quadriceps reflex						
Exaggerated	0	0	0	0	0	0
Normal	35 (74.5)	19 (70.4)	22 (91.7)	37 (78.7)	18 (66.7)	21 (87.5)
Reduced	9 (19.1)	4 (14.8)	1 (4.2)	8 (17.0)	5 (18.5)	0
Absent	1 (2.1)	2 (7.4)	0	0	2 (7.4)	2 (8.3)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] The smallest value over all assessed flexors (ankle, hip) and extensors (ankle, knee, big toe) at a visit was taken into consideration

[2] The worst outcome of sensory deficit over all assessed locations was taken into consideration

[3] The worst outcome in each category (tingle, numb, hypersensitive) was taken into consideration

Table 14.2.3.1: Summary of neurological examination for items assessed on both sides (Jenny Scale) - full analysis set

Jenny Scale items	Left			Right		
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 7						
Motor deficits [1]						
5	44 (93.6)	24 (88.9)	21 (87.5)	45 (95.7)	26 (96.3)	20 (83.3)
4	2 (4.3)	2 (7.4)	0	1 (2.1)	0	0
3	0	0	0	0	0	1 (4.2)
2	0	0	0	0	0	0
1	0	0	0	0	0	0
0	0	0	0	0	0	0
Sensory deficits [2]						
None	31 (66.0)	18 (66.7)	18 (75.0)	31 (66.0)	18 (66.7)	18 (75.0)
Partial	6 (12.8)	7 (25.9)	2 (8.3)	8 (17.0)	1 (3.7)	1 (4.2)
Complete	0	0	0	0	0	0
Quality [3]						
None	31 (66.0)	16 (59.3)	18 (75.0)	31 (66.0)	16 (59.3)	18 (75.0)
Intermittent	1 (2.1)	1 (3.7)	1 (4.2)	1 (2.1)	1 (3.7)	1 (4.2)
Always	5 (10.6)	6 (22.2)	1 (4.2)	6 (12.8)	1 (3.7)	0
Ankle reflex						
Exaggerated	0	0	0	0	0	0
Normal	33 (70.2)	15 (55.6)	14 (58.3)	33 (70.2)	15 (55.6)	17 (70.8)
Reduced	9 (19.1)	7 (25.9)	3 (12.5)	9 (19.1)	7 (25.9)	1 (4.2)
Absent	4 (8.5)	4 (14.8)	4 (16.7)	4 (8.5)	4 (14.8)	3 (12.5)
Quadriceps reflex						
Exaggerated	1 (2.1)	0	0	1 (2.1)	0	0
Normal	37 (78.7)	19 (70.4)	20 (83.3)	38 (80.9)	20 (74.1)	18 (75.0)
Reduced	7 (14.9)	6 (22.2)	1 (4.2)	7 (14.9)	6 (22.2)	2 (8.3)
Absent	1 (2.1)	1 (3.7)	0	0	0	1 (4.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] The smallest value over all assessed flexors (ankle, hip) and extensors (ankle, knee, big toe) at a visit was taken into consideration

[2] The worst outcome of sensory deficit over all assessed locations was taken into consideration

[3] The worst outcome in each category (tingle, numb, hypersensitive) was taken into consideration

Table 14.2.3.1: Summary of neurological examination for items assessed on both sides (Jenny Scale) - full analysis set

Jenny Scale items	Left			Right		
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 8						
Motor deficits [1]						
5	41 (87.2)	25 (92.6)	22 (91.7)	43 (91.5)	25 (92.6)	20 (83.3)
4	2 (4.3)	1 (3.7)	0	0	1 (3.7)	2 (8.3)
3	0	0	0	0	0	0
2	0	0	0	0	0	0
1	0	0	0	0	0	0
0	0	0	0	0	0	0
Sensory deficits [2]						
None	29 (61.7)	18 (66.7)	16 (66.7)	29 (61.7)	18 (66.7)	16 (66.7)
Partial	6 (12.8)	5 (18.5)	4 (16.7)	10 (21.3)	2 (7.4)	3 (12.5)
Complete	0	0	0	0	1 (3.7)	0
Quality [3]						
None	29 (61.7)	19 (70.4)	16 (66.7)	29 (61.7)	19 (70.4)	16 (66.7)
Intermittent	1 (2.1)	0	2 (8.3)	3 (6.4)	2 (7.4)	2 (8.3)
Always	5 (10.6)	4 (14.8)	2 (8.3)	7 (14.9)	1 (3.7)	0
Ankle reflex						
Exaggerated	0	0	0	0	0	0
Normal	36 (76.6)	16 (59.3)	16 (66.7)	30 (63.8)	17 (63.0)	17 (70.8)
Reduced	4 (8.5)	6 (22.2)	5 (20.8)	9 (19.1)	5 (18.5)	4 (16.7)
Absent	2 (4.3)	3 (11.1)	1 (4.2)	3 (6.4)	3 (11.1)	1 (4.2)
Quadriceps reflex						
Exaggerated	1 (2.1)	0	0	1 (2.1)	0	0
Normal	35 (74.5)	21 (77.8)	20 (83.3)	37 (78.7)	20 (74.1)	18 (75.0)
Reduced	5 (10.6)	3 (11.1)	2 (8.3)	2 (4.3)	3 (11.1)	2 (8.3)
Absent	1 (2.1)	1 (3.7)	0	2 (4.3)	2 (7.4)	2 (8.3)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] The smallest value over all assessed flexors (ankle, hip) and extensors (ankle, knee, big toe) at a visit was taken into consideration

[2] The worst outcome of sensory deficit over all assessed locations was taken into consideration

[3] The worst outcome in each category (tingle, numb, hypersensitive) was taken into consideration

Table 14.2.3.1: Summary of neurological examination for items assessed on both sides (Jenny Scale) - full analysis set

Jenny Scale items	Left			Right		
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
End of Trial						
Motor deficits [1]						
5	39 (83.0)	24 (88.9)	20 (83.3)	41 (87.2)	25 (92.6)	19 (79.2)
4	2 (4.3)	1 (3.7)	0	0	0	0
3	0	0	0	0	0	1 (4.2)
2	0	0	0	0	0	0
1	0	0	0	0	0	0
0	0	0	0	0	0	0
Sensory deficits [2]						
None	28 (59.6)	18 (66.7)	20 (83.3)	28 (59.6)	18 (66.7)	20 (83.3)
Partial	8 (17.0)	5 (18.5)	0	5 (10.6)	2 (7.4)	0
Complete	0	0	0	0	0	0
Quality [3]						
None	29 (61.7)	17 (63.0)	19 (79.2)	29 (61.7)	17 (63.0)	19 (79.2)
Intermittent	0	1 (3.7)	1 (4.2)	1 (2.1)	1 (3.7)	0
Always	8 (17.0)	4 (14.8)	0	3 (6.4)	2 (7.4)	0
Ankle reflex						
Exaggerated	0	0	0	0	0	0
Normal	35 (74.5)	19 (70.4)	17 (70.8)	35 (74.5)	20 (74.1)	18 (75.0)
Reduced	2 (4.3)	2 (7.4)	2 (8.3)	2 (4.3)	1 (3.7)	2 (8.3)
Absent	3 (6.4)	4 (14.8)	1 (4.2)	4 (8.5)	4 (14.8)	0
Quadriceps reflex						
Exaggerated	0	0	0	0	0	0
Normal	37 (78.7)	20 (74.1)	19 (79.2)	38 (80.9)	21 (77.8)	18 (75.0)
Reduced	2 (4.3)	2 (7.4)	1 (4.2)	2 (4.3)	3 (11.1)	1 (4.2)
Absent	1 (2.1)	3 (11.1)	0	1 (2.1)	1 (3.7)	1 (4.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] The smallest value over all assessed flexors (ankle, hip) and extensors (ankle, knee, big toe) at a visit was taken into consideration

[2] The worst outcome of sensory deficit over all assessed locations was taken into consideration

[3] The worst outcome in each category (tingle, numb, hypersensitive) was taken into consideration

Table 14.2.3.2: Improvement of motor deficits (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Location	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Improvement at Visit 3a* compared to Baseline				
Ankle flexor	6 (12.8)	3 (11.1)		9 (9.2)
Ankle extensor	3 (6.4)	7 (25.9)		10 (10.2)
Hip flexor	3 (6.4)	1 (3.7)		4 (4.1)
Knee extensor	1 (2.1)	1 (3.7)		2 (2.0)
Big toe extensor	4 (8.5)	5 (18.5)		9 (9.2)
Improvement at Visit 4 compared to Baseline				
Ankle flexor	6 (12.8)	3 (11.1)	5 (20.8)	14 (14.3)
Ankle extensor	3 (6.4)	7 (25.9)	2 (8.3)	12 (12.2)
Hip flexor	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Knee extensor	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Big toe extensor	6 (12.8)	7 (25.9)	1 (4.2)	14 (14.3)
Improvement at Visit 5 compared to Baseline				
Ankle flexor	7 (14.9)	4 (14.8)	5 (20.8)	16 (16.3)
Ankle extensor	4 (8.5)	7 (25.9)	2 (8.3)	13 (13.3)
Hip flexor	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Knee extensor	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Big toe extensor	6 (12.8)	8 (29.6)	1 (4.2)	15 (15.3)
Improvement at Visit 6 compared to Baseline				
Ankle flexor	7 (14.9)	4 (14.8)	5 (20.8)	16 (16.3)
Ankle extensor	3 (6.4)	6 (22.2)	2 (8.3)	11 (11.2)
Hip flexor	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Knee extensor	0	0	2 (8.3)	2 (2.0)
Big toe extensor	6 (12.8)	7 (25.9)	2 (8.3)	15 (15.3)
Improvement at Visit 7 compared to Baseline				
Ankle flexor	7 (14.9)	4 (14.8)	5 (20.8)	16 (16.3)
Ankle extensor	3 (6.4)	6 (22.2)	1 (4.2)	10 (10.2)
Hip flexor	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Knee extensor	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Big toe extensor	6 (12.8)	8 (29.6)	1 (4.2)	15 (15.3)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Visit 11 = End of Trial

Note: Improvement is defined as an increase in motor deficit score of one point or more. If assessment was documented for both sides, the worst outcome at Baseline was used for all further assessments.

Table 14.2.3.2: Improvement of motor deficits (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Location	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Improvement at Visit 8 compared to Baseline				
Ankle flexor	7 (14.9)	4 (14.8)	4 (16.7)	15 (15.3)
Ankle extensor	3 (6.4)	6 (22.2)	1 (4.2)	10 (10.2)
Hip flexor	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Knee extensor	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Big toe extensor	5 (10.6)	8 (29.6)	1 (4.2)	14 (14.3)
Improvement at Visit 11 compared to Baseline				
Ankle flexor	6 (12.8)	4 (14.8)	5 (20.8)	15 (15.3)
Ankle extensor	3 (6.4)	6 (22.2)	1 (4.2)	10 (10.2)
Hip flexor	2 (4.3)	1 (3.7)	0	3 (3.1)
Knee extensor	1 (2.1)	1 (3.7)	0	2 (2.0)
Big toe extensor	7 (14.9)	8 (29.6)	1 (4.2)	16 (16.3)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Visit 11 = End of Trial

Note: Improvement is defined as an increase in motor deficit score of one point or more. If assessment was documented for both sides, the worst outcome at Baseline was used for all further assessments.

Table 14.2.3.3: Change in sensory deficits (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Location	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Improvement at Visit 3a* compared to Baseline				
S1	8 (17.0)	6 (22.2)		14 (14.3)
S2	0	0		0
L5	3 (6.4)	5 (18.5)		8 (8.2)
L4	4 (8.5)	0		4 (4.1)
L3	2 (4.3)	1 (3.7)		3 (3.1)
L2	0	0		0
L1	0	0		0
Improvement at Visit 4 compared to Baseline				
S1	11 (23.4)	4 (14.8)	6 (25.0)	21 (21.4)
S2	0	0	0	0
L5	5 (10.6)	7 (25.9)	1 (4.2)	13 (13.3)
L4	5 (10.6)	2 (7.4)	2 (8.3)	9 (9.2)
L3	2 (4.3)	1 (3.7)	0	3 (3.1)
L2	0	0	0	0
L1	0	0	0	0
Improvement at Visit 5 compared to Baseline				
S1	10 (21.3)	5 (18.5)	7 (29.2)	22 (22.4)
S2	0	0	0	0
L5	3 (6.4)	7 (25.9)	3 (12.5)	13 (13.3)
L4	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
L3	2 (4.3)	1 (3.7)	0	3 (3.1)
L2	0	0	0	0
L1	0	0	0	0
Improvement at Visit 6 compared to Baseline				
S1	9 (19.1)	5 (18.5)	9 (37.5)	23 (23.5)
S2	0	0	0	0
L5	6 (12.8)	7 (25.9)	4 (16.7)	17 (17.3)
L4	4 (8.5)	0	1 (4.2)	5 (5.1)
L3	2 (4.3)	1 (3.7)	0	3 (3.1)
L2	0	0	0	0
L1	0	0	0	0

Table 14.2.3.3: Change in sensory deficits (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Location	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Improvement at Visit 7 compared to Baseline				
S1	12 (25.5)	6 (22.2)	7 (29.2)	25 (25.5)
S2	0	0	0	0
L5	5 (10.6)	8 (29.6)	2 (8.3)	15 (15.3)
L4	5 (10.6)	1 (3.7)	1 (4.2)	7 (7.1)
L3	2 (4.3)	1 (3.7)	0	3 (3.1)
L2	0	0	0	0
L1	0	0	0	0
Improvement at Visit 8 compared to Baseline				
S1	9 (19.1)	6 (22.2)	6 (25.0)	21 (21.4)
S2	0	0	0	0
L5	6 (12.8)	8 (29.6)	1 (4.2)	15 (15.3)
L4	4 (8.5)	0	1 (4.2)	5 (5.1)
L3	2 (4.3)	1 (3.7)	0	3 (3.1)
L2	0	0	0	0
L1	0	0	0	0
Improvement at Visit 11 compared to Baseline				
S1	11 (23.4)	5 (18.5)	8 (33.3)	24 (24.5)
S2	0	0	0	0
L5	6 (12.8)	9 (33.3)	3 (12.5)	18 (18.4)
L4	4 (8.5)	1 (3.7)	1 (4.2)	6 (6.1)
L3	2 (4.3)	1 (3.7)	0	3 (3.1)
L2	0	0	0	0
L1	0	0	0	0

Table 14.2.3.4: Frequencies of quality and reflexes (Jenny Scale) - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline				
Tingle nerve roots				
None	13 (27.7)	4 (14.8)	9 (37.5)	26 (26.5)
Intermittent	5 (10.6)	3 (11.1)	6 (25.0)	14 (14.3)
Always	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Numb nerve roots				
None	13 (27.7)	4 (14.8)	9 (37.5)	26 (26.5)
Intermittent	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
Always	24 (51.1)	18 (66.7)	6 (25.0)	48 (49.0)
Hypersensitive nerve roots				
None	13 (27.7)	4 (14.8)	9 (37.5)	26 (26.5)
Intermittent	0	1 (3.7)	1 (4.2)	2 (2.0)
Always	0	0	1 (4.2)	1 (1.0)
Ankle reflex				
None	0	0	0	0
Exaggerated	1 (2.1)	0	0	1 (1.0)
Normal	20 (42.6)	16 (59.3)	8 (33.3)	44 (44.9)
Reduced	12 (25.5)	5 (18.5)	11 (45.8)	28 (28.6)
Absent	14 (29.8)	6 (22.2)	5 (20.8)	25 (25.5)
Quadriceps reflex				
None	0	0	0	0
Exaggerated	1 (2.1)	0	0	1 (1.0)
Normal	31 (66.0)	20 (74.1)	21 (87.5)	72 (73.5)
Reduced	8 (17.0)	3 (11.1)	2 (8.3)	13 (13.3)
Absent	6 (12.8)	4 (14.8)	1 (4.2)	11 (11.2)

Table 14.2.3.4: Frequencies of quality and reflexes (Jenny Scale) - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3a*				
Tingle nerve roots				
None	23 (48.9)	12 (44.4)		35 (35.7)
Intermittent	5 (10.6)	2 (7.4)		7 (7.1)
Always	1 (2.1)	2 (7.4)		3 (3.1)
Numb nerve roots				
None	22 (46.8)	12 (44.4)		34 (34.7)
Intermittent	5 (10.6)	3 (11.1)		8 (8.2)
Always	8 (17.0)	6 (22.2)		14 (14.3)
Hypersensitive nerve roots				
None	23 (48.9)	12 (44.4)		35 (35.7)
Intermittent	1 (2.1)	1 (3.7)		2 (2.0)
Always	0	1 (3.7)		1 (1.0)
Ankle reflex				
None	0	0		0
Exaggerated	2 (4.3)	0		2 (2.0)
Normal	26 (55.3)	17 (63.0)		43 (43.9)
Reduced	9 (19.1)	7 (25.9)		16 (16.3)
Absent	9 (19.1)	2 (7.4)		11 (11.2)
Quadriceps reflex				
None	0	0		0
Exaggerated	2 (4.3)	0		2 (2.0)
Normal	36 (76.6)	20 (74.1)		56 (57.1)
Reduced	5 (10.6)	5 (18.5)		10 (10.2)
Absent	3 (6.4)	1 (3.7)		4 (4.1)

Table 14.2.3.4: Frequencies of quality and reflexes (Jenny Scale) - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4				
Tingle nerve roots				
None	24 (51.1)	14 (51.9)	18 (75.0)	56 (57.1)
Intermittent	3 (6.4)	3 (11.1)	1 (4.2)	7 (7.1)
Always	0	3 (11.1)	2 (8.3)	5 (5.1)
Numb nerve roots				
None	24 (51.1)	14 (51.9)	18 (75.0)	56 (57.1)
Intermittent	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Always	9 (19.1)	5 (18.5)	4 (16.7)	18 (18.4)
Hypersensitive nerve roots				
None	24 (51.1)	14 (51.9)	18 (75.0)	56 (57.1)
Intermittent	0	0	0	0
Always	0	2 (7.4)	0	2 (2.0)
Ankle reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	26 (55.3)	19 (70.4)	12 (50.0)	57 (58.2)
Reduced	11 (23.4)	6 (22.2)	6 (25.0)	23 (23.5)
Absent	9 (19.1)	2 (7.4)	6 (25.0)	17 (17.3)
Quadriceps reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	35 (74.5)	21 (77.8)	20 (83.3)	76 (77.6)
Reduced	8 (17.0)	4 (14.8)	3 (12.5)	15 (15.3)
Absent	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)

Table 14.2.3.4: Frequencies of quality and reflexes (Jenny Scale) - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5				
Tingle nerve roots				
None	26 (55.3)	13 (48.1)	16 (66.7)	55 (56.1)
Intermittent	2 (4.3)	2 (7.4)	3 (12.5)	7 (7.1)
Always	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)
Numb nerve roots				
None	26 (55.3)	13 (48.1)	16 (66.7)	55 (56.1)
Intermittent	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Always	12 (25.5)	8 (29.6)	0	20 (20.4)
Hypersensitive nerve roots				
None	26 (55.3)	13 (48.1)	16 (66.7)	55 (56.1)
Intermittent	0	1 (3.7)	1 (4.2)	2 (2.0)
Always	0	2 (7.4)	0	2 (2.0)
Ankle reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	29 (61.7)	20 (74.1)	13 (54.2)	62 (63.3)
Reduced	10 (21.3)	4 (14.8)	4 (16.7)	18 (18.4)
Absent	7 (14.9)	3 (11.1)	4 (16.7)	14 (14.3)
Quadriceps reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	37 (78.7)	20 (74.1)	18 (75.0)	75 (76.5)
Reduced	7 (14.9)	5 (18.5)	2 (8.3)	14 (14.3)
Absent	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)

Table 14.2.3.4: Frequencies of quality and reflexes (Jenny Scale) - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
Tingle nerve roots				
None	29 (61.7)	16 (59.3)	19 (79.2)	64 (65.3)
Intermittent	2 (4.3)	3 (11.1)	2 (8.3)	7 (7.1)
Always	0	2 (7.4)	0	2 (2.0)
Numb nerve roots				
None	29 (61.7)	16 (59.3)	19 (79.2)	64 (65.3)
Intermittent	0	1 (3.7)	0	1 (1.0)
Always	11 (23.4)	4 (14.8)	2 (8.3)	17 (17.3)
Hypersensitive nerve roots				
None	29 (61.7)	16 (59.3)	19 (79.2)	64 (65.3)
Intermittent	1 (2.1)	1 (3.7)	0	2 (2.0)
Always	1 (2.1)	4 (14.8)	0	5 (5.1)
Ankle reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	25 (53.2)	13 (48.1)	13 (54.2)	51 (52.0)
Reduced	13 (27.7)	5 (18.5)	6 (25.0)	24 (24.5)
Absent	7 (14.9)	7 (25.9)	4 (16.7)	18 (18.4)
Quadriceps reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	35 (74.5)	18 (66.7)	21 (87.5)	74 (75.5)
Reduced	9 (19.1)	5 (18.5)	0	14 (14.3)
Absent	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)

Table 14.2.3.4: Frequencies of quality and reflexes (Jenny Scale) - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7				
Tingle nerve roots				
None	31 (66.0)	16 (59.3)	18 (75.0)	65 (66.3)
Intermittent	2 (4.3)	1 (3.7)	2 (8.3)	5 (5.1)
Always	2 (4.3)	3 (11.1)	0	5 (5.1)
Numb nerve roots				
None	31 (66.0)	16 (59.3)	18 (75.0)	65 (66.3)
Intermittent	0	0	1 (4.2)	1 (1.0)
Always	10 (21.3)	6 (22.2)	1 (4.2)	17 (17.3)
Hypersensitive nerve roots				
None	31 (66.0)	16 (59.3)	18 (75.0)	65 (66.3)
Intermittent	0	1 (3.7)	0	1 (1.0)
Always	2 (4.3)	1 (3.7)	0	3 (3.1)
Ankle reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	30 (63.8)	14 (51.9)	12 (50.0)	56 (57.1)
Reduced	8 (17.0)	7 (25.9)	3 (12.5)	18 (18.4)
Absent	8 (17.0)	5 (18.5)	6 (25.0)	19 (19.4)
Quadriceps reflex				
None	0	0	0	0
Exaggerated	1 (2.1)	0	0	1 (1.0)
Normal	36 (76.6)	18 (66.7)	18 (75.0)	72 (73.5)
Reduced	8 (17.0)	7 (25.9)	2 (8.3)	17 (17.3)
Absent	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

Table 14.2.3.4: Frequencies of quality and reflexes (Jenny Scale) - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8				
Tingle nerve roots				
None	29 (61.7)	19 (70.4)	16 (66.7)	64 (65.3)
Intermittent	2 (4.3)	0	1 (4.2)	3 (3.1)
Always	0	1 (3.7)	0	1 (1.0)
Numb nerve roots				
None	29 (61.7)	19 (70.4)	16 (66.7)	64 (65.3)
Intermittent	2 (4.3)	2 (7.4)	3 (12.5)	7 (7.1)
Always	10 (21.3)	5 (18.5)	2 (8.3)	17 (17.3)
Hypersensitive nerve roots				
None	29 (61.7)	19 (70.4)	16 (66.7)	64 (65.3)
Intermittent	0	0	0	0
Always	0	1 (3.7)	0	1 (1.0)
Ankle reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	28 (59.6)	14 (51.9)	13 (54.2)	55 (56.1)
Reduced	10 (21.3)	7 (25.9)	7 (29.2)	24 (24.5)
Absent	4 (8.5)	4 (14.8)	2 (8.3)	10 (10.2)
Quadriceps reflex				
None	0	0	0	0
Exaggerated	1 (2.1)	0	0	1 (1.0)
Normal	35 (74.5)	20 (74.1)	18 (75.0)	73 (74.5)
Reduced	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
Absent	2 (4.3)	2 (7.4)	2 (8.3)	6 (6.1)

Table 14.2.3.4: Frequencies of quality and reflexes (Jenny Scale) - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial				
Tingle nerve roots				
None	29 (61.7)	17 (63.0)	19 (79.2)	65 (66.3)
Intermittent	1 (2.1)	1 (3.7)	0	2 (2.0)
Always	0	3 (11.1)	0	3 (3.1)
Numb nerve roots				
None	29 (61.7)	17 (63.0)	19 (79.2)	65 (66.3)
Intermittent	0	1 (3.7)	1 (4.2)	2 (2.0)
Always	11 (23.4)	4 (14.8)	0	15 (15.3)
Hypersensitive nerve roots				
None	29 (61.7)	17 (63.0)	19 (79.2)	65 (66.3)
Intermittent	0	0	0	0
Always	0	1 (3.7)	0	1 (1.0)
Ankle reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	32 (68.1)	19 (70.4)	16 (66.7)	67 (68.4)
Reduced	3 (6.4)	2 (7.4)	3 (12.5)	8 (8.2)
Absent	6 (12.8)	4 (14.8)	1 (4.2)	11 (11.2)
Quadriceps reflex				
None	0	0	0	0
Exaggerated	0	0	0	0
Normal	37 (78.7)	20 (74.1)	18 (75.0)	75 (76.5)
Reduced	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)
Absent	2 (4.3)	3 (11.1)	1 (4.2)	6 (6.1)

Table 14.2.3.5: Change in sciatic stretch test (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Variable	Treatment group work status	Number (%) of subjects	
		Test Outcome at baseline (Visit 2a/Visit 1)	
		Positive	Negative
Visit 3a*	NDisc plus (N = 47)		
	Positive	5 (10.6)	0
	Negative	35 (74.5)	4 (8.5)
	NDisc basic (N = 27)		
	Positive	1 (3.7)	1 (3.7)
	Negative	21 (77.8)	1 (3.7)
Visit 4	NDisc plus (N = 47)		
	Positive	3 (6.4)	0
	Negative	35 (74.5)	4 (8.5)
	NDisc basic (N = 27)		
	Positive	3 (11.1)	1 (3.7)
	Negative	21 (77.8)	1 (3.7)
	SC (N = 24)		
	Positive	2 (8.3)	0
	Negative	14 (58.3)	7 (29.2)
Visit 5	NDisc plus (N = 47)		
	Positive	4 (8.5)	0
	Negative	34 (72.3)	5 (10.6)
	NDisc basic (N = 27)		
	Positive	2 (7.4)	0
	Negative	18 (66.7)	2 (7.4)
	SC (N = 24)		
	Positive	3 (12.5)	0
	Negative	13 (54.2)	5 (20.8)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.3.5: Change in sciatic stretch test (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Variable	Treatment group work status	Number (%) of subjects	
		Test Outcome at baseline (Visit 2a/Visit 1)	
		Positive	Negative
Visit 6	NDisc plus (N = 47)		
	Positive	0	0
	Negative	36 (76.6)	4 (8.5)
	NDisc basic (N = 27)		
	Positive	1 (3.7)	0
	Negative	21 (77.8)	1 (3.7)
	SC (N = 24)		
	Positive	2 (8.3)	0
	Negative	15 (62.5)	6 (25.0)
Visit 7	NDisc plus (N = 47)		
	Positive	5 (10.6)	0
	Negative	31 (66.0)	4 (8.5)
	NDisc basic (N = 27)		
	Positive	1 (3.7)	0
	Negative	19 (70.4)	1 (3.7)
	SC (N = 24)		
	Positive	1 (4.2)	0
	Negative	14 (58.3)	5 (20.8)
Visit 8	NDisc plus (N = 47)		
	Positive	2 (4.3)	0
	Negative	32 (68.1)	4 (8.5)
	NDisc basic (N = 27)		
	Positive	2 (7.4)	0
	Negative	20 (74.1)	1 (3.7)
	SC (N = 24)		
	Positive	2 (8.3)	0
	Negative	15 (62.5)	5 (20.8)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:41 / jenshft1.lst / jenshft.sas

Table 14.2.3.5: Change in sciatic stretch test (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Variable	Treatment group work status	Number (%) of subjects	
		Test Outcome at baseline (Visit 2a/Visit 1)	
		Positive	Negative
End of Trial	NDisc plus (N = 47)		
	Positive	2 (4.3)	0
	Negative	34 (72.3)	4 (8.5)
	NDisc basic (N = 27)		
	Positive	1 (3.7)	0
	Negative	22 (81.5)	1 (3.7)
	SC (N = 24)		
	Positive	0	0
	Negative	14 (58.3)	5 (20.8)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.3.6: Change in cauda equina syndrom (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Variable	Treatment group work status	Number (%) of subjects	
		Test Outcome at baseline (Visit 2a/Visit 1)	
		Yes	No
Visit 3a*	NDisc plus (N = 47)		
	Yes	0	0
	No	0	46 (97.9)
	NDisc basic (N = 27)		
	Yes	0	1 (3.7)
	No	0	26 (96.3)
Visit 4	NDisc plus (N = 47)		
	Yes	0	0
	No	0	46 (97.9)
	NDisc basic (N = 27)		
	Yes	0	0
	No	0	27 (100)
Visit 5	SC (N = 24)		
	Yes	0	0
	No	0	24 (100)
	NDisc plus (N = 47)		
	Yes	0	0
	No	0	46 (97.9)
Visit 5	NDisc basic (N = 27)		
	Yes	0	0
	No	0	27 (100)
	SC (N = 24)		
	Yes	0	0
	No	0	22 (91.7)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Table 14.2.3.6: Change in cauda equina syndrom (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Variable	Treatment group work status	Number (%) of subjects	
		Test Outcome at baseline (Visit 2a/Visit 1)	
		Yes	No
Visit 6	NDisc plus (N = 47)		
	Yes	0	0
	No	0	45 (95.7)
	NDisc basic (N = 27)		
	Yes	0	0
	No	0	26 (96.3)
	SC (N = 24)		
	Yes	0	0
	No	0	23 (95.8)
Visit 7	NDisc plus (N = 47)		
	Yes	0	0
	No	0	46 (97.9)
	NDisc basic (N = 27)		
	Yes	0	0
	No	0	26 (96.3)
	SC (N = 24)		
	Yes	0	1 (4.2)
	No	0	20 (83.3)
Visit 8	NDisc plus (N = 47)		
	Yes	0	0
	No	0	43 (91.5)
	NDisc basic (N = 27)		
	Yes	0	0
	No	0	26 (96.3)
	SC (N = 24)		
	Yes	0	0
	No	0	22 (91.7)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.3.6: Change in cauda equina syndrom (Jenny Scale) compared to Baseline (Visit 2a/Visit1) - full analysis set

Variable	Treatment group work status	Number (%) of subjects	
		Test Outcome at baseline (Visit 2a/Visit 1)	
		Yes	No
End of Trial	NDisc plus (N = 47)		
	Yes	0	0
	No	0	41 (87.2)
	NDisc basic (N = 27)		
	Yes	0	0
	No	0	25 (92.6)
SC (N = 24)	Yes	0	0
	No	0	20 (83.3)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.3.7: Summary of walking range (Jenny Scale) - full analysis set

Parameter	Statistic	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Baseline				
Unlimited	N (%)	25 (53.2)	13 (48.1)	14 (58.3)
Walking range in m [1]	N with data	21	13	10
	N missing	1	1	0
	Mean	1066.1	620.4	590.3
	SD	2144.80	1148.12	1214.75
	Min	10	5	0
	25% quantile	100.0	30.0	50.0
	Median	500.0	100.0	200.0
	75% quantile	1000.0	500.0	500.0
	Max	9999	4000	4000
Visit 3a*				
Unlimited	N (%)	36 (76.6)	23 (85.2)	0
Walking range in m [1]	N with data	10	3	-
	N missing	1	1	-
	Mean	2800.0	2166.7	-
	SD	1670.00	763.76	-
	Min	1000	1500	-
	25% quantile	1500.0	1500.0	-
	Median	2500.0	2000.0	-
	75% quantile	5000.0	3000.0	-
	Max	5000	3000	-
Visit 4				
Unlimited	N (%)	31 (66.0)	23 (85.2)	19 (79.2)
Walking range in m [1]	N with data	14	4	5
	N missing	2	0	0
	Mean	3250.0	1325.0	1220.0
	SD	2026.27	537.74	998.50
	Min	500	800	300
	25% quantile	1000.0	900.0	300.0
	Median	4000.0	1250.0	1000.0
	75% quantile	5000.0	1750.0	2000.0
	Max	7000	2000	2500

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] Statistics only for patients with limited walking range

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Table 14.2.3.7: Summary of walking range (Jenny Scale) - full analysis set

Parameter	Statistic	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 5				
Unlimited	N (%)	39 (83.0)	24 (88.9)	20 (83.3)
Walking range in m [1]	N with data	7	2	3
	N missing	1	1	1
	Mean	2357.1	1000.0	766.7
	SD	1313.85	0	404.15
	Min	1000	1000	300
	25% quantile	1000.0	1000.0	300.0
	Median	2000.0	1000.0	1000.0
	75% quantile	4000.0	1000.0	1000.0
	Max	4000	1000	1000
Visit 6				
Unlimited	N (%)	37 (78.7)	23 (85.2)	21 (87.5)
Walking range in m [1]	N with data	8	3	2
	N missing	2	1	1
	Mean	2750.0	1066.7	1250.0
	SD	1281.74	901.85	1060.66
	Min	1000	200	500
	25% quantile	2000.0	200.0	500.0
	Median	2500.0	1000.0	1250.0
	75% quantile	3500.0	2000.0	2000.0
	Max	5000	2000	2000
Visit 7				
Unlimited	N (%)	38 (80.9)	22 (81.5)	19 (79.2)
Walking range in m [1]	N with data	7	3	2
	N missing	2	2	3
	Mean	2785.7	766.7	5000.0
	SD	2157.49	1069.27	0
	Min	1000	100	5000
	25% quantile	1000.0	100.0	5000.0
	Median	2000.0	200.0	5000.0
	75% quantile	4000.0	2000.0	5000.0
	Max	7000	2000	5000

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] Statistics only for patients with limited walking range

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Table 14.2.3.7: Summary of walking range (Jenny Scale) - full analysis set

Parameter	Statistic	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 8				
Unlimited	N (%)	40 (85.1)	24 (88.9)	22 (91.7)
Walking range in m [1]	N with data	3	2	0
	N missing	4	1	2
	Mean	2333.3	550.0	-
	SD	763.76	70.71	-
	Min	1500	500	-
	25% quantile	1500.0	500.0	-
	Median	2500.0	550.0	-
	75% quantile	3000.0	600.0	-
	Max	3000	600	-
End of Trial				
Unlimited	N (%)	38 (80.9)	21 (77.8)	19 (79.2)
Walking range in m [1]	N with data	3	4	1
	N missing	6	2	4
	Mean	3666.7	1175.0	2500.0
	SD	1527.53	960.47	-
	Min	2000	200	2500
	25% quantile	2000.0	350.0	2500.0
	Median	4000.0	1250.0	2500.0
	75% quantile	5000.0	2000.0	2500.0
	Max	5000	2000	2500

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

[1] Statistics only for patients with limited walking range

Clinipace: 14DEC21 / 7:41 / jenwlc.lst / jenwlc.sas

Table 14.2.4.1: Summary of Finger-Ground Distance (cm) and changes in Finger-Ground Distance (cm) from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Baseline							
	N with data	38	21	19			
	N missing	9	6	5			
	Mean	25.0	32.6	26.9			
	SD	18.77	15.71	19.22			
	Min	0	9	0			
	25% quantile	10.0	16.0	15.0			
	Median	20.0	34.0	25.0			
	75% quantile	40.0	40.0	40.0			
	Max	71	65	58			
Visit 3a							
	N with data	40	24	0	37	20	0
	N missing	7	3	24	10	7	24
	Mean	16.9	16.8	-	-7.1	-15.7	-
	SD	12.49	11.02	-	18.15	12.69	-
	Min	0	0	-	-71	-40	-
	25% quantile	6.5	10.0	-	-13.5	-24.8	-
	Median	15.5	18.0	-	-3.0	-15.0	-
	75% quantile	25.0	24.0	-	2.0	-7.5	-
	Max	41	43	-	28	7	-
Visit 4							
	N with data	43	24	21	38	20	18
	N missing	4	3	3	9	7	6
	Mean	14.3	14.6	24.0	-9.9	-17.2	-2.2
	SD	11.69	11.71	14.19	19.58	13.76	15.63
	Min	0	0	2	-71	-56	-37
	25% quantile	5.0	4.0	15.0	-21.0	-26.0	-13.5
	Median	15.0	11.5	21.0	-7.5	-15.8	-1.3
	75% quantile	23.0	24.3	33.0	0	-7.5	5.0
	Max	41	38	53	36	2	30

Table 14.2.4.1: Summary of Finger-Ground Distance (cm) and changes in Finger-Ground Distance (cm) from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 5							
	N with data	43	26	19	38	21	17
	N missing	4	1	5	9	6	7
	Mean	11.8	12.2	16.4	-12.9	-20.9	-11.5
	SD	10.92	11.17	13.75	19.28	15.10	14.95
	Min	0	0	0	-71	-56	-38
	25% quantile	0	2.0	2.0	-22.0	-34.0	-24.0
	Median	10.0	10.0	14.0	-8.5	-21.0	-9.0
	75% quantile	19.0	20.0	25.0	0	-8.0	-3.0
	Max	45	40	46	17	0	22
Visit 6							
	N with data	42	25	22	36	20	18
	N missing	5	2	2	11	7	6
	Mean	10.5	10.9	13.2	-14.3	-22.4	-13.5
	SD	10.83	11.19	10.52	19.80	15.58	15.50
	Min	0	0	0	-71	-56	-41
	25% quantile	0	0	8.0	-29.0	-33.8	-25.0
	Median	8.8	8.0	10.0	-10.0	-22.0	-16.5
	75% quantile	17.0	18.0	20.0	-2.3	-11.0	0
	Max	35	38	33	26	3	16
Visit 7							
	N with data	44	23	19	38	20	16
	N missing	3	4	5	9	7	8
	Mean	9.6	10.9	11.1	-15.4	-22.6	-16.7
	SD	10.35	10.17	10.41	19.08	18.37	15.28
	Min	0	0	0	-71	-56	-38
	25% quantile	0	1.0	0	-27.0	-35.5	-29.8
	Median	7.0	8.0	8.0	-10.0	-21.0	-19.5
	75% quantile	15.5	21.0	24.0	0	-8.0	-2.5
	Max	44	29	30	15	17	7

Table 14.2.4.1: Summary of Finger-Ground Distance (cm) and changes in Finger-Ground Distance (cm) from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 8							
	N with data	39	21	20	35	19	17
	N missing	8	6	4	12	8	7
	Mean	10.3	9.3	11.5	-14.5	-25.0	-16.5
	SD	11.89	10.76	12.13	21.24	16.41	14.70
	Min	0	0	0	-71	-56	-38
	25% quantile	0	0	0.5	-25.0	-37.0	-28.0
	Median	6.0	5.0	9.5	-13.0	-24.0	-16.0
	75% quantile	19.0	20.0	15.0	-2.0	-11.5	-3.0
	Max	45	29	39	32	-3	6
End of Trial							
	N with data	38	21	17	33	18	15
	N missing	9	6	7	14	9	9
	Mean	8.2	9.5	12.4	-17.3	-23.3	-17.3
	SD	8.88	10.62	11.41	19.97	17.23	16.96
	Min	0	0	0	-69	-56	-42
	25% quantile	1.0	1.0	5.0	-31.0	-37.0	-35.0
	Median	6.3	5.0	10.0	-12.0	-17.8	-20.0
	75% quantile	10.0	13.0	20.0	0	-9.5	-3.0
	Max	40	32	38	27	4	5

Table 14.2.4.2: Summary of Schober's sign (cm) and changes in Schober's sign (cm) from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Baseline							
	N with data	35	19	17			
	N missing	12	8	7			
	Mean	3.0	2.8	2.7			
	SD	1.68	1.09	1.37			
	Min	1	1	1			
	25% quantile	1.8	2.0	2.0			
	Median	2.5	2.5	3.0			
	75% quantile	4.5	3.5	3.0			
	Max	7	5	7			
Visit 3a							
	N with data	39	23	0	33	18	0
	N missing	8	4	24	14	9	24
	Mean	4.0	4.2	-	0.6	1.3	-
	SD	2.46	1.43	-	1.97	1.01	-
	Min	1	2	-	-3	-1	-
	25% quantile	3.0	3.0	-	-0.5	0.5	-
	Median	3.5	4.0	-	0.5	1.1	-
	75% quantile	4.5	5.0	-	1.2	1.5	-
	Max	15	7	-	7	4	-
Visit 4							
	N with data	38	21	18	33	18	14
	N missing	9	6	6	14	9	10
	Mean	4.1	4.4	4.0	1.0	1.5	0.9
	SD	1.28	1.63	2.17	1.84	1.43	1.25
	Min	2	2	1	-4	-3	-1
	25% quantile	3.5	3.5	2.5	0	1.0	0
	Median	4.0	4.0	3.5	1.0	1.5	0.6
	75% quantile	4.5	5.5	5.0	2.0	2.0	1.5
	Max	9	9	10	4	4	3

Table 14.2.4.2: Summary of Schober's sign (cm) and changes in Schober's sign (cm) from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 5							
	N with data	38	23	18	34	18	15
	N missing	9	4	6	13	9	9
	Mean	4.7	5.0	3.7	1.7	1.8	1.0
	SD	2.18	1.91	1.46	2.24	0.97	2.04
	Min	2	2	2	-4	0	-5
	25% quantile	3.5	4.0	3.0	0.5	1.0	0
	Median	4.0	4.5	4.0	1.5	2.0	1.5
	75% quantile	5.5	5.0	4.0	3.0	2.5	2.0
	Max	14	9	8	10	4	4
Visit 6							
	N with data	37	22	20	32	18	15
	N missing	10	5	4	15	9	9
	Mean	4.2	4.7	4.7	1.0	2.1	1.7
	SD	1.26	1.94	2.01	1.81	1.86	1.71
	Min	2	1	3	-4	-1	-2
	25% quantile	3.5	4.0	3.3	0.5	0.5	1.0
	Median	4.0	4.0	4.0	1.0	1.6	1.5
	75% quantile	4.5	6.0	5.0	2.0	3.5	3.0
	Max	9	9	9	4	6	5
Visit 7							
	N with data	41	21	17	35	18	15
	N missing	6	6	7	12	9	9
	Mean	4.4	4.4	4.6	1.2	1.5	1.6
	SD	1.84	1.67	1.70	2.23	1.61	1.33
	Min	1	2	2	-3	-3	-1
	25% quantile	3.5	4.0	3.5	0	1.0	0.5
	Median	4.0	4.0	4.0	1.0	1.8	2.0
	75% quantile	5.0	4.5	5.0	2.5	2.5	2.5
	Max	9	9	9	7	5	4

Table 14.2.4.2: Summary of Schober's sign (cm) and changes in Schober's sign (cm) from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 8							
	N with data	37	21	17	32	18	15
	N missing	10	6	7	15	9	9
	Mean	4.7	4.7	4.7	1.6	1.7	2.0
	SD	1.28	1.51	1.25	1.90	1.21	1.82
	Min	3	3	3	-2	0	-1
	25% quantile	4.0	4.0	4.0	0.4	1.0	0
	Median	4.0	4.5	4.0	1.9	1.5	2.0
	75% quantile	5.0	5.0	5.5	3.3	2.5	3.0
	Max	9	10	7	5	4	6
End of Trial							
	N with data	29	21	15	25	17	14
	N missing	18	6	9	22	10	10
	Mean	4.5	4.9	4.6	1.6	1.8	2.0
	SD	1.40	1.49	1.15	2.40	1.45	1.76
	Min	3	3	3	-3	-2	-1
	25% quantile	3.4	4.0	3.5	-0.5	1.0	1.0
	Median	4.5	4.7	4.5	2.0	2.0	2.5
	75% quantile	5.0	5.0	5.5	3.0	3.0	2.5
	Max	8	9	7	6	4	6

Table 14.2.5.1: Incidence of pain medication (mean cumulative function) - full analysis set

Time frame	Statistics	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	
Compared to sequestrectomy (Visit 2b)	Week 1 before sequestrectomy	m	101	46	53
		C	0	0	0
		NR	47.0	27.0	24.0
		M (%)	214.89	170.37	220.83
		MCF (%)	214.89	170.37	220.83
	Week 1 after sequestrectomy	m	33	21	21
		C	0	0	0
		NR	47.0	27.0	24.0
		M (%)	70.21	77.78	87.50
		MCF (%)	285.11	248.15	308.33
	Week 2 after sequestrectomy	m	2	4	7
		C	0	0	0
		NR	47.0	27.0	24.0
		M (%)	4.26	14.81	29.17
		MCF (%)	289.36	262.96	337.50
	Week 2 until 3 months after sequestrectomy (Visit 3b (NDplus and NDbasic) and Visit 5 (SC))	m	42	24	10
		C	0	0	0
		NR	47.0	27.0	24.0
		M (%)	89.36	88.89	41.67
		MCF (%)	378.72	351.85	379.17
3 months until 6 months after sequestrectomy (Visit 5 (NDplus and NDbasic) and Visit 6 (SC))	m	34	23	2	
	C	0	0	0	
	NR	47.0	27.0	24.0	
	M (%)	72.34	85.19	8.33	
	MCF (%)	451.06	437.04	387.50	

SC = Standard Care; m = Number of pain medications with start date during respective time frame.

C = Number of subjects censored (e.g. subjects that discontinued the study prematurely).

NR = Number of subjects at risk of starting a pain medication at mid of time period (NR(previous time frame) - C(previous time frame) - 0.5*C).

M = Observed increment within respective time frame (m/NR)*100, i.e. probability of having started pain medication during respective time frame.

MCF = Mean cumulative function (sum of all observed increments up to respective time frame), i.e. probability of having started pain medication from the beginning up to respective time frame.

* Operation: Sequestrectomy (V2b) for patients of SC group; Transplantation (V3b) for patients of NDplus and NDbasic group.

Table 14.2.5.1: Incidence of pain medication (mean cumulative function) - full analysis set

Time frame	Statistics	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	
Compared to operation (OP)*	1.5 months after OP	m	55	25	34
		C	0	1	0
		NR	47.0	26.5	24.0
		M (%)	117.02	94.34	141.67
		MCF (%)	117.02	94.34	141.67
1.5 months until 3 months after OP		m	5	8	3
		C	0	0	0
		NR	47.0	25.5	24.0
		M (%)	10.64	31.37	12.50
		MCF (%)	127.66	125.71	154.17
3 months until 6 months after OP		m	24	7	2
		C	0	0	0
		NR	47.0	25.5	24.0
		M (%)	51.06	27.45	8.33
		MCF (%)	178.72	153.16	162.50
6 months until 12 months after OP		m	13	8	1
		C	0	0	0
		NR	47.0	25.5	24.0
		M (%)	27.66	31.37	4.17
		MCF (%)	206.38	184.54	166.67
12 months until 24 months after OP		m	22	6	13
		C	1	0	0
		NR	46.5	25.5	24.0
		M (%)	47.31	23.53	54.17
		MCF (%)	253.69	208.07	220.83

SC = Standard Care; m = Number of pain medications with start date during respective time frame.

C = Number of subjects censored (e.g. subjects that discontinued the study prematurely).

NR = Number of subjects at risk of starting a pain medication at mid of time period (NR(previous time frame) - C(previous time frame) - 0.5*C).

M = Observed increment within respective time frame (m/NR)*100, i.e. probability of having started pain medication during respective time frame.

MCF = Mean cumulative function (sum of all observed increments up to respective time frame), i.e. probability of having started pain medication from the beginning up to respective time frame.

* Operation: Sequestrectomy (V2b) for patients of SC group; Transplantation (V3b) for patients of NDplus and NDbasic group.

Table 14.2.5.2: Extent of exposure to pain medication - full analysis set

Time frame	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Compared to sequestrectomy (Visit 2b)			
Week 1 before sequestrectomy	0.2686170213	0.212962963	0.2760416667
Week 1 after sequestrectomy	0.1170212766	0.1296296296	0.1458333333
Week 2 after sequestrectomy	0.0060790274	0.0211640212	0.0416666667
Week 2 until 3 months after sequestrectomy (Visit 3b (NDplus and NDbasic) and Visit 5 (SC))	0.0119081372	0.0116448326	0.0054229935
3 months until 6 months after sequestrectomy (Visit 5 (NDplus and NDbasic) and Visit 6 (SC))	0.0082484231	0.0094494659	0.0010060362
Compared to operation (OP)*			
1.5 months after OP	0.0276520865	0.0225835592	0.0314523589
1.5 months until 3 months after OP	0.0021533161	0.006028636	0.0027173913
3 months until 6 months after OP	0.0062321475	0.003066141	0.0010060362
6 months until 12 months after OP	0.0015199345	0.0016256858	0.0002096436
12 months until 24 months after OP	0.0013719132	0.0006391818	0.0016995686

SC = Standard Care

* Operation: Sequestrectomy (V2b) for patients of SC group; Transplantation (V3b) for patients of NDplus and NDbasic group.

Extent of exposure to pain medication is derived by the total number of pain medications taken by patients of respective treatment group during respective time frame relative to the total patient days of respective treatment group of respective time frame.

Table 14.2.5.3: Extent of exposure to opioids - full analysis set

Time frame	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Compared to sequestrectomy (Visit 2b)			
Week 1 before sequestrectomy	0.1040189125	0.0617283951	0.0787037037
Week 1 after sequestrectomy	0.0334346505	0.0211640212	0.0714285714
Week 2 after sequestrectomy	0	0.0046296296	0.015625
Week 2 until 3 months after sequestrectomy (Visit 3b (NDplus and NDbasic) and Visit 5 (SC))	0.0025181869	0.002394636	0.0005356186
3 months until 6 months after sequestrectomy (Visit 5 (NDplus and NDbasic) and Visit 6 (SC))	0.0028790787	0.0020316944	0.000497265
Compared to operation (OP)*			
1.5 months after OP	0.0088408644	0.0052910053	0.014479638
1.5 months until 3 months after OP	0.000422119	0.0007385524	0
3 months until 6 months after OP	0.0030800821	0	0.000497265
6 months until 12 months after OP	0.0010466333	0.0002021427	0
12 months until 24 months after OP	0.0003731343	0.0004249442	0.0002607562

SC = Standard Care

* Operation: Sequestrectomy (V2b) for patients of SC group; Transplantation (V3b) for patients of NDplus and NDbasic group.

Extent of exposure to pain medication is derived by the total number of pain medications taken by patients of respective treatment group during respective time frame relative to the total patient days of respective treatment group of respective time frame.

Table 14.2.6.1: Change in work status - full analysis set

Visit	Treatment group work status	Number (%) of subjects			
		Employment at healthy status			
		Working fulltime	Working part-time	Unemployed/ not employed	Retired
Baseline (visit 1 or 2a)	NDisc plus (N = 47)				
	Working fulltime	32 (68.1)	0	0	0
	Working part-time	0	8 (17.0)	0	0
	Unemployed/not employed	1 (2.1)	1 (2.1)	5 (10.6)	0
	Retired	0	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	20 (74.1)	0	0	0
	Working part-time	0	6 (22.2)	0	0
	Unemployed/not employed	0	0	1 (3.7)	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	16 (66.7)	0	0	0
Working part-time	0	5 (20.8)	0	0	
Unemployed/not employed	0	0	3 (12.5)	0	
Retired	0	0	0	0	
Visit 3a*	NDisc plus (N = 47)				
	Working fulltime	31 (66.0)	0	0	0
	Working part-time	2 (4.3)	8 (17.0)	0	0
	Unemployed/not employed	0	1 (2.1)	5 (10.6)	0
	Retired	0	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	20 (74.1)	0	0	0
	Working part-time	0	6 (22.2)	0	0
	Unemployed/not employed	0	0	1 (3.7)	0
	Retired	0	0	0	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / wst.lst / work.sas

Table 14.2.6.1: Change in work status - full analysis set

Visit	Treatment group work status	Number (%) of subjects			
		Employment at healthy status			
		Working fulltime	Working part-time	Unemployed/ not employed	Retired
Visit 4	NDisc plus (N = 47)				
	Working fulltime	32 (68.1)	0	0	0
	Working part-time	0	8 (17.0)	0	0
	Unemployed/not employed	1 (2.1)	1 (2.1)	5 (10.6)	0
	Retired	0	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	19 (70.4)	0	0	0
	Working part-time	1 (3.7)	6 (22.2)	0	0
	Unemployed/not employed	0	0	1 (3.7)	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	16 (66.7)	0	0	0
Working part-time	0	4 (16.7)	0	0	
Unemployed/not employed	0	1 (4.2)	3 (12.5)	0	
Retired	0	0	0	0	
Visit 5	NDisc plus (N = 47)				
	Working fulltime	33 (70.2)	0	0	0
	Working part-time	0	8 (17.0)	0	0
	Unemployed/not employed	0	1 (2.1)	4 (8.5)	0
	Retired	0	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	19 (70.4)	0	0	0
	Working part-time	1 (3.7)	6 (22.2)	0	0
	Unemployed/not employed	0	0	1 (3.7)	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	15 (62.5)	1 (4.2)	0	0
Working part-time	0	3 (12.5)	0	0	
Unemployed/not employed	1 (4.2)	0	3 (12.5)	0	
Retired	0	0	0	0	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / wst.lst / work.sas

Table 14.2.6.1: Change in work status - full analysis set

Visit	Treatment group work status	Number (%) of subjects			
		Employment at healthy status			
		Working fulltime	Working part-time	Unemployed/ not employed	Retired
Visit 6	NDisc plus (N = 47)				
	Working fulltime	30 (63.8)	0	1 (2.1)	0
	Working part-time	0	8 (17.0)	0	0
	Unemployed/not employed	2 (4.3)	1 (2.1)	4 (8.5)	0
	Retired	0	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	18 (66.7)	0	0	0
	Working part-time	1 (3.7)	6 (22.2)	0	0
	Unemployed/not employed	0	0	1 (3.7)	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	12 (50.0)	0	0	0
Working part-time	2 (8.3)	3 (12.5)	0	0	
Unemployed/not employed	1 (4.2)	1 (4.2)	3 (12.5)	0	
Retired	1 (4.2)	0	0	0	
Visit 7	NDisc plus (N = 47)				
	Working fulltime	29 (61.7)	0	1 (2.1)	0
	Working part-time	1 (2.1)	8 (17.0)	1 (2.1)	0
	Unemployed/not employed	2 (4.3)	1 (2.1)	3 (6.4)	0
	Retired	0	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	17 (63.0)	0	0	0
	Working part-time	2 (7.4)	6 (22.2)	0	0
	Unemployed/not employed	0	0	1 (3.7)	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	12 (50.0)	0	0	0
Working part-time	0	2 (8.3)	0	0	
Unemployed/not employed	2 (8.3)	1 (4.2)	3 (12.5)	0	
Retired	1 (4.2)	0	0	0	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / wst.lst / work.sas

Table 14.2.6.1: Change in work status - full analysis set

Visit	Treatment group work status	Number (%) of subjects			
		Employment at healthy status			
		Working fulltime	Working part-time	Unemployed/ not employed	Retired
Visit 8	NDisc plus (N = 47)				
	Working fulltime	26 (55.3)	0	1 (2.1)	0
	Working part-time	1 (2.1)	8 (17.0)	0	0
	Unemployed/not employed	3 (6.4)	1 (2.1)	3 (6.4)	0
	Retired	1 (2.1)	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	16 (59.3)	0	0	0
	Working part-time	2 (7.4)	6 (22.2)	1 (3.7)	0
	Unemployed/not employed	1 (3.7)	0	0	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	14 (58.3)	0	0	0
Working part-time	0	3 (12.5)	0	0	
Unemployed/not employed	1 (4.2)	0	3 (12.5)	0	
Retired	1 (4.2)	0	0	0	
Visit 9	NDisc plus (N = 47)				
	Working fulltime	25 (53.2)	0	1 (2.1)	0
	Working part-time	1 (2.1)	5 (10.6)	1 (2.1)	0
	Unemployed/not employed	3 (6.4)	3 (6.4)	3 (6.4)	0
	Retired	1 (2.1)	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	16 (59.3)	0	0	0
	Working part-time	2 (7.4)	6 (22.2)	1 (3.7)	0
	Unemployed/not employed	1 (3.7)	0	0	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	14 (58.3)	0	1 (4.2)	0
Working part-time	0	3 (12.5)	0	0	
Unemployed/not employed	0	0	2 (8.3)	0	
Retired	1 (4.2)	0	0	0	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / wst.lst / work.sas

Table 14.2.6.1: Change in work status - full analysis set

Visit	Treatment group work status	Number (%) of subjects			
		Employment at healthy status			
		Working fulltime	Working part-time	Unemployed/ not employed	Retired
Visit 10	NDisc plus (N = 47)				
	Working fulltime	23 (48.9)	0	1 (2.1)	0
	Working part-time	2 (4.3)	5 (10.6)	0	0
	Unemployed/not employed	2 (4.3)	3 (6.4)	3 (6.4)	0
	Retired	1 (2.1)	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	17 (63.0)	1 (3.7)	0	0
	Working part-time	2 (7.4)	5 (18.5)	1 (3.7)	0
	Unemployed/not employed	0	0	0	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	14 (58.3)	0	2 (8.3)	0
Working part-time	0	3 (12.5)	0	0	
Unemployed/not employed	1 (4.2)	0	1 (4.2)	0	
Retired	1 (4.2)	0	0	0	
End of Trial	NDisc plus (N = 47)				
	Working fulltime	23 (48.9)	0	3 (6.4)	0
	Working part-time	2 (4.3)	5 (10.6)	0	0
	Unemployed/not employed	1 (2.1)	3 (6.4)	1 (2.1)	0
	Retired	3 (6.4)	0	0	0
	NDisc basic (N = 27)				
	Working fulltime	14 (51.9)	1 (3.7)	0	0
	Working part-time	1 (3.7)	5 (18.5)	1 (3.7)	0
	Unemployed/not employed	4 (14.8)	0	0	0
	Retired	0	0	0	0
	SC (N = 24)				
	Working fulltime	13 (54.2)	0	2 (8.3)	0
Working part-time	1 (4.2)	3 (12.5)	0	0	
Unemployed/not employed	0	0	1 (4.2)	0	
Retired	1 (4.2)	0	0	0	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / wst.lst / work.sas

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc							
Baseline/Screening**							
	N with data	23	12	9			
	N missing	24	15	15			
	Mean	12225.4	13311.7	14006.9			
	SD	3936.09	2997.56	5033.09			
	Min	4191	9121	7202			
	25% quantile	9951.0	11375.0	10827.5			
	Median	12048.5	12451.5	15299.5			
	75% quantile	14253.5	15360.3	16482.5			
	Max	24149	19845	21030			
Visit 3a*							
	N with data	20	13	-	20	12	-
	N missing	27	14	-	27	15	-
	Mean	12862.3	14613.9	-	25.3	428.7	-
	LSMeans[1]				30.655	419.658	
	SD	3741.26	4315.52	-	902.43	786.56	-
	Min	8919	9381	-	-1794	-1312	-
	25% quantile	10164.8	12251.0	-	-623.5	190.0	-
	Median	12243.0	13517.0	-	35.3	288.5	-
	75% quantile	13625.3	16275.5	-	614.8	943.5	-
	Max	25589	25097	-	1702	1604	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 4							
	N with data	20	13	11	20	12	9
	N missing	27	14	13	27	15	15
	Mean	12899.8	14526.7	13292.3	77.9	323.1	244.3
	LSMeans[1]				108.154	359.041	129.214
	SD	3766.10	4209.98	5812.63	902.71	1324.39	1003.16
	Min	9312	10140	3722	-1713	-1871	-1484
	25% quantile	9816.3	11938.5	7910.0	-541.3	-399.8	-417.0
	Median	12289.3	13466.0	14233.0	93.3	329.5	-47.5
	75% quantile	14558.5	16354.5	16109.5	457.3	1561.3	1187.5
	Max	25028	25229	22364	2162	2075	1518
Visit 5							
	N with data	4	2	0	4	2	0
	N missing	43	25	24	43	25	24
	Mean	12149.5	13786.0	-	308.4	-218.3	-
	LSMeans[1]				291.303	-184.107	
	SD	2736.54	1619.27	-	1096.76	83.09	-
	Min	8967	12641	-	-1317	-277	-
	25% quantile	9898.8	12641.0	-	-343.8	-277.0	-
	Median	12374.0	13786.0	-	754.5	-218.3	-
	75% quantile	14400.3	14931.0	-	960.5	-159.5	-
	Max	14883	14931	-	1042	-160	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 6	N with data	21	12	9	21	11	8
	N missing	26	15	15	26	16	16
	Mean	13144.0	14535.4	14060.9	254.0	621.5	203.8
	LSMeans[1]				274.552	580.300	206.450
	SD	3810.49	3995.92	5450.75	1099.94	1227.38	884.02
	Min	8820	10605	7238	-2115	-1406	-654
	25% quantile	10426.5	12338.8	10191.5	-433.5	-516.0	-569.3
	Median	12581.0	13108.3	15134.0	340.0	989.5	39.8
	75% quantile	14010.5	15978.8	17392.5	962.0	1640.5	723.3
	Max	25697	24560	22003	1962	2385	1897
Visit 7	N with data	21	12	7	21	12	6
	N missing	26	15	17	26	15	18
	Mean	13059.9	13631.6	14104.2	169.9	319.9	496.9
	LSMeans[1]				180.557	299.699	499.985
	SD	3819.07	3105.53	6539.34	971.39	1346.64	1280.50
	Min	9216	9888	7050	-1960	-2966	-638
	25% quantile	10280.5	11781.0	7254.0	-180.0	34.8	-587.0
	Median	12573.0	12457.8	13392.5	298.0	493.3	153.5
	75% quantile	13729.5	15965.8	22240.5	708.0	964.5	1211.0
	Max	26015	20546	22794	1867	2335	2689

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 8	N with data	18	12	8	18	12	7
	N missing	29	15	16	29	15	17
	Mean	12253.1	13313.5	14816.7	-180.1	1.8	802.7
	LSMeans[1]				-181.344	-33.270	866.060
	SD	2322.43	2713.53	6108.64	1166.15	1689.02	1364.16
	Min	8816	10820	7058	-2235	-3914	-1103
	25% quantile	10269.5	11409.0	8802.5	-1213.5	-912.5	-834.0
	Median	12411.0	12076.5	15771.0	-302.8	71.0	983.0
	75% quantile	13719.5	15434.3	19746.8	915.0	954.5	1805.5
	Max	16772	19778	22835	1767	2397	2645
End of Trial							
	N with data	18	11	7	18	11	6
	N missing	29	16	17	29	16	18
	Mean	12515.8	13486.5	13293.6	-488.6	128.3	-479.0
	LSMeans[1]				-447.167	-226.150	46.528
	SD	4366.20	2498.75	5542.52	1378.36	2212.52	711.81
	Min	7518	9644	7290	-2869	-3792	-1459
	25% quantile	9437.0	11416.0	7858.0	-1541.5	-1952.5	-1322.5
	Median	11948.3	12971.0	13574.0	-480.8	512.5	-93.5
	75% quantile	13439.0	15582.5	20112.0	239.5	2231.5	6.5
	Max	26024	17892	20877	1875	2786	88

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc							
Baseline/Screening**							
	N with data	47	26	23			
	N missing	0	1	1			
	Mean	13559.3	14641.8	14286.0			
	SD	3883.64	3466.94	3780.91			
	Min	7615	9889	8210			
	25% quantile	10699.5	12246.0	11239.0			
	Median	13018.0	13953.0	14000.0			
	75% quantile	16000.5	16490.5	16414.5			
	Max	25322	21030	25118			
Visit 3a*							
	N with data	46	26	-	46	25	-
	N missing	1	1	-	1	2	-
	Mean	13347.6	14663.1	-	43.9	-148.4	-
	LSMeans[1]				35.905	-133.665	
	SD	3628.88	3928.78	-	1239.90	1070.02	-
	Min	7300	9018	-	-3175	-2925	-
	25% quantile	10415.5	11821.5	-	-541.0	-606.0	-
	Median	13038.0	13586.0	-	53.8	-140.5	-
	75% quantile	15859.5	16237.0	-	645.5	540.5	-
	Max	23862	24805	-	4700	1445	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 4	N with data	45	27	24	45	26	23
	N missing	2	0	0	2	1	1
	Mean	13888.7	15100.5	14671.6	206.5	5.5	380.6
	LSMeans[1]				244.490	41.386	265.714
	SD	4143.73	4363.65	3872.27	1216.52	1265.39	1505.34
	Min	8355	9094	8226	-1812	-2201	-3013
	25% quantile	10800.5	11798.0	11486.3	-732.5	-1066.5	-1040.5
	Median	12626.5	14081.0	15218.5	-2.5	-0.5	520.0
	75% quantile	16861.5	18617.0	16951.3	1141.5	780.0	1649.0
	Max	26806	26883	23470	3486	3254	2782
Visit 5	N with data	11	7	0	11	7	0
	N missing	36	20	24	36	20	24
	Mean	15857.5	15584.4	-	819.3	-307.2	-
	LSMeans[1]				765.679	-222.924	
	SD	3561.32	3724.91	-	1911.32	1703.30	-
	Min	9779	10643	-	-942	-3038	-
	25% quantile	12791.0	12277.5	-	-499.5	-1608.5	-
	Median	17320.5	14268.0	-	-12.0	-642.0	-
	75% quantile	18582.5	19313.0	-	1742.0	1196.5	-
	Max	21536	20507	-	4471	1846	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 6							
	N with data	45	25	22	45	24	21
	N missing	2	2	2	2	3	3
	Mean	13635.6	14500.4	14362.0	143.9	-119.6	7.4
	LSMeans[1]				141.764	-42.911	-75.786
	SD	3897.04	3953.54	3945.30	1383.10	1415.04	1647.05
	Min	9149	8658	8220	-1718	-2888	-3753
	25% quantile	10714.5	12439.0	11473.5	-764.0	-1208.8	-700.5
	Median	12624.0	14024.0	14647.5	-60.0	-185.3	-65.0
	75% quantile	15921.0	16474.0	16181.0	867.0	697.8	1135.0
	Max	28603	25703	22706	3938	2726	3725
Visit 7							
	N with data	44	25	20	44	25	19
	N missing	3	2	4	3	2	5
	Mean	13614.4	14071.2	14800.7	168.9	-334.6	442.7
	LSMeans[1]				162.239	-282.470	389.591
	SD	4064.75	3290.43	4436.02	1382.25	1360.99	1843.39
	Min	8639	8384	8008	-2201	-2850	-3434
	25% quantile	10314.3	12291.0	11552.3	-606.8	-1209.5	-1058.5
	Median	12752.3	13104.5	14605.3	-339.5	-104.0	198.5
	75% quantile	16687.5	17903.5	17019.8	837.8	650.5	1608.5
	Max	28146	20667	24059	3297	2637	4813

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 8	N with data	39	24	22	39	24	21
	N missing	8	3	2	8	3	3
	Mean	12776.7	13608.5	14610.3	-434.6	-521.3	384.8
	LSMeans[1]				-431.180	-504.203	358.851
	SD	3323.01	3223.04	4514.62	1529.06	1465.73	1817.02
	Min	7201	7350	7658	-3807	-3346	-3058
	25% quantile	10101.5	11138.8	11580.0	-1225.5	-1587.8	-1015.5
	Median	12114.5	13376.0	14225.5	-374.0	-684.8	452.0
	75% quantile	15172.5	16381.8	18489.0	325.5	559.3	2074.5
	Max	20099	19789	24289	3443	1826	3011
End of Trial							
	N with data	37	22	20	37	22	19
	N missing	10	5	4	10	5	5
	Mean	12554.4	13340.0	13133.3	-1056.1	-927.0	-1030.7
	LSMeans[1]				-1090.073	-876.516	-1023.049
	SD	3733.14	3444.19	4219.27	1989.63	2131.08	2040.71
	Min	7800	8227	7149	-6251	-5028	-4448
	25% quantile	10283.0	10554.0	10377.3	-1897.0	-2079.5	-2230.0
	Median	11539.0	13580.3	12300.0	-832.0	-926.0	-1143.0
	75% quantile	13818.0	15466.0	15415.3	155.0	169.0	-26.0
	Max	26239	20182	22769	2632	3692	3787

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated							
Baseline/Screening**							
	N with data	7	4	2			
	N missing	40	23	22			
	Mean	15422.5	16209.5	17408.8			
	SD	4759.96	4834.91	2206.53			
	Min	9877	11400	15849			
	25% quantile	11595.5	12274.3	15848.5			
	Median	15271.5	15734.5	17408.8			
	75% quantile	19012.0	20144.8	18969.0			
	Max	23890	21969	18969			
Visit 3a*							
	N with data	7	4	-	7	4	-
	N missing	40	23	-	40	23	-
	Mean	15830.0	16353.5	-	407.5	144.0	-
	LSMeans[1]				593.399	-181.323	
	SD	5003.87	5121.92	-	1015.90	1470.53	-
	Min	10650	12463	-	-1821	-1726	-
	25% quantile	11166.5	12654.8	-	493.5	-1013.5	-
	Median	15846.5	14721.0	-	688.5	380.5	-
	75% quantile	19505.5	20052.3	-	853.0	1301.5	-
	Max	24743	23510	-	1291	1541	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 4							
	N with data	7	4	2	7	4	2
	N missing	40	23	22	40	23	22
	Mean	16012.7	15710.1	19018.3	590.2	-499.4	1609.5
	LSMeans[1]				1000.877	-1392.542	1958.513
	SD	5011.97	4280.72	346.13	1144.48	1615.96	2552.66
	Min	9715	12413	18774	-1045	-2789	-196
	25% quantile	11943.0	12750.0	18773.5	-162.5	-1474.5	-195.5
	Median	15829.5	14309.5	19018.3	505.5	-111.0	1609.5
	75% quantile	19136.0	18670.3	19263.0	1135.5	475.8	3414.5
	Max	25026	21809	19263	2573	1013	3415
Visit 5							
	N with data	1	3	0	1	3	0
	N missing	46	24	24	46	24	24
	Mean	15583.0	16855.3	-	259.0	-374.5	-
	LSMeans[1]				384.867	-416.456	
	SD	-	4784.84	-	-	622.71	-
	Min	15583	11745	-	259	-741	-
	25% quantile	15583.0	11744.5	-	259.0	-740.5	-
	Median	15583.0	17593.0	-	259.0	-727.5	-
	75% quantile	15583.0	21228.5	-	259.0	344.5	-
	Max	15583	21229	-	259	345	-

SC = Standard Care

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[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 6							
	N with data	6	4	1	6	4	1
	N missing	41	23	23	41	23	23
	Mean	14563.2	15279.5	18223.0	551.9	-930.0	-746.0
	LSMeans[1]				439.134	-897.141	-200.745
	SD	3142.20	4148.81	-	1187.63	768.94	-
	Min	10792	11172	18223	-1352	-2025	-746
	25% quantile	11635.5	11819.0	18223.0	21.0	-1404.8	-746.0
	Median	14603.0	15001.3	18223.0	592.5	-733.3	-746.0
	75% quantile	16713.0	18740.0	18223.0	1441.5	-455.3	-746.0
	Max	19033	19944	18223	2016	-229	-746
Visit 7							
	N with data	5	4	2	5	4	2
	N missing	42	23	22	42	23	22
	Mean	13166.2	15266.4	19776.3	155.1	-943.1	2367.5
	LSMeans[1]				-80.270	-1265.027	3599.730
	SD	1912.61	3692.91	221.68	937.00	1791.03	1984.85
	Min	10580	12103	19620	-771	-3234	964
	25% quantile	12217.0	12742.5	19619.5	-692.5	-2354.5	964.0
	Median	13029.0	14234.5	19776.3	102.5	-621.0	2367.5
	75% quantile	14631.5	17790.3	19933.0	702.5	468.3	3771.0
	Max	15374	20494	19933	1434	703	3771

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 8							
	N with data	4	4	2	4	4	2
	N missing	43	23	22	43	23	22
	Mean	13469.9	15269.4	17717.8	-324.8	-940.1	309.0
	LSMeans[1]				58.942	-2021.648	1704.663
	SD	1309.86	3834.08	241.48	1657.72	1462.13	1965.05
	Min	11607	11946	17547	-1410	-2035	-1081
	25% quantile	12650.3	12268.8	17547.0	-1395.3	-1874.8	-1080.5
	Median	13804.3	14438.8	17717.8	-994.0	-1458.8	309.0
	75% quantile	14289.5	18270.0	17888.5	745.8	-5.5	1698.5
	Max	14665	20255	17889	2099	1192	1699
End of Trial							
	N with data	4	3	1	4	3	1
	N missing	43	24	23	43	24	23
	Mean	16033.9	13602.7	18569.5	84.6	-3627.2	2721.0
	LSMeans[1]				330.906	-3934.847	2658.918
	SD	5137.01	3013.34	-	1636.25	2731.24	-
	Min	12534	10925	18570	-1406	-5303	2721
	25% quantile	13226.3	10924.5	18569.5	-929.5	-5302.5	2721.0
	Median	13964.5	13018.0	18569.5	-335.5	-5103.5	2721.0
	75% quantile	18841.5	16865.5	18569.5	1098.8	-475.5	2721.0
	Max	23673	16866	18570	2415	-476	2721

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[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated							
Baseline/Screening**							
	N with data	40	23	21			
	N missing	7	4	3			
	Mean	16671.0	17933.0	17340.9			
	SD	4292.00	4681.93	3582.07			
	Min	10586	10544	11180			
	25% quantile	13220.8	14280.5	15383.0			
	Median	15867.3	17267.5	16834.0			
	75% quantile	20258.8	20201.5	20082.0			
	Max	27656	27426	23876			
Visit 3a*							
	N with data	40	23	-	40	23	-
	N missing	7	4	-	7	4	-
	Mean	17005.2	18157.4	-	334.3	224.4	-
	LSMeans[1]				345.912	204.132	
	SD	4584.49	4985.01	-	1297.17	1327.39	-
	Min	11406	12147	-	-2688	-1888	-
	25% quantile	13046.5	13816.0	-	-765.8	-741.0	-
	Median	15744.3	17620.5	-	364.8	233.5	-
	75% quantile	20259.5	21731.5	-	1003.8	690.5	-
	Max	28742	28122	-	3504	3172	-

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* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 4							
	N with data	38	23	22	38	23	21
	N missing	9	4	2	9	4	3
	Mean	17205.8	18433.2	18072.3	282.1	500.2	780.3
	LSMeans[1]				360.617	482.213	657.912
	SD	4440.97	4949.26	4027.86	1441.05	1443.01	1392.09
	Min	9438	12156	11446	-1954	-2440	-2107
	25% quantile	13545.5	14181.5	15402.0	-549.5	-418.5	-238.0
	Median	17106.3	17890.0	17489.8	127.3	446.0	1163.0
	75% quantile	20580.0	21672.5	20273.0	864.5	1548.5	1556.5
	Max	26078	28804	25030	5063	3500	2868
Visit 5							
	N with data	10	4	0	10	4	0
	N missing	37	23	24	37	23	24
	Mean	20536.9	20879.9	-	286.2	-1103.0	-
	LSMeans[1]				288.741	-1109.478	
	SD	4647.49	5177.90	-	1103.65	951.34	-
	Min	12993	15568	-	-988	-2098	-
	25% quantile	17680.0	16996.8	-	-808.5	-1763.8	-
	Median	20579.0	20178.5	-	438.8	-1241.5	-
	75% quantile	23846.5	24763.0	-	1095.5	-442.3	-
	Max	28012	27595	-	2212	169	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 6							
	N with data	39	21	21	39	21	20
	N missing	8	6	3	8	6	4
	Mean	17163.8	17912.3	17933.0	376.1	463.0	429.2
	LSMeans[1]				405.743	469.878	364.130
	SD	4483.72	4570.47	3664.84	1350.09	1344.02	1281.62
	Min	10338	11833	10942	-1764	-1901	-2213
	25% quantile	13305.0	14094.0	15948.0	-610.5	-443.0	-305.5
	Median	17346.0	17244.0	17345.0	406.5	4.5	524.8
	75% quantile	20673.5	19972.5	20258.0	1030.0	1468.0	1307.3
	Max	27425	28402	24925	3596	3098	2763
Visit 7							
	N with data	39	21	18	39	21	17
	N missing	8	6	6	8	6	7
	Mean	17113.2	17639.1	18666.4	325.6	455.7	883.4
	LSMeans[1]				321.670	468.941	875.860
	SD	4350.52	4075.52	4155.64	1279.48	1253.42	1151.49
	Min	10689	11976	10517	-2022	-2017	-1230
	25% quantile	13578.5	13991.0	15340.0	-566.0	-289.5	78.0
	Median	17088.5	16701.0	18538.8	146.0	332.0	1171.0
	75% quantile	20415.5	19987.0	21621.5	956.5	880.5	1848.5
	Max	27050	27732	25858	3836	3404	2898

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[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.1: Summary of volume (mm³) and changes in volume (mm³) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 8							
	N with data	35	20	20	35	20	19
	N missing	12	7	4	12	7	5
	Mean	16600.8	16899.2	18306.0	153.1	227.9	723.1
	LSMeans[1]				172.461	198.109	718.799
	SD	4377.52	3183.58	4029.81	1581.72	1517.66	1546.88
	Min	10715	12036	10097	-4534	-2583	-1433
	25% quantile	12723.5	14161.8	15428.5	-609.5	-750.8	-609.0
	Median	16654.5	17062.0	17804.3	274.5	380.5	773.0
	75% quantile	19751.0	20454.8	21999.3	954.0	1610.8	2007.0
	Max	26922	21446	24395	3884	2645	3534
End of Trial							
	N with data	33	19	19	33	19	18
	N missing	14	8	5	14	8	6
	Mean	16394.8	16524.6	17619.0	-251.3	-149.4	29.5
	LSMeans[1]				-264.110	-211.882	119.021
	SD	4114.06	3166.39	3523.48	1647.91	1903.21	1561.83
	Min	8745	12309	11779	-3413	-4349	-3052
	25% quantile	12954.5	13044.5	15477.5	-1517.0	-1236.0	-787.0
	Median	16367.5	17500.0	17071.5	-249.5	276.5	301.5
	75% quantile	19628.5	19188.5	20372.0	748.0	1684.5	1165.0
	Max	24747	21481	24561	3523	2562	2399

SC = Standard Care

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[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.2: Summary of height from volume (mm) and changes in height from volume (mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc							
Baseline/Screening**							
	N with data	23	13	9			
	N missing	24	14	15			
	Mean	13.1	14.3	12.6			
	SD	2.56	2.76	2.73			
	Min	7	11	8			
	25% quantile	12.2	12.0	10.2			
	Median	12.9	14.0	14.0			
	75% quantile	14.4	15.8	14.4			
	Max	21	20	16			
Visit 3a*							
	N with data	20	13	-	20	13	-
	N missing	27	14	-	27	14	-
	Mean	13.5	14.6	-	-0.1	0.3	-
	LSMeans[1]				-0.205	0.512	
	SD	1.11	2.53	-	1.91	0.98	-
	Min	11	11	-	-7	-1	-
	25% quantile	12.8	13.2	-	-0.5	-0.1	-
	Median	13.6	14.2	-	0.3	0.4	-
	75% quantile	14.0	16.2	-	1.0	1.0	-
	Max	16	20	-	2	2	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.2: Summary of height from volume (mm) and changes in height from volume (mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 4	N with data	20	13	11	20	13	9
	N missing	27	14	13	27	14	15
	Mean	13.6	15.0	13.0	0.1	0.6	0.6
	LSMeans[1]				0.071	0.929	0.151
	SD	1.55	2.40	3.13	2.22	1.51	1.11
	Min	9	12	8	-8	-2	-2
	25% quantile	12.6	14.0	9.8	0	-0.5	0.2
	Median	14.0	14.4	14.5	0.6	0.5	0.5
	75% quantile	14.8	16.3	15.5	1.1	2.1	1.0
	Max	15	21	16	2	3	2
Visit 5	N with data	4	2	0	4	2	0
	N missing	43	25	24	43	25	24
	Mean	13.0	14.4	-	-1.9	0.6	-
	LSMeans[1]				-1.550	-0.107	
	SD	0.99	2.68	-	3.67	0.11	-
	Min	12	13	-	-7	0	-
	25% quantile	12.1	12.5	-	-4.6	0.5	-
	Median	12.9	14.4	-	-0.9	0.6	-
	75% quantile	13.8	16.3	-	0.8	0.6	-
	Max	14	16	-	1	1	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.2: Summary of height from volume (mm) and changes in height from volume (mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 6							
	N with data	21	12	9	21	12	8
	N missing	26	15	15	26	15	16
	Mean	13.6	14.3	13.3	0.1	0.1	0.7
	LSMeans[1]				0.072	0.272	0.378
	SD	1.46	2.54	3.14	1.87	1.07	0.86
	Min	10	11	8	-6	-2	0
	25% quantile	12.9	12.6	9.9	-0.2	-0.9	0.1
	Median	13.4	13.8	14.6	0.3	0.5	0.6
	75% quantile	14.7	15.0	15.9	1.0	0.8	1.3
	Max	16	20	16	3	2	2
Visit 7							
	N with data	21	12	8	21	12	7
	N missing	26	15	16	26	15	17
	Mean	13.6	14.3	12.8	0	0.4	0.2
	LSMeans[1]				0.076	0.547	-0.169
	SD	1.44	2.14	3.32	2.01	0.98	0.90
	Min	9	11	8	-7	-2	-1
	25% quantile	13.2	12.6	9.3	-0.1	0	-0.7
	Median	13.5	14.0	14.8	0.7	0.5	0.3
	75% quantile	14.7	16.0	15.2	1.0	1.1	0.8
	Max	16	18	16	2	2	2

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.2: Summary of height from volume (mm) and changes in height from volume (mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 8	N with data	18	12	8	18	12	7
	N missing	29	15	16	29	15	17
	Mean	13.4	14.5	13.6	0.2	0.6	1.0
	LSMeans[1]				0.230	0.636	0.920
	SD	1.69	1.95	3.36	1.52	0.99	0.86
	Min	9	11	9	-4	-1	0
	25% quantile	12.5	13.4	10.2	-0.7	-0.1	0.1
	Median	13.7	14.5	15.0	0.2	0.5	1.4
	75% quantile	14.4	15.8	16.3	1.4	1.1	1.5
	Max	16	18	17	2	3	2
End of Trial							
	N with data	18	11	7	18	11	6
	N missing	29	16	17	29	16	18
	Mean	13.1	15.8	12.9	-0.5	2.1	0.1
	LSMeans[1]				-0.335	1.959	0.022
	SD	1.98	7.11	3.76	2.57	6.99	1.67
	Min	9	11	8	-8	-3	-2
	25% quantile	11.6	12.4	9.5	-0.8	-1.3	-1.0
	Median	13.7	14.0	12.4	0.4	0.6	-0.5
	75% quantile	14.3	16.2	17.1	1.3	1.7	1.7
	Max	16	37	18	2	23	3

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.2: Summary of height from volume (mm) and changes in height from volume (mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc							
Baseline/Screening**							
	N with data	47	27	23			
	N missing	0	0	1			
	Mean	13.2	14.4	13.9			
	SD	2.08	3.02	2.11			
	Min	9	11	10			
	25% quantile	11.8	12.7	11.8			
	Median	13.0	13.5	14.3			
	75% quantile	14.7	14.5	15.4			
	Max	18	23	18			
Visit 3a*							
	N with data	47	27	-	47	27	-
	Mean	13.6	14.1	-	0.3	-0.3	-
	LSMeans[1]				0.226	-0.116	
	SD	2.25	2.49	-	1.27	1.67	-
	Min	9	11	-	-3	-7	-
	25% quantile	11.9	12.6	-	-0.3	-0.6	-
	Median	13.1	13.8	-	0.3	-0.1	-
	75% quantile	15.2	15.4	-	1.1	0.6	-
	Max	18	22	-	4	2	-
Visit 4							
	N with data	45	27	24	45	27	23
	N missing	2	0	0	2	0	1
	Mean	13.7	14.2	14.4	0.3	-0.2	0.5
	LSMeans[1]				0.244	-0.025	0.402
	SD	2.16	2.45	2.28	1.58	2.00	1.42
	Min	8	11	9	-4	-8	-2
	25% quantile	12.2	12.2	13.6	-0.9	-0.7	-0.3
	Median	13.3	13.8	14.7	0.3	0.2	0.1
	75% quantile	15.4	15.2	15.5	1.3	0.7	1.4
	Max	19	21	18	4	3	3

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

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Table 14.2.7.2: Summary of height from volume (mm) and changes in height from volume (mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 5	N with data	12	7	0	12	7	0
	N missing	35	20	24	35	20	24
	Mean	15.1	15.4	-	0.4	0	-
	LSMeans[1]				0.295	0.159	
	SD	1.71	2.60	-	1.37	1.36	-
	Min	13	13	-	-1	-2	-
	25% quantile	13.7	13.5	-	-0.4	-0.9	-
	Median	14.7	14.3	-	-0.1	0	-
	75% quantile	16.9	17.5	-	1.1	1.3	-
	Max	18	20	-	3	2	-
Visit 6	N with data	46	25	22	46	25	21
	N missing	1	2	2	1	2	3
	Mean	13.3	13.7	14.3	0	-0.2	0.3
	LSMeans[1]				-0.056	-0.098	0.370
	SD	1.91	2.24	2.19	1.44	1.31	1.18
	Min	9	10	9	-4	-2	-2
	25% quantile	12.1	12.8	13.6	-0.9	-1.1	-0.5
	Median	13.1	13.5	14.4	-0.1	-0.4	0.3
	75% quantile	14.9	14.3	15.4	0.8	0.6	0.9
	Max	18	21	18	4	2	3

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Table 14.2.7.2: Summary of height from volume (mm) and changes in height from volume (mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 7	N with data	45	25	21	45	25	20
	N missing	2	2	3	2	2	4
	Mean	13.3	13.8	14.2	0	-0.4	0.1
	LSMeans[1]				-0.056	-0.237	0.182
	SD	2.01	2.53	2.37	1.35	1.76	1.38
	Min	9	10	9	-3	-7	-2
	25% quantile	12.1	12.6	13.5	-1.1	-1.1	-0.7
	Median	13.3	13.1	14.2	0.4	-0.3	0
	75% quantile	14.8	14.9	15.5	0.9	0.8	1.2
	Max	19	21	18	3	2	3
Visit 8	N with data	41	24	22	41	24	21
	N missing	6	3	2	6	3	3
	Mean	13.1	13.4	14.3	-0.1	-0.6	0.4
	LSMeans[1]				-0.199	-0.446	0.372
	SD	2.23	2.14	2.40	1.81	1.98	1.39
	Min	9	10	9	-4	-8	-2
	25% quantile	11.9	12.0	13.4	-1.1	-1.4	-0.9
	Median	13.0	13.6	14.8	-0.2	-0.3	0.5
	75% quantile	14.2	14.5	15.3	0.7	0.8	1.5
	Max	20	20	19	7	2	3

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Table 14.2.7.2: Summary of height from volume (mm) and changes in height from volume (mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
End of Trial	N with data	37	22	20	37	22	19
	N missing	10	5	4	10	5	5
	Mean	12.2	13.2	13.2	-0.9	-0.9	-0.6
	LSMeans[1]				-1.062	-0.663	-0.473
	SD	1.76	2.35	2.44	1.92	2.19	1.70
	Min	8	10	8	-6	-8	-3
	25% quantile	10.9	11.8	11.1	-2.0	-1.7	-2.0
	Median	12.2	12.9	13.5	-0.7	-0.5	-0.2
	75% quantile	13.3	14.7	15.3	0.3	0.3	0.6
	Max	16	21	17	2	2	3

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[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated							
Baseline/Screening**							
	N with data	7	4	2			
	N missing	40	23	22			
	Mean	13.1	13.2	14.9			
	SD	1.76	2.69	2.31			
	Min	11	10	13			
	25% quantile	11.5	11.2	13.3			
	Median	13.7	12.9	14.9			
	75% quantile	14.6	15.1	16.6			
	Max	15	17	17			
Visit 3a*							
	N with data	7	4	-	7	4	-
	N missing	40	23	-	40	23	-
	Mean	13.9	13.5	-	0.7	0.3	-
	LSMeans[1]				0.790	0.200	
	SD	2.24	2.23	-	0.92	0.69	-
	Min	11	12	-	-1	0	-
	25% quantile	12.0	11.9	-	0.7	-0.1	-
	Median	14.6	12.8	-	1.1	0	-
	75% quantile	15.8	15.0	-	1.3	0.7	-
	Max	16	17	-	1	1	-

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 4							
	N with data	7	4	2	7	4	2
	N missing	40	23	22	40	23	22
	Mean	14.2	13.0	16.1	1.1	-0.1	1.2
	LSMeans[1]				1.326	-0.697	1.377
	SD	2.11	2.54	1.63	0.89	1.43	0.68
	Min	12	10	15	0	-2	1
	25% quantile	11.6	11.1	15.0	0.3	-1.2	0.7
	Median	14.9	12.8	16.1	0.9	-0.2	1.2
	75% quantile	15.6	15.0	17.3	2.0	0.9	1.6
	Max	17	16	17	2	2	2
Visit 5							
	N with data	2	3	0	2	3	0
	N missing	45	24	24	45	24	24
	Mean	15.5	14.0	-	0.6	1.0	-
	LSMeans[1]				1.175	0.627	-
	SD	0.01	2.58	-	0.39	0.85	-
	Min	15	12	-	0	0	-
	25% quantile	15.5	12.2	-	0.3	0.4	-
	Median	15.5	12.9	-	0.6	0.7	-
	75% quantile	15.5	17.0	-	0.9	2.0	-
	Max	15	17	-	1	2	-

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 6							
	N with data	7	4	1	7	4	1
	N missing	40	23	23	40	23	23
	Mean	14.4	13.2	18.6	1.2	0.1	2.0
	LSMeans[1]				1.155	-0.020	2.858
	SD	2.00	1.51	-	1.16	1.30	-
	Min	11	11	19	-1	-2	2
	25% quantile	12.9	12.3	18.6	-0.3	-1.0	2.0
	Median	14.1	13.2	18.6	1.8	0.3	2.0
	75% quantile	16.0	14.2	18.6	2.1	1.1	2.0
	Max	17	15	19	2	1	2
Visit 7							
	N with data	6	4	2	6	4	2
	N missing	41	23	22	41	23	22
	Mean	13.5	12.9	17.7	0.6	-0.2	2.7
	LSMeans[1]				0.680	-0.731	3.563
	SD	2.15	2.38	0.60	1.41	1.57	1.71
	Min	11	10	17	-1	-2	2
	25% quantile	11.4	11.0	17.3	-0.4	-1.5	1.5
	Median	13.7	13.0	17.7	0.7	-0.3	2.7
	75% quantile	14.9	14.9	18.1	1.5	1.1	3.9
	Max	17	16	18	3	2	4

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 8							
	N with data	5	4	2	5	4	2
	N missing	42	23	22	42	23	22
	Mean	13.7	13.2	16.8	0.3	0	1.8
	LSMeans[1]				0.481	-0.681	2.804
	SD	1.50	1.38	1.99	1.25	1.67	0.31
	Min	11	12	15	-1	-2	2
	25% quantile	13.9	12.0	15.3	-0.6	-1.2	1.6
	Median	13.9	13.2	16.8	0.2	0.2	1.8
	75% quantile	14.1	14.4	18.2	0.2	1.2	2.0
	Max	15	14	18	2	2	2
End of Trial							
	N with data	4	3	1	4	3	1
	N missing	43	24	23	43	24	23
	Mean	13.7	12.0	15.7	0.4	-1.0	2.4
	LSMeans[1]				0.689	-1.420	2.458
	SD	1.86	1.77	-	1.13	1.76	-
	Min	11	11	16	-1	-3	2
	25% quantile	12.4	10.8	15.7	-0.5	-2.6	2.4
	Median	13.7	11.1	15.7	0.2	-1.3	2.4
	75% quantile	15.0	14.0	15.7	1.3	0.9	2.4
	Max	16	14	16	2	1	2

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated							
Baseline/Screening**							
	N with data	40	23	21			
	N missing	7	4	3			
	Mean	13.9	14.8	14.3			
	SD	1.96	1.91	2.06			
	Min	10	12	10			
	25% quantile	12.6	13.3	13.6			
	Median	13.4	14.7	14.3			
	75% quantile	15.4	16.5	15.7			
	Max	18	19	18			
Visit 3a*							
	N with data	40	23	-	40	23	-
	N missing	7	4	-	7	4	-
	Mean	14.1	15.4	-	0.2	0.6	-
	LSMeans[1]				0.112	0.693	
	SD	2.08	3.52	-	1.08	3.30	-
	Min	11	11	-	-2	-4	-
	25% quantile	12.6	13.3	-	-0.5	-0.8	-
	Median	13.4	15.2	-	0.2	0.3	-
	75% quantile	15.2	16.5	-	0.7	0.8	-
	Max	19	29	-	3	15	-

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		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 4	N with data	38	23	22	38	23	21
	N missing	9	4	2	9	4	3
	Mean	14.4	14.8	14.8	0.4	-0.1	0.6
	LSMeans[1]				0.419	-0.008	0.433
	SD	1.95	1.90	2.45	1.04	1.51	1.28
	Min	10	12	10	-2	-5	-1
	25% quantile	13.2	13.4	13.6	-0.4	-0.8	-0.2
	Median	13.9	14.2	15.2	0.4	0	0.6
	75% quantile	16.0	16.6	16.4	0.9	0.8	1.4
	Max	18	18	20	3	2	3
Visit 5	N with data	10	4	0	10	4	0
	N missing	37	23	24	37	23	24
	Mean	15.5	19.3	-	-0.1	1.5	-
	LSMeans[1]				-0.373	2.172	
	SD	2.24	6.65	-	0.83	7.13	-
	Min	12	15	-	-1	-3	-
	25% quantile	14.1	15.3	-	-0.9	-2.6	-
	Median	16.0	16.5	-	0	-1.2	-
	75% quantile	16.3	23.3	-	0.3	5.7	-
	Max	19	29	-	1	12	-

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		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 6							
	N with data	39	21	21	39	21	20
	N missing	8	6	3	8	6	4
	Mean	14.0	14.7	14.9	0.1	0.1	0.5
	LSMeans[1]				0.058	0.148	0.474
	SD	1.80	1.97	1.86	0.94	1.36	1.11
	Min	10	12	11	-2	-3	-1
	25% quantile	12.7	13.2	14.1	-0.6	-0.6	-0.4
	Median	13.7	14.4	15.1	0.1	0.2	0.4
	75% quantile	15.2	15.4	16.1	0.7	0.8	1.2
	Max	18	19	18	2	3	3
Visit 7							
	N with data	39	21	19	39	21	18
	N missing	8	6	5	8	6	6
	Mean	13.9	14.6	14.8	0	0	0.3
	LSMeans[1]				-0.025	0.112	0.311
	SD	1.86	1.73	1.82	0.91	1.29	1.01
	Min	11	12	10	-2	-3	-1
	25% quantile	12.8	13.4	13.8	-0.5	-0.3	-0.4
	Median	13.8	14.6	15.1	0.2	0.2	0.1
	75% quantile	15.6	15.4	15.5	0.8	0.6	0.9
	Max	19	18	18	1	3	3

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 8	N with data	36	20	20	36	20	19
	N missing	11	7	4	11	7	5
	Mean	14.0	14.5	15.1	0.2	0	0.6
	LSMeans[1]				0.160	0.058	0.656
	SD	2.04	1.39	2.27	1.01	1.70	1.24
	Min	11	12	10	-2	-5	-1
	25% quantile	12.5	13.5	13.9	-0.5	-0.5	-0.1
	Median	13.6	14.8	15.4	0.3	0.6	0.4
	75% quantile	15.8	15.5	16.2	0.9	1.0	1.5
	Max	18	17	19	2	2	3
End of Trial	N with data	33	19	19	33	19	18
	N missing	14	8	5	14	8	6
	Mean	13.7	14.2	14.5	-0.1	-0.1	0
	LSMeans[1]				-0.151	-0.058	0.075
	SD	2.04	1.46	1.89	1.14	1.07	1.18
	Min	9	12	11	-2	-2	-2
	25% quantile	11.9	12.9	13.0	-1.0	-0.8	-0.8
	Median	13.5	14.2	14.9	-0.2	-0.2	0.1
	75% quantile	15.0	14.8	16.1	0.8	0.8	1.0
	Max	18	17	18	2	2	2

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc							
Baseline/Screening**							
	N with data	23	13	9			
	N missing	24	14	15			
	Mean	8.8	10.4	9.8			
	SD	1.84	1.64	2.12			
	Min	5	8	6			
	25% quantile	7.2	9.2	8.4			
	Median	9.1	10.3	10.5			
	75% quantile	10.3	10.9	11.1			
	Max	12	13	12			
Visit 3a*							
	N with data	21	13	-	21	13	-
	N missing	26	14	-	26	14	-
	Mean	9.2	10.4	-	0.1	-0.1	-
	LSMeans[1]				0.033	0.036	
	SD	1.48	1.70	-	0.61	0.51	-
	Min	6	7	-	-1	-1	-
	25% quantile	8.4	9.2	-	-0.2	-0.3	-
	Median	9.3	10.6	-	0.1	-0.1	-
	75% quantile	10.4	11.2	-	0.4	0.1	-
	Max	11	13	-	2	1	-

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Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 4							
	N with data	21	13	11	21	13	9
	N missing	26	14	13	26	14	15
	Mean	9.1	9.9	9.4	0.1	-0.5	-0.2
	LSMeans[1]				0.006	-0.425	-0.271
	SD	1.76	1.34	2.10	0.64	0.95	0.67
	Min	5	7	6	-1	-3	-1
	25% quantile	7.8	9.1	6.9	-0.3	-1.3	-0.6
	Median	9.1	9.6	10.6	-0.1	-0.5	-0.5
	75% quantile	10.1	10.5	10.8	0.5	-0.2	0.2
	Max	12	12	12	1	1	1
Visit 5							
	N with data	4	2	0	4	2	0
	N missing	43	25	24	43	25	24
	Mean	8.4	8.5	-	0	-0.9	-
	LSMeans[1]				0.025	-0.904	
	SD	2.36	1.92	-	0.37	0.28	-
	Min	5	7	-	0	-1	-
	25% quantile	6.7	7.1	-	-0.3	-1.1	-
	Median	8.8	8.5	-	0	-0.9	-
	75% quantile	10.0	9.8	-	0.3	-0.7	-
	Max	11	10	-	0	-1	-

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Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 6							
	N with data	22	12	9	21	12	8
	N missing	25	15	15	26	15	16
	Mean	9.1	9.9	9.5	0.1	-0.4	-0.3
	LSMeans[1]				0.050	-0.228	-0.263
	SD	1.60	1.37	2.05	0.88	0.93	0.56
	Min	5	7	6	-1	-2	-1
	25% quantile	8.4	9.5	7.9	-0.4	-1.0	-0.6
	Median	9.1	10.1	10.3	0.2	0	-0.5
	75% quantile	10.1	10.6	10.8	0.3	0.4	0.2
	Max	12	12	12	2	1	1
Visit 7							
	N with data	22	12	8	21	12	7
	N missing	25	15	16	26	15	17
	Mean	8.8	10.0	9.6	-0.2	-0.6	-0.2
	LSMeans[1]				-0.253	-0.548	-0.216
	SD	1.91	1.36	2.40	0.69	0.76	0.48
	Min	5	7	6	-2	-2	-1
	25% quantile	7.3	9.5	7.6	-0.7	-1.2	-0.5
	Median	9.0	10.1	9.5	-0.2	-0.5	-0.1
	75% quantile	10.1	10.7	11.8	0.3	0.1	0
	Max	13	12	13	1	0	0

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Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 8	N with data	19	12	8	19	12	7
	N missing	28	15	16	28	15	17
	Mean	9.2	10.0	9.7	0.1	-0.4	0
	LSMeans[1]				-0.007	-0.292	-0.043
	SD	1.75	1.57	2.22	0.59	0.99	0.88
	Min	5	7	7	-1	-2	-1
	25% quantile	7.8	9.6	7.7	-0.4	-1.1	-0.7
	Median	9.3	9.9	9.6	-0.2	-0.1	-0.1
	75% quantile	10.6	10.4	11.6	0.3	0.4	0.5
	Max	12	14	13	1	1	1
End of Trial							
	N with data	18	13	7	18	13	6
	N missing	29	14	17	29	14	18
	Mean	8.7	10.2	9.7	-0.2	-0.3	0
	LSMeans[1]				-0.195	-0.354	0.222
	SD	2.04	1.53	2.26	0.68	1.41	0.62
	Min	5	7	7	-2	-2	-1
	25% quantile	7.8	9.6	7.3	-0.7	-1.3	-0.3
	Median	9.4	9.8	9.1	-0.2	-0.4	-0.2
	75% quantile	9.7	11.0	11.7	0.3	0.9	0
	Max	12	13	13	1	2	1

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Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc							
Baseline/Screening**							
	N with data	47	27	23			
	N missing	0	0	1			
	Mean	9.2	9.6	9.7			
	SD	1.62	1.57	1.94			
	Min	6	6	6			
	25% quantile	8.1	8.4	8.2			
	Median	9.2	9.4	9.3			
	75% quantile	10.4	10.6	11.7			
	Max	13	14	14			
Visit 3a*							
	N with data	47	27	-	47	27	-
	Mean	8.9	9.1	-	-0.3	-0.5	-
	LSMeans[1]				-0.330	-0.466	
	SD	1.74	1.52	-	0.81	0.69	-
	Min	6	5	-	-3	-2	-
	25% quantile	7.8	8.1	-	-0.8	-1.1	-
	Median	9.0	9.3	-	-0.2	-0.5	-
	75% quantile	10.1	9.8	-	0.4	0	-
	Max	13	13	-	1	1	-
Visit 4							
	N with data	46	27	24	46	27	23
	N missing	1	0	0	1	0	1
	Mean	9.1	9.1	9.5	-0.2	-0.5	-0.2
	LSMeans[1]				-0.178	-0.454	-0.245
	SD	1.65	1.82	1.87	0.72	0.75	1.09
	Min	5	6	6	-2	-2	-2
	25% quantile	8.0	8.1	7.9	-0.6	-1.1	-1.0
	Median	9.2	9.0	10.0	0	-0.4	-0.1
	75% quantile	10.3	9.7	10.9	0.2	0.2	0.3
	Max	13	14	13	1	1	2

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 5	N with data	12	7	0	12	7	0
	N missing	35	20	24	35	20	24
	Mean	9.6	9.1	-	-0.1	-0.2	-
	LSMeans[1]				-0.079	-0.224	
	SD	2.03	1.08	-	0.89	0.50	-
	Min	7	8	-	-2	-1	-
	25% quantile	8.3	8.1	-	-0.5	-0.7	-
	Median	9.7	9.1	-	-0.1	-0.2	-
	75% quantile	10.8	10.4	-	0.5	0	-
	Max	14	11	-	1	1	-
Visit 6	N with data	46	25	23	46	25	22
	N missing	1	2	1	1	2	2
	Mean	9.0	8.7	9.2	-0.3	-0.7	-0.5
	LSMeans[1]				-0.309	-0.630	-0.500
	SD	1.57	1.31	1.78	0.76	1.01	0.79
	Min	6	6	6	-2	-4	-2
	25% quantile	7.8	7.6	8.1	-0.8	-1.1	-0.9
	Median	8.7	8.7	9.2	-0.2	-0.5	-0.6
	75% quantile	9.9	9.9	10.9	0.2	-0.1	0.1
	Max	14	11	12	1	1	1

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 7	N with data	45	25	21	45	25	20
	N missing	2	2	3	2	2	4
	Mean	8.7	8.8	9.3	-0.5	-0.7	-0.5
	LSMeans[1]				-0.539	-0.695	-0.500
	SD	1.70	1.64	1.91	0.89	0.99	0.91
	Min	5	6	6	-3	-3	-2
	25% quantile	7.5	7.6	7.8	-0.9	-0.9	-1.3
	Median	8.8	8.6	9.5	-0.3	-0.5	-0.4
	75% quantile	9.7	9.0	10.5	0.1	-0.1	0.1
	Max	13	14	12	1	1	1
Visit 8	N with data	42	25	22	42	25	21
	N missing	5	2	2	5	2	3
	Mean	8.6	8.7	9.4	-0.7	-0.7	-0.3
	LSMeans[1]				-0.699	-0.709	-0.270
	SD	1.71	1.45	1.86	0.94	1.13	0.98
	Min	5	6	6	-3	-4	-2
	25% quantile	7.7	7.7	7.5	-1.5	-1.3	-1.0
	Median	8.6	8.5	9.4	-0.7	-0.4	-0.2
	75% quantile	9.7	9.8	11.3	0	-0.1	0.6
	Max	14	11	12	1	1	2

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
End of Trial	N with data	37	24	20	37	24	19
	N missing	10	3	4	10	3	5
	Mean	7.8	8.3	8.9	-1.3	-1.2	-0.7
	LSMeans[1]				-1.359	-1.188	-0.646
	SD	1.63	1.86	2.31	1.59	1.34	1.16
	Min	4	5	5	-6	-5	-3
	25% quantile	6.9	6.8	7.0	-2.3	-1.7	-1.4
	Median	7.9	8.5	8.4	-0.9	-1.1	-0.7
	75% quantile	8.9	9.2	11.2	-0.1	-0.1	0.1
	Max	11	13	12	1	0	1

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated							
Baseline/Screening**							
	N with data	7	4	2			
	N missing	40	23	22			
	Mean	10.2	9.6	11.2			
	SD	1.11	1.88	1.25			
	Min	9	7	10			
	25% quantile	9.1	8.0	10.4			
	Median	10.3	9.6	11.2			
	75% quantile	11.4	11.1	12.1			
	Max	12	12	12			
Visit 3a*							
	N with data	7	4	-	7	4	-
	N missing	40	23	-	40	23	-
	Mean	10.2	9.2	-	0	-0.3	-
	LSMeans[1]				-0.002	-0.338	
	SD	1.41	1.83	-	0.71	0.14	-
	Min	8	7	-	-1	0	-
	25% quantile	9.1	7.8	-	-0.7	-0.4	-
	Median	10.8	9.3	-	0	-0.3	-
	75% quantile	11.2	10.7	-	0.4	-0.2	-
	Max	12	11	-	1	0	-

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Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 4							
	N with data	7	4	2	7	4	2
	N missing	40	23	22	40	23	22
	Mean	10.4	9.6	12.1	0.1	0.1	0.8
	LSMeans[1]				0.156	0.048	0.852
	SD	1.38	1.80	0.44	0.40	0.28	0.81
	Min	9	8	12	-1	0	0
	25% quantile	9.1	8.3	11.8	-0.1	-0.1	0.3
	Median	10.7	9.5	12.1	0.2	0.2	0.8
	75% quantile	11.7	11.0	12.4	0.5	0.2	1.4
	Max	12	12	12	1	0	1
Visit 5							
	N with data	2	3	0	2	3	0
	N missing	45	24	24	45	24	24
	Mean	11.7	9.4	-	0.7	0.1	-
	LSMeans[1]				0.219	0.469	-
	SD	1.33	2.49	-	0.65	0.40	-
	Min	11	7	-	0	0	-
	25% quantile	10.7	7.1	-	0.3	-0.3	-
	Median	11.7	8.9	-	0.7	0.3	-
	75% quantile	12.6	12.0	-	1.2	0.4	-
	Max	13	12	-	1	0	-

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		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 6							
	N with data	7	4	2	7	4	2
	N missing	40	23	22	40	23	22
	Mean	10.0	9.9	10.7	-0.2	0.3	-0.6
	LSMeans[1]				-0.259	0.512	-0.737
	SD	1.23	1.78	1.49	0.49	0.67	0.24
	Min	9	8	10	-1	-1	-1
	25% quantile	9.0	8.5	9.6	-0.7	-0.1	-0.7
	Median	9.7	10.1	10.7	-0.1	0.4	-0.6
	75% quantile	11.2	11.3	11.7	0.4	0.8	-0.4
	Max	12	12	12	0	1	0
Visit 7							
	N with data	6	4	2	6	4	2
	N missing	41	23	22	41	23	22
	Mean	9.8	9.6	11.6	-0.1	0.1	0.4
	LSMeans[1]				-0.165	0.033	0.519
	SD	1.26	1.68	0.43	0.56	1.09	0.83
	Min	8	7	11	-1	-1	0
	25% quantile	8.6	8.4	11.3	-0.5	-0.7	-0.2
	Median	10.1	9.7	11.6	-0.1	0.4	0.4
	75% quantile	10.3	10.8	11.9	0.2	0.8	1.0
	Max	12	12	12	1	1	1

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Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 8							
	N with data	5	4	2	5	4	2
	N missing	42	23	22	42	23	22
	Mean	9.9	9.4	11.2	-0.2	-0.2	0
	LSMeans[1]				-0.120	-0.333	0.145
	SD	1.35	1.51	1.14	0.55	0.70	0.12
	Min	8	8	10	-1	-1	0
	25% quantile	9.5	8.1	10.4	-0.1	-0.6	-0.1
	Median	10.1	9.5	11.2	-0.1	0.1	0
	75% quantile	10.4	10.6	12.0	0.2	0.3	0.1
	Max	12	11	12	0	0	0
End of Trial							
	N with data	5	3	1	5	3	1
	N missing	42	24	23	42	24	23
	Mean	10.7	8.1	11.2	0.5	-1.1	0.9
	LSMeans[1]				0.878	-1.736	1.014
	SD	1.43	1.12	-	0.89	1.11	-
	Min	9	7	11	-1	-2	1
	25% quantile	10.1	7.4	11.2	-0.2	-2.2	0.9
	Median	10.7	7.5	11.2	0.7	-1.1	0.9
	75% quantile	11.8	9.4	11.2	1.3	0	0.9
	Max	12	9	11	1	0	1

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated							
Baseline/Screening**							
	N with data	40	23	21			
	N missing	7	4	3			
	Mean	11.2	11.3	11.5			
	SD	1.68	1.60	2.00			
	Min	8	9	8			
	25% quantile	10.3	10.3	10.4			
	Median	11.1	10.8	11.2			
	75% quantile	12.0	12.8	13.0			
	Max	15	15	15			
Visit 3a*							
	N with data	40	23	-	40	23	-
	N missing	7	4	-	7	4	-
	Mean	11.0	11.2	-	-0.2	-0.2	-
	LSMeans[1]				-0.245	-0.153	
	SD	1.73	1.49	-	1.10	0.64	-
	Min	8	10	-	-4	-2	-
	25% quantile	9.9	9.9	-	-0.7	-0.7	-
	Median	10.7	10.8	-	0	-0.1	-
	75% quantile	11.5	12.6	-	0.4	0.3	-
	Max	17	16	-	2	1	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 4							
	N with data	39	23	22	39	23	21
	N missing	8	4	2	8	4	3
	Mean	11.1	11.1	11.2	-0.2	-0.3	-0.3
	LSMeans[1]				-0.150	-0.263	-0.351
	SD	1.60	1.53	2.13	0.75	0.79	0.91
	Min	8	8	8	-2	-2	-2
	25% quantile	10.2	10.1	9.3	-0.7	-0.9	-1.0
	Median	10.9	10.7	11.1	-0.2	-0.1	-0.4
	75% quantile	12.1	12.2	12.6	0.2	0.5	0.3
	Max	15	15	14	3	1	2
Visit 5							
	N with data	10	4	0	10	4	0
	N missing	37	23	24	37	23	24
	Mean	12.2	11.6	-	0.1	-0.2	-
	LSMeans[1]				0.111	-0.185	
	SD	2.37	1.32	-	0.70	0.34	-
	Min	9	10	-	-1	0	-
	25% quantile	11.5	10.5	-	-0.3	-0.4	-
	Median	12.0	11.5	-	0.1	-0.3	-
	75% quantile	13.2	12.8	-	0.5	0	-
	Max	16	13	-	1	0	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 6							
	N with data	39	21	21	39	21	20
	N missing	8	6	3	8	6	4
	Mean	11.1	10.9	11.5	-0.1	-0.3	-0.2
	LSMeans[1]				-0.124	-0.288	-0.198
	SD	1.61	1.36	1.97	0.86	0.82	0.85
	Min	8	8	7	-2	-2	-2
	25% quantile	9.9	10.1	9.9	-0.5	-0.7	-0.9
	Median	10.8	10.6	11.3	-0.2	0	-0.3
	75% quantile	12.1	11.5	13.2	0.4	0.2	0.6
	Max	16	14	14	2	1	1
Visit 7							
	N with data	39	21	19	39	21	18
	N missing	8	6	5	8	6	6
	Mean	11.0	11.1	11.3	-0.3	-0.2	-0.3
	LSMeans[1]				-0.282	-0.198	-0.300
	SD	1.71	1.34	1.84	0.68	0.86	0.82
	Min	8	9	8	-2	-2	-2
	25% quantile	9.7	10.1	9.2	-0.7	-0.5	-1.0
	Median	11.0	10.8	11.9	-0.1	0	-0.3
	75% quantile	11.8	11.9	12.9	0.2	0.5	0.4
	Max	15	14	14	1	1	1

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.3: Summary of height(manual, mm) and changes in height(manual, mm) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 8							
	N with data	37	21	20	37	21	19
	N missing	10	6	4	10	6	5
	Mean	10.9	10.9	11.5	-0.3	-0.2	-0.1
	LSMeans[1]				-0.289	-0.242	-0.087
	SD	1.67	1.22	1.94	0.94	0.75	0.85
	Min	8	9	8	-2	-1	-2
	25% quantile	9.7	10.0	9.7	-0.8	-0.9	-0.7
	Median	11.0	11.1	11.6	-0.3	-0.1	-0.1
	75% quantile	11.9	11.6	13.1	0.3	0.3	0.5
	Max	15	13	14	1	1	1
End of Trial							
	N with data	33	22	19	33	22	18
	N missing	14	5	5	14	5	6
	Mean	11.1	11.2	11.3	0	0	-0.3
	LSMeans[1]				-0.045	-0.011	-0.236
	SD	1.83	1.47	1.97	1.00	0.86	0.93
	Min	7	9	7	-2	-1	-3
	25% quantile	9.9	10.0	9.4	-0.8	-0.7	-0.7
	Median	11.3	11.1	11.8	0	-0.1	0
	75% quantile	12.0	12.3	13.1	0.5	0.6	0.3
	Max	15	14	14	2	2	1

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc							
Baseline/Screening**							
	N with data	21	13	9			
	N missing	26	14	15			
	Mean	81.1	84.5	77.8			
	SD	10.98	18.55	11.99			
	Min	54	51	58			
	25% quantile	76.8	73.6	67.7			
	Median	81.1	84.7	79.9			
	75% quantile	88.3	94.4	84.0			
	Max	100	116	96			
Visit 3a*							
	N with data	20	13	-	18	13	-
	N missing	27	14	-	29	14	-
	Mean	81.6	86.6	-	0	2.1	-
	LSMeans[1]				-0.096	2.273	
	SD	11.94	17.07	-	4.99	4.95	-
	Min	61	59	-	-9	-6	-
	25% quantile	71.6	77.6	-	-2.4	-0.9	-
	Median	82.0	89.9	-	-0.1	1.3	-
	75% quantile	92.4	95.1	-	3.6	4.9	-
	Max	100	116	-	9	12	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 4	N with data	20	13	11	18	13	9
	N missing	27	14	13	29	14	15
	Mean	82.5	85.9	77.7	1.0	1.4	-0.2
	LSMeans[1]				1.156	2.104	-1.563
	SD	12.14	15.60	9.37	8.80	6.35	7.21
	Min	59	62	62	-22	-6	-13
	25% quantile	73.1	75.5	67.7	-4.1	-3.1	-6.5
	Median	84.3	89.6	77.7	1.4	0.7	1.4
	75% quantile	92.8	93.2	85.8	4.1	3.7	4.6
	Max	101	111	90	15	18	10
Visit 5	N with data	4	2	0	4	2	0
	N missing	43	25	24	43	25	24
	Mean	90.2	101.4	-	0.7	-0.3	-
	LSMeans[1]				-2.247	5.647	
	SD	7.16	6.71	-	7.79	13.18	-
	Min	83	97	-	-5	-10	-
	25% quantile	85.9	96.6	-	-4.4	-9.6	-
	Median	88.7	101.4	-	-2.0	-0.3	-
	75% quantile	94.6	106.1	-	5.9	9.0	-
	Max	100	106	-	12	9	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 6							
	N with data	22	12	9	19	12	8
	N missing	25	15	15	28	15	16
	Mean	83.7	84.6	79.3	1.3	-0.1	0
	LSMeans[1]				1.227	0.285	-0.318
	SD	12.25	17.22	12.08	7.58	4.99	8.93
	Min	57	61	63	-14	-9	-14
	25% quantile	74.6	69.8	66.5	-2.8	-2.1	-5.0
	Median	87.7	83.8	80.8	1.0	-1.0	-1.2
	75% quantile	94.9	94.7	89.2	6.3	1.4	5.5
	Max	101	114	96	15	11	16
Visit 7							
	N with data	22	12	8	19	12	7
	N missing	25	15	16	28	15	17
	Mean	80.5	87.4	80.6	-1.6	0	2.9
	LSMeans[1]				-2.115	1.560	1.601
	SD	9.05	14.50	8.81	8.89	7.12	10.93
	Min	64	59	68	-24	-16	-10
	25% quantile	74.2	78.6	72.8	-4.9	-2.6	-3.1
	Median	80.2	87.5	82.2	-0.7	-1.0	1.2
	75% quantile	88.1	98.0	85.8	3.7	2.3	5.8
	Max	96	111	95	14	14	25

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Caudal Disc (continued)							
Visit 8	N with data	18	13	8	16	13	7
	N missing	29	14	16	31	14	17
	Mean	77.0	83.2	83.3	-3.3	-1.3	5.9
	LSMeans[1]				-4.067	0.086	5.048
	SD	9.73	12.82	10.61	9.64	7.04	15.42
	Min	59	62	71	-24	-9	-6
	25% quantile	71.5	72.5	73.9	-8.2	-6.2	-5.3
	Median	74.7	84.9	82.8	-1.3	-2.9	-1.5
	75% quantile	85.3	89.2	89.5	3.8	1.8	13.6
	Max	93	106	103	10	17	37
End of Trial							
	N with data	17	13	7	15	13	6
	N missing	30	14	17	32	14	18
	Mean	73.6	81.5	79.7	-6.5	-3.0	1.9
	LSMeans[1]				-7.134	-2.208	1.656
	SD	9.35	13.44	3.96	8.27	11.82	13.55
	Min	60	60	73	-21	-24	-12
	25% quantile	70.2	74.1	77.1	-13.6	-7.5	-9.3
	Median	71.3	82.2	79.6	-5.9	-4.7	-1.3
	75% quantile	79.7	91.8	84.1	-2.2	1.4	10.9
	Max	93	104	84	8	23	24

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc							
Baseline/Screening**							
	N with data	45	27	23			
	N missing	2	0	1			
	Mean	76.1	74.7	70.8			
	SD	10.18	11.15	8.53			
	Min	59	58	57			
	25% quantile	69.3	65.6	64.7			
	Median	75.4	74.2	70.3			
	75% quantile	82.7	86.6	76.5			
	Max	97	98	86			
Visit 3a*							
	N with data	46	27	-	44	27	-
	N missing	1	0	-	3	0	-
	Mean	76.2	75.1	-	0.5	0.5	-
	LSMeans[1]				0.610	0.249	
	SD	9.21	10.82	-	7.44	7.20	-
	Min	58	56	-	-15	-11	-
	25% quantile	70.3	67.7	-	-3.1	-2.7	-
	Median	76.0	76.2	-	0.8	0.1	-
	75% quantile	82.7	85.4	-	4.0	2.9	-
	Max	94	93	-	18	28	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 4	N with data	45	27	24	43	27	23
	N missing	2	0	0	4	0	1
	Mean	77.4	75.4	73.3	1.5	0.7	2.6
	LSMeans[1]				1.896	0.789	1.875
	SD	10.78	10.56	8.70	7.72	6.56	6.28
	Min	58	55	59	-25	-11	-9
	25% quantile	68.7	66.8	67.0	-1.3	-4.1	-0.7
	Median	76.0	75.7	72.0	1.7	0.3	2.2
	75% quantile	83.8	83.9	79.4	5.7	4.3	6.8
	Max	104	92	93	18	16	14
Visit 5	N with data	12	7	0	12	7	0
	N missing	35	20	24	35	20	24
	Mean	82.8	78.7	-	-3.4	-5.6	-
	LSMeans[1]				-3.149	-6.125	
	SD	7.92	7.57	-	7.74	5.61	-
	Min	73	66	-	-20	-13	-
	25% quantile	76.4	69.5	-	-8.4	-11.4	-
	Median	81.4	81.6	-	-0.5	-5.2	-
	75% quantile	87.9	84.4	-	1.1	-4.1	-
	Max	98	85	-	6	4	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 6	N with data	46	25	23	44	25	22
	N missing	1	2	1	3	2	2
	Mean	77.2	72.7	73.5	0.7	-1.2	2.8
	LSMeans[1]				1.368	-1.109	1.235
	SD	10.96	10.08	10.97	9.93	7.49	10.17
	Min	55	53	58	-22	-21	-18
	25% quantile	69.5	66.3	66.7	-4.3	-4.7	-2.5
	Median	75.5	70.5	69.3	1.0	-0.9	0.8
	75% quantile	87.5	77.9	77.5	4.2	2.8	8.9
	Max	98	98	97	29	13	30
Visit 7	N with data	44	25	21	42	25	20
	N missing	3	2	3	5	2	4
	Mean	74.8	73.0	72.6	-2.2	-1.4	3.0
	LSMeans[1]				-1.296	-1.292	0.952
	SD	8.80	10.85	8.32	9.39	8.00	6.64
	Min	57	56	61	-28	-25	-7
	25% quantile	68.4	67.4	66.3	-8.5	-5.4	-2.5
	Median	74.1	72.0	71.1	-1.6	0.6	2.6
	75% quantile	80.8	76.8	77.4	2.8	3.6	7.9
	Max	102	106	89	18	9	18

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Central Disc (continued)							
Visit 8	N with data	42	25	22	40	25	21
	N missing	5	2	2	7	2	3
	Mean	75.5	72.3	74.0	-0.9	-1.3	4.0
	LSMeans[1]				0.108	-1.563	2.443
	SD	10.10	10.39	9.54	9.48	9.35	9.34
	Min	60	52	64	-29	-34	-9
	25% quantile	68.9	67.0	65.9	-6.1	-5.4	-3.0
	Median	74.3	72.8	73.1	-0.1	-1.4	2.0
	75% quantile	81.1	77.3	77.6	3.8	5.4	9.4
	Max	107	104	97	19	14	23
End of Trial							
	N with data	36	24	20	34	24	19
	N missing	11	3	4	13	3	5
	Mean	73.3	70.6	71.2	-2.0	-3.1	1.5
	LSMeans[1]				-0.973	-3.060	-0.470
	SD	9.06	9.80	9.60	8.97	10.40	11.78
	Min	57	52	58	-20	-24	-15
	25% quantile	69.3	62.2	64.1	-8.6	-10.1	-7.6
	Median	71.0	71.4	70.2	-0.6	-2.1	-0.7
	75% quantile	74.8	76.7	75.6	2.5	5.1	13.9
	Max	101	91	101	20	15	24

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated							
Baseline/Screening**							
	N with data	7	4	2			
	N missing	40	23	22			
	Mean	79.9	80.1	90.1			
	SD	17.38	8.22	14.95			
	Min	62	75	79			
	25% quantile	68.4	75.5	79.5			
	Median	74.1	76.3	90.1			
	75% quantile	93.1	84.6	100.6			
	Max	112	92	101			
Visit 3a*							
	N with data	7	4	-	7	4	-
	N missing	40	23	-	40	23	-
	Mean	81.9	80.5	-	2.1	0.4	-
	LSMeans[1]				1.853	0.822	
	SD	12.31	8.05	-	6.57	2.31	-
	Min	66	73	-	-12	-2	-
	25% quantile	72.2	75.6	-	1.6	-1.5	-
	Median	81.2	78.6	-	3.8	0.7	-
	75% quantile	95.6	85.3	-	6.4	2.3	-
	Max	100	92	-	8	3	-

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 4							
	N with data	7	4	2	7	4	2
	N missing	40	23	22	40	23	22
	Mean	82.6	81.1	90.7	2.7	1.0	0.7
	LSMeans[1]				3.664	-1.104	1.603
	SD	17.28	6.24	18.59	3.84	2.64	3.65
	Min	59	76	78	-4	-2	-2
	25% quantile	72.4	76.9	77.6	-0.1	-0.9	-1.9
	Median	78.2	79.3	90.7	3.3	1.3	0.7
	75% quantile	96.4	85.3	103.9	4.0	2.9	3.3
	Max	112	90	104	9	4	3
Visit 5							
	N with data	2	3	0	2	3	0
	N missing	45	24	24	45	24	24
	Mean	95.3	86.9	-	-0.6	5.3	-
	LSMeans[1]				4.554	1.840	
	SD	13.36	4.01	-	9.77	6.15	-
	Min	86	83	-	-7	-1	-
	25% quantile	85.9	83.0	-	-7.5	-1.3	-
	Median	95.3	86.7	-	-0.6	6.2	-
	75% quantile	104.8	91.1	-	6.3	10.9	-
	Max	105	91	-	6	11	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 6							
	N with data	7	4	2	7	4	2
	N missing	40	23	22	40	23	22
	Mean	82.0	83.1	96.6	2.1	3.0	6.5
	LSMeans[1]				2.491	1.207	8.960
	SD	14.33	7.35	27.43	4.21	5.15	12.48
	Min	64	73	77	-5	-2	-2
	25% quantile	71.8	78.5	77.2	-1.4	-1.4	-2.3
	Median	80.9	83.8	96.6	2.5	2.9	6.5
	75% quantile	91.7	87.7	116.0	5.6	7.5	15.3
	Max	107	91	116	7	8	15
Visit 7							
	N with data	6	4	2	6	4	2
	N missing	41	23	22	41	23	22
	Mean	81.9	75.6	94.4	1.1	-4.5	4.3
	LSMeans[1]				1.236	-5.077	5.098
	SD	17.01	12.50	21.61	5.51	6.46	6.66
	Min	63	63	79	-6	-13	0
	25% quantile	71.1	66.7	79.1	-4.8	-9.7	-0.4
	Median	75.8	73.4	94.4	1.9	-3.3	4.3
	75% quantile	99.2	84.5	109.7	6.1	0.6	9.1
	Max	106	92	110	7	1	9

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, add. treated (continued)							
Visit 8							
	N with data	5	4	2	5	4	2
	N missing	42	23	22	42	23	22
	Mean	75.1	70.8	89.5	-3.3	-9.3	-0.6
	LSMeans[1]				-1.437	-17.487	11.262
	SD	8.28	3.90	25.00	14.05	11.74	10.06
	Min	64	66	72	-28	-27	-8
	25% quantile	69.4	68.4	71.8	1.0	-16.2	-7.7
	Median	75.8	71.1	89.5	2.1	-5.0	-0.6
	75% quantile	81.7	73.2	107.2	2.1	-2.3	6.5
	Max	84	75	107	6	0	7
End of Trial							
	N with data	5	3	1	5	3	1
	N missing	42	24	23	42	24	23
	Mean	76.9	88.4	102.3	-1.4	6.7	1.7
	LSMeans[1]				-5.443	9.216	14.131
	SD	8.65	13.02	-	16.97	8.79	-
	Min	68	74	102	-24	-2	2
	25% quantile	71.0	73.8	102.3	-8.6	-2.0	1.7
	Median	73.8	92.4	102.3	-0.6	6.6	1.7
	75% quantile	84.0	98.9	102.3	4.5	15.6	1.7
	Max	88	99	102	22	16	2

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated							
Baseline/Screening**							
	N with data	38	23	21			
	N missing	9	4	3			
	Mean	88.3	85.5	83.9			
	SD	15.73	15.22	12.22			
	Min	61	55	66			
	25% quantile	76.0	71.3	75.0			
	Median	85.7	87.7	80.6			
	75% quantile	100.8	95.6	94.8			
	Max	122	118	109			
Visit 3a*							
	N with data	39	23	-	37	23	-
	N missing	8	4	-	10	4	-
	Mean	86.4	85.8	-	-0.5	0.3	-
	LSMeans[1]				-0.463	0.245	
	SD	16.59	14.75	-	4.75	4.48	-
	Min	58	65	-	-17	-6	-
	25% quantile	72.9	71.9	-	-2.6	-2.7	-
	Median	84.8	88.1	-	-0.5	-0.7	-
	75% quantile	102.6	97.1	-	2.3	2.9	-
	Max	114	117	-	11	10	-

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 4							
	N with data	38	23	22	36	23	21
	N missing	9	4	2	11	4	3
	Mean	86.6	86.4	84.0	-0.8	0.9	0.1
	LSMeans[1]				-0.615	0.819	-0.226
	SD	15.62	14.72	10.49	5.44	6.42	5.47
	Min	58	67	68	-17	-10	-15
	25% quantile	74.0	71.1	75.7	-3.4	-3.8	-2.3
	Median	84.3	85.4	81.5	-0.3	0.4	0.6
	75% quantile	99.3	97.5	92.7	2.2	6.2	3.3
	Max	118	116	104	11	17	10
Visit 5							
	N with data	10	4	0	10	4	0
	N missing	37	23	24	37	23	24
	Mean	89.1	82.2	-	-3.9	-8.9	-
	LSMeans[1]				-3.748	-9.241	
	SD	16.18	10.54	-	9.12	6.32	-
	Min	66	71	-	-20	-14	-
	25% quantile	77.4	73.8	-	-10.7	-13.4	-
	Median	89.1	81.9	-	-2.3	-10.9	-
	75% quantile	103.1	90.6	-	2.4	-4.4	-
	Max	113	94	-	10	0	-

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 6							
	N with data	39	21	21	37	21	20
	N missing	8	6	3	10	6	4
	Mean	86.3	84.6	83.8	-1.8	-0.4	-0.9
	LSMeans[1]				-1.563	-0.415	-1.236
	SD	17.27	14.14	11.84	6.48	7.37	6.54
	Min	53	65	61	-15	-14	-10
	25% quantile	72.4	73.6	75.0	-4.0	-3.1	-4.8
	Median	83.6	80.2	81.4	-2.4	1.1	-1.1
	75% quantile	104.6	94.3	95.3	2.4	4.1	3.4
	Max	114	112	104	13	14	15
Visit 7							
	N with data	38	21	19	36	21	18
	N missing	9	6	5	11	6	6
	Mean	83.5	84.7	83.8	-4.0	-2.2	1.0
	LSMeans[1]				-3.955	-2.200	0.780
	SD	16.51	15.20	10.34	7.38	5.00	5.99
	Min	59	62	73	-33	-15	-11
	25% quantile	69.8	71.8	75.8	-6.2	-4.6	-2.7
	Median	80.3	84.8	80.2	-3.1	-2.1	0.6
	75% quantile	99.0	94.8	88.2	0.7	0	2.6
	Max	115	117	108	9	9	15

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.4: Summary of T2 (ms) and changes in T2 (ms) from Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Disc Visit	Statistic	Observed			Changes from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Cranial Disc, not treated (continued)							
Visit 8	N with data	37	21	20	35	21	19
	N missing	10	6	4	12	6	5
	Mean	83.2	82.3	84.5	-3.9	-2.8	0.5
	LSMeans[1]				-3.621	-2.983	0.161
	SD	15.08	14.91	9.98	6.57	9.25	8.19
	Min	59	63	74	-25	-32	-13
	25% quantile	73.0	68.1	75.8	-7.7	-6.5	-7.2
	Median	77.1	79.6	80.6	-3.9	-2.5	-0.7
	75% quantile	93.8	94.3	92.8	0.4	2.9	6.0
	Max	112	107	103	8	12	22
End of Trial	N with data	32	22	19	30	22	18
	N missing	15	5	5	17	5	6
	Mean	79.8	81.5	79.7	-6.5	-4.0	-4.7
	LSMeans[1]				-6.188	-4.178	-5.023
	SD	16.29	14.87	14.47	8.64	11.59	10.37
	Min	54	63	63	-31	-29	-23
	25% quantile	67.6	67.9	72.0	-11.4	-9.9	-10.9
	Median	75.1	80.2	75.5	-6.0	-4.2	-5.8
	75% quantile	91.5	90.1	89.4	-0.3	1.5	-0.7
	Max	113	108	124	12	23	18

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

[1] LS Mean = Least Square Mean of changes of MRI parameter from Baseline estimated by ANCOVA model with treatment as factor, outcome of MRI parameter at Baseline and time of MRI (hour of the day) as covariate.

Table 14.2.7.5: Frequencies of T2 relaxation time (ms) in comparison with Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects		
			NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 3a*	Caudal Disc				
	Change > 10 %	N (%)	2 (4.3)	1 (3.7)	0
	Change <= 10 %	N (%)	16 (34.0)	12 (44.4)	0
	Missing	N (%)	29 (61.7)	14 (51.9)	0
	Central Disc				
	Change > 10 %	N (%)	8 (17.0)	2 (7.4)	0
	Change <= 10 %	N (%)	36 (76.6)	25 (92.6)	0
	Missing	N (%)	3 (6.4)	0	0
	Cranial Disc				
	Change > 10 %	N (%)	2 (4.3)	2 (7.4)	0
	Change <= 10 %	N (%)	42 (89.4)	25 (92.6)	0
	Missing	N (%)	3 (6.4)	0	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.2.7.5: Frequencies of T2 relaxation time (ms) in comparison with Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects		
			NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 4	Caudal Disc				
	Change > 10 %	N (%)	4 (8.5)	1 (3.7)	1 (4.2)
	Change <= 10 %	N (%)	14 (29.8)	12 (44.4)	8 (33.3)
	Missing	N (%)	29 (61.7)	14 (51.9)	15 (62.5)
	Central Disc				
	Change > 10 %	N (%)	7 (14.9)	4 (14.8)	5 (20.8)
	Change <= 10 %	N (%)	36 (76.6)	23 (85.2)	18 (75.0)
	Missing	N (%)	4 (8.5)	0	1 (4.2)
	Cranial Disc				
	Change > 10 %	N (%)	2 (4.3)	2 (7.4)	1 (4.2)
	Change <= 10 %	N (%)	41 (87.2)	25 (92.6)	22 (91.7)
	Missing	N (%)	4 (8.5)	0	1 (4.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.2.7.5: Frequencies of T2 relaxation time (ms) in comparison with Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects		
			NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 5	Caudal Disc				
	Change > 10 %	N (%)	1 (2.1)	1 (3.7)	0
	Change <= 10 %	N (%)	3 (6.4)	1 (3.7)	0
	Missing	N (%)	43 (91.5)	25 (92.6)	24 (100)
	Central Disc				
	Change > 10 %	N (%)	0	0	0
	Change <= 10 %	N (%)	12 (25.5)	7 (25.9)	0
	Missing	N (%)	35 (74.5)	20 (74.1)	24 (100)
	Cranial Disc				
Change > 10 %	N (%)	1 (2.1)	1 (3.7)	0	
Change <= 10 %	N (%)	11 (23.4)	6 (22.2)	0	
Missing	N (%)	35 (74.5)	20 (74.1)	24 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.2.7.5: Frequencies of T2 relaxation time (ms) in comparison with Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects		
			NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 6	Caudal Disc				
	Change > 10 %	N (%)	4 (8.5)	1 (3.7)	2 (8.3)
	Change <= 10 %	N (%)	15 (31.9)	11 (40.7)	6 (25.0)
	Missing	N (%)	28 (59.6)	15 (55.6)	16 (66.7)
	Central Disc				
	Change > 10 %	N (%)	8 (17.0)	4 (14.8)	9 (37.5)
	Change <= 10 %	N (%)	36 (76.6)	21 (77.8)	13 (54.2)
	Missing	N (%)	3 (6.4)	2 (7.4)	2 (8.3)
	Cranial Disc				
Change > 10 %	N (%)	2 (4.3)	3 (11.1)	2 (8.3)	
Change <= 10 %	N (%)	42 (89.4)	22 (81.5)	20 (83.3)	
Missing	N (%)	3 (6.4)	2 (7.4)	2 (8.3)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.2.7.5: Frequencies of T2 relaxation time (ms) in comparison with Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects		
			NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 7	Caudal Disc				
	Change > 10 %	N (%)	2 (4.3)	2 (7.4)	1 (4.2)
	Change <= 10 %	N (%)	17 (36.2)	10 (37.0)	6 (25.0)
	Missing	N (%)	28 (59.6)	15 (55.6)	17 (70.8)
	Central Disc				
	Change > 10 %	N (%)	6 (12.8)	3 (11.1)	7 (29.2)
	Change <= 10 %	N (%)	36 (76.6)	22 (81.5)	13 (54.2)
	Missing	N (%)	5 (10.6)	2 (7.4)	4 (16.7)
	Cranial Disc				
Change > 10 %	N (%)	1 (2.1)	0	2 (8.3)	
Change <= 10 %	N (%)	41 (87.2)	25 (92.6)	18 (75.0)	
Missing	N (%)	5 (10.6)	2 (7.4)	4 (16.7)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.2.7.5: Frequencies of T2 relaxation time (ms) in comparison with Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects		
			NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Visit 8	Caudal Disc				
	Change > 10 %	N (%)	1 (2.1)	1 (3.7)	3 (12.5)
	Change <= 10 %	N (%)	15 (31.9)	12 (44.4)	4 (16.7)
	Missing	N (%)	31 (66.0)	14 (51.9)	17 (70.8)
	Central Disc				
	Change > 10 %	N (%)	6 (12.8)	3 (11.1)	7 (29.2)
	Change <= 10 %	N (%)	34 (72.3)	22 (81.5)	14 (58.3)
	Missing	N (%)	7 (14.9)	2 (7.4)	3 (12.5)
	Cranial Disc				
	Change > 10 %	N (%)	1 (2.1)	2 (7.4)	3 (12.5)
	Change <= 10 %	N (%)	39 (83.0)	23 (85.2)	18 (75.0)
	Missing	N (%)	7 (14.9)	2 (7.4)	3 (12.5)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.2.7.5: Frequencies of T2 relaxation time (ms) in comparison with Screening (Visit 1) or Baseline (Visit 2a)** - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects		
			NDplus (N=47)	NDbasic (N=27)	SC (N=24)
End of Trial	Caudal Disc				
	Change > 10 %	N (%)	1 (2.1)	2 (7.4)	2 (8.3)
	Change <= 10 %	N (%)	14 (29.8)	11 (40.7)	4 (16.7)
	Missing	N (%)	32 (68.1)	14 (51.9)	18 (75.0)
	Central Disc				
	Change > 10 %	N (%)	4 (8.5)	5 (18.5)	5 (20.8)
	Change <= 10 %	N (%)	30 (63.8)	19 (70.4)	14 (58.3)
	Missing	N (%)	13 (27.7)	3 (11.1)	5 (20.8)
	Cranial Disc				
	Change > 10 %	N (%)	2 (4.3)	5 (18.5)	2 (8.3)
	Change <= 10 %	N (%)	33 (70.2)	20 (74.1)	17 (70.8)
	Missing	N (%)	12 (25.5)	2 (7.4)	5 (20.8)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.2.7.6: Frequencies of T2 relaxation time (ms) in comparison with Visit 3a - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects	
			NDplus (N=47)	NDbasic (N=27)
Visit 4	Caudal Disc			
	Change > 10 %	N (%)	5 (10.6)	0
	Change <= 10 %	N (%)	15 (31.9)	13 (48.1)
	Missing	N (%)	27 (57.4)	14 (51.9)
	Central Disc			
	Change > 10 %	N (%)	6 (12.8)	4 (14.8)
	Change <= 10 %	N (%)	39 (83.0)	23 (85.2)
	Missing	N (%)	2 (4.3)	0
	Cranial Disc			
	Change > 10 %	N (%)	1 (2.1)	1 (3.7)
	Change <= 10 %	N (%)	44 (93.6)	26 (96.3)
	Missing	N (%)	2 (4.3)	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:40 / mri22.lst / mri2.sas

Table 14.2.7.6: Frequencies of T2 relaxation time (ms) in comparison with Visit 3a - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects	
			NDplus (N=47)	NDbasic (N=27)
Visit 5	Caudal Disc			
	Change > 10 %	N (%)	0	0
	Change <= 10 %	N (%)	4 (8.5)	2 (7.4)
	Missing	N (%)	43 (91.5)	25 (92.6)
	Central Disc			
	Change > 10 %	N (%)	1 (2.1)	0
	Change <= 10 %	N (%)	11 (23.4)	7 (25.9)
	Missing	N (%)	35 (74.5)	20 (74.1)
	Cranial Disc			
	Change > 10 %	N (%)	0	1 (3.7)
	Change <= 10 %	N (%)	12 (25.5)	6 (22.2)
	Missing	N (%)	35 (74.5)	20 (74.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:40 / mri22.lst / mri2.sas

Table 14.2.7.6: Frequencies of T2 relaxation time (ms) in comparison with Visit 3a - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects	
			NDplus (N=47)	NDbasic (N=27)
Visit 6	Caudal Disc			
	Change > 10 %	N (%)	3 (6.4)	0
	Change <= 10 %	N (%)	17 (36.2)	12 (44.4)
	Missing	N (%)	27 (57.4)	15 (55.6)
	Central Disc			
	Change > 10 %	N (%)	7 (14.9)	3 (11.1)
	Change <= 10 %	N (%)	38 (80.9)	22 (81.5)
	Missing	N (%)	2 (4.3)	2 (7.4)
	Cranial Disc			
	Change > 10 %	N (%)	3 (6.4)	2 (7.4)
	Change <= 10 %	N (%)	42 (89.4)	23 (85.2)
	Missing	N (%)	2 (4.3)	2 (7.4)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:40 / mri22.lst / mri2.sas

Table 14.2.7.6: Frequencies of T2 relaxation time (ms) in comparison with Visit 3a - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects	
			NDplus (N=47)	NDbasic (N=27)
Visit 7	Caudal Disc			
	Change > 10 %	N (%)	2 (4.3)	0
	Change <= 10 %	N (%)	18 (38.3)	12 (44.4)
	Missing	N (%)	27 (57.4)	15 (55.6)
	Central Disc			
	Change > 10 %	N (%)	5 (10.6)	3 (11.1)
	Change <= 10 %	N (%)	38 (80.9)	22 (81.5)
	Missing	N (%)	4 (8.5)	2 (7.4)
	Cranial Disc			
	Change > 10 %	N (%)	1 (2.1)	0
	Change <= 10 %	N (%)	42 (89.4)	25 (92.6)
	Missing	N (%)	4 (8.5)	2 (7.4)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:40 / mri22.lst / mri2.sas

Table 14.2.7.6: Frequencies of T2 relaxation time (ms) in comparison with Visit 3a - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects	
			NDplus (N=47)	NDbasic (N=27)
Visit 8	Caudal Disc			
	Change > 10 %	N (%)	1 (2.1)	0
	Change <= 10 %	N (%)	16 (34.0)	13 (48.1)
	Missing	N (%)	30 (63.8)	14 (51.9)
	Central Disc			
	Change > 10 %	N (%)	6 (12.8)	4 (14.8)
	Change <= 10 %	N (%)	35 (74.5)	21 (77.8)
	Missing	N (%)	6 (12.8)	2 (7.4)
	Cranial Disc			
	Change > 10 %	N (%)	2 (4.3)	1 (3.7)
	Change <= 10 %	N (%)	39 (83.0)	24 (88.9)
	Missing	N (%)	6 (12.8)	2 (7.4)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:40 / mri22.lst / mri2.sas

Table 14.2.7.6: Frequencies of T2 relaxation time (ms) in comparison with Visit 3a - full analysis set

Visit	Disc Frequencies of T2 relaxation times	Statistic	Number(%) of subjects	
			NDplus (N=47)	NDbasic (N=27)
End of Trial	Caudal Disc			
	Change > 10 %	N (%)	1 (2.1)	1 (3.7)
	Change <= 10 %	N (%)	15 (31.9)	12 (44.4)
	Missing	N (%)	31 (66.0)	14 (51.9)
	Central Disc			
	Change > 10 %	N (%)	5 (10.6)	5 (18.5)
	Change <= 10 %	N (%)	30 (63.8)	19 (70.4)
	Missing	N (%)	12 (25.5)	3 (11.1)
	Cranial Disc			
Change > 10 %	N (%)	2 (4.3)	3 (11.1)	
Change <= 10 %	N (%)	34 (72.3)	22 (81.5)	
Missing	N (%)	11 (23.4)	2 (7.4)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:40 / mri22.lst / mri2.sas

Table 14.2.7.7: Ancova of changes in T2 relaxation time from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 4	68					
NDplus		-0.6	-1.33	2.02	-0.66	0.5123
NDbasic		0.8	0.06	2.32	0.02	0.9804
SC		0.7	0.00			
ADD			-3.87	2.80	-1.38	0.1727
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			0.11	2.11	0.05	0.9575
size of annulus defect > 6 mm			-1.86	3.66	-0.51	0.6135
ODI total score at Baseline			-0.30	0.10	-2.91	0.0051
Number of cigarettes per day on baseline			0.21	0.15	1.41	0.1638
Age			0.09	0.10	0.92	0.3607
Pfarrmann score at Baseline			-1.48	1.80	-0.82	0.4133
Amount of extracted tissue (g)			0.76	0.71	1.07	0.2879
Pain score as assessed on VAS at Baseline			-0.09	0.33	-0.29	0.7726

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.7.7: Ancova of changes in T2 relaxation time from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
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Visit 5
Adverse data situation does not allow to fit an Ancova

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.7.7: Ancova of changes in T2 relaxation time from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 6	67					
NDplus		2.7	-1.79	2.62	-0.68	0.4964
NDbasic		3.0	-1.40	3.05	-0.46	0.6489
SC		4.4	0.00			
ADD			3.53	3.60	0.98	0.3312
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			-2.56	2.75	-0.93	0.3563
size of annulus defect > 6 mm			-3.21	4.74	-0.68	0.5015
ODI total score at Baseline			-0.35	0.13	-2.65	0.0104
Number of cigarettes per day on baseline			0.11	0.19	0.56	0.5787
Age			0.07	0.13	0.53	0.5957
Pfarrmann score at Baseline			0.18	2.40	0.07	0.9415
Amount of extracted tissue (g)			0.52	0.91	0.57	0.5683
Pain score as assessed on VAS at Baseline			0.15	0.43	0.36	0.7208

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.7.7: Ancova of changes in T2 relaxation time from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 7	62					
NDplus		0.2	-1.25	2.09	-0.60	0.5519
NDbasic		0.5	-1.03	2.42	-0.42	0.6738
SC		1.5	0.00			
ADD			-2.92	2.93	-1.00	0.3227
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			0.66	2.20	0.30	0.7663
size of annulus defect > 6 mm			-1.44	3.65	-0.39	0.6948
ODI total score at Baseline			-0.16	0.11	-1.48	0.1444
Number of cigarettes per day on baseline			0.25	0.16	1.57	0.1223
Age			0.19	0.10	1.83	0.0727
Pfarrmann score at Baseline			1.54	1.87	0.82	0.4152
Amount of extracted tissue (g)			0.72	0.70	1.02	0.3110
Pain score as assessed on VAS at Baseline			0.33	0.35	0.96	0.3399

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.7.7: Ancova of changes in T2 relaxation time from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
Visit 8	63					
NDplus		1.7	-1.72	2.32	-0.74	0.4617
NDbasic		2.6	-0.78	2.61	-0.30	0.7658
SC		3.4	0.00			
ADD			0.05	3.37	0.02	0.9876
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			-3.68	2.40	-1.53	0.1314
size of annulus defect > 6 mm			-1.93	4.08	-0.47	0.6374
ODI total score at Baseline			-0.19	0.12	-1.64	0.1077
Number of cigarettes per day on baseline			0.31	0.18	1.72	0.0910
Age			-0.00	0.11	-0.02	0.9880
Pfarrmann score at Baseline			1.95	2.03	0.96	0.3425
Amount of extracted tissue (g)			-0.06	0.79	-0.07	0.9423
Pain score as assessed on VAS at Baseline			-0.36	0.39	-0.94	0.3512

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.7.7: Ancova of changes in T2 relaxation time from Baseline (Visit 2a) - full analysis set

Visit Parameter	N*	LSMeans**	Estimate	Standard Error	t-value	p-value
End of Trial	56					
NDplus		1.9	0.97	3.13	0.31	0.7570
NDbasic		-1.7	-2.62	3.38	-0.78	0.4424
SC		0.9	0.00			
ADD			1.62	5.55	0.29	0.7710
HD			0.00			
size of annulus defect 0 to 3 mm			0.00			
size of annulus defect 3 to 6 mm			0.11	3.21	0.03	0.9736
size of annulus defect > 6 mm			0.20	5.39	0.04	0.9703
ODI total score at Baseline			-0.51	0.16	-3.24	0.0023
Number of cigarettes per day on baseline			0.08	0.24	0.34	0.7327
Age			-0.07	0.14	-0.51	0.6123
Pfarrmann score at Baseline			0.16	2.93	0.05	0.9578
Amount of extracted tissue (g)			0.04	0.99	0.04	0.9660
Pain score as assessed on VAS at Baseline			-0.04	0.55	-0.07	0.9421

SC = Standard Care, ADD = presence of adjacent degenerated disc, HD = absence of adjacent degenerated disc

*Number of observations used in the ANCOVA model

** Least-Square means only available for treatment group

Note: Volume of injection and Time since start of complaints were omitted from the model due to colinearities and sparse data.

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a)				
In general, would you say your health is:				
Excellent	1 (2.1)	1 (3.7)	0	2 (2.0)
Very good	14 (29.8)	5 (18.5)	5 (20.8)	24 (24.5)
Good	20 (42.6)	11 (40.7)	11 (45.8)	42 (42.9)
Fair	11 (23.4)	7 (25.9)	6 (25.0)	24 (24.5)
Poor	1 (2.1)	3 (11.1)	2 (8.3)	6 (6.1)
Missing	0	0	0	0
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	2 (4.3)	0	0	2 (2.0)
Somewhat better now than one year ago	0	2 (7.4)	0	2 (2.0)
About the same as one year ago	11 (23.4)	4 (14.8)	7 (29.2)	22 (22.4)
Somewhat worse now than one year ago	17 (36.2)	6 (22.2)	3 (12.5)	26 (26.5)
Much worse now than one year ago	17 (36.2)	15 (55.6)	14 (58.3)	46 (46.9)
Missing	0	0	0	0
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	41 (87.2)	26 (96.3)	24 (100)	91 (92.9)
YES, limited a little	5 (10.6)	0	0	5 (5.1)
NO, NOT limited at all	1 (2.1)	1 (3.7)	0	2 (2.0)
Missing	0	0	0	0
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	25 (53.2)	14 (51.9)	14 (58.3)	53 (54.1)
YES, limited a little	19 (40.4)	11 (40.7)	9 (37.5)	39 (39.8)
NO, NOT limited at all	3 (6.4)	0	0	3 (3.1)
Missing	0	2 (7.4)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	22 (46.8)	6 (22.2)	11 (45.8)	39 (39.8)
YES, limited a little	23 (48.9)	19 (70.4)	10 (41.7)	52 (53.1)
NO, NOT limited at all	2 (4.3)	1 (3.7)	3 (12.5)	6 (6.1)
Missing	0	1 (3.7)	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	13 (27.7)	7 (25.9)	10 (41.7)	30 (30.6)
YES, limited a little	28 (59.6)	16 (59.3)	11 (45.8)	55 (56.1)
NO, NOT limited at all	6 (12.8)	4 (14.8)	3 (12.5)	13 (13.3)
Missing	0	0	0	0
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	6 (12.8)	2 (7.4)	4 (16.7)	12 (12.2)
YES, limited a little	23 (48.9)	14 (51.9)	11 (45.8)	48 (49.0)
NO, NOT limited at all	18 (38.3)	10 (37.0)	9 (37.5)	37 (37.8)
Missing	0	1 (3.7)	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	23 (48.9)	16 (59.3)	14 (58.3)	53 (54.1)
YES, limited a little	19 (40.4)	10 (37.0)	10 (41.7)	39 (39.8)
NO, NOT limited at all	4 (8.5)	1 (3.7)	0	5 (5.1)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	26 (55.3)	16 (59.3)	10 (41.7)	52 (53.1)
YES, limited a little	14 (29.8)	8 (29.6)	11 (45.8)	33 (33.7)
NO, NOT limited at all	7 (14.9)	3 (11.1)	3 (12.5)	13 (13.3)
Missing	0	0	0	0
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	20 (42.6)	13 (48.1)	8 (33.3)	41 (41.8)
YES, limited a little	21 (44.7)	10 (37.0)	13 (54.2)	44 (44.9)
NO, NOT limited at all	6 (12.8)	3 (11.1)	3 (12.5)	12 (12.2)
Missing	0	1 (3.7)	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	4 (8.5)	5 (18.5)	6 (25.0)	15 (15.3)
YES, limited a little	26 (55.3)	12 (44.4)	11 (45.8)	49 (50.0)
NO, NOT limited at all	17 (36.2)	9 (33.3)	7 (29.2)	33 (33.7)
Missing	0	1 (3.7)	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	8 (17.0)	4 (14.8)	4 (16.7)	16 (16.3)
YES, limited a little	29 (61.7)	19 (70.4)	14 (58.3)	62 (63.3)
NO, NOT limited at all	10 (21.3)	4 (14.8)	6 (25.0)	20 (20.4)
Missing	0	0	0	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	4 (8.5)	3 (11.1)	3 (12.5)	10 (10.2)
Yes	43 (91.5)	24 (88.9)	21 (87.5)	88 (89.8)
Missing	0	0	0	0
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Yes	41 (87.2)	26 (96.3)	20 (83.3)	87 (88.8)
Missing	0	0	1 (4.2)	1 (1.0)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	6 (12.8)	2 (7.4)	1 (4.2)	9 (9.2)
Yes	41 (87.2)	25 (92.6)	21 (87.5)	87 (88.8)
Missing	0	0	2 (8.3)	2 (2.0)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	7 (14.9)	4 (14.8)	1 (4.2)	12 (12.2)
Yes	40 (85.1)	23 (85.2)	22 (91.7)	85 (86.7)
Missing	0	0	1 (4.2)	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	30 (63.8)	19 (70.4)	15 (62.5)	64 (65.3)
Yes	16 (34.0)	7 (25.9)	9 (37.5)	32 (32.7)
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	29 (61.7)	14 (51.9)	13 (54.2)	56 (57.1)
Yes	17 (36.2)	12 (44.4)	10 (41.7)	39 (39.8)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	31 (66.0)	17 (63.0)	12 (50.0)	60 (61.2)
Yes	15 (31.9)	9 (33.3)	11 (45.8)	35 (35.7)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	18 (38.3)	5 (18.5)	4 (16.7)	27 (27.6)
Slightly	13 (27.7)	12 (44.4)	9 (37.5)	34 (34.7)
Moderately	6 (12.8)	6 (22.2)	4 (16.7)	16 (16.3)
Quite a bit	7 (14.9)	3 (11.1)	2 (8.3)	12 (12.2)
Extremely	2 (4.3)	1 (3.7)	5 (20.8)	8 (8.2)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	0	0	1 (4.2)	1 (1.0)
Very mild	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)
Mild	1 (2.1)	0	1 (4.2)	2 (2.0)
Moderate	12 (25.5)	5 (18.5)	6 (25.0)	23 (23.5)
Severe	19 (40.4)	16 (59.3)	7 (29.2)	42 (42.9)
Very severe	12 (25.5)	4 (14.8)	8 (33.3)	24 (24.5)
Missing	1 (2.1)	0	0	1 (1.0)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	1 (2.1)	1 (3.7)	0	2 (2.0)
A little bit	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Moderately	6 (12.8)	4 (14.8)	3 (12.5)	13 (13.3)
Quite a bit	20 (42.6)	13 (48.1)	8 (33.3)	41 (41.8)
Extremely	15 (31.9)	8 (29.6)	10 (41.7)	33 (33.7)
Missing	0	0	0	0
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	1 (2.1)	0	0	1 (1.0)
Most of the time	3 (6.4)	4 (14.8)	2 (8.3)	9 (9.2)
A good bit of the time	7 (14.9)	2 (7.4)	2 (8.3)	11 (11.2)
Some of the time	14 (29.8)	8 (29.6)	8 (33.3)	30 (30.6)
A little of the time	15 (31.9)	10 (37.0)	9 (37.5)	34 (34.7)
None of the time	7 (14.9)	3 (11.1)	3 (12.5)	13 (13.3)
Missing	0	0	0	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?				
All of the time	1 (2.1)	0	1 (4.2)	2 (2.0)
Most of the time	0	2 (7.4)	1 (4.2)	3 (3.1)
A good bit of the time	8 (17.0)	4 (14.8)	4 (16.7)	16 (16.3)
Some of the time	15 (31.9)	8 (29.6)	6 (25.0)	29 (29.6)
A little of the time	14 (29.8)	4 (14.8)	4 (16.7)	22 (22.4)
None of the time	9 (19.1)	9 (33.3)	8 (33.3)	26 (26.5)
Missing	0	0	0	0
How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	0	0	0
Most of the time	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
A good bit of the time	4 (8.5)	2 (7.4)	5 (20.8)	11 (11.2)
Some of the time	14 (29.8)	9 (33.3)	7 (29.2)	30 (30.6)
A little of the time	14 (29.8)	6 (22.2)	4 (16.7)	24 (24.5)
None of the time	13 (27.7)	9 (33.3)	7 (29.2)	29 (29.6)
Missing	0	0	0	0
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	0	0	0	0
Most of the time	10 (21.3)	5 (18.5)	6 (25.0)	21 (21.4)
A good bit of the time	9 (19.1)	7 (25.9)	3 (12.5)	19 (19.4)
Some of the time	16 (34.0)	8 (29.6)	10 (41.7)	34 (34.7)
A little of the time	10 (21.3)	7 (25.9)	5 (20.8)	22 (22.4)
None of the time	2 (4.3)	0	0	2 (2.0)
Missing	0	0	0	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?				
All of the time	2 (4.3)	0	0	2 (2.0)
Most of the time	5 (10.6)	4 (14.8)	3 (12.5)	12 (12.2)
A good bit of the time	9 (19.1)	4 (14.8)	1 (4.2)	14 (14.3)
Some of the time	7 (14.9)	8 (29.6)	6 (25.0)	21 (21.4)
A little of the time	18 (38.3)	8 (29.6)	8 (33.3)	34 (34.7)
None of the time	6 (12.8)	3 (11.1)	6 (25.0)	15 (15.3)
Missing	0	0	0	0
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?				
All of the time	0	0	0	0
Most of the time	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
A good bit of the time	12 (25.5)	5 (18.5)	4 (16.7)	21 (21.4)
Some of the time	14 (29.8)	4 (14.8)	8 (33.3)	26 (26.5)
A little of the time	15 (31.9)	10 (37.0)	3 (12.5)	28 (28.6)
None of the time	5 (10.6)	7 (25.9)	7 (29.2)	19 (19.4)
Missing	0	0	0	0
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0	3 (12.5)	3 (3.1)
Most of the time	4 (8.5)	2 (7.4)	3 (12.5)	9 (9.2)
A good bit of the time	17 (36.2)	8 (29.6)	6 (25.0)	31 (31.6)
Some of the time	17 (36.2)	10 (37.0)	7 (29.2)	34 (34.7)
A little of the time	8 (17.0)	5 (18.5)	3 (12.5)	16 (16.3)
None of the time	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)
Missing	0	0	0	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?				
All of the time	2 (4.3)	0	1 (4.2)	3 (3.1)
Most of the time	9 (19.1)	9 (33.3)	4 (16.7)	22 (22.4)
A good bit of the time	10 (21.3)	1 (3.7)	7 (29.2)	18 (18.4)
Some of the time	17 (36.2)	12 (44.4)	6 (25.0)	35 (35.7)
A little of the time	9 (19.1)	4 (14.8)	4 (16.7)	17 (17.3)
None of the time	0	1 (3.7)	2 (8.3)	3 (3.1)
Missing	0	0	0	0
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?				
All of the time	1 (2.1)	2 (7.4)	3 (12.5)	6 (6.1)
Most of the time	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
A good bit of the time	17 (36.2)	9 (33.3)	9 (37.5)	35 (35.7)
Some of the time	19 (40.4)	8 (29.6)	8 (33.3)	35 (35.7)
A little of the time	5 (10.6)	5 (18.5)	2 (8.3)	12 (12.2)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	0	0	0	0
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	1 (2.1)	2 (7.4)	3 (12.5)	6 (6.1)
Most of the time	11 (23.4)	4 (14.8)	5 (20.8)	20 (20.4)
Some of the time	14 (29.8)	12 (44.4)	7 (29.2)	33 (33.7)
A little of the time	12 (25.5)	8 (29.6)	2 (8.3)	22 (22.4)
None of the time	9 (19.1)	1 (3.7)	7 (29.2)	17 (17.3)
Missing	0	0	0	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Baseline (Visit 2a) (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	0	0	1 (4.2)	1 (1.0)
Mostly true	3 (6.4)	2 (7.4)	4 (16.7)	9 (9.2)
Don't know	2 (4.3)	4 (14.8)	1 (4.2)	7 (7.1)
Mostly false	21 (44.7)	6 (22.2)	7 (29.2)	34 (34.7)
Definitely false	21 (44.7)	15 (55.6)	11 (45.8)	47 (48.0)
Missing	0	0	0	0
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	8 (17.0)	6 (22.2)	6 (25.0)	20 (20.4)
Mostly true	25 (53.2)	10 (37.0)	8 (33.3)	43 (43.9)
Don't know	9 (19.1)	2 (7.4)	2 (8.3)	13 (13.3)
Mostly false	2 (4.3)	5 (18.5)	4 (16.7)	11 (11.2)
Definitely false	3 (6.4)	4 (14.8)	4 (16.7)	11 (11.2)
Missing	0	0	0	0
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	1 (2.1)	0	0	1 (1.0)
Mostly true	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Don't know	5 (10.6)	5 (18.5)	6 (25.0)	16 (16.3)
Mostly false	16 (34.0)	10 (37.0)	3 (12.5)	29 (29.6)
Definitely false	24 (51.1)	11 (40.7)	14 (58.3)	49 (50.0)
Missing	0	0	0	0
How TRUE or FALSE is each of the following statements for you... My health is excellent				
Definitely true	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
Mostly true	20 (42.6)	9 (33.3)	9 (37.5)	38 (38.8)
Don't know	4 (8.5)	7 (25.9)	1 (4.2)	12 (12.2)
Mostly false	15 (31.9)	5 (18.5)	7 (29.2)	27 (27.6)
Definitely false	5 (10.6)	4 (14.8)	6 (25.0)	15 (15.3)
Missing	0	0	0	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3*				
In general, would you say your health is:				
Excellent	4 (8.5)	4 (14.8)		8 (8.2)
Very good	18 (38.3)	6 (22.2)		24 (24.5)
Good	22 (46.8)	16 (59.3)		38 (38.8)
Fair	3 (6.4)	0		3 (3.1)
Poor	0	0		0
Missing	0	1 (3.7)		1 (1.0)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	14 (29.8)	9 (33.3)		23 (23.5)
Somewhat better now than one year ago	9 (19.1)	3 (11.1)		12 (12.2)
About the same as one year ago	15 (31.9)	7 (25.9)		22 (22.4)
Somewhat worse now than one year ago	9 (19.1)	7 (25.9)		16 (16.3)
Much worse now than one year ago	0	0		0
Missing	0	1 (3.7)		1 (1.0)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	24 (51.1)	12 (44.4)		36 (36.7)
YES, limited a little	23 (48.9)	13 (48.1)		36 (36.7)
NO, NOT limited at all	0	2 (7.4)		2 (2.0)
Missing	0	0		0
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	7 (14.9)	2 (7.4)		9 (9.2)
YES, limited a little	26 (55.3)	15 (55.6)		41 (41.8)
NO, NOT limited at all	14 (29.8)	10 (37.0)		24 (24.5)
Missing	0	0		0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	3 (6.4)	2 (7.4)		5 (5.1)
YES, limited a little	31 (66.0)	13 (48.1)		44 (44.9)
NO, NOT limited at all	13 (27.7)	12 (44.4)		25 (25.5)
Missing	0	0		0
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	0	0		0
YES, limited a little	15 (31.9)	7 (25.9)		22 (22.4)
NO, NOT limited at all	32 (68.1)	20 (74.1)		52 (53.1)
Missing	0	0		0
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	0	0		0
YES, limited a little	5 (10.6)	2 (7.4)		7 (7.1)
NO, NOT limited at all	40 (85.1)	24 (88.9)		64 (65.3)
Missing	2 (4.3)	1 (3.7)		3 (3.1)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	4 (8.5)	0		4 (4.1)
YES, limited a little	28 (59.6)	13 (48.1)		41 (41.8)
NO, NOT limited at all	15 (31.9)	13 (48.1)		28 (28.6)
Missing	0	1 (3.7)		1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	3 (6.4)	0		3 (3.1)
YES, limited a little	15 (31.9)	4 (14.8)		19 (19.4)
NO, NOT limited at all	29 (61.7)	23 (85.2)		52 (53.1)
Missing	0	0		0
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	1 (2.1)	0		1 (1.0)
YES, limited a little	12 (25.5)	3 (11.1)		15 (15.3)
NO, NOT limited at all	34 (72.3)	24 (88.9)		58 (59.2)
Missing	0	0		0
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	0	0		0
YES, limited a little	4 (8.5)	1 (3.7)		5 (5.1)
NO, NOT limited at all	43 (91.5)	26 (96.3)		69 (70.4)
Missing	0	0		0
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	0	0		0
YES, limited a little	11 (23.4)	5 (18.5)		16 (16.3)
NO, NOT limited at all	36 (76.6)	22 (81.5)		58 (59.2)
Missing	0	0		0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	16 (34.0)	11 (40.7)		27 (27.6)
Yes	31 (66.0)	16 (59.3)		47 (48.0)
Missing	0	0		0
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	21 (44.7)	12 (44.4)		33 (33.7)
Yes	26 (55.3)	15 (55.6)		41 (41.8)
Missing	0	0		0
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	21 (44.7)	12 (44.4)		33 (33.7)
Yes	26 (55.3)	15 (55.6)		41 (41.8)
Missing	0	0		0
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	25 (53.2)	16 (59.3)		41 (41.8)
Yes	22 (46.8)	11 (40.7)		33 (33.7)
Missing	0	0		0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	37 (78.7)	21 (77.8)		58 (59.2)
Yes	10 (21.3)	6 (22.2)		16 (16.3)
Missing	0	0		0
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	36 (76.6)	18 (66.7)		54 (55.1)
Yes	11 (23.4)	9 (33.3)		20 (20.4)
Missing	0	0		0
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	40 (85.1)	22 (81.5)		62 (63.3)
Yes	7 (14.9)	5 (18.5)		12 (12.2)
Missing	0	0		0
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	26 (55.3)	14 (51.9)		40 (40.8)
Slightly	17 (36.2)	11 (40.7)		28 (28.6)
Moderately	2 (4.3)	1 (3.7)		3 (3.1)
Quite a bit	2 (4.3)	1 (3.7)		3 (3.1)
Extremely	0	0		0
Missing	0	0		0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	10 (21.3)	7 (25.9)		17 (17.3)
Very mild	15 (31.9)	11 (40.7)		26 (26.5)
Mild	12 (25.5)	4 (14.8)		16 (16.3)
Moderate	8 (17.0)	5 (18.5)		13 (13.3)
Severe	2 (4.3)	0		2 (2.0)
Very severe	0	0		0
Missing	0	0		0
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	11 (23.4)	9 (33.3)		20 (20.4)
A little bit	21 (44.7)	10 (37.0)		31 (31.6)
Moderately	11 (23.4)	8 (29.6)		19 (19.4)
Quite a bit	2 (4.3)	0		2 (2.0)
Extremely	1 (2.1)	0		1 (1.0)
Missing	1 (2.1)	0		1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	1 (2.1)	2 (7.4)		3 (3.1)
Most of the time	17 (36.2)	9 (33.3)		26 (26.5)
A good bit of the time	16 (34.0)	12 (44.4)		28 (28.6)
Some of the time	7 (14.9)	3 (11.1)		10 (10.2)
A little of the time	4 (8.5)	1 (3.7)		5 (5.1)
None of the time	1 (2.1)	0		1 (1.0)
Missing	1 (2.1)	0		1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	0	0		0
Most of the time	1 (2.1)	0		1 (1.0)
A good bit of the time	1 (2.1)	2 (7.4)		3 (3.1)
Some of the time	11 (23.4)	5 (18.5)		16 (16.3)
A little of the time	18 (38.3)	11 (40.7)		29 (29.6)
None of the time	15 (31.9)	9 (33.3)		24 (24.5)
Missing	1 (2.1)	0		1 (1.0)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	0		0
Most of the time	0	1 (3.7)		1 (1.0)
A good bit of the time	0	0		0
Some of the time	6 (12.8)	4 (14.8)		10 (10.2)
A little of the time	10 (21.3)	5 (18.5)		15 (15.3)
None of the time	30 (63.8)	17 (63.0)		47 (48.0)
Missing	1 (2.1)	0		1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	3 (6.4)	2 (7.4)		5 (5.1)
Most of the time	16 (34.0)	11 (40.7)		27 (27.6)
A good bit of the time	13 (27.7)	8 (29.6)		21 (21.4)
Some of the time	10 (21.3)	3 (11.1)		13 (13.3)
A little of the time	4 (8.5)	1 (3.7)		5 (5.1)
None of the time	0	1 (3.7)		1 (1.0)
Missing	1 (2.1)	1 (3.7)		2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?				
All of the time	2 (4.3)	2 (7.4)		4 (4.1)
Most of the time	15 (31.9)	9 (33.3)		24 (24.5)
A good bit of the time	11 (23.4)	6 (22.2)		17 (17.3)
Some of the time	13 (27.7)	8 (29.6)		21 (21.4)
A little of the time	4 (8.5)	1 (3.7)		5 (5.1)
None of the time	1 (2.1)	1 (3.7)		2 (2.0)
Missing	1 (2.1)	0		1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?				
All of the time	0	0		0
Most of the time	1 (2.1)	1 (3.7)		2 (2.0)
A good bit of the time	0	1 (3.7)		1 (1.0)
Some of the time	7 (14.9)	4 (14.8)		11 (11.2)
A little of the time	17 (36.2)	7 (25.9)		24 (24.5)
None of the time	21 (44.7)	14 (51.9)		35 (35.7)
Missing	1 (2.1)	0		1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0		0
Most of the time	2 (4.3)	1 (3.7)		3 (3.1)
A good bit of the time	4 (8.5)	3 (11.1)		7 (7.1)
Some of the time	23 (48.9)	7 (25.9)		30 (30.6)
A little of the time	14 (29.8)	13 (48.1)		27 (27.6)
None of the time	3 (6.4)	3 (11.1)		6 (6.1)
Missing	1 (2.1)	0		1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?				
All of the time	5 (10.6)	2 (7.4)		7 (7.1)
Most of the time	18 (38.3)	12 (44.4)		30 (30.6)
A good bit of the time	13 (27.7)	8 (29.6)		21 (21.4)
Some of the time	10 (21.3)	4 (14.8)		14 (14.3)
A little of the time	0	0		0
None of the time	0	1 (3.7)		1 (1.0)
Missing	1 (2.1)	0		1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?				
All of the time	1 (2.1)	0		1 (1.0)
Most of the time	2 (4.3)	2 (7.4)		4 (4.1)
A good bit of the time	6 (12.8)	2 (7.4)		8 (8.2)
Some of the time	19 (40.4)	11 (40.7)		30 (30.6)
A little of the time	17 (36.2)	10 (37.0)		27 (27.6)
None of the time	1 (2.1)	2 (7.4)		3 (3.1)
Missing	1 (2.1)	0		1 (1.0)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	0	0		0
Most of the time	1 (2.1)	2 (7.4)		3 (3.1)
Some of the time	7 (14.9)	6 (22.2)		13 (13.3)
A little of the time	13 (27.7)	6 (22.2)		19 (19.4)
None of the time	26 (55.3)	13 (48.1)		39 (39.8)
Missing	0	0		0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 3* (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	2 (4.3)	0		2 (2.0)
Mostly true	5 (10.6)	2 (7.4)		7 (7.1)
Don't know	4 (8.5)	4 (14.8)		8 (8.2)
Mostly false	16 (34.0)	6 (22.2)		22 (22.4)
Definitely false	20 (42.6)	15 (55.6)		35 (35.7)
Missing	0	0		0
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	14 (29.8)	7 (25.9)		21 (21.4)
Mostly true	13 (27.7)	16 (59.3)		29 (29.6)
Don't know	12 (25.5)	1 (3.7)		13 (13.3)
Mostly false	8 (17.0)	2 (7.4)		10 (10.2)
Definitely false	0	0		0
Missing	0	1 (3.7)		1 (1.0)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	1 (2.1)	0		1 (1.0)
Mostly true	2 (4.3)	1 (3.7)		3 (3.1)
Don't know	5 (10.6)	1 (3.7)		6 (6.1)
Mostly false	10 (21.3)	9 (33.3)		19 (19.4)
Definitely false	29 (61.7)	16 (59.3)		45 (45.9)
Missing	0	0		0
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	8 (17.0)	3 (11.1)		11 (11.2)
Mostly true	27 (57.4)	18 (66.7)		45 (45.9)
Don't know	3 (6.4)	3 (11.1)		6 (6.1)
Mostly false	8 (17.0)	2 (7.4)		10 (10.2)
Definitely false	1 (2.1)	1 (3.7)		2 (2.0)
Missing	0	0		0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4				
In general, would you say your health is:				
Excellent	2 (4.3)	3 (11.1)	1 (4.2)	6 (6.1)
Very good	20 (42.6)	11 (40.7)	5 (20.8)	36 (36.7)
Good	20 (42.6)	10 (37.0)	16 (66.7)	46 (46.9)
Fair	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
Poor	0	0	0	0
Missing	1 (2.1)	0	0	1 (1.0)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	13 (27.7)	10 (37.0)	10 (41.7)	33 (33.7)
Somewhat better now than one year ago	13 (27.7)	5 (18.5)	4 (16.7)	22 (22.4)
About the same as one year ago	15 (31.9)	8 (29.6)	4 (16.7)	27 (27.6)
Somewhat worse now than one year ago	5 (10.6)	4 (14.8)	5 (20.8)	14 (14.3)
Much worse now than one year ago	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	0	0	1 (1.0)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	8 (17.0)	8 (29.6)	13 (54.2)	29 (29.6)
YES, limited a little	35 (74.5)	13 (48.1)	11 (45.8)	59 (60.2)
NO, NOT limited at all	3 (6.4)	6 (22.2)	0	9 (9.2)
Missing	1 (2.1)	0	0	1 (1.0)
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	5 (10.6)	1 (3.7)	6 (25.0)	12 (12.2)
YES, limited a little	19 (40.4)	12 (44.4)	15 (62.5)	46 (46.9)
NO, NOT limited at all	22 (46.8)	14 (51.9)	3 (12.5)	39 (39.8)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	2 (4.3)	1 (3.7)	5 (20.8)	8 (8.2)
YES, limited a little	24 (51.1)	9 (33.3)	14 (58.3)	47 (48.0)
NO, NOT limited at all	20 (42.6)	17 (63.0)	5 (20.8)	42 (42.9)
Missing	1 (2.1)	0	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	1 (2.1)	0	2 (8.3)	3 (3.1)
YES, limited a little	8 (17.0)	9 (33.3)	10 (41.7)	27 (27.6)
NO, NOT limited at all	37 (78.7)	18 (66.7)	12 (50.0)	67 (68.4)
Missing	1 (2.1)	0	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	0	0	0	0
YES, limited a little	3 (6.4)	2 (7.4)	6 (25.0)	11 (11.2)
NO, NOT limited at all	42 (89.4)	25 (92.6)	18 (75.0)	85 (86.7)
Missing	2 (4.3)	0	0	2 (2.0)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	2 (4.3)	1 (3.7)	8 (33.3)	11 (11.2)
YES, limited a little	26 (55.3)	14 (51.9)	14 (58.3)	54 (55.1)
NO, NOT limited at all	18 (38.3)	12 (44.4)	2 (8.3)	32 (32.7)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	2 (4.3)	0	2 (8.3)	4 (4.1)
YES, limited a little	14 (29.8)	5 (18.5)	7 (29.2)	26 (26.5)
NO, NOT limited at all	30 (63.8)	22 (81.5)	15 (62.5)	67 (68.4)
Missing	1 (2.1)	0	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	2 (4.3)	0	1 (4.2)	3 (3.1)
YES, limited a little	8 (17.0)	5 (18.5)	9 (37.5)	22 (22.4)
NO, NOT limited at all	36 (76.6)	22 (81.5)	14 (58.3)	72 (73.5)
Missing	1 (2.1)	0	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	1 (2.1)	0	0	1 (1.0)
YES, limited a little	5 (10.6)	2 (7.4)	3 (12.5)	10 (10.2)
NO, NOT limited at all	40 (85.1)	25 (92.6)	21 (87.5)	86 (87.8)
Missing	1 (2.1)	0	0	1 (1.0)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	1 (2.1)	0	0	1 (1.0)
YES, limited a little	6 (12.8)	5 (18.5)	13 (54.2)	24 (24.5)
NO, NOT limited at all	39 (83.0)	22 (81.5)	11 (45.8)	72 (73.5)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	28 (59.6)	15 (55.6)	3 (12.5)	46 (46.9)
Yes	18 (38.3)	12 (44.4)	21 (87.5)	51 (52.0)
Missing	1 (2.1)	0	0	1 (1.0)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	28 (59.6)	13 (48.1)	6 (25.0)	47 (48.0)
Yes	18 (38.3)	14 (51.9)	18 (75.0)	50 (51.0)
Missing	1 (2.1)	0	0	1 (1.0)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	28 (59.6)	15 (55.6)	4 (16.7)	47 (48.0)
Yes	18 (38.3)	12 (44.4)	20 (83.3)	50 (51.0)
Missing	1 (2.1)	0	0	1 (1.0)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	33 (70.2)	18 (66.7)	4 (16.7)	55 (56.1)
Yes	13 (27.7)	9 (33.3)	20 (83.3)	42 (42.9)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	37 (78.7)	19 (70.4)	14 (58.3)	70 (71.4)
Yes	9 (19.1)	8 (29.6)	10 (41.7)	27 (27.6)
Missing	1 (2.1)	0	0	1 (1.0)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	39 (83.0)	18 (66.7)	12 (50.0)	69 (70.4)
Yes	7 (14.9)	9 (33.3)	12 (50.0)	28 (28.6)
Missing	1 (2.1)	0	0	1 (1.0)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	39 (83.0)	21 (77.8)	13 (54.2)	73 (74.5)
Yes	7 (14.9)	6 (22.2)	11 (45.8)	24 (24.5)
Missing	1 (2.1)	0	0	1 (1.0)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	32 (68.1)	17 (63.0)	9 (37.5)	58 (59.2)
Slightly	13 (27.7)	7 (25.9)	8 (33.3)	28 (28.6)
Moderately	1 (2.1)	2 (7.4)	4 (16.7)	7 (7.1)
Quite a bit	0	1 (3.7)	2 (8.3)	3 (3.1)
Extremely	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	5 (10.6)	7 (25.9)	2 (8.3)	14 (14.3)
Very mild	16 (34.0)	7 (25.9)	5 (20.8)	28 (28.6)
Mild	16 (34.0)	6 (22.2)	7 (29.2)	29 (29.6)
Moderate	7 (14.9)	4 (14.8)	8 (33.3)	19 (19.4)
Severe	2 (4.3)	1 (3.7)	2 (8.3)	5 (5.1)
Very severe	0	1 (3.7)	0	1 (1.0)
Missing	1 (2.1)	1 (3.7)	0	2 (2.0)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	8 (17.0)	8 (29.6)	4 (16.7)	20 (20.4)
A little bit	26 (55.3)	11 (40.7)	5 (20.8)	42 (42.9)
Moderately	8 (17.0)	5 (18.5)	10 (41.7)	23 (23.5)
Quite a bit	3 (6.4)	2 (7.4)	4 (16.7)	9 (9.2)
Extremely	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Missing	1 (2.1)	0	0	1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	5 (10.6)	4 (14.8)	0	9 (9.2)
Most of the time	17 (36.2)	8 (29.6)	4 (16.7)	29 (29.6)
A good bit of the time	16 (34.0)	7 (25.9)	5 (20.8)	28 (28.6)
Some of the time	6 (12.8)	7 (25.9)	11 (45.8)	24 (24.5)
A little of the time	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	0	0	0	0
Most of the time	1 (2.1)	0	0	1 (1.0)
A good bit of the time	4 (8.5)	3 (11.1)	4 (16.7)	11 (11.2)
Some of the time	7 (14.9)	6 (22.2)	4 (16.7)	17 (17.3)
A little of the time	21 (44.7)	10 (37.0)	8 (33.3)	39 (39.8)
None of the time	13 (27.7)	8 (29.6)	8 (33.3)	29 (29.6)
Missing	1 (2.1)	0	0	1 (1.0)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	0	0	0
Most of the time	0	1 (3.7)	1 (4.2)	2 (2.0)
A good bit of the time	1 (2.1)	0	0	1 (1.0)
Some of the time	5 (10.6)	7 (25.9)	6 (25.0)	18 (18.4)
A little of the time	9 (19.1)	5 (18.5)	6 (25.0)	20 (20.4)
None of the time	31 (66.0)	14 (51.9)	11 (45.8)	56 (57.1)
Missing	1 (2.1)	0	0	1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	4 (8.5)	4 (14.8)	0	8 (8.2)
Most of the time	22 (46.8)	8 (29.6)	9 (37.5)	39 (39.8)
A good bit of the time	11 (23.4)	8 (29.6)	4 (16.7)	23 (23.5)
Some of the time	6 (12.8)	4 (14.8)	9 (37.5)	19 (19.4)
A little of the time	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)
None of the time	1 (2.1)	1 (3.7)	0	2 (2.0)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you have a lot of energy?				
All of the time	3 (6.4)	4 (14.8)	0	7 (7.1)
Most of the time	18 (38.3)	8 (29.6)	5 (20.8)	31 (31.6)
A good bit of the time	14 (29.8)	6 (22.2)	7 (29.2)	27 (27.6)
Some of the time	6 (12.8)	7 (25.9)	7 (29.2)	20 (20.4)
A little of the time	4 (8.5)	1 (3.7)	3 (12.5)	8 (8.2)
None of the time	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Missing	1 (2.1)	0	0	1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you felt downhearted and blue?				
All of the time	0	0	0	0
Most of the time	0	0	1 (4.2)	1 (1.0)
A good bit of the time	0	1 (3.7)	1 (4.2)	2 (2.0)
Some of the time	10 (21.3)	6 (22.2)	6 (25.0)	22 (22.4)
A little of the time	16 (34.0)	6 (22.2)	7 (29.2)	29 (29.6)
None of the time	20 (42.6)	14 (51.9)	9 (37.5)	43 (43.9)
Missing	1 (2.1)	0	0	1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	0	2 (7.4)	2 (8.3)	4 (4.1)
A good bit of the time	6 (12.8)	0	4 (16.7)	10 (10.2)
Some of the time	13 (27.7)	10 (37.0)	10 (41.7)	33 (33.7)
A little of the time	22 (46.8)	9 (33.3)	5 (20.8)	36 (36.7)
None of the time	3 (6.4)	6 (22.2)	2 (8.3)	11 (11.2)
Missing	3 (6.4)	0	0	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Have you been a happy person?				
All of the time	6 (12.8)	4 (14.8)	2 (8.3)	12 (12.2)
Most of the time	24 (51.1)	10 (37.0)	7 (29.2)	41 (41.8)
A good bit of the time	8 (17.0)	3 (11.1)	4 (16.7)	15 (15.3)
Some of the time	6 (12.8)	7 (25.9)	8 (33.3)	21 (21.4)
A little of the time	2 (4.3)	3 (11.1)	3 (12.5)	8 (8.2)
None of the time	0	0	0	0
Missing	1 (2.1)	0	0	1 (1.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Did you feel tired?				
All of the time	0	0	2 (8.3)	2 (2.0)
Most of the time	1 (2.1)	3 (11.1)	2 (8.3)	6 (6.1)
A good bit of the time	9 (19.1)	4 (14.8)	3 (12.5)	16 (16.3)
Some of the time	21 (44.7)	8 (29.6)	12 (50.0)	41 (41.8)
A little of the time	15 (31.9)	8 (29.6)	4 (16.7)	27 (27.6)
None of the time	0	4 (14.8)	1 (4.2)	5 (5.1)
Missing	1 (2.1)	0	0	1 (1.0)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	1 (2.1)	0	0	1 (1.0)
Most of the time	2 (4.3)	1 (3.7)	3 (12.5)	6 (6.1)
Some of the time	4 (8.5)	6 (22.2)	10 (41.7)	20 (20.4)
A little of the time	12 (25.5)	5 (18.5)	4 (16.7)	21 (21.4)
None of the time	27 (57.4)	15 (55.6)	7 (29.2)	49 (50.0)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 4 (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	1 (2.1)	0	3 (12.5)	4 (4.1)
Mostly true	3 (6.4)	3 (11.1)	4 (16.7)	10 (10.2)
Don't know	8 (17.0)	4 (14.8)	0	12 (12.2)
Mostly false	15 (31.9)	4 (14.8)	6 (25.0)	25 (25.5)
Definitely false	19 (40.4)	16 (59.3)	11 (45.8)	46 (46.9)
Missing	1 (2.1)	0	0	1 (1.0)
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	11 (23.4)	7 (25.9)	4 (16.7)	22 (22.4)
Mostly true	25 (53.2)	11 (40.7)	12 (50.0)	48 (49.0)
Don't know	8 (17.0)	1 (3.7)	1 (4.2)	10 (10.2)
Mostly false	1 (2.1)	6 (22.2)	4 (16.7)	11 (11.2)
Definitely false	1 (2.1)	2 (7.4)	3 (12.5)	6 (6.1)
Missing	1 (2.1)	0	0	1 (1.0)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	0	0	1 (4.2)	1 (1.0)
Mostly true	4 (8.5)	0	1 (4.2)	5 (5.1)
Don't know	3 (6.4)	5 (18.5)	3 (12.5)	11 (11.2)
Mostly false	15 (31.9)	9 (33.3)	10 (41.7)	34 (34.7)
Definitely false	24 (51.1)	13 (48.1)	9 (37.5)	46 (46.9)
Missing	1 (2.1)	0	0	1 (1.0)
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	6 (12.8)	8 (29.6)	0	14 (14.3)
Mostly true	29 (61.7)	9 (33.3)	14 (58.3)	52 (53.1)
Don't know	4 (8.5)	2 (7.4)	3 (12.5)	9 (9.2)
Mostly false	7 (14.9)	8 (29.6)	3 (12.5)	18 (18.4)
Definitely false	0	0	4 (16.7)	4 (4.1)
Missing	1 (2.1)	0	0	1 (1.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5				
In general, would you say your health is:				
Excellent	5 (10.6)	6 (22.2)	2 (8.3)	13 (13.3)
Very good	17 (36.2)	11 (40.7)	7 (29.2)	35 (35.7)
Good	20 (42.6)	10 (37.0)	12 (50.0)	42 (42.9)
Fair	4 (8.5)	0	2 (8.3)	6 (6.1)
Poor	0	0	0	0
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	22 (46.8)	11 (40.7)	11 (45.8)	44 (44.9)
Somewhat better now than one year ago	5 (10.6)	6 (22.2)	3 (12.5)	14 (14.3)
About the same as one year ago	14 (29.8)	7 (25.9)	4 (16.7)	25 (25.5)
Somewhat worse now than one year ago	5 (10.6)	3 (11.1)	5 (20.8)	13 (13.3)
Much worse now than one year ago	0	0	0	0
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	8 (17.0)	4 (14.8)	5 (20.8)	17 (17.3)
YES, limited a little	29 (61.7)	14 (51.9)	17 (70.8)	60 (61.2)
NO, NOT limited at all	9 (19.1)	9 (33.3)	1 (4.2)	19 (19.4)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	4 (8.5)	1 (3.7)	3 (12.5)	8 (8.2)
YES, limited a little	14 (29.8)	6 (22.2)	11 (45.8)	31 (31.6)
NO, NOT limited at all	28 (59.6)	20 (74.1)	9 (37.5)	57 (58.2)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
YES, limited a little	20 (42.6)	7 (25.9)	13 (54.2)	40 (40.8)
NO, NOT limited at all	24 (51.1)	19 (70.4)	9 (37.5)	52 (53.1)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	0	1 (3.7)	2 (8.3)	3 (3.1)
YES, limited a little	10 (21.3)	3 (11.1)	5 (20.8)	18 (18.4)
NO, NOT limited at all	36 (76.6)	23 (85.2)	16 (66.7)	75 (76.5)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	0	0	1 (4.2)	1 (1.0)
YES, limited a little	3 (6.4)	3 (11.1)	2 (8.3)	8 (8.2)
NO, NOT limited at all	43 (91.5)	24 (88.9)	20 (83.3)	87 (88.8)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	0	0	2 (8.3)	2 (2.0)
YES, limited a little	19 (40.4)	9 (33.3)	13 (54.2)	41 (41.8)
NO, NOT limited at all	27 (57.4)	18 (66.7)	8 (33.3)	53 (54.1)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
YES, limited a little	9 (19.1)	1 (3.7)	4 (16.7)	14 (14.3)
NO, NOT limited at all	34 (72.3)	24 (88.9)	17 (70.8)	75 (76.5)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)
YES, limited a little	9 (19.1)	0	3 (12.5)	12 (12.2)
NO, NOT limited at all	36 (76.6)	25 (92.6)	18 (75.0)	79 (80.6)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	0	0	0	0
YES, limited a little	4 (8.5)	2 (7.4)	3 (12.5)	9 (9.2)
NO, NOT limited at all	42 (89.4)	25 (92.6)	20 (83.3)	87 (88.8)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	0	0	0	0
YES, limited a little	4 (8.5)	3 (11.1)	6 (25.0)	13 (13.3)
NO, NOT limited at all	41 (87.2)	24 (88.9)	17 (70.8)	82 (83.7)
Missing	2 (4.3)	0	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	30 (63.8)	22 (81.5)	14 (58.3)	66 (67.3)
Yes	15 (31.9)	5 (18.5)	8 (33.3)	28 (28.6)
Missing	2 (4.3)	0	2 (8.3)	4 (4.1)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	31 (66.0)	22 (81.5)	14 (58.3)	67 (68.4)
Yes	14 (29.8)	5 (18.5)	8 (33.3)	27 (27.6)
Missing	2 (4.3)	0	2 (8.3)	4 (4.1)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	32 (68.1)	22 (81.5)	13 (54.2)	67 (68.4)
Yes	13 (27.7)	5 (18.5)	9 (37.5)	27 (27.6)
Missing	2 (4.3)	0	2 (8.3)	4 (4.1)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	33 (70.2)	22 (81.5)	15 (62.5)	70 (71.4)
Yes	12 (25.5)	5 (18.5)	7 (29.2)	24 (24.5)
Missing	2 (4.3)	0	2 (8.3)	4 (4.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	41 (87.2)	25 (92.6)	16 (66.7)	82 (83.7)
Yes	5 (10.6)	2 (7.4)	7 (29.2)	14 (14.3)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	39 (83.0)	24 (88.9)	16 (66.7)	79 (80.6)
Yes	7 (14.9)	3 (11.1)	7 (29.2)	17 (17.3)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	39 (83.0)	24 (88.9)	19 (79.2)	82 (83.7)
Yes	7 (14.9)	3 (11.1)	4 (16.7)	14 (14.3)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	33 (70.2)	21 (77.8)	15 (62.5)	69 (70.4)
Slightly	11 (23.4)	5 (18.5)	5 (20.8)	21 (21.4)
Moderately	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Quite a bit	1 (2.1)	0	1 (4.2)	2 (2.0)
Extremely	0	0	0	0
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	10 (21.3)	10 (37.0)	4 (16.7)	24 (24.5)
Very mild	17 (36.2)	9 (33.3)	7 (29.2)	33 (33.7)
Mild	10 (21.3)	5 (18.5)	6 (25.0)	21 (21.4)
Moderate	7 (14.9)	1 (3.7)	5 (20.8)	13 (13.3)
Severe	2 (4.3)	2 (7.4)	0	4 (4.1)
Very severe	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	16 (34.0)	16 (59.3)	4 (16.7)	36 (36.7)
A little bit	20 (42.6)	6 (22.2)	12 (50.0)	38 (38.8)
Moderately	8 (17.0)	3 (11.1)	5 (20.8)	16 (16.3)
Quite a bit	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
Extremely	1 (2.1)	0	1 (4.2)	2 (2.0)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?				
All of the time	5 (10.6)	5 (18.5)	1 (4.2)	11 (11.2)
Most of the time	18 (38.3)	12 (44.4)	9 (37.5)	39 (39.8)
A good bit of the time	16 (34.0)	3 (11.1)	4 (16.7)	23 (23.5)
Some of the time	5 (10.6)	5 (18.5)	6 (25.0)	16 (16.3)
A little of the time	2 (4.3)	2 (7.4)	2 (8.3)	6 (6.1)
None of the time	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	0	0	0	0
Most of the time	1 (2.1)	0	0	1 (1.0)
A good bit of the time	2 (4.3)	0	2 (8.3)	4 (4.1)
Some of the time	10 (21.3)	10 (37.0)	4 (16.7)	24 (24.5)
A little of the time	20 (42.6)	8 (29.6)	11 (45.8)	39 (39.8)
None of the time	13 (27.7)	9 (33.3)	6 (25.0)	28 (28.6)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	0	0	0
Most of the time	0	0	0	0
A good bit of the time	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Some of the time	3 (6.4)	5 (18.5)	3 (12.5)	11 (11.2)
A little of the time	11 (23.4)	7 (25.9)	5 (20.8)	23 (23.5)
None of the time	31 (66.0)	14 (51.9)	14 (58.3)	59 (60.2)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	7 (14.9)	5 (18.5)	0	12 (12.2)
Most of the time	17 (36.2)	11 (40.7)	12 (50.0)	40 (40.8)
A good bit of the time	12 (25.5)	7 (25.9)	5 (20.8)	24 (24.5)
Some of the time	7 (14.9)	2 (7.4)	5 (20.8)	14 (14.3)
A little of the time	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you have a lot of energy?				
All of the time	6 (12.8)	4 (14.8)	0	10 (10.2)
Most of the time	16 (34.0)	10 (37.0)	14 (58.3)	40 (40.8)
A good bit of the time	14 (29.8)	5 (18.5)	3 (12.5)	22 (22.4)
Some of the time	9 (19.1)	6 (22.2)	3 (12.5)	18 (18.4)
A little of the time	1 (2.1)	2 (7.4)	3 (12.5)	6 (6.1)
None of the time	0	0	0	0
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you felt downhearted and blue?				
All of the time	0	0	0	0
Most of the time	0	0	0	0
A good bit of the time	2 (4.3)	2 (7.4)	2 (8.3)	6 (6.1)
Some of the time	6 (12.8)	7 (25.9)	1 (4.2)	14 (14.3)
A little of the time	17 (36.2)	4 (14.8)	11 (45.8)	32 (32.7)
None of the time	21 (44.7)	14 (51.9)	9 (37.5)	44 (44.9)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0	0	0
Most of the time	0	0	2 (8.3)	2 (2.0)
A good bit of the time	4 (8.5)	5 (18.5)	2 (8.3)	11 (11.2)
Some of the time	19 (40.4)	5 (18.5)	7 (29.2)	31 (31.6)
A little of the time	18 (38.3)	11 (40.7)	8 (33.3)	37 (37.8)
None of the time	5 (10.6)	5 (18.5)	4 (16.7)	14 (14.3)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Have you been a happy person?				
All of the time	8 (17.0)	6 (22.2)	0	14 (14.3)
Most of the time	20 (42.6)	9 (33.3)	15 (62.5)	44 (44.9)
A good bit of the time	11 (23.4)	5 (18.5)	3 (12.5)	19 (19.4)
Some of the time	7 (14.9)	4 (14.8)	3 (12.5)	14 (14.3)
A little of the time	0	3 (11.1)	2 (8.3)	5 (5.1)
None of the time	0	0	0	0
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Did you feel tired?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	0	2 (7.4)	1 (4.2)	3 (3.1)
A good bit of the time	9 (19.1)	2 (7.4)	3 (12.5)	14 (14.3)
Some of the time	21 (44.7)	10 (37.0)	12 (50.0)	43 (43.9)
A little of the time	13 (27.7)	9 (33.3)	6 (25.0)	28 (28.6)
None of the time	3 (6.4)	4 (14.8)	0	7 (7.1)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	0	0	0	0
Most of the time	2 (4.3)	0	2 (8.3)	4 (4.1)
Some of the time	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
A little of the time	10 (21.3)	6 (22.2)	8 (33.3)	24 (24.5)
None of the time	30 (63.8)	18 (66.7)	11 (45.8)	59 (60.2)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 5 (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	2 (4.3)	0	0	2 (2.0)
Mostly true	1 (2.1)	4 (14.8)	3 (12.5)	8 (8.2)
Don't know	8 (17.0)	4 (14.8)	2 (8.3)	14 (14.3)
Mostly false	14 (29.8)	1 (3.7)	5 (20.8)	20 (20.4)
Definitely false	21 (44.7)	18 (66.7)	13 (54.2)	52 (53.1)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	13 (27.7)	12 (44.4)	6 (25.0)	31 (31.6)
Mostly true	18 (38.3)	8 (29.6)	5 (20.8)	31 (31.6)
Don't know	8 (17.0)	5 (18.5)	4 (16.7)	17 (17.3)
Mostly false	5 (10.6)	2 (7.4)	7 (29.2)	14 (14.3)
Definitely false	2 (4.3)	0	1 (4.2)	3 (3.1)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	1 (2.1)	0	0	1 (1.0)
Mostly true	5 (10.6)	2 (7.4)	1 (4.2)	8 (8.2)
Don't know	4 (8.5)	2 (7.4)	3 (12.5)	9 (9.2)
Mostly false	7 (14.9)	9 (33.3)	9 (37.5)	25 (25.5)
Definitely false	29 (61.7)	14 (51.9)	9 (37.5)	52 (53.1)
Missing	1 (2.1)	0	2 (8.3)	3 (3.1)
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	10 (21.3)	9 (33.3)	2 (8.3)	21 (21.4)
Mostly true	23 (48.9)	14 (51.9)	12 (50.0)	49 (50.0)
Don't know	4 (8.5)	2 (7.4)	2 (8.3)	8 (8.2)
Mostly false	7 (14.9)	2 (7.4)	6 (25.0)	15 (15.3)
Definitely false	2 (4.3)	0	1 (4.2)	3 (3.1)
Missing	1 (2.1)	0	1 (4.2)	2 (2.0)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6				
In general, would you say your health is:				
Excellent	7 (14.9)	5 (18.5)	0	12 (12.2)
Very good	22 (46.8)	9 (33.3)	14 (58.3)	45 (45.9)
Good	12 (25.5)	11 (40.7)	8 (33.3)	31 (31.6)
Fair	4 (8.5)	1 (3.7)	1 (4.2)	6 (6.1)
Poor	1 (2.1)	0	0	1 (1.0)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	22 (46.8)	18 (66.7)	14 (58.3)	54 (55.1)
Somewhat better now than one year ago	12 (25.5)	3 (11.1)	7 (29.2)	22 (22.4)
About the same as one year ago	10 (21.3)	2 (7.4)	1 (4.2)	13 (13.3)
Somewhat worse now than one year ago	2 (4.3)	3 (11.1)	1 (4.2)	6 (6.1)
Much worse now than one year ago	0	0	0	0
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	7 (14.9)	3 (11.1)	3 (12.5)	13 (13.3)
YES, limited a little	27 (57.4)	13 (48.1)	17 (70.8)	57 (58.2)
NO, NOT limited at all	12 (25.5)	10 (37.0)	3 (12.5)	25 (25.5)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	0	0	1 (4.2)	1 (1.0)
YES, limited a little	17 (36.2)	7 (25.9)	8 (33.3)	32 (32.7)
NO, NOT limited at all	29 (61.7)	19 (70.4)	14 (58.3)	62 (63.3)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	0	0	1 (4.2)	1 (1.0)
YES, limited a little	16 (34.0)	4 (14.8)	9 (37.5)	29 (29.6)
NO, NOT limited at all	30 (63.8)	22 (81.5)	13 (54.2)	65 (66.3)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	0	1 (3.7)	1 (4.2)	2 (2.0)
YES, limited a little	6 (12.8)	3 (11.1)	3 (12.5)	12 (12.2)
NO, NOT limited at all	40 (85.1)	21 (77.8)	19 (79.2)	80 (81.6)
Missing	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	0	0	0	0
YES, limited a little	2 (4.3)	2 (7.4)	2 (8.3)	6 (6.1)
NO, NOT limited at all	44 (93.6)	24 (88.9)	21 (87.5)	89 (90.8)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
YES, limited a little	17 (36.2)	7 (25.9)	12 (50.0)	36 (36.7)
NO, NOT limited at all	28 (59.6)	18 (66.7)	10 (41.7)	56 (57.1)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	0	2 (7.4)	1 (4.2)	3 (3.1)
YES, limited a little	9 (19.1)	3 (11.1)	4 (16.7)	16 (16.3)
NO, NOT limited at all	37 (78.7)	21 (77.8)	18 (75.0)	76 (77.6)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	0	1 (3.7)	0	1 (1.0)
YES, limited a little	8 (17.0)	1 (3.7)	2 (8.3)	11 (11.2)
NO, NOT limited at all	38 (80.9)	24 (88.9)	21 (87.5)	83 (84.7)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	0	0	0	0
YES, limited a little	4 (8.5)	2 (7.4)	1 (4.2)	7 (7.1)
NO, NOT limited at all	42 (89.4)	24 (88.9)	22 (91.7)	88 (89.8)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	0	0	0	0
YES, limited a little	4 (8.5)	2 (7.4)	5 (20.8)	11 (11.2)
NO, NOT limited at all	42 (89.4)	24 (88.9)	18 (75.0)	84 (85.7)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	32 (68.1)	21 (77.8)	17 (70.8)	70 (71.4)
Yes	14 (29.8)	5 (18.5)	5 (20.8)	24 (24.5)
Missing	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	31 (66.0)	22 (81.5)	17 (70.8)	70 (71.4)
Yes	15 (31.9)	4 (14.8)	5 (20.8)	24 (24.5)
Missing	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	34 (72.3)	20 (74.1)	17 (70.8)	71 (72.4)
Yes	12 (25.5)	6 (22.2)	5 (20.8)	23 (23.5)
Missing	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	35 (74.5)	24 (88.9)	17 (70.8)	76 (77.6)
Yes	11 (23.4)	2 (7.4)	6 (25.0)	19 (19.4)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

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Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	42 (89.4)	24 (88.9)	19 (79.2)	85 (86.7)
Yes	4 (8.5)	2 (7.4)	4 (16.7)	10 (10.2)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	39 (83.0)	22 (81.5)	19 (79.2)	80 (81.6)
Yes	7 (14.9)	4 (14.8)	4 (16.7)	15 (15.3)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	41 (87.2)	23 (85.2)	20 (83.3)	84 (85.7)
Yes	5 (10.6)	3 (11.1)	3 (12.5)	11 (11.2)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	31 (66.0)	21 (77.8)	18 (75.0)	70 (71.4)
Slightly	11 (23.4)	3 (11.1)	4 (16.7)	18 (18.4)
Moderately	4 (8.5)	1 (3.7)	1 (4.2)	6 (6.1)
Quite a bit	0	1 (3.7)	0	1 (1.0)
Extremely	0	0	0	0
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

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Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	14 (29.8)	10 (37.0)	5 (20.8)	29 (29.6)
Very mild	14 (29.8)	7 (25.9)	8 (33.3)	29 (29.6)
Mild	9 (19.1)	5 (18.5)	5 (20.8)	19 (19.4)
Moderate	7 (14.9)	3 (11.1)	4 (16.7)	14 (14.3)
Severe	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Very severe	1 (2.1)	0	0	1 (1.0)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	20 (42.6)	16 (59.3)	11 (45.8)	47 (48.0)
A little bit	18 (38.3)	7 (25.9)	5 (20.8)	30 (30.6)
Moderately	5 (10.6)	2 (7.4)	6 (25.0)	13 (13.3)
Quite a bit	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Extremely	0	0	0	0
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	4 (8.5)	6 (22.2)	2 (8.3)	12 (12.2)
Most of the time	21 (44.7)	11 (40.7)	13 (54.2)	45 (45.9)
A good bit of the time	9 (19.1)	4 (14.8)	0	13 (13.3)
Some of the time	9 (19.1)	5 (18.5)	5 (20.8)	19 (19.4)
A little of the time	3 (6.4)	0	2 (8.3)	5 (5.1)
None of the time	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	1 (2.1)	1 (3.7)	0	2 (2.0)
A good bit of the time	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Some of the time	7 (14.9)	1 (3.7)	5 (20.8)	13 (13.3)
A little of the time	26 (55.3)	12 (44.4)	6 (25.0)	44 (44.9)
None of the time	11 (23.4)	11 (40.7)	9 (37.5)	31 (31.6)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	1 (3.7)	1 (4.2)	2 (2.0)
Most of the time	0	0	0	0
A good bit of the time	1 (2.1)	0	2 (8.3)	3 (3.1)
Some of the time	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
A little of the time	13 (27.7)	6 (22.2)	7 (29.2)	26 (26.5)
None of the time	29 (61.7)	17 (63.0)	12 (50.0)	58 (59.2)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	4 (8.5)	3 (11.1)	1 (4.2)	8 (8.2)
Most of the time	21 (44.7)	13 (48.1)	14 (58.3)	48 (49.0)
A good bit of the time	9 (19.1)	4 (14.8)	2 (8.3)	15 (15.3)
Some of the time	7 (14.9)	5 (18.5)	5 (20.8)	17 (17.3)
A little of the time	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
None of the time	2 (4.3)	0	0	2 (2.0)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?				
All of the time	3 (6.4)	5 (18.5)	1 (4.2)	9 (9.2)
Most of the time	19 (40.4)	12 (44.4)	12 (50.0)	43 (43.9)
A good bit of the time	10 (21.3)	2 (7.4)	2 (8.3)	14 (14.3)
Some of the time	10 (21.3)	5 (18.5)	5 (20.8)	20 (20.4)
A little of the time	2 (4.3)	2 (7.4)	3 (12.5)	7 (7.1)
None of the time	2 (4.3)	0	0	2 (2.0)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	1 (2.1)	0	1 (4.2)	2 (2.0)
A good bit of the time	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
Some of the time	5 (10.6)	1 (3.7)	1 (4.2)	7 (7.1)
A little of the time	17 (36.2)	10 (37.0)	8 (33.3)	35 (35.7)
None of the time	22 (46.8)	13 (48.1)	11 (45.8)	46 (46.9)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	3 (6.4)	0	2 (8.3)	5 (5.1)
A good bit of the time	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Some of the time	17 (36.2)	9 (33.3)	6 (25.0)	32 (32.7)
A little of the time	19 (40.4)	12 (44.4)	8 (33.3)	39 (39.8)
None of the time	4 (8.5)	4 (14.8)	5 (20.8)	13 (13.3)
Missing	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Have you been a happy person?				
All of the time	5 (10.6)	4 (14.8)	4 (16.7)	13 (13.3)
Most of the time	21 (44.7)	14 (51.9)	11 (45.8)	46 (46.9)
A good bit of the time	11 (23.4)	3 (11.1)	2 (8.3)	16 (16.3)
Some of the time	8 (17.0)	4 (14.8)	3 (12.5)	15 (15.3)
A little of the time	1 (2.1)	1 (3.7)	3 (12.5)	5 (5.1)
None of the time	0	0	0	0
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Did you feel tired?				
All of the time	0	0	3 (12.5)	3 (3.1)
Most of the time	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)
A good bit of the time	6 (12.8)	2 (7.4)	3 (12.5)	11 (11.2)
Some of the time	22 (46.8)	9 (33.3)	6 (25.0)	37 (37.8)
A little of the time	16 (34.0)	9 (33.3)	8 (33.3)	33 (33.7)
None of the time	0	4 (14.8)	2 (8.3)	6 (6.1)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	0	0	0	0
Most of the time	0	0	2 (8.3)	2 (2.0)
Some of the time	8 (17.0)	4 (14.8)	3 (12.5)	15 (15.3)
A little of the time	7 (14.9)	3 (11.1)	4 (16.7)	14 (14.3)
None of the time	31 (66.0)	19 (70.4)	14 (58.3)	64 (65.3)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 6 (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	1 (2.1)	0	0	1 (1.0)
Mostly true	3 (6.4)	1 (3.7)	3 (12.5)	7 (7.1)
Don't know	5 (10.6)	4 (14.8)	3 (12.5)	12 (12.2)
Mostly false	12 (25.5)	4 (14.8)	4 (16.7)	20 (20.4)
Definitely false	25 (53.2)	17 (63.0)	13 (54.2)	55 (56.1)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	13 (27.7)	8 (29.6)	6 (25.0)	27 (27.6)
Mostly true	18 (38.3)	11 (40.7)	11 (45.8)	40 (40.8)
Don't know	6 (12.8)	1 (3.7)	1 (4.2)	8 (8.2)
Mostly false	9 (19.1)	3 (11.1)	5 (20.8)	17 (17.3)
Definitely false	0	3 (11.1)	0	3 (3.1)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	0	0	0	0
Mostly true	2 (4.3)	1 (3.7)	0	3 (3.1)
Don't know	6 (12.8)	2 (7.4)	6 (25.0)	14 (14.3)
Mostly false	11 (23.4)	5 (18.5)	5 (20.8)	21 (21.4)
Definitely false	27 (57.4)	18 (66.7)	12 (50.0)	57 (58.2)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	11 (23.4)	8 (29.6)	4 (16.7)	23 (23.5)
Mostly true	24 (51.1)	11 (40.7)	12 (50.0)	47 (48.0)
Don't know	4 (8.5)	4 (14.8)	1 (4.2)	9 (9.2)
Mostly false	6 (12.8)	3 (11.1)	4 (16.7)	13 (13.3)
Definitely false	1 (2.1)	0	2 (8.3)	3 (3.1)
Missing	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7				
In general, would you say your health is:				
Excellent	6 (12.8)	4 (14.8)	4 (16.7)	14 (14.3)
Very good	23 (48.9)	10 (37.0)	8 (33.3)	41 (41.8)
Good	15 (31.9)	11 (40.7)	5 (20.8)	31 (31.6)
Fair	2 (4.3)	1 (3.7)	2 (8.3)	5 (5.1)
Poor	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	29 (61.7)	15 (55.6)	15 (62.5)	59 (60.2)
Somewhat better now than one year ago	9 (19.1)	3 (11.1)	3 (12.5)	15 (15.3)
About the same as one year ago	7 (14.9)	5 (18.5)	1 (4.2)	13 (13.3)
Somewhat worse now than one year ago	0	2 (7.4)	1 (4.2)	3 (3.1)
Much worse now than one year ago	1 (2.1)	1 (3.7)	0	2 (2.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	8 (17.0)	2 (7.4)	2 (8.3)	12 (12.2)
YES, limited a little	22 (46.8)	14 (51.9)	10 (41.7)	46 (46.9)
NO, NOT limited at all	15 (31.9)	10 (37.0)	8 (33.3)	33 (33.7)
Missing	2 (4.3)	1 (3.7)	4 (16.7)	7 (7.1)
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	1 (2.1)	0	1 (4.2)	2 (2.0)
YES, limited a little	16 (34.0)	7 (25.9)	5 (20.8)	28 (28.6)
NO, NOT limited at all	29 (61.7)	19 (70.4)	14 (58.3)	62 (63.3)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	0	0	1 (4.2)	1 (1.0)
YES, limited a little	14 (29.8)	5 (18.5)	3 (12.5)	22 (22.4)
NO, NOT limited at all	32 (68.1)	21 (77.8)	16 (66.7)	69 (70.4)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	0	1 (3.7)	0	1 (1.0)
YES, limited a little	8 (17.0)	3 (11.1)	6 (25.0)	17 (17.3)
NO, NOT limited at all	38 (80.9)	22 (81.5)	14 (58.3)	74 (75.5)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	0	0	0	0
YES, limited a little	0	2 (7.4)	2 (8.3)	4 (4.1)
NO, NOT limited at all	46 (97.9)	24 (88.9)	18 (75.0)	88 (89.8)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	2 (4.3)	0	1 (4.2)	3 (3.1)
YES, limited a little	13 (27.7)	8 (29.6)	7 (29.2)	28 (28.6)
NO, NOT limited at all	31 (66.0)	18 (66.7)	12 (50.0)	61 (62.2)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	0	2 (7.4)	0	2 (2.0)
YES, limited a little	4 (8.5)	1 (3.7)	3 (12.5)	8 (8.2)
NO, NOT limited at all	42 (89.4)	23 (85.2)	17 (70.8)	82 (83.7)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	1 (2.1)	1 (3.7)	0	2 (2.0)
YES, limited a little	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
NO, NOT limited at all	42 (89.4)	23 (85.2)	19 (79.2)	84 (85.7)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	0	0	0	0
YES, limited a little	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
NO, NOT limited at all	45 (95.7)	24 (88.9)	19 (79.2)	88 (89.8)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	0	0	0	0
YES, limited a little	2 (4.3)	4 (14.8)	3 (12.5)	9 (9.2)
NO, NOT limited at all	44 (93.6)	22 (81.5)	17 (70.8)	83 (84.7)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	36 (76.6)	23 (85.2)	14 (58.3)	73 (74.5)
Yes	10 (21.3)	3 (11.1)	6 (25.0)	19 (19.4)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	37 (78.7)	22 (81.5)	15 (62.5)	74 (75.5)
Yes	9 (19.1)	4 (14.8)	5 (20.8)	18 (18.4)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	34 (72.3)	20 (74.1)	15 (62.5)	69 (70.4)
Yes	12 (25.5)	6 (22.2)	5 (20.8)	23 (23.5)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	38 (80.9)	21 (77.8)	14 (58.3)	73 (74.5)
Yes	8 (17.0)	5 (18.5)	6 (25.0)	19 (19.4)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	41 (87.2)	25 (92.6)	17 (70.8)	83 (84.7)
Yes	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	39 (83.0)	23 (85.2)	16 (66.7)	78 (79.6)
Yes	7 (14.9)	3 (11.1)	4 (16.7)	14 (14.3)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	39 (83.0)	24 (88.9)	16 (66.7)	79 (80.6)
Yes	7 (14.9)	2 (7.4)	4 (16.7)	13 (13.3)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	38 (80.9)	20 (74.1)	13 (54.2)	71 (72.4)
Slightly	5 (10.6)	4 (14.8)	4 (16.7)	13 (13.3)
Moderately	2 (4.3)	1 (3.7)	2 (8.3)	5 (5.1)
Quite a bit	1 (2.1)	1 (3.7)	0	2 (2.0)
Extremely	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	15 (31.9)	7 (25.9)	5 (20.8)	27 (27.6)
Very mild	18 (38.3)	9 (33.3)	4 (16.7)	31 (31.6)
Mild	5 (10.6)	3 (11.1)	3 (12.5)	11 (11.2)
Moderate	7 (14.9)	6 (22.2)	7 (29.2)	20 (20.4)
Severe	1 (2.1)	1 (3.7)	0	2 (2.0)
Very severe	0	0	1 (4.2)	1 (1.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	20 (42.6)	10 (37.0)	10 (41.7)	40 (40.8)
A little bit	21 (44.7)	11 (40.7)	4 (16.7)	36 (36.7)
Moderately	5 (10.6)	5 (18.5)	4 (16.7)	14 (14.3)
Quite a bit	0	0	2 (8.3)	2 (2.0)
Extremely	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	6 (12.8)	4 (14.8)	2 (8.3)	12 (12.2)
Most of the time	22 (46.8)	14 (51.9)	9 (37.5)	45 (45.9)
A good bit of the time	10 (21.3)	4 (14.8)	2 (8.3)	16 (16.3)
Some of the time	6 (12.8)	2 (7.4)	3 (12.5)	11 (11.2)
A little of the time	1 (2.1)	2 (7.4)	4 (16.7)	7 (7.1)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	1 (2.1)	2 (7.4)	0	3 (3.1)
A good bit of the time	1 (2.1)	1 (3.7)	3 (12.5)	5 (5.1)
Some of the time	8 (17.0)	3 (11.1)	2 (8.3)	13 (13.3)
A little of the time	26 (55.3)	10 (37.0)	4 (16.7)	40 (40.8)
None of the time	10 (21.3)	10 (37.0)	10 (41.7)	30 (30.6)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	0	0	0
Most of the time	0	0	1 (4.2)	1 (1.0)
A good bit of the time	2 (4.3)	0	1 (4.2)	3 (3.1)
Some of the time	3 (6.4)	4 (14.8)	2 (8.3)	9 (9.2)
A little of the time	12 (25.5)	7 (25.9)	4 (16.7)	23 (23.5)
None of the time	29 (61.7)	15 (55.6)	12 (50.0)	56 (57.1)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	8 (17.0)	3 (11.1)	1 (4.2)	12 (12.2)
Most of the time	22 (46.8)	15 (55.6)	11 (45.8)	48 (49.0)
A good bit of the time	7 (14.9)	4 (14.8)	1 (4.2)	12 (12.2)
Some of the time	6 (12.8)	2 (7.4)	2 (8.3)	10 (10.2)
A little of the time	2 (4.3)	2 (7.4)	5 (20.8)	9 (9.2)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?				
All of the time	5 (10.6)	2 (7.4)	2 (8.3)	9 (9.2)
Most of the time	18 (38.3)	16 (59.3)	10 (41.7)	44 (44.9)
A good bit of the time	12 (25.5)	3 (11.1)	2 (8.3)	17 (17.3)
Some of the time	7 (14.9)	3 (11.1)	2 (8.3)	12 (12.2)
A little of the time	3 (6.4)	2 (7.4)	4 (16.7)	9 (9.2)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	1 (2.1)	2 (7.4)	0	3 (3.1)
A good bit of the time	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
Some of the time	7 (14.9)	3 (11.1)	2 (8.3)	12 (12.2)
A little of the time	13 (27.7)	5 (18.5)	6 (25.0)	24 (24.5)
None of the time	24 (51.1)	14 (51.9)	10 (41.7)	48 (49.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0	0	0
Most of the time	0	0	4 (16.7)	4 (4.1)
A good bit of the time	6 (12.8)	2 (7.4)	2 (8.3)	10 (10.2)
Some of the time	15 (31.9)	8 (29.6)	4 (16.7)	27 (27.6)
A little of the time	19 (40.4)	11 (40.7)	8 (33.3)	38 (38.8)
None of the time	6 (12.8)	5 (18.5)	2 (8.3)	13 (13.3)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?				
All of the time	9 (19.1)	4 (14.8)	3 (12.5)	16 (16.3)
Most of the time	19 (40.4)	13 (48.1)	10 (41.7)	42 (42.9)
A good bit of the time	8 (17.0)	3 (11.1)	1 (4.2)	12 (12.2)
Some of the time	9 (19.1)	4 (14.8)	5 (20.8)	18 (18.4)
A little of the time	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
None of the time	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?				
All of the time	0	1 (3.7)	2 (8.3)	3 (3.1)
Most of the time	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
A good bit of the time	6 (12.8)	4 (14.8)	3 (12.5)	13 (13.3)
Some of the time	22 (46.8)	4 (14.8)	8 (33.3)	34 (34.7)
A little of the time	13 (27.7)	13 (48.1)	4 (16.7)	30 (30.6)
None of the time	4 (8.5)	3 (11.1)	1 (4.2)	8 (8.2)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	0	0	0	0
Most of the time	2 (4.3)	0	1 (4.2)	3 (3.1)
Some of the time	3 (6.4)	2 (7.4)	3 (12.5)	8 (8.2)
A little of the time	9 (19.1)	4 (14.8)	3 (12.5)	16 (16.3)
None of the time	32 (68.1)	20 (74.1)	13 (54.2)	65 (66.3)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 7 (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	1 (2.1)	0	0	1 (1.0)
Mostly true	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Don't know	8 (17.0)	3 (11.1)	2 (8.3)	13 (13.3)
Mostly false	15 (31.9)	6 (22.2)	7 (29.2)	28 (28.6)
Definitely false	21 (44.7)	16 (59.3)	9 (37.5)	46 (46.9)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	14 (29.8)	8 (29.6)	4 (16.7)	26 (26.5)
Mostly true	19 (40.4)	13 (48.1)	10 (41.7)	42 (42.9)
Don't know	4 (8.5)	2 (7.4)	1 (4.2)	7 (7.1)
Mostly false	9 (19.1)	3 (11.1)	5 (20.8)	17 (17.3)
Definitely false	0	0	0	0
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	0	0	0	0
Mostly true	5 (10.6)	1 (3.7)	0	6 (6.1)
Don't know	1 (2.1)	4 (14.8)	4 (16.7)	9 (9.2)
Mostly false	15 (31.9)	7 (25.9)	6 (25.0)	28 (28.6)
Definitely false	25 (53.2)	14 (51.9)	10 (41.7)	49 (50.0)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	10 (21.3)	7 (25.9)	4 (16.7)	21 (21.4)
Mostly true	26 (55.3)	13 (48.1)	9 (37.5)	48 (49.0)
Don't know	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Mostly false	8 (17.0)	5 (18.5)	4 (16.7)	17 (17.3)
Definitely false	1 (2.1)	0	2 (8.3)	3 (3.1)
Missing	1 (2.1)	1 (3.7)	4 (16.7)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8				
In general, would you say your health is:				
Excellent	7 (14.9)	6 (22.2)	3 (12.5)	16 (16.3)
Very good	20 (42.6)	7 (25.9)	7 (29.2)	34 (34.7)
Good	13 (27.7)	10 (37.0)	10 (41.7)	33 (33.7)
Fair	4 (8.5)	1 (3.7)	1 (4.2)	6 (6.1)
Poor	0	1 (3.7)	1 (4.2)	2 (2.0)
Missing	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	6 (12.8)	6 (22.2)	4 (16.7)	16 (16.3)
Somewhat better now than one year ago	7 (14.9)	4 (14.8)	2 (8.3)	13 (13.3)
About the same as one year ago	24 (51.1)	11 (40.7)	12 (50.0)	47 (48.0)
Somewhat worse now than one year ago	7 (14.9)	3 (11.1)	4 (16.7)	14 (14.3)
Much worse now than one year ago	0	1 (3.7)	0	1 (1.0)
Missing	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	8 (17.0)	3 (11.1)	4 (16.7)	15 (15.3)
YES, limited a little	20 (42.6)	11 (40.7)	10 (41.7)	41 (41.8)
NO, NOT limited at all	16 (34.0)	12 (44.4)	8 (33.3)	36 (36.7)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	1 (2.1)	0	0	1 (1.0)
YES, limited a little	16 (34.0)	6 (22.2)	10 (41.7)	32 (32.7)
NO, NOT limited at all	27 (57.4)	20 (74.1)	12 (50.0)	59 (60.2)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	0	0	1 (4.2)	1 (1.0)
YES, limited a little	13 (27.7)	5 (18.5)	7 (29.2)	25 (25.5)
NO, NOT limited at all	31 (66.0)	21 (77.8)	14 (58.3)	66 (67.3)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
YES, limited a little	5 (10.6)	1 (3.7)	4 (16.7)	10 (10.2)
NO, NOT limited at all	38 (80.9)	24 (88.9)	17 (70.8)	79 (80.6)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	1 (2.1)	0	0	1 (1.0)
YES, limited a little	0	1 (3.7)	3 (12.5)	4 (4.1)
NO, NOT limited at all	42 (89.4)	24 (88.9)	19 (79.2)	85 (86.7)
Missing	4 (8.5)	2 (7.4)	2 (8.3)	8 (8.2)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	0	2 (7.4)	1 (4.2)	3 (3.1)
YES, limited a little	16 (34.0)	4 (14.8)	8 (33.3)	28 (28.6)
NO, NOT limited at all	28 (59.6)	20 (74.1)	12 (50.0)	60 (61.2)
Missing	3 (6.4)	1 (3.7)	3 (12.5)	7 (7.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	1 (2.1)	2 (7.4)	0	3 (3.1)
YES, limited a little	4 (8.5)	0	3 (12.5)	7 (7.1)
NO, NOT limited at all	39 (83.0)	24 (88.9)	19 (79.2)	82 (83.7)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	1 (2.1)	2 (7.4)	0	3 (3.1)
YES, limited a little	3 (6.4)	0	1 (4.2)	4 (4.1)
NO, NOT limited at all	40 (85.1)	24 (88.9)	21 (87.5)	85 (86.7)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	1 (2.1)	0	0	1 (1.0)
YES, limited a little	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
NO, NOT limited at all	42 (89.4)	24 (88.9)	21 (87.5)	87 (88.8)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	0	0	0	0
YES, limited a little	4 (8.5)	4 (14.8)	2 (8.3)	10 (10.2)
NO, NOT limited at all	40 (85.1)	22 (81.5)	20 (83.3)	82 (83.7)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	35 (74.5)	20 (74.1)	16 (66.7)	71 (72.4)
Yes	9 (19.1)	6 (22.2)	5 (20.8)	20 (20.4)
Missing	3 (6.4)	1 (3.7)	3 (12.5)	7 (7.1)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	35 (74.5)	20 (74.1)	15 (62.5)	70 (71.4)
Yes	9 (19.1)	6 (22.2)	6 (25.0)	21 (21.4)
Missing	3 (6.4)	1 (3.7)	3 (12.5)	7 (7.1)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	35 (74.5)	21 (77.8)	19 (79.2)	75 (76.5)
Yes	9 (19.1)	5 (18.5)	3 (12.5)	17 (17.3)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	37 (78.7)	22 (81.5)	14 (58.3)	73 (74.5)
Yes	7 (14.9)	4 (14.8)	8 (33.3)	19 (19.4)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	39 (83.0)	22 (81.5)	18 (75.0)	79 (80.6)
Yes	4 (8.5)	4 (14.8)	4 (16.7)	12 (12.2)
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	38 (80.9)	19 (70.4)	16 (66.7)	73 (74.5)
Yes	6 (12.8)	7 (25.9)	5 (20.8)	18 (18.4)
Missing	3 (6.4)	1 (3.7)	3 (12.5)	7 (7.1)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	37 (78.7)	21 (77.8)	18 (75.0)	76 (77.6)
Yes	6 (12.8)	5 (18.5)	3 (12.5)	14 (14.3)
Missing	4 (8.5)	1 (3.7)	3 (12.5)	8 (8.2)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	35 (74.5)	19 (70.4)	17 (70.8)	71 (72.4)
Slightly	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
Moderately	1 (2.1)	2 (7.4)	0	3 (3.1)
Quite a bit	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
Extremely	0	1 (3.7)	1 (4.2)	2 (2.0)
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	14 (29.8)	13 (48.1)	8 (33.3)	35 (35.7)
Very mild	13 (27.7)	5 (18.5)	1 (4.2)	19 (19.4)
Mild	7 (14.9)	4 (14.8)	7 (29.2)	18 (18.4)
Moderate	8 (17.0)	2 (7.4)	4 (16.7)	14 (14.3)
Severe	2 (4.3)	2 (7.4)	2 (8.3)	6 (6.1)
Very severe	0	0	0	0
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	25 (53.2)	20 (74.1)	9 (37.5)	54 (55.1)
A little bit	9 (19.1)	3 (11.1)	6 (25.0)	18 (18.4)
Moderately	5 (10.6)	1 (3.7)	7 (29.2)	13 (13.3)
Quite a bit	3 (6.4)	2 (7.4)	0	5 (5.1)
Extremely	1 (2.1)	0	0	1 (1.0)
Missing	4 (8.5)	1 (3.7)	2 (8.3)	7 (7.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	5 (10.6)	4 (14.8)	1 (4.2)	10 (10.2)
Most of the time	25 (53.2)	14 (51.9)	11 (45.8)	50 (51.0)
A good bit of the time	7 (14.9)	3 (11.1)	2 (8.3)	12 (12.2)
Some of the time	4 (8.5)	2 (7.4)	5 (20.8)	11 (11.2)
A little of the time	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
None of the time	0	2 (7.4)	1 (4.2)	3 (3.1)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	1 (2.1)	0	0	1 (1.0)
Most of the time	0	4 (14.8)	2 (8.3)	6 (6.1)
A good bit of the time	1 (2.1)	2 (7.4)	0	3 (3.1)
Some of the time	11 (23.4)	1 (3.7)	4 (16.7)	16 (16.3)
A little of the time	16 (34.0)	13 (48.1)	9 (37.5)	38 (38.8)
None of the time	15 (31.9)	6 (22.2)	7 (29.2)	28 (28.6)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	1 (2.1)	0	0	1 (1.0)
Most of the time	1 (2.1)	1 (3.7)	3 (12.5)	5 (5.1)
A good bit of the time	0	3 (11.1)	0	3 (3.1)
Some of the time	6 (12.8)	3 (11.1)	0	9 (9.2)
A little of the time	5 (10.6)	5 (18.5)	5 (20.8)	15 (15.3)
None of the time	31 (66.0)	14 (51.9)	14 (58.3)	59 (60.2)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	4 (8.5)	3 (11.1)	0	7 (7.1)
Most of the time	24 (51.1)	12 (44.4)	11 (45.8)	47 (48.0)
A good bit of the time	6 (12.8)	3 (11.1)	3 (12.5)	12 (12.2)
Some of the time	6 (12.8)	5 (18.5)	8 (33.3)	19 (19.4)
A little of the time	3 (6.4)	2 (7.4)	0	5 (5.1)
None of the time	1 (2.1)	1 (3.7)	0	2 (2.0)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?				
All of the time	2 (4.3)	3 (11.1)	0	5 (5.1)
Most of the time	23 (48.9)	10 (37.0)	11 (45.8)	44 (44.9)
A good bit of the time	12 (25.5)	6 (22.2)	3 (12.5)	21 (21.4)
Some of the time	5 (10.6)	3 (11.1)	4 (16.7)	12 (12.2)
A little of the time	2 (4.3)	3 (11.1)	4 (16.7)	9 (9.2)
None of the time	0	1 (3.7)	0	1 (1.0)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?				
All of the time	1 (2.1)	0	0	1 (1.0)
Most of the time	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
A good bit of the time	0	3 (11.1)	3 (12.5)	6 (6.1)
Some of the time	5 (10.6)	1 (3.7)	0	6 (6.1)
A little of the time	16 (34.0)	6 (22.2)	5 (20.8)	27 (27.6)
None of the time	21 (44.7)	14 (51.9)	13 (54.2)	48 (49.0)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	1 (2.1)	0	1 (4.2)	2 (2.0)
Most of the time	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
A good bit of the time	4 (8.5)	3 (11.1)	1 (4.2)	8 (8.2)
Some of the time	11 (23.4)	7 (25.9)	9 (37.5)	27 (27.6)
A little of the time	19 (40.4)	9 (33.3)	9 (37.5)	37 (37.8)
None of the time	8 (17.0)	6 (22.2)	0	14 (14.3)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?				
All of the time	7 (14.9)	4 (14.8)	2 (8.3)	13 (13.3)
Most of the time	22 (46.8)	11 (40.7)	14 (58.3)	47 (48.0)
A good bit of the time	5 (10.6)	4 (14.8)	2 (8.3)	11 (11.2)
Some of the time	8 (17.0)	4 (14.8)	2 (8.3)	14 (14.3)
A little of the time	1 (2.1)	3 (11.1)	2 (8.3)	6 (6.1)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?				
All of the time	1 (2.1)	1 (3.7)	3 (12.5)	5 (5.1)
Most of the time	0	3 (11.1)	1 (4.2)	4 (4.1)
A good bit of the time	4 (8.5)	4 (14.8)	6 (25.0)	14 (14.3)
Some of the time	16 (34.0)	6 (22.2)	6 (25.0)	28 (28.6)
A little of the time	23 (48.9)	8 (29.6)	6 (25.0)	37 (37.8)
None of the time	0	4 (14.8)	0	4 (4.1)
Missing	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	2 (4.3)	0	1 (4.2)	3 (3.1)
Most of the time	2 (4.3)	2 (7.4)	0	4 (4.1)
Some of the time	3 (6.4)	3 (11.1)	3 (12.5)	9 (9.2)
A little of the time	10 (21.3)	3 (11.1)	2 (8.3)	15 (15.3)
None of the time	27 (57.4)	17 (63.0)	16 (66.7)	60 (61.2)
Missing	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 8 (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	0	0	0	0
Mostly true	2 (4.3)	3 (11.1)	5 (20.8)	10 (10.2)
Don't know	9 (19.1)	5 (18.5)	0	14 (14.3)
Mostly false	9 (19.1)	5 (18.5)	7 (29.2)	21 (21.4)
Definitely false	24 (51.1)	12 (44.4)	10 (41.7)	46 (46.9)
Missing	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	11 (23.4)	7 (25.9)	3 (12.5)	21 (21.4)
Mostly true	17 (36.2)	10 (37.0)	9 (37.5)	36 (36.7)
Don't know	6 (12.8)	4 (14.8)	0	10 (10.2)
Mostly false	7 (14.9)	4 (14.8)	9 (37.5)	20 (20.4)
Definitely false	3 (6.4)	0	1 (4.2)	4 (4.1)
Missing	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	0	0	0	0
Mostly true	3 (6.4)	4 (14.8)	1 (4.2)	8 (8.2)
Don't know	4 (8.5)	3 (11.1)	6 (25.0)	13 (13.3)
Mostly false	18 (38.3)	8 (29.6)	9 (37.5)	35 (35.7)
Definitely false	19 (40.4)	10 (37.0)	6 (25.0)	35 (35.7)
Missing	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	11 (23.4)	6 (22.2)	3 (12.5)	20 (20.4)
Mostly true	21 (44.7)	11 (40.7)	11 (45.8)	43 (43.9)
Don't know	4 (8.5)	2 (7.4)	1 (4.2)	7 (7.1)
Mostly false	6 (12.8)	4 (14.8)	7 (29.2)	17 (17.3)
Definitely false	2 (4.3)	2 (7.4)	0	4 (4.1)
Missing	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9				
In general, would you say your health is:				
Excellent	3 (6.4)	3 (11.1)	2 (8.3)	8 (8.2)
Very good	21 (44.7)	12 (44.4)	6 (25.0)	39 (39.8)
Good	12 (25.5)	8 (29.6)	11 (45.8)	31 (31.6)
Fair	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
Poor	2 (4.3)	0	0	2 (2.0)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	6 (12.8)	2 (7.4)	2 (8.3)	10 (10.2)
Somewhat better now than one year ago	5 (10.6)	8 (29.6)	0	13 (13.3)
About the same as one year ago	24 (51.1)	9 (33.3)	16 (66.7)	49 (50.0)
Somewhat worse now than one year ago	6 (12.8)	7 (25.9)	3 (12.5)	16 (16.3)
Much worse now than one year ago	1 (2.1)	0	0	1 (1.0)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	6 (12.8)	5 (18.5)	5 (20.8)	16 (16.3)
YES, limited a little	21 (44.7)	10 (37.0)	9 (37.5)	40 (40.8)
NO, NOT limited at all	15 (31.9)	11 (40.7)	7 (29.2)	33 (33.7)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	2 (4.3)	0	0	2 (2.0)
YES, limited a little	9 (19.1)	9 (33.3)	11 (45.8)	29 (29.6)
NO, NOT limited at all	31 (66.0)	17 (63.0)	10 (41.7)	58 (59.2)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	1 (2.1)	0	1 (4.2)	2 (2.0)
YES, limited a little	11 (23.4)	12 (44.4)	5 (20.8)	28 (28.6)
NO, NOT limited at all	30 (63.8)	14 (51.9)	15 (62.5)	59 (60.2)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
YES, limited a little	6 (12.8)	6 (22.2)	3 (12.5)	15 (15.3)
NO, NOT limited at all	34 (72.3)	18 (66.7)	17 (70.8)	69 (70.4)
Missing	5 (10.6)	2 (7.4)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	1 (2.1)	0	0	1 (1.0)
YES, limited a little	1 (2.1)	4 (14.8)	3 (12.5)	8 (8.2)
NO, NOT limited at all	39 (83.0)	22 (81.5)	18 (75.0)	79 (80.6)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
YES, limited a little	17 (36.2)	9 (33.3)	6 (25.0)	32 (32.7)
NO, NOT limited at all	22 (46.8)	16 (59.3)	13 (54.2)	51 (52.0)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
YES, limited a little	7 (14.9)	5 (18.5)	2 (8.3)	14 (14.3)
NO, NOT limited at all	32 (68.1)	20 (74.1)	18 (75.0)	70 (71.4)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	1 (2.1)	1 (3.7)	0	2 (2.0)
YES, limited a little	6 (12.8)	6 (22.2)	3 (12.5)	15 (15.3)
NO, NOT limited at all	35 (74.5)	19 (70.4)	18 (75.0)	72 (73.5)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	0	0	0	0
YES, limited a little	2 (4.3)	2 (7.4)	2 (8.3)	6 (6.1)
NO, NOT limited at all	40 (85.1)	24 (88.9)	19 (79.2)	83 (84.7)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	1 (2.1)	0	0	1 (1.0)
YES, limited a little	3 (6.4)	4 (14.8)	1 (4.2)	8 (8.2)
NO, NOT limited at all	37 (78.7)	22 (81.5)	20 (83.3)	79 (80.6)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	31 (66.0)	19 (70.4)	17 (70.8)	67 (68.4)
Yes	11 (23.4)	7 (25.9)	4 (16.7)	22 (22.4)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	31 (66.0)	17 (63.0)	17 (70.8)	65 (66.3)
Yes	11 (23.4)	9 (33.3)	4 (16.7)	24 (24.5)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	34 (72.3)	19 (70.4)	19 (79.2)	72 (73.5)
Yes	8 (17.0)	7 (25.9)	2 (8.3)	17 (17.3)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	32 (68.1)	18 (66.7)	16 (66.7)	66 (67.3)
Yes	10 (21.3)	8 (29.6)	5 (20.8)	23 (23.5)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	36 (76.6)	19 (70.4)	20 (83.3)	75 (76.5)
Yes	6 (12.8)	6 (22.2)	1 (4.2)	13 (13.3)
Missing	5 (10.6)	2 (7.4)	3 (12.5)	10 (10.2)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	35 (74.5)	17 (63.0)	19 (79.2)	71 (72.4)
Yes	7 (14.9)	8 (29.6)	2 (8.3)	17 (17.3)
Missing	5 (10.6)	2 (7.4)	3 (12.5)	10 (10.2)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	38 (80.9)	20 (74.1)	19 (79.2)	77 (78.6)
Yes	4 (8.5)	5 (18.5)	2 (8.3)	11 (11.2)
Missing	5 (10.6)	2 (7.4)	3 (12.5)	10 (10.2)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	31 (66.0)	15 (55.6)	15 (62.5)	61 (62.2)
Slightly	7 (14.9)	5 (18.5)	2 (8.3)	14 (14.3)
Moderately	2 (4.3)	3 (11.1)	2 (8.3)	7 (7.1)
Quite a bit	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
Extremely	1 (2.1)	0	1 (4.2)	2 (2.0)
Missing	5 (10.6)	2 (7.4)	3 (12.5)	10 (10.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	13 (27.7)	9 (33.3)	7 (29.2)	29 (29.6)
Very mild	15 (31.9)	4 (14.8)	2 (8.3)	21 (21.4)
Mild	3 (6.4)	5 (18.5)	6 (25.0)	14 (14.3)
Moderate	6 (12.8)	5 (18.5)	4 (16.7)	15 (15.3)
Severe	5 (10.6)	2 (7.4)	2 (8.3)	9 (9.2)
Very severe	0	0	0	0
Missing	5 (10.6)	2 (7.4)	3 (12.5)	10 (10.2)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	21 (44.7)	15 (55.6)	9 (37.5)	45 (45.9)
A little bit	12 (25.5)	5 (18.5)	6 (25.0)	23 (23.5)
Moderately	4 (8.5)	4 (14.8)	3 (12.5)	11 (11.2)
Quite a bit	4 (8.5)	2 (7.4)	2 (8.3)	8 (8.2)
Extremely	1 (2.1)	0	1 (4.2)	2 (2.0)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	2 (4.3)	2 (7.4)	2 (8.3)	6 (6.1)
Most of the time	18 (38.3)	8 (29.6)	7 (29.2)	33 (33.7)
A good bit of the time	11 (23.4)	5 (18.5)	4 (16.7)	20 (20.4)
Some of the time	9 (19.1)	6 (22.2)	6 (25.0)	21 (21.4)
A little of the time	2 (4.3)	5 (18.5)	1 (4.2)	8 (8.2)
None of the time	0	0	1 (4.2)	1 (1.0)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	1 (2.1)	0	1 (4.2)	2 (2.0)
Most of the time	0	3 (11.1)	0	3 (3.1)
A good bit of the time	3 (6.4)	2 (7.4)	3 (12.5)	8 (8.2)
Some of the time	9 (19.1)	5 (18.5)	1 (4.2)	15 (15.3)
A little of the time	15 (31.9)	8 (29.6)	9 (37.5)	32 (32.7)
None of the time	14 (29.8)	8 (29.6)	7 (29.2)	29 (29.6)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	0	0	0
Most of the time	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
A good bit of the time	3 (6.4)	2 (7.4)	0	5 (5.1)
Some of the time	0	5 (18.5)	2 (8.3)	7 (7.1)
A little of the time	12 (25.5)	6 (22.2)	7 (29.2)	25 (25.5)
None of the time	26 (55.3)	11 (40.7)	11 (45.8)	48 (49.0)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	5 (10.6)	4 (14.8)	3 (12.5)	12 (12.2)
Most of the time	18 (38.3)	8 (29.6)	10 (41.7)	36 (36.7)
A good bit of the time	9 (19.1)	4 (14.8)	0	13 (13.3)
Some of the time	6 (12.8)	5 (18.5)	7 (29.2)	18 (18.4)
A little of the time	3 (6.4)	5 (18.5)	1 (4.2)	9 (9.2)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?				
All of the time	2 (4.3)	2 (7.4)	2 (8.3)	6 (6.1)
Most of the time	15 (31.9)	10 (37.0)	8 (33.3)	33 (33.7)
A good bit of the time	10 (21.3)	5 (18.5)	4 (16.7)	19 (19.4)
Some of the time	12 (25.5)	4 (14.8)	2 (8.3)	18 (18.4)
A little of the time	3 (6.4)	5 (18.5)	4 (16.7)	12 (12.2)
None of the time	0	0	1 (4.2)	1 (1.0)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	1 (2.1)	3 (11.1)	1 (4.2)	5 (5.1)
A good bit of the time	1 (2.1)	3 (11.1)	1 (4.2)	5 (5.1)
Some of the time	3 (6.4)	4 (14.8)	1 (4.2)	8 (8.2)
A little of the time	15 (31.9)	4 (14.8)	7 (29.2)	26 (26.5)
None of the time	22 (46.8)	12 (44.4)	10 (41.7)	44 (44.9)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0	2 (8.3)	2 (2.0)
Most of the time	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
A good bit of the time	4 (8.5)	4 (14.8)	0	8 (8.2)
Some of the time	13 (27.7)	7 (25.9)	9 (37.5)	29 (29.6)
A little of the time	18 (38.3)	6 (22.2)	6 (25.0)	30 (30.6)
None of the time	5 (10.6)	7 (25.9)	3 (12.5)	15 (15.3)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Have you been a happy person?				
All of the time	5 (10.6)	5 (18.5)	4 (16.7)	14 (14.3)
Most of the time	18 (38.3)	9 (33.3)	7 (29.2)	34 (34.7)
A good bit of the time	9 (19.1)	2 (7.4)	4 (16.7)	15 (15.3)
Some of the time	7 (14.9)	5 (18.5)	4 (16.7)	16 (16.3)
A little of the time	3 (6.4)	5 (18.5)	2 (8.3)	10 (10.2)
None of the time	0	0	0	0
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Did you feel tired?				
All of the time	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Most of the time	1 (2.1)	3 (11.1)	1 (4.2)	5 (5.1)
A good bit of the time	6 (12.8)	6 (22.2)	2 (8.3)	14 (14.3)
Some of the time	18 (38.3)	4 (14.8)	8 (33.3)	30 (30.6)
A little of the time	14 (29.8)	8 (29.6)	7 (29.2)	29 (29.6)
None of the time	2 (4.3)	4 (14.8)	1 (4.2)	7 (7.1)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	1 (2.1)	0	1 (4.2)	2 (2.0)
Most of the time	1 (2.1)	0	1 (4.2)	2 (2.0)
Some of the time	6 (12.8)	8 (29.6)	2 (8.3)	16 (16.3)
A little of the time	7 (14.9)	5 (18.5)	3 (12.5)	15 (15.3)
None of the time	27 (57.4)	13 (48.1)	14 (58.3)	54 (55.1)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 9 (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	0	0	0	0
Mostly true	1 (2.1)	4 (14.8)	2 (8.3)	7 (7.1)
Don't know	6 (12.8)	5 (18.5)	1 (4.2)	12 (12.2)
Mostly false	14 (29.8)	7 (25.9)	6 (25.0)	27 (27.6)
Definitely false	21 (44.7)	10 (37.0)	12 (50.0)	43 (43.9)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	11 (23.4)	5 (18.5)	5 (20.8)	21 (21.4)
Mostly true	15 (31.9)	12 (44.4)	11 (45.8)	38 (38.8)
Don't know	8 (17.0)	2 (7.4)	0	10 (10.2)
Mostly false	6 (12.8)	6 (22.2)	5 (20.8)	17 (17.3)
Definitely false	2 (4.3)	1 (3.7)	0	3 (3.1)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	0	0	0	0
Mostly true	5 (10.6)	4 (14.8)	0	9 (9.2)
Don't know	6 (12.8)	4 (14.8)	7 (29.2)	17 (17.3)
Mostly false	12 (25.5)	6 (22.2)	9 (37.5)	27 (27.6)
Definitely false	19 (40.4)	12 (44.4)	5 (20.8)	36 (36.7)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	8 (17.0)	5 (18.5)	2 (8.3)	15 (15.3)
Mostly true	22 (46.8)	11 (40.7)	12 (50.0)	45 (45.9)
Don't know	6 (12.8)	2 (7.4)	2 (8.3)	10 (10.2)
Mostly false	3 (6.4)	6 (22.2)	4 (16.7)	13 (13.3)
Definitely false	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
Missing	5 (10.6)	1 (3.7)	3 (12.5)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10				
In general, would you say your health is:				
Excellent	3 (6.4)	3 (11.1)	2 (8.3)	8 (8.2)
Very good	22 (46.8)	9 (33.3)	6 (25.0)	37 (37.8)
Good	11 (23.4)	11 (40.7)	9 (37.5)	31 (31.6)
Fair	5 (10.6)	2 (7.4)	5 (20.8)	12 (12.2)
Poor	0	1 (3.7)	0	1 (1.0)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Somewhat better now than one year ago	9 (19.1)	3 (11.1)	4 (16.7)	16 (16.3)
About the same as one year ago	25 (53.2)	16 (59.3)	11 (45.8)	52 (53.1)
Somewhat worse now than one year ago	6 (12.8)	5 (18.5)	6 (25.0)	17 (17.3)
Much worse now than one year ago	0	1 (3.7)	0	1 (1.0)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	5 (10.6)	4 (14.8)	6 (25.0)	15 (15.3)
YES, limited a little	23 (48.9)	13 (48.1)	9 (37.5)	45 (45.9)
NO, NOT limited at all	13 (27.7)	9 (33.3)	7 (29.2)	29 (29.6)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
YES, limited a little	12 (25.5)	9 (33.3)	11 (45.8)	32 (32.7)
NO, NOT limited at all	26 (55.3)	16 (59.3)	10 (41.7)	52 (53.1)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	2 (4.3)	0	2 (8.3)	4 (4.1)
YES, limited a little	9 (19.1)	5 (18.5)	7 (29.2)	21 (21.4)
NO, NOT limited at all	30 (63.8)	21 (77.8)	13 (54.2)	64 (65.3)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
YES, limited a little	7 (14.9)	3 (11.1)	3 (12.5)	13 (13.3)
NO, NOT limited at all	33 (70.2)	22 (81.5)	17 (70.8)	72 (73.5)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	0	0	1 (4.2)	1 (1.0)
YES, limited a little	3 (6.4)	3 (11.1)	1 (4.2)	7 (7.1)
NO, NOT limited at all	38 (80.9)	23 (85.2)	20 (83.3)	81 (82.7)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
YES, limited a little	16 (34.0)	7 (25.9)	10 (41.7)	33 (33.7)
NO, NOT limited at all	24 (51.1)	18 (66.7)	11 (45.8)	53 (54.1)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
YES, limited a little	8 (17.0)	2 (7.4)	2 (8.3)	12 (12.2)
NO, NOT limited at all	32 (68.1)	22 (81.5)	19 (79.2)	73 (74.5)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	1 (2.1)	2 (7.4)	0	3 (3.1)
YES, limited a little	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
NO, NOT limited at all	34 (72.3)	23 (85.2)	20 (83.3)	77 (78.6)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	0	0	0	0
YES, limited a little	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
NO, NOT limited at all	38 (80.9)	24 (88.9)	20 (83.3)	82 (83.7)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	0	0	0	0
YES, limited a little	6 (12.8)	5 (18.5)	5 (20.8)	16 (16.3)
NO, NOT limited at all	35 (74.5)	21 (77.8)	17 (70.8)	73 (74.5)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	31 (66.0)	22 (81.5)	13 (54.2)	66 (67.3)
Yes	10 (21.3)	4 (14.8)	9 (37.5)	23 (23.5)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	29 (61.7)	17 (63.0)	15 (62.5)	61 (62.2)
Yes	12 (25.5)	9 (33.3)	7 (29.2)	28 (28.6)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	30 (63.8)	19 (70.4)	15 (62.5)	64 (65.3)
Yes	11 (23.4)	7 (25.9)	7 (29.2)	25 (25.5)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	31 (66.0)	19 (70.4)	15 (62.5)	65 (66.3)
Yes	10 (21.3)	7 (25.9)	7 (29.2)	24 (24.5)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

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Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	34 (72.3)	23 (85.2)	17 (70.8)	74 (75.5)
Yes	7 (14.9)	3 (11.1)	5 (20.8)	15 (15.3)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	33 (70.2)	18 (66.7)	17 (70.8)	68 (69.4)
Yes	8 (17.0)	7 (25.9)	5 (20.8)	20 (20.4)
Missing	6 (12.8)	2 (7.4)	2 (8.3)	10 (10.2)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	35 (74.5)	21 (77.8)	17 (70.8)	73 (74.5)
Yes	6 (12.8)	4 (14.8)	5 (20.8)	15 (15.3)
Missing	6 (12.8)	2 (7.4)	2 (8.3)	10 (10.2)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	29 (61.7)	18 (66.7)	15 (62.5)	62 (63.3)
Slightly	8 (17.0)	5 (18.5)	3 (12.5)	16 (16.3)
Moderately	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)
Quite a bit	2 (4.3)	0	2 (8.3)	4 (4.1)
Extremely	0	1 (3.7)	1 (4.2)	2 (2.0)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	11 (23.4)	6 (22.2)	5 (20.8)	22 (22.4)
Very mild	8 (17.0)	6 (22.2)	4 (16.7)	18 (18.4)
Mild	10 (21.3)	6 (22.2)	3 (12.5)	19 (19.4)
Moderate	8 (17.0)	5 (18.5)	5 (20.8)	18 (18.4)
Severe	4 (8.5)	3 (11.1)	4 (16.7)	11 (11.2)
Very severe	0	0	1 (4.2)	1 (1.0)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	17 (36.2)	12 (44.4)	8 (33.3)	37 (37.8)
A little bit	13 (27.7)	8 (29.6)	4 (16.7)	25 (25.5)
Moderately	5 (10.6)	3 (11.1)	5 (20.8)	13 (13.3)
Quite a bit	5 (10.6)	3 (11.1)	5 (20.8)	13 (13.3)
Extremely	0	0	0	0
Missing	7 (14.9)	1 (3.7)	2 (8.3)	10 (10.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	1 (2.1)	3 (11.1)	1 (4.2)	5 (5.1)
Most of the time	17 (36.2)	8 (29.6)	8 (33.3)	33 (33.7)
A good bit of the time	11 (23.4)	6 (22.2)	1 (4.2)	18 (18.4)
Some of the time	8 (17.0)	8 (29.6)	6 (25.0)	22 (22.4)
A little of the time	2 (4.3)	1 (3.7)	5 (20.8)	8 (8.2)
None of the time	2 (4.3)	0	1 (4.2)	3 (3.1)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	0	0	0	0
Most of the time	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
A good bit of the time	2 (4.3)	1 (3.7)	3 (12.5)	6 (6.1)
Some of the time	6 (12.8)	5 (18.5)	2 (8.3)	13 (13.3)
A little of the time	18 (38.3)	10 (37.0)	5 (20.8)	33 (33.7)
None of the time	14 (29.8)	9 (33.3)	11 (45.8)	34 (34.7)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	0	0	0
Most of the time	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
A good bit of the time	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Some of the time	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
A little of the time	9 (19.1)	9 (33.3)	4 (16.7)	22 (22.4)
None of the time	27 (57.4)	13 (48.1)	14 (58.3)	54 (55.1)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	4 (8.5)	3 (11.1)	1 (4.2)	8 (8.2)
Most of the time	16 (34.0)	8 (29.6)	9 (37.5)	33 (33.7)
A good bit of the time	10 (21.3)	7 (25.9)	6 (25.0)	23 (23.5)
Some of the time	7 (14.9)	6 (22.2)	2 (8.3)	15 (15.3)
A little of the time	3 (6.4)	2 (7.4)	4 (16.7)	9 (9.2)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?				
All of the time	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)
Most of the time	14 (29.8)	8 (29.6)	7 (29.2)	29 (29.6)
A good bit of the time	14 (29.8)	8 (29.6)	4 (16.7)	26 (26.5)
Some of the time	8 (17.0)	6 (22.2)	3 (12.5)	17 (17.3)
A little of the time	4 (8.5)	1 (3.7)	5 (20.8)	10 (10.2)
None of the time	0	1 (3.7)	1 (4.2)	2 (2.0)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?				
All of the time	0	0	0	0
Most of the time	2 (4.3)	1 (3.7)	0	3 (3.1)
A good bit of the time	1 (2.1)	1 (3.7)	3 (12.5)	5 (5.1)
Some of the time	4 (8.5)	4 (14.8)	2 (8.3)	10 (10.2)
A little of the time	13 (27.7)	7 (25.9)	8 (33.3)	28 (28.6)
None of the time	21 (44.7)	13 (48.1)	9 (37.5)	43 (43.9)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	2 (4.3)	2 (7.4)	1 (4.2)	5 (5.1)
A good bit of the time	5 (10.6)	1 (3.7)	2 (8.3)	8 (8.2)
Some of the time	14 (29.8)	14 (51.9)	10 (41.7)	38 (38.8)
A little of the time	17 (36.2)	1 (3.7)	4 (16.7)	22 (22.4)
None of the time	3 (6.4)	8 (29.6)	4 (16.7)	15 (15.3)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Have you been a happy person?				
All of the time	6 (12.8)	4 (14.8)	2 (8.3)	12 (12.2)
Most of the time	18 (38.3)	6 (22.2)	8 (33.3)	32 (32.7)
A good bit of the time	8 (17.0)	8 (29.6)	3 (12.5)	19 (19.4)
Some of the time	8 (17.0)	6 (22.2)	8 (33.3)	22 (22.4)
A little of the time	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
None of the time	0	0	0	0
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Did you feel tired?				
All of the time	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
Most of the time	2 (4.3)	2 (7.4)	3 (12.5)	7 (7.1)
A good bit of the time	9 (19.1)	6 (22.2)	4 (16.7)	19 (19.4)
Some of the time	16 (34.0)	11 (40.7)	6 (25.0)	33 (33.7)
A little of the time	12 (25.5)	3 (11.1)	8 (33.3)	23 (23.5)
None of the time	1 (2.1)	3 (11.1)	0	4 (4.1)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	0	0	0	0
Most of the time	4 (8.5)	1 (3.7)	1 (4.2)	6 (6.1)
Some of the time	4 (8.5)	5 (18.5)	6 (25.0)	15 (15.3)
A little of the time	9 (19.1)	7 (25.9)	2 (8.3)	18 (18.4)
None of the time	23 (48.9)	13 (48.1)	13 (54.2)	49 (50.0)
Missing	7 (14.9)	1 (3.7)	2 (8.3)	10 (10.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
Visit 10 (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	0	0	0	0
Mostly true	2 (4.3)	1 (3.7)	2 (8.3)	5 (5.1)
Don't know	7 (14.9)	4 (14.8)	3 (12.5)	14 (14.3)
Mostly false	12 (25.5)	12 (44.4)	8 (33.3)	32 (32.7)
Definitely false	20 (42.6)	9 (33.3)	9 (37.5)	38 (38.8)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	9 (19.1)	3 (11.1)	5 (20.8)	17 (17.3)
Mostly true	13 (27.7)	16 (59.3)	10 (41.7)	39 (39.8)
Don't know	9 (19.1)	4 (14.8)	4 (16.7)	17 (17.3)
Mostly false	6 (12.8)	2 (7.4)	3 (12.5)	11 (11.2)
Definitely false	4 (8.5)	1 (3.7)	0	5 (5.1)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	0	0	0	0
Mostly true	8 (17.0)	4 (14.8)	2 (8.3)	14 (14.3)
Don't know	8 (17.0)	4 (14.8)	8 (33.3)	20 (20.4)
Mostly false	12 (25.5)	7 (25.9)	6 (25.0)	25 (25.5)
Definitely false	13 (27.7)	11 (40.7)	6 (25.0)	30 (30.6)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	8 (17.0)	5 (18.5)	2 (8.3)	15 (15.3)
Mostly true	21 (44.7)	13 (48.1)	9 (37.5)	43 (43.9)
Don't know	4 (8.5)	3 (11.1)	5 (20.8)	12 (12.2)
Mostly false	5 (10.6)	3 (11.1)	4 (16.7)	12 (12.2)
Definitely false	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Missing	6 (12.8)	1 (3.7)	2 (8.3)	9 (9.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial				
In general, would you say your health is:				
Excellent	4 (8.5)	6 (22.2)	2 (8.3)	12 (12.2)
Very good	21 (44.7)	10 (37.0)	7 (29.2)	38 (38.8)
Good	13 (27.7)	8 (29.6)	10 (41.7)	31 (31.6)
Fair	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Poor	0	0	0	0
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Compared to one year ago, how would you rate your health in general now?				
Much better than one year ago	2 (4.3)	5 (18.5)	1 (4.2)	8 (8.2)
Somewhat better now than one year ago	7 (14.9)	2 (7.4)	2 (8.3)	11 (11.2)
About the same as one year ago	28 (59.6)	17 (63.0)	14 (58.3)	59 (60.2)
Somewhat worse now than one year ago	3 (6.4)	2 (7.4)	4 (16.7)	9 (9.2)
Much worse now than one year ago	1 (2.1)	0	0	1 (1.0)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?				
YES, limited a lot	6 (12.8)	3 (11.1)	3 (12.5)	12 (12.2)
YES, limited a little	22 (46.8)	8 (29.6)	11 (45.8)	41 (41.8)
NO, NOT limited at all	13 (27.7)	15 (55.6)	7 (29.2)	35 (35.7)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf				
YES, limited a lot	2 (4.3)	0	0	2 (2.0)
YES, limited a little	9 (19.1)	8 (29.6)	10 (41.7)	27 (27.6)
NO, NOT limited at all	30 (63.8)	18 (66.7)	11 (45.8)	59 (60.2)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
Does your health now limit you in these activities? If so, how much?				
Lifting or carrying groceries				
YES, limited a lot	0	0	2 (8.3)	2 (2.0)
YES, limited a little	10 (21.3)	3 (11.1)	4 (16.7)	17 (17.3)
NO, NOT limited at all	31 (66.0)	23 (85.2)	15 (62.5)	69 (70.4)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much?				
Climbing several flights of stairs				
YES, limited a lot	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)
YES, limited a little	3 (6.4)	1 (3.7)	2 (8.3)	6 (6.1)
NO, NOT limited at all	37 (78.7)	23 (85.2)	17 (70.8)	77 (78.6)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much?				
Climbing one flight of stairs				
YES, limited a lot	1 (2.1)	1 (3.7)	0	2 (2.0)
YES, limited a little	0	2 (7.4)	2 (8.3)	4 (4.1)
NO, NOT limited at all	40 (85.1)	23 (85.2)	19 (79.2)	82 (83.7)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much?				
Bending, kneeling, or stooping				
YES, limited a lot	1 (2.1)	1 (3.7)	3 (12.5)	5 (5.1)
YES, limited a little	15 (31.9)	7 (25.9)	11 (45.8)	33 (33.7)
NO, NOT limited at all	25 (53.2)	18 (66.7)	7 (29.2)	50 (51.0)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care

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Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
Does your health now limit you in these activities? If so, how much?				
Walking more than a mile				
YES, limited a lot	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
YES, limited a little	4 (8.5)	2 (7.4)	1 (4.2)	7 (7.1)
NO, NOT limited at all	36 (76.6)	23 (85.2)	19 (79.2)	78 (79.6)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much?				
Walking several blocks				
YES, limited a lot	1 (2.1)	1 (3.7)	1 (4.2)	3 (3.1)
YES, limited a little	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
NO, NOT limited at all	37 (78.7)	23 (85.2)	19 (79.2)	79 (80.6)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much?				
Walking one block				
YES, limited a lot	0	1 (3.7)	0	1 (1.0)
YES, limited a little	1 (2.1)	2 (7.4)	1 (4.2)	4 (4.1)
NO, NOT limited at all	40 (85.1)	23 (85.2)	20 (83.3)	83 (84.7)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
Does your health now limit you in these activities? If so, how much?				
Bathing or dressing yourself				
YES, limited a lot	0	0	0	0
YES, limited a little	7 (14.9)	4 (14.8)	1 (4.2)	12 (12.2)
NO, NOT limited at all	34 (72.3)	22 (81.5)	20 (83.3)	76 (77.6)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

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Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities				
No	35 (74.5)	24 (88.9)	16 (66.7)	75 (76.5)
Yes	6 (12.8)	2 (7.4)	5 (20.8)	13 (13.3)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like				
No	35 (74.5)	23 (85.2)	17 (70.8)	75 (76.5)
Yes	6 (12.8)	3 (11.1)	4 (16.7)	13 (13.3)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities				
No	34 (72.3)	23 (85.2)	17 (70.8)	74 (75.5)
Yes	7 (14.9)	3 (11.1)	4 (16.7)	14 (14.3)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities				
No	35 (74.5)	24 (88.9)	14 (58.3)	73 (74.5)
Yes	6 (12.8)	2 (7.4)	7 (29.2)	15 (15.3)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care

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Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities				
No	39 (83.0)	22 (81.5)	18 (75.0)	79 (80.6)
Yes	2 (4.3)	4 (14.8)	3 (12.5)	9 (9.2)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like				
No	39 (83.0)	22 (81.5)	18 (75.0)	79 (80.6)
Yes	2 (4.3)	4 (14.8)	3 (12.5)	9 (9.2)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual				
No	39 (83.0)	24 (88.9)	16 (66.7)	79 (80.6)
Yes	2 (4.3)	2 (7.4)	5 (20.8)	9 (9.2)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?				
Not at all	30 (63.8)	18 (66.7)	15 (62.5)	63 (64.3)
Slightly	9 (19.1)	4 (14.8)	3 (12.5)	16 (16.3)
Moderately	0	4 (14.8)	0	4 (4.1)
Quite a bit	1 (2.1)	0	1 (4.2)	2 (2.0)
Extremely	1 (2.1)	0	2 (8.3)	3 (3.1)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
How much bodily pain have you had during the past 4 weeks?				
None	13 (27.7)	10 (37.0)	6 (25.0)	29 (29.6)
Very mild	11 (23.4)	7 (25.9)	6 (25.0)	24 (24.5)
Mild	10 (21.3)	3 (11.1)	1 (4.2)	14 (14.3)
Moderate	5 (10.6)	5 (18.5)	7 (29.2)	17 (17.3)
Severe	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Very severe	0	0	0	0
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?				
Not at all	16 (34.0)	17 (63.0)	11 (45.8)	44 (44.9)
A little bit	18 (38.3)	5 (18.5)	6 (25.0)	29 (29.6)
Moderately	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
Quite a bit	2 (4.3)	1 (3.7)	1 (4.2)	4 (4.1)
Extremely	0	0	1 (4.2)	1 (1.0)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you feel full of pep?				
All of the time	3 (6.4)	2 (7.4)	1 (4.2)	6 (6.1)
Most of the time	23 (48.9)	14 (51.9)	11 (45.8)	48 (49.0)
A good bit of the time	7 (14.9)	3 (11.1)	2 (8.3)	12 (12.2)
Some of the time	5 (10.6)	3 (11.1)	3 (12.5)	11 (11.2)
A little of the time	2 (4.3)	4 (14.8)	3 (12.5)	9 (9.2)
None of the time	0	0	1 (4.2)	1 (1.0)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you been a very nervous person?				
All of the time	0	0	0	0
Most of the time	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)
A good bit of the time	1 (2.1)	1 (3.7)	0	2 (2.0)
Some of the time	9 (19.1)	3 (11.1)	5 (20.8)	17 (17.3)
A little of the time	19 (40.4)	11 (40.7)	5 (20.8)	35 (35.7)
None of the time	10 (21.3)	9 (33.3)	9 (37.5)	28 (28.6)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
How much of the time during the past 4 weeks....Have you felt so down in the dumps that nothing could cheer you up?				
All of the time	0	0	0	0
Most of the time	0	0	1 (4.2)	1 (1.0)
A good bit of the time	3 (6.4)	3 (11.1)	1 (4.2)	7 (7.1)
Some of the time	2 (4.3)	3 (11.1)	0	5 (5.1)
A little of the time	11 (23.4)	6 (22.2)	5 (20.8)	22 (22.4)
None of the time	24 (51.1)	14 (51.9)	14 (58.3)	52 (53.1)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?				
All of the time	4 (8.5)	4 (14.8)	3 (12.5)	11 (11.2)
Most of the time	21 (44.7)	9 (33.3)	9 (37.5)	39 (39.8)
A good bit of the time	8 (17.0)	6 (22.2)	2 (8.3)	16 (16.3)
Some of the time	4 (8.5)	3 (11.1)	5 (20.8)	12 (12.2)
A little of the time	2 (4.3)	4 (14.8)	2 (8.3)	8 (8.2)
None of the time	1 (2.1)	0	0	1 (1.0)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group
Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?				
All of the time	3 (6.4)	3 (11.1)	3 (12.5)	9 (9.2)
Most of the time	16 (34.0)	11 (40.7)	7 (29.2)	34 (34.7)
A good bit of the time	12 (25.5)	6 (22.2)	3 (12.5)	21 (21.4)
Some of the time	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
A little of the time	3 (6.4)	5 (18.5)	3 (12.5)	11 (11.2)
None of the time	0	0	2 (8.3)	2 (2.0)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?				
All of the time	0	1 (3.7)	0	1 (1.0)
Most of the time	0	1 (3.7)	1 (4.2)	2 (2.0)
A good bit of the time	3 (6.4)	2 (7.4)	0	5 (5.1)
Some of the time	4 (8.5)	3 (11.1)	4 (16.7)	11 (11.2)
A little of the time	17 (36.2)	7 (25.9)	5 (20.8)	29 (29.6)
None of the time	16 (34.0)	12 (44.4)	11 (45.8)	39 (39.8)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	0	3 (11.1)	2 (8.3)	5 (5.1)
A good bit of the time	6 (12.8)	1 (3.7)	0	7 (7.1)
Some of the time	12 (25.5)	8 (29.6)	4 (16.7)	24 (24.5)
A little of the time	16 (34.0)	7 (25.9)	9 (37.5)	32 (32.7)
None of the time	6 (12.8)	7 (25.9)	5 (20.8)	18 (18.4)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Have you been a happy person?				
All of the time	5 (10.6)	4 (14.8)	4 (16.7)	13 (13.3)
Most of the time	18 (38.3)	10 (37.0)	9 (37.5)	37 (37.8)
A good bit of the time	12 (25.5)	5 (18.5)	1 (4.2)	18 (18.4)
Some of the time	4 (8.5)	5 (18.5)	5 (20.8)	14 (14.3)
A little of the time	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)
None of the time	0	0	0	0
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks... Did you feel tired?				
All of the time	0	1 (3.7)	1 (4.2)	2 (2.0)
Most of the time	1 (2.1)	2 (7.4)	2 (8.3)	5 (5.1)
A good bit of the time	5 (10.6)	4 (14.8)	1 (4.2)	10 (10.2)
Some of the time	20 (42.6)	9 (33.3)	10 (41.7)	39 (39.8)
A little of the time	13 (27.7)	7 (25.9)	6 (25.0)	26 (26.5)
None of the time	1 (2.1)	3 (11.1)	1 (4.2)	5 (5.1)
Missing	7 (14.9)	1 (3.7)	3 (12.5)	11 (11.2)
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?				
All of the time	0	0	1 (4.2)	1 (1.0)
Most of the time	1 (2.1)	0	1 (4.2)	2 (2.0)
Some of the time	5 (10.6)	6 (22.2)	3 (12.5)	14 (14.3)
A little of the time	9 (19.1)	5 (18.5)	3 (12.5)	17 (17.3)
None of the time	26 (55.3)	15 (55.6)	13 (54.2)	54 (55.1)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.1: Frequencies of SF-36 items - full analysis set

Visit Parameter	Number (%) of subjects			
	NDplus (N=47)	NDbasic (N=27)	SC (N=24)	Overall (N=98)
End of Trial (continued)				
How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people				
Definitely true	0	0	0	0
Mostly true	1 (2.1)	1 (3.7)	2 (8.3)	4 (4.1)
Don't know	7 (14.9)	4 (14.8)	2 (8.3)	13 (13.3)
Mostly false	13 (27.7)	5 (18.5)	5 (20.8)	23 (23.5)
Definitely false	20 (42.6)	16 (59.3)	12 (50.0)	48 (49.0)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know				
Definitely true	13 (27.7)	9 (33.3)	6 (25.0)	28 (28.6)
Mostly true	15 (31.9)	12 (44.4)	10 (41.7)	37 (37.8)
Don't know	3 (6.4)	2 (7.4)	2 (8.3)	7 (7.1)
Mostly false	7 (14.9)	2 (7.4)	2 (8.3)	11 (11.2)
Definitely false	3 (6.4)	1 (3.7)	1 (4.2)	5 (5.1)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse				
Definitely true	1 (2.1)	0	0	1 (1.0)
Mostly true	4 (8.5)	3 (11.1)	2 (8.3)	9 (9.2)
Don't know	2 (4.3)	3 (11.1)	4 (16.7)	9 (9.2)
Mostly false	11 (23.4)	7 (25.9)	7 (29.2)	25 (25.5)
Definitely false	23 (48.9)	13 (48.1)	8 (33.3)	44 (44.9)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)
How TRUE or FALSE is each of the following statements for you?... My health is excellent				
Definitely true	11 (23.4)	5 (18.5)	4 (16.7)	20 (20.4)
Mostly true	23 (48.9)	17 (63.0)	8 (33.3)	48 (49.0)
Don't know	3 (6.4)	0	3 (12.5)	6 (6.1)
Mostly false	2 (4.3)	4 (14.8)	4 (16.7)	10 (10.2)
Definitely false	2 (4.3)	0	2 (8.3)	4 (4.1)
Missing	6 (12.8)	1 (3.7)	3 (12.5)	10 (10.2)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:42 / sf36t.lst / hrqlt.sas

Table 14.2.8.2.1: Summary of SF-36 domain score 'physical functioning' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Physical Functioning Score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	31.06	30.31	29.93			
	SD	9.104	8.012	9.563			
	Min	15.19	15.19	15.19			
	25% quantile	23.58	24.52	22.54			
	Median	29.88	31.97	30.93			
	75% quantile	36.17	36.17	37.22			
	Max	52.95	44.56	44.56			
Visit 3a*							
	N with data	47	27	-	47	27	-
	Mean	45.72	48.68	-	14.66	18.37	-
	SD	6.843	5.723	-	10.900	8.360	-
	Min	27.78	34.07	-	-6.29	4.19	-
	25% quantile	42.46	44.56	-	6.29	12.58	-
	Median	46.66	48.75	-	14.68	18.88	-
	75% quantile	50.85	52.95	-	25.17	23.07	-
	Max	55.05	57.14	-	33.56	37.75	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	48.18	49.53	41.76	17.00	19.22	11.84
	SD	7.720	6.763	7.231	12.337	8.902	8.207
	Min	21.49	34.07	29.88	-14.68	2.10	-14.68
	25% quantile	44.56	46.66	37.22	9.56	12.58	7.34
	Median	50.85	48.75	40.36	18.88	18.88	14.10
	75% quantile	52.95	55.05	48.75	27.27	25.17	15.73
	Max	57.14	57.14	55.05	35.66	37.75	27.27

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf1.lst / hrql.sas

Table 14.2.8.2.1: Summary of SF-36 domain score 'physical functioning' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Physical Functioning Score (continued)							
Visit 5							
	N with data	46	27	23	46	27	23
	N missing	1	0	1	1	0	1
	Mean	49.97	51.71	46.84	19.02	21.40	16.36
	SD	7.164	7.810	8.121	11.363	10.558	10.009
	Min	31.97	27.78	25.68	-8.39	-2.10	-18.88
	25% quantile	46.66	50.85	40.36	12.58	14.68	10.49
	Median	52.95	55.05	50.85	19.46	23.07	18.88
	75% quantile	55.05	57.14	52.95	29.36	29.36	23.07
	Max	57.14	57.14	57.14	35.66	41.95	31.46
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	51.40	52.27	49.94	20.23	22.51	19.47
	SD	6.198	7.353	6.567	10.753	10.968	9.983
	Min	34.07	29.88	36.17	-10.49	-2.10	-8.39
	25% quantile	48.75	50.85	46.66	12.58	16.78	12.58
	Median	55.05	55.05	52.95	19.93	24.55	18.88
	75% quantile	55.05	57.14	55.05	28.43	29.36	27.27
	Max	57.14	57.14	57.14	39.85	41.95	37.75
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	52.26	52.30	51.80	21.09	22.54	20.71
	SD	5.661	6.732	6.255	10.553	11.159	10.484
	Min	31.97	31.97	38.27	-6.29	0	-4.19
	25% quantile	50.85	50.85	47.71	12.58	14.68	14.68
	Median	52.95	54.00	55.05	20.97	23.97	22.02
	75% quantile	57.14	57.14	57.14	31.46	31.46	27.27
	Max	57.14	57.14	57.14	37.75	41.95	37.75

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.1: Summary of SF-36 domain score 'physical functioning' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Physical Functioning Score (continued)							
Visit 8							
	N with data	44	26	22	44	26	22
	N missing	3	1	2	3	1	2
	Mean	51.89	52.67	51.06	20.94	22.91	20.18
	SD	6.530	7.660	6.269	10.350	11.059	9.777
	Min	27.78	26.85	38.27	-6.29	-5.13	2.10
	25% quantile	48.75	52.95	46.66	15.73	14.68	12.58
	Median	55.05	55.05	52.95	20.97	25.17	22.02
	75% quantile	57.14	57.14	57.14	27.62	31.46	27.27
	Max	57.14	57.14	57.14	41.95	41.95	39.85
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	51.12	50.21	50.65	19.38	20.44	19.02
	SD	8.085	8.406	7.501	11.229	11.691	8.769
	Min	23.58	29.88	34.07	-10.49	-2.10	2.10
	25% quantile	50.85	40.36	48.75	14.68	12.58	14.68
	Median	55.05	54.00	52.95	18.88	19.93	18.88
	75% quantile	57.14	57.14	57.14	27.27	29.36	25.17
	Max	57.14	57.14	57.14	41.95	41.95	39.85
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	50.95	51.34	49.52	19.32	21.57	18.63
	SD	7.430	7.966	8.303	11.618	12.166	8.593
	Min	23.58	29.88	27.78	-6.29	-2.10	4.19
	25% quantile	46.66	48.75	44.56	12.58	14.68	12.58
	Median	55.05	55.05	51.90	18.88	22.02	16.78
	75% quantile	57.14	57.14	57.14	31.46	31.46	23.07
	Max	57.14	57.14	57.14	41.95	41.95	39.85

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf1.lst / hrql.sas

Table 14.2.8.2.1: Summary of SF-36 domain score 'physical functioning' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Physical Functioning Score (continued)							
End of Trial	N with data	41	26	21	41	26	21
	N missing	6	1	3	6	1	3
	Mean	52.03	52.39	50.35	20.24	22.62	18.72
	SD	6.432	8.339	7.957	10.862	11.856	8.806
	Min	27.78	27.78	25.68	-6.29	-6.29	2.10
	25% quantile	50.85	52.95	48.75	14.68	16.78	14.68
	Median	55.05	55.05	52.95	20.97	25.17	18.88
	75% quantile	55.05	57.14	57.14	29.36	31.46	25.17
	Max	57.14	57.14	57.14	41.95	41.95	33.56

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf1.lst / hrql.sas

Table 14.2.8.2.2: Summary of SF-36 domain score 'role limitations due to health problems' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Role Physical Score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	52.78	53.62	53.69			
	SD	6.897	6.249	6.914			
	Min	27.95	27.95	27.95			
	25% quantile	49.17	56.24	56.24			
	Median	56.24	56.24	56.24			
	75% quantile	56.24	56.24	56.24			
	Max	56.24	56.24	56.24			
Visit 3a*							
	N with data	47	27	-	47	27	-
	Mean	43.75	42.88	-	-9.03	-10.74	-
	SD	11.348	12.145	-	12.660	15.241	-
	Min	27.95	27.95	-	-28.29	-28.29	-
	25% quantile	35.03	27.95	-	-21.22	-28.29	-
	Median	49.17	49.17	-	-7.07	-7.07	-
	75% quantile	56.24	56.24	-	0	0	-
	Max	56.24	56.24	-	28.29	28.29	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	38.25	40.26	51.23	-14.76	-13.36	-2.46
	SD	11.424	12.951	8.205	12.636	14.722	11.538
	Min	27.95	27.95	27.95	-28.29	-28.29	-28.29
	25% quantile	27.95	27.95	45.63	-28.29	-28.29	-7.07
	Median	35.03	35.03	56.24	-17.68	-14.14	0
	75% quantile	49.17	56.24	56.24	0	0	0
	Max	56.24	56.24	56.24	21.22	14.14	28.29

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf2.lst / hrql.sas

Table 14.2.8.2.2: Summary of SF-36 domain score 'role limitations due to health problems' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Role Physical Score (continued)							
Visit 5							
	N with data	45	27	22	45	27	22
	N missing	2	0	2	2	0	2
	Mean	36.44	33.19	38.24	-16.35	-20.43	-15.22
	SD	10.726	9.923	12.099	13.043	11.824	12.783
	Min	27.95	27.95	27.95	-28.29	-28.29	-28.29
	25% quantile	27.95	27.95	27.95	-28.29	-28.29	-28.29
	Median	27.95	27.95	35.03	-21.22	-28.29	-21.22
	75% quantile	49.17	35.03	56.24	-7.07	-14.14	0
	Max	56.24	56.24	56.24	21.22	7.07	4.71
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	35.95	32.58	35.33	-17.07	-21.22	-18.24
	SD	10.711	8.234	10.550	12.074	9.800	12.739
	Min	27.95	27.95	27.95	-28.29	-28.29	-28.29
	25% quantile	27.95	27.95	27.95	-28.29	-28.29	-28.29
	Median	27.95	27.95	27.95	-21.22	-28.29	-28.29
	75% quantile	42.10	35.03	42.10	-7.07	-14.14	-7.07
	Max	56.24	56.24	56.24	21.22	0	7.07
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	33.95	32.85	35.73	-19.06	-20.95	-17.45
	SD	10.433	8.894	11.901	11.728	10.486	12.785
	Min	27.95	27.95	27.95	-28.29	-28.29	-28.29
	25% quantile	27.95	27.95	27.95	-28.29	-28.29	-28.29
	Median	27.95	27.95	27.95	-24.75	-28.29	-24.75
	75% quantile	35.03	35.03	45.63	-14.14	-14.14	0
	Max	56.24	56.24	56.24	14.14	7.07	0

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf2.lst / hrql.sas

Table 14.2.8.2.2: Summary of SF-36 domain score 'role limitations due to health problems' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Role Physical Score (continued)							
Visit 8							
	N with data	44	26	22	44	26	22
	N missing	3	1	2	3	1	2
	Mean	33.42	33.67	35.67	-19.61	-20.13	-17.79
	SD	10.552	10.960	11.110	11.899	12.761	12.968
	Min	27.95	27.95	27.95	-28.29	-28.29	-28.29
	25% quantile	27.95	27.95	27.95	-28.29	-28.29	-28.29
	Median	27.95	27.95	27.95	-28.29	-28.29	-24.75
	75% quantile	31.49	27.95	49.17	-10.61	-7.07	-7.07
	Max	56.24	56.24	56.24	7.07	7.07	11.79
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	34.69	36.39	33.01	-18.02	-17.41	-20.32
	SD	11.150	12.005	9.785	12.418	13.153	12.987
	Min	27.95	27.95	27.95	-28.29	-28.29	-28.29
	25% quantile	27.95	27.95	27.95	-28.29	-28.29	-28.29
	Median	27.95	27.95	27.95	-21.22	-24.75	-28.29
	75% quantile	42.10	49.17	27.95	-7.07	-7.07	-14.14
	Max	56.24	56.24	56.24	21.22	7.07	11.79
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	35.37	35.30	37.60	-17.42	-18.50	-15.86
	SD	10.720	10.294	12.259	11.415	11.847	13.788
	Min	27.95	27.95	27.95	-28.29	-28.29	-28.29
	25% quantile	27.95	27.95	27.95	-28.29	-28.29	-28.29
	Median	27.95	27.95	27.95	-21.22	-24.75	-24.75
	75% quantile	35.03	42.10	49.17	-7.07	-7.07	0
	Max	56.24	56.24	56.24	0	7.07	4.71

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf2.lst / hrql.sas

Table 14.2.8.2.2: Summary of SF-36 domain score 'role limitations due to health problems' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Role Physical Score (continued)							
End of Trial							
	N with data	41	26	21	41	26	21
	N missing	6	1	3	6	1	3
	Mean	32.27	30.67	34.69	-20.35	-23.12	-18.64
	SD	8.929	8.021	10.364	10.979	10.309	12.517
	Min	27.95	27.95	27.95	-28.29	-28.29	-28.29
	25% quantile	27.95	27.95	27.95	-28.29	-28.29	-28.29
	Median	27.95	27.95	27.95	-28.29	-28.29	-28.29
	75% quantile	27.95	27.95	42.10	-14.14	-21.22	-7.07
	Max	56.24	56.24	56.24	7.07	7.07	4.71

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.3: Summary of SF-36 domain score 'role limitations due to emotional problems' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Role Emotional Score							
Baseline (Visit 2a)							
	N with data	46	26	24			
	N missing	1	1	0			
	Mean	34.73	35.08	36.90			
	SD	14.039	12.962	14.979			
	Min	23.74	23.74	23.74			
	25% quantile	23.74	23.74	23.74			
	Median	23.74	29.00	29.00			
	75% quantile	55.34	44.81	55.34			
	Max	55.34	55.34	55.34			
Visit 3a*							
	N with data	47	27	-	46	26	-
	N missing	0	0	-	1	1	-
	Mean	30.01	31.54	-	-4.58	-3.24	-
	SD	11.553	11.537	-	15.006	8.824	-
	Min	23.74	23.74	-	-31.60	-21.07	-
	25% quantile	23.74	23.74	-	-10.53	0	-
	Median	23.74	23.74	-	0	0	-
	75% quantile	34.27	44.81	-	0	0	-
	Max	55.34	55.34	-	21.07	10.53	-
Visit 4							
	N with data	46	27	24	45	26	24
	N missing	1	0	0	2	1	0
	Mean	29.00	32.71	38.22	-5.85	-2.03	1.32
	SD	10.358	13.612	14.509	17.478	15.199	13.652
	Min	23.74	23.74	23.74	-31.60	-21.07	-31.60
	25% quantile	23.74	23.74	23.74	-21.07	-10.53	0
	Median	23.74	23.74	34.27	0	0	0
	75% quantile	34.27	44.81	55.34	0	0	0
	Max	55.34	55.34	55.34	31.60	31.60	31.60

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf3.lst / hrql.sas

Table 14.2.8.2.3: Summary of SF-36 domain score 'role limitations due to emotional problems' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Role Emotional Score (continued)							
Visit 5							
	N with data	46	27	23	45	26	23
	N missing	1	0	1	2	1	1
	Mean	28.09	26.86	31.98	-6.79	-8.10	-5.50
	SD	10.074	8.168	13.080	17.275	15.853	13.798
	Min	23.74	23.74	23.74	-31.60	-31.60	-31.60
	25% quantile	23.74	23.74	23.74	-21.07	-21.07	-10.53
	Median	23.74	23.74	23.74	0	0	0
	75% quantile	23.74	23.74	44.81	0	0	0
	Max	55.34	55.34	55.34	31.60	31.60	21.07
Visit 6							
	N with data	46	26	23	45	25	23
	N missing	1	1	1	2	2	1
	Mean	27.40	27.38	28.77	-7.49	-8.01	-8.70
	SD	8.664	9.395	11.395	16.751	16.172	12.962
	Min	23.74	23.74	23.74	-31.60	-31.60	-31.60
	25% quantile	23.74	23.74	23.74	-21.07	-21.07	-10.53
	Median	23.74	23.74	23.74	0	0	0
	75% quantile	23.74	23.74	23.74	0	0	0
	Max	55.34	55.34	55.34	31.60	31.60	0
Visit 7							
	N with data	46	26	20	45	25	20
	N missing	1	1	4	2	2	4
	Mean	28.09	26.17	29.53	-7.02	-9.27	-6.85
	SD	9.826	7.483	11.578	17.685	13.709	13.358
	Min	23.74	23.74	23.74	-31.60	-31.60	-31.60
	25% quantile	23.74	23.74	23.74	-21.07	-21.07	-10.53
	Median	23.74	23.74	23.74	0	0	0
	75% quantile	23.74	23.74	29.00	0	0	0
	Max	55.34	55.34	55.34	31.60	21.07	10.53

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

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Table 14.2.8.2.3: Summary of SF-36 domain score 'role limitations due to emotional problems' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Role Emotional Score (continued)							
Visit 8							
	N with data	44	26	22	43	25	22
	N missing	3	1	2	4	2	2
	Mean	28.05	30.22	29.48	-6.37	-5.06	-8.62
	SD	9.986	11.570	10.648	18.122	15.837	14.035
	Min	23.74	23.74	23.74	-31.60	-31.60	-31.60
	25% quantile	23.74	23.74	23.74	-31.60	-10.53	-10.53
	Median	23.74	23.74	23.74	0	0	0
	75% quantile	23.74	34.27	34.27	0	0	0
	Max	55.34	55.34	55.34	31.60	31.60	10.53
Visit 9							
	N with data	42	25	21	42	24	21
	N missing	5	2	3	5	3	3
	Mean	28.00	31.74	26.24	-5.52	-2.63	-11.04
	SD	10.158	11.888	7.378	14.941	14.320	15.438
	Min	23.74	23.74	23.74	-31.60	-31.60	-31.60
	25% quantile	23.74	23.74	23.74	-21.07	-10.53	-31.60
	Median	23.74	23.74	23.74	0	0	0
	75% quantile	23.74	44.81	23.74	0	0	0
	Max	55.34	55.34	55.34	21.07	31.60	10.53
Visit 10							
	N with data	41	26	22	41	25	22
	N missing	6	1	2	6	2	2
	Mean	29.13	29.41	30.92	-4.11	-5.90	-7.18
	SD	10.826	10.838	13.556	16.802	15.230	14.679
	Min	23.74	23.74	23.74	-31.60	-31.60	-31.60
	25% quantile	23.74	23.74	23.74	-10.53	-21.07	-10.53
	Median	23.74	23.74	23.74	0	0	0
	75% quantile	23.74	34.27	23.74	0	0	0
	Max	55.34	55.34	55.34	31.60	21.07	21.07

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf3.lst / hrql.sas

Table 14.2.8.2.3: Summary of SF-36 domain score 'role limitations due to emotional problems' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Role Emotional Score (continued)							
End of Trial							
	N with data	41	26	21	41	25	21
	N missing	6	1	3	6	2	3
	Mean	25.28	27.79	29.25	-8.48	-7.58	-8.03
	SD	6.034	9.917	11.356	14.563	15.059	14.485
	Min	23.74	23.74	23.74	-31.60	-31.60	-31.60
	25% quantile	23.74	23.74	23.74	-21.07	-21.07	-10.53
	Median	23.74	23.74	23.74	0	0	0
	75% quantile	23.74	23.74	23.74	0	0	0
	Max	55.34	55.34	55.34	21.07	21.07	10.53

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.4: Summary of SF-36 domain score 'vitality' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Vitality Score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	39.23	39.59	36.43			
	SD	8.213	9.260	9.737			
	Min	25.39	20.65	18.29			
	25% quantile	32.49	32.49	31.30			
	Median	39.59	39.59	36.04			
	75% quantile	44.32	46.69	41.95			
	Max	56.15	58.52	51.42			
Visit 3a*							
	N with data	46	27	-	46	27	-
	N missing	1	0	-	1	0	-
	Mean	47.41	49.32	-	8.13	9.73	-
	SD	8.451	7.803	-	8.299	7.858	-
	Min	23.02	32.49	-	-9.47	-7.10	-
	25% quantile	41.95	44.32	-	2.37	2.37	-
	Median	46.69	49.05	-	7.10	11.83	-
	75% quantile	53.79	56.15	-	11.83	16.57	-
	Max	60.89	60.89	-	28.40	21.30	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	49.12	49.67	42.94	9.74	10.08	6.51
	SD	7.404	10.432	9.177	9.691	9.749	8.265
	Min	30.12	25.39	23.02	-23.67	-4.73	-11.83
	25% quantile	46.69	41.95	37.22	4.73	2.37	0
	Median	50.24	51.42	45.50	9.47	11.83	7.10
	75% quantile	53.79	56.15	49.05	16.57	14.20	13.02
	Max	63.25	65.62	58.52	33.13	35.50	21.30

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.4: Summary of SF-36 domain score 'vitality' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Vitality Score (continued)							
Visit 5							
	N with data	46	27	23	46	27	23
	N missing	1	0	1	1	0	1
	Mean	50.29	50.81	47.82	11.01	11.22	10.80
	SD	7.446	9.902	9.107	9.843	10.032	7.779
	Min	32.49	30.12	27.75	-9.47	-4.73	-11.83
	25% quantile	46.69	41.95	44.32	4.73	2.37	7.10
	Median	50.24	53.79	49.05	9.47	9.47	11.83
	75% quantile	56.15	56.15	56.15	16.57	18.93	16.57
	Max	65.62	65.62	58.52	33.13	33.13	23.67
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	48.87	52.24	48.33	9.48	12.74	11.32
	SD	8.182	8.623	12.056	9.246	9.539	9.678
	Min	25.39	37.22	23.02	-14.20	-2.37	-14.20
	25% quantile	41.95	44.32	41.95	4.73	4.73	4.73
	Median	51.42	54.97	53.79	7.10	11.83	11.83
	75% quantile	56.15	56.15	56.15	16.57	21.30	16.57
	Max	63.25	65.62	65.62	30.77	30.77	28.40
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	50.44	51.97	46.81	11.06	12.47	8.76
	SD	8.146	8.369	11.733	10.177	9.782	10.305
	Min	30.12	32.49	25.39	-14.20	-4.73	-14.20
	25% quantile	46.69	46.69	40.77	4.73	4.73	3.55
	Median	51.42	53.79	51.42	9.47	13.02	8.28
	75% quantile	56.15	58.52	53.79	18.93	21.30	14.20
	Max	65.62	63.25	60.89	37.87	28.40	26.03

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.4: Summary of SF-36 domain score 'vitality' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Vitality Score (continued)							
Visit 8							
	N with data	44	26	22	44	26	22
	N missing	3	1	2	3	1	2
	Mean	51.26	49.87	45.61	11.73	10.38	8.39
	SD	8.236	11.220	10.552	8.766	12.929	9.487
	Min	25.39	25.39	20.65	-9.47	-23.67	-18.93
	25% quantile	47.87	41.95	39.59	4.73	0	4.73
	Median	53.79	53.79	50.24	11.83	11.83	8.28
	75% quantile	56.15	56.15	53.79	18.93	18.93	11.83
	Max	63.25	65.62	56.15	28.40	30.77	30.77
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	48.81	47.51	46.91	9.34	8.01	9.02
	SD	8.560	11.574	11.855	10.549	11.302	11.242
	Min	25.39	27.75	20.65	-18.93	-16.57	-18.93
	25% quantile	41.95	37.22	39.59	2.37	2.37	4.73
	Median	50.24	49.05	49.05	8.28	9.47	9.47
	75% quantile	53.79	56.15	56.15	18.93	14.20	14.20
	Max	65.62	65.62	63.25	37.87	30.77	30.77
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	47.44	47.87	45.18	7.91	8.37	7.96
	SD	8.909	10.135	11.857	10.338	10.984	10.773
	Min	25.39	27.75	18.29	-9.47	-21.30	-9.47
	25% quantile	39.59	41.95	37.22	2.37	2.37	2.37
	Median	49.05	46.69	44.32	4.73	9.47	7.10
	75% quantile	53.79	56.15	56.15	11.83	16.57	16.57
	Max	60.89	65.62	63.25	33.13	28.40	30.77

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf4.lst / hrql.sas

Table 14.2.8.2.4: Summary of SF-36 domain score 'vitality' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Vitality Score (continued)							
End of Trial							
	N with data	40	26	21	40	26	21
	N missing	7	1	3	7	1	3
	Mean	50.24	49.33	47.93	10.18	9.83	10.03
	SD	7.110	10.986	12.012	8.375	12.625	10.475
	Min	32.49	25.39	18.29	-4.73	-16.57	-14.20
	25% quantile	46.69	39.59	44.32	4.73	2.37	4.73
	Median	51.42	51.42	51.42	9.47	11.83	7.10
	75% quantile	56.15	58.52	56.15	14.20	18.93	18.93
	Max	60.89	65.62	65.62	33.13	30.77	26.03

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.5: Summary of SF-36 domain score 'mental health' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Mental Health Score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	37.30	38.50	37.10			
	SD	9.925	10.704	12.286			
	Min	14.09	18.64	16.37			
	25% quantile	27.73	30.00	28.86			
	Median	36.81	39.08	36.81			
	75% quantile	43.63	48.17	48.17			
	Max	54.99	54.99	57.26			
Visit 3a*							
	N with data	46	27	-	46	27	-
	N missing	1	0	-	1	0	-
	Mean	46.39	46.28	-	8.89	7.78	-
	SD	8.445	9.705	-	8.632	8.992	-
	Min	23.18	16.37	-	-11.36	-6.82	-
	25% quantile	41.36	41.36	-	2.27	1.14	-
	Median	48.17	45.90	-	6.82	6.82	-
	75% quantile	52.72	54.99	-	15.90	13.63	-
	Max	59.53	57.26	-	29.53	24.99	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	47.18	44.97	42.89	9.88	6.48	5.80
	SD	8.630	11.381	10.287	9.853	9.917	8.589
	Min	25.45	16.37	18.64	-9.09	-11.36	-6.82
	25% quantile	41.36	39.08	34.54	2.27	-2.27	0
	Median	48.17	48.17	45.05	9.09	4.54	3.41
	75% quantile	52.72	52.72	50.44	18.17	15.90	11.36
	Max	59.53	59.53	54.99	27.26	24.99	27.83

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.5: Summary of SF-36 domain score 'mental health' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Mental Health Score (continued)							
Visit 5							
	N with data	46	27	23	46	27	23
	N missing	1	0	1	1	0	1
	Mean	47.53	46.57	46.00	9.98	8.08	8.99
	SD	8.428	10.910	8.944	9.856	11.207	8.865
	Min	23.18	25.45	25.45	-9.09	-9.09	-4.54
	25% quantile	43.63	36.81	43.63	2.27	0	2.27
	Median	48.17	48.17	50.44	6.82	4.54	6.82
	75% quantile	52.72	54.99	52.72	15.90	18.17	15.90
	Max	59.53	59.53	54.99	31.81	29.53	29.53
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	46.89	48.17	45.50	9.58	9.79	8.49
	SD	8.137	8.254	12.549	10.655	9.591	9.170
	Min	20.91	25.45	11.82	-22.72	-9.09	-9.09
	25% quantile	41.36	43.63	41.36	2.27	4.54	2.27
	Median	48.17	50.44	50.44	6.82	7.95	9.09
	75% quantile	52.72	54.99	54.99	18.17	18.17	13.63
	Max	59.53	59.53	59.53	27.26	27.26	34.08
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	47.68	47.04	45.33	10.37	8.65	7.04
	SD	9.137	11.190	13.162	10.939	11.405	12.132
	Min	23.18	18.64	9.55	-20.45	-20.45	-13.63
	25% quantile	43.63	41.36	39.08	4.54	0	-1.14
	Median	50.44	52.72	52.72	9.09	9.09	5.68
	75% quantile	52.72	54.99	53.85	20.45	18.17	14.77
	Max	59.53	59.53	57.26	29.53	24.99	31.81

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.5: Summary of SF-36 domain score 'mental health' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Mental Health Score (continued)							
Visit 8							
	N with data	44	26	22	44	26	22
	N missing	3	1	2	3	1	2
	Mean	46.98	44.24	45.80	9.29	5.85	8.47
	SD	10.796	13.472	10.962	11.767	13.093	10.332
	Min	7.28	14.09	16.37	-20.45	-31.81	-4.54
	25% quantile	43.63	39.08	43.63	2.27	0	0
	Median	50.44	48.17	50.44	9.09	7.95	4.54
	75% quantile	54.99	54.99	52.72	18.17	13.63	15.90
	Max	59.53	59.53	57.26	29.53	24.99	34.08
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	46.55	42.23	45.36	8.55	3.84	7.25
	SD	10.444	14.398	12.627	12.144	11.309	11.840
	Min	16.37	14.09	9.55	-27.26	-24.99	-9.09
	25% quantile	43.63	30.00	39.08	2.27	0	-2.27
	Median	48.17	47.04	50.44	5.68	4.54	6.82
	75% quantile	54.99	54.99	54.99	18.17	9.09	13.63
	Max	59.53	59.53	57.26	29.53	22.72	34.08
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	46.79	45.11	44.66	8.48	6.73	7.33
	SD	9.743	11.073	11.364	10.620	10.876	10.445
	Min	14.09	16.37	20.91	-13.63	-29.53	-6.82
	25% quantile	43.63	39.08	39.08	0	2.27	0
	Median	48.17	45.90	48.17	9.09	7.95	6.82
	75% quantile	52.72	54.99	54.99	15.90	13.63	13.63
	Max	59.53	59.53	57.26	29.53	24.99	31.81

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

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Table 14.2.8.2.5: Summary of SF-36 domain score 'mental health' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Mental Health Score (continued)							
End of Trial							
	N with data	40	26	21	40	26	21
	N missing	7	1	3	7	1	3
	Mean	46.92	45.03	46.33	8.35	6.64	8.22
	SD	8.562	11.568	12.247	9.561	11.968	10.373
	Min	23.18	18.64	18.64	-9.09	-27.26	-6.82
	25% quantile	42.49	39.08	39.08	3.41	-2.27	2.27
	Median	48.17	47.04	50.44	6.82	6.82	6.82
	75% quantile	51.58	52.72	54.99	13.63	15.90	13.63
	Max	59.53	59.53	59.53	29.53	24.99	31.81

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.6: Summary of SF-36 domain score 'social functioning' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Social Functioning Score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	41.78	39.24	37.69			
	SD	10.993	9.380	13.385			
	Min	19.14	13.71	13.71			
	25% quantile	35.42	35.42	30.00			
	Median	40.85	40.85	38.14			
	75% quantile	51.71	46.28	48.99			
	Max	57.14	57.14	57.14			
Visit 3a*							
	N with data	47	27	-	47	27	-
	Mean	50.55	49.10	-	8.78	9.85	-
	SD	8.157	9.080	-	8.952	10.435	-
	Min	24.57	24.57	-	-5.43	-16.28	-
	25% quantile	46.28	40.85	-	0	5.43	-
	Median	51.71	51.71	-	5.43	10.86	-
	75% quantile	57.14	57.14	-	16.28	16.28	-
	Max	57.14	57.14	-	38.00	32.57	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	51.83	50.30	43.79	10.27	11.06	6.11
	SD	7.007	8.982	11.203	10.377	10.374	11.905
	Min	35.42	30.00	24.57	-16.28	-10.86	-21.71
	25% quantile	46.28	40.85	35.42	5.43	0	0
	Median	57.14	57.14	40.85	10.86	10.86	5.43
	75% quantile	57.14	57.14	57.14	16.28	16.28	10.86
	Max	57.14	57.14	57.14	38.00	32.57	38.00

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf6.lst / hrql.sas

Table 14.2.8.2.6: Summary of SF-36 domain score 'social functioning' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Social Functioning Score (continued)							
Visit 5							
	N with data	46	27	23	46	27	23
	N missing	1	0	1	1	0	1
	Mean	52.42	53.32	50.06	10.62	14.07	12.04
	SD	7.643	6.354	9.464	11.498	9.902	12.778
	Min	24.57	35.42	24.57	-10.86	-5.43	-10.86
	25% quantile	46.28	51.71	46.28	5.43	5.43	0
	Median	57.14	57.14	51.71	5.43	10.86	10.86
	75% quantile	57.14	57.14	57.14	21.71	21.71	21.71
	Max	57.14	57.14	57.14	38.00	38.00	38.00
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	52.18	53.17	51.94	10.62	13.99	13.92
	SD	7.576	7.609	7.930	11.780	8.572	12.446
	Min	35.42	30.00	35.42	-16.28	-5.43	0
	25% quantile	46.28	51.71	46.28	5.43	10.86	5.43
	Median	57.14	57.14	57.14	8.14	16.28	10.86
	75% quantile	57.14	57.14	57.14	16.28	16.28	16.28
	Max	57.14	57.14	57.14	38.00	32.57	43.43
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	53.24	53.59	50.62	11.68	14.41	12.49
	SD	7.562	7.192	10.359	11.780	9.581	15.262
	Min	24.57	30.00	19.14	-16.28	-5.43	-10.86
	25% quantile	51.71	51.71	43.57	0	10.86	0
	Median	57.14	57.14	57.14	10.86	13.57	8.14
	75% quantile	57.14	57.14	57.14	16.28	21.71	21.71
	Max	57.14	57.14	57.14	38.00	38.00	43.43

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.6: Summary of SF-36 domain score 'social functioning' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Social Functioning Score (continued)							
Visit 8							
	N with data	44	26	22	44	26	22
	N missing	3	1	2	3	1	2
	Mean	51.59	51.08	51.22	9.87	11.90	13.32
	SD	9.759	10.562	11.835	14.013	14.073	14.384
	Min	19.14	19.14	13.71	-16.28	-21.71	-10.86
	25% quantile	51.71	46.28	51.71	0	0	5.43
	Median	57.14	57.14	57.14	8.14	13.57	10.86
	75% quantile	57.14	57.14	57.14	16.28	21.71	21.71
	Max	57.14	57.14	57.14	38.00	43.43	43.43
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	51.45	48.99	50.16	9.05	9.81	12.15
	SD	9.955	9.741	12.276	13.599	11.491	14.352
	Min	13.71	30.00	13.71	-27.14	-16.28	-10.86
	25% quantile	46.28	40.85	51.71	0	5.43	0
	Median	57.14	54.42	57.14	10.86	10.86	10.86
	75% quantile	57.14	57.14	57.14	16.28	16.28	16.28
	Max	57.14	57.14	57.14	38.00	32.57	43.43
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	50.91	50.25	49.24	8.47	11.07	11.35
	SD	9.446	9.534	11.451	12.201	11.940	16.147
	Min	24.57	19.14	19.14	-16.28	-21.71	-16.28
	25% quantile	46.28	40.85	46.28	0	5.43	0
	Median	57.14	54.42	57.14	5.43	13.57	10.86
	75% quantile	57.14	57.14	57.14	16.28	21.71	21.71
	Max	57.14	57.14	57.14	38.00	32.57	43.43

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.6: Summary of SF-36 domain score 'social functioning' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Social Functioning Score (continued)							
End of Trial	N with data	41	26	21	41	26	21
	N missing	6	1	3	6	1	3
	Mean	52.11	51.08	49.38	9.93	11.90	11.37
	SD	7.809	8.315	13.137	12.253	9.591	14.041
	Min	30.00	35.42	13.71	-10.86	-5.43	-5.43
	25% quantile	46.28	46.28	46.28	0	5.43	0
	Median	57.14	57.14	57.14	5.43	10.86	5.43
	75% quantile	57.14	57.14	57.14	16.28	16.28	16.28
	Max	57.14	57.14	57.14	38.00	27.14	43.43

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf6.lst / hrql.sas

Table 14.2.8.2.7: Summary of SF-36 domain score 'bodily pain' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Bodily Pain Score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	29.97	30.47	30.03			
	SD	8.458	8.160	9.945			
	Min	19.93	19.93	19.93			
	25% quantile	19.93	25.07	19.93			
	Median	29.35	29.35	29.35			
	75% quantile	33.63	33.20	33.42			
	Max	55.90	55.90	54.18			
Visit 3a*							
	N with data	47	27	-	47	27	-
	Mean	48.60	50.81	-	18.63	20.33	-
	SD	9.337	8.942	-	13.176	13.276	-
	Min	28.92	37.48	-	-18.41	-18.41	-
	25% quantile	42.19	42.19	-	9.42	12.42	-
	Median	49.90	51.61	-	17.98	22.27	-
	75% quantile	54.18	55.90	-	31.69	31.69	-
	Max	62.75	62.75	-	42.82	42.82	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	47.55	48.13	43.23	17.56	17.66	13.20
	SD	8.176	12.365	9.763	12.192	16.520	10.619
	Min	25.07	19.93	28.92	-18.41	-31.69	-8.14
	25% quantile	46.05	41.77	37.48	8.99	8.14	6.64
	Median	46.48	51.61	42.19	18.20	17.13	15.20
	75% quantile	51.61	62.75	49.47	26.55	31.69	17.56
	Max	62.75	62.75	62.75	42.82	42.82	33.40

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.7: Summary of SF-36 domain score 'bodily pain' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Bodily Pain Score (continued)							
Visit 5							
	N with data	46	27	23	46	27	23
	N missing	1	0	1	1	0	1
	Mean	50.08	52.77	47.20	20.19	22.30	16.74
	SD	9.407	9.494	9.970	14.310	13.342	12.242
	Min	25.07	29.35	19.93	-18.41	-9.42	-17.56
	25% quantile	46.48	50.76	41.77	12.85	12.85	11.13
	Median	51.61	55.90	46.48	22.27	25.26	17.13
	75% quantile	55.90	62.75	51.61	31.69	31.69	26.55
	Max	62.75	62.75	62.75	42.82	42.82	37.68
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	51.23	53.57	50.24	21.25	23.91	19.77
	SD	10.127	9.654	9.910	13.564	12.277	12.017
	Min	24.21	29.35	33.20	-4.28	3.85	-4.28
	25% quantile	46.48	46.48	42.19	13.27	13.27	8.56
	Median	51.61	55.90	51.61	21.41	22.48	21.41
	75% quantile	62.75	62.75	55.90	33.40	33.40	31.69
	Max	62.75	62.75	62.75	42.82	42.82	42.82
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	52.70	50.89	48.60	22.72	21.23	17.02
	SD	8.432	9.243	11.804	12.645	13.344	13.217
	Min	33.63	33.63	24.21	-8.14	-14.13	-13.27
	25% quantile	46.48	41.77	37.48	14.13	12.85	8.35
	Median	51.61	51.61	48.62	22.48	21.62	17.56
	75% quantile	62.75	62.75	59.32	33.40	33.40	22.70
	Max	62.75	62.75	62.75	42.82	42.82	42.82

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.7: Summary of SF-36 domain score 'bodily pain' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Bodily Pain Score (continued)							
Visit 8							
	N with data	44	26	22	44	26	22
	N missing	3	1	2	3	1	2
	Mean	51.73	54.91	49.63	21.81	25.25	18.69
	SD	10.672	10.352	10.358	13.318	12.999	11.693
	Min	25.07	29.35	33.63	-16.70	-5.14	0
	25% quantile	44.34	50.76	42.19	13.70	17.13	11.13
	Median	53.76	59.32	46.48	21.84	29.55	17.34
	75% quantile	62.75	62.75	62.75	33.40	35.97	26.55
	Max	62.75	62.75	62.75	42.82	38.54	42.82
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	50.94	50.48	49.05	20.25	20.82	17.58
	SD	11.535	11.595	12.211	14.305	13.841	14.465
	Min	25.07	29.35	25.07	-12.42	-4.28	-12.42
	25% quantile	41.77	37.48	41.77	9.42	8.14	11.13
	Median	51.61	53.33	46.48	22.48	19.48	16.27
	75% quantile	62.75	62.75	62.75	33.40	33.40	26.55
	Max	62.75	62.75	62.75	42.82	42.82	42.82
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	49.25	49.03	45.52	18.63	19.37	14.58
	SD	11.084	10.876	13.160	15.289	13.543	15.419
	Min	29.35	29.35	24.21	-18.41	-4.28	-16.70
	25% quantile	41.77	41.77	33.63	8.99	8.99	4.28
	Median	50.76	50.76	46.48	20.98	17.34	14.99
	75% quantile	62.75	55.90	55.90	31.69	29.12	22.70
	Max	62.75	62.75	62.75	42.82	42.82	42.82

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

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Table 14.2.8.2.7: Summary of SF-36 domain score 'bodily pain' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Bodily Pain Score (continued)							
End of Trial							
	N with data	41	26	21	41	26	21
	N missing	6	1	3	6	1	3
	Mean	51.42	53.21	50.00	20.78	23.55	18.54
	SD	9.524	9.772	10.888	13.553	12.567	12.173
	Min	29.35	33.63	25.07	-5.14	0	1.71
	25% quantile	46.48	46.05	41.77	9.42	12.85	8.56
	Median	51.61	55.90	51.61	21.84	27.83	16.27
	75% quantile	62.75	62.75	55.90	33.40	33.40	27.41
	Max	62.75	62.75	62.75	42.82	42.82	42.82

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.8: Summary of SF-36 domain score 'general health perceptions' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Global Health Score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	49.41	47.98	47.20			
	SD	4.639	5.742	7.620			
	Min	37.85	35.62	30.83			
	25% quantile	45.82	45.18	42.31			
	Median	49.01	48.37	47.90			
	75% quantile	53.79	52.20	53.79			
	Max	59.53	58.58	55.39			
Visit 3a*							
	N with data	47	27	-	47	27	-
	Mean	50.92	52.21	-	1.51	4.22	-
	SD	4.754	4.482	-	4.347	4.733	-
	Min	40.40	42.63	-	-6.38	-4.78	-
	25% quantile	47.42	50.61	-	-1.59	1.59	-
	Median	50.61	52.20	-	1.59	3.19	-
	75% quantile	55.39	55.39	-	4.15	8.77	-
	Max	59.53	59.53	-	11.16	11.80	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	51.25	50.82	48.20	1.76	2.83	1.00
	SD	4.528	6.276	6.875	3.891	5.552	5.188
	Min	42.00	38.81	30.83	-7.97	-8.93	-8.61
	25% quantile	47.42	45.82	46.30	-1.59	0	-3.19
	Median	50.61	50.61	49.01	1.59	3.83	1.59
	75% quantile	55.39	56.35	53.00	3.83	6.38	4.30
	Max	59.53	58.58	56.98	9.57	13.39	10.20

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Clinipace: 14DEC21 / 7:41 / sf8.lst / hrql.sas

Table 14.2.8.2.8: Summary of SF-36 domain score 'general health perceptions' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Global Health Score (continued)							
Visit 5							
	N with data	46	27	23	46	27	23
	N missing	1	0	1	1	0	1
	Mean	51.00	53.00	49.67	1.53	5.02	1.75
	SD	5.414	5.636	5.566	5.512	5.635	5.235
	Min	38.81	42.63	39.44	-11.16	-6.38	-8.61
	25% quantile	45.82	47.42	45.82	-1.59	0	-0.64
	Median	51.40	55.39	49.01	3.19	5.42	1.59
	75% quantile	55.39	57.94	55.39	4.78	10.20	5.42
	Max	59.53	59.53	59.53	11.80	14.99	11.80
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	51.79	52.48	51.06	2.30	4.54	3.15
	SD	5.881	5.993	5.904	5.805	5.873	5.194
	Min	34.02	37.21	37.21	-12.76	-7.97	-9.57
	25% quantile	47.42	47.42	45.82	-0.64	0.96	0.64
	Median	52.20	53.48	52.20	1.91	4.46	3.19
	75% quantile	55.39	56.98	55.39	4.78	8.61	7.02
	Max	59.53	59.53	58.58	14.99	18.18	11.80
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	51.78	52.45	50.62	2.29	4.50	2.17
	SD	5.600	5.703	7.217	6.047	5.605	5.248
	Min	35.62	38.81	34.02	-18.18	-4.78	-13.39
	25% quantile	47.42	49.01	47.42	0	0	0.80
	Median	52.20	53.79	52.20	3.19	3.51	3.67
	75% quantile	55.39	56.98	56.66	5.42	8.61	5.42
	Max	59.53	59.53	59.53	14.99	13.39	9.57

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.8: Summary of SF-36 domain score 'general health perceptions' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Global Health Score (continued)							
Visit 8							
	N with data	44	26	22	44	26	22
	N missing	3	1	2	3	1	2
	Mean	51.21	50.28	48.87	1.52	2.34	0.90
	SD	5.903	6.664	6.319	5.607	6.373	6.431
	Min	37.21	35.62	35.62	-16.58	-11.16	-15.94
	25% quantile	48.21	46.78	44.23	0	-1.59	-1.59
	Median	52.20	49.49	49.81	3.19	1.59	1.28
	75% quantile	55.39	55.39	53.16	4.78	7.33	4.78
	Max	59.53	59.53	58.58	9.57	13.39	11.80
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	50.73	49.54	50.26	1.40	1.59	1.55
	SD	6.647	7.158	5.904	6.423	7.054	4.864
	Min	34.02	34.02	37.21	-19.77	-13.39	-9.57
	25% quantile	45.82	47.42	47.42	-0.96	-4.78	0
	Median	52.20	50.61	52.20	2.07	2.39	1.59
	75% quantile	56.98	55.39	53.79	4.78	6.38	4.78
	Max	59.53	58.58	59.53	11.16	11.80	10.20
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	49.78	50.15	48.88	0.38	2.21	0.91
	SD	6.210	6.361	6.587	5.931	7.053	6.099
	Min	35.62	32.43	35.62	-14.35	-11.16	-10.20
	25% quantile	45.82	45.82	44.23	-3.19	-3.19	-3.19
	Median	50.61	51.40	49.01	0	2.39	1.59
	75% quantile	54.75	55.39	55.39	4.78	7.02	5.74
	Max	59.53	58.58	59.53	11.16	17.54	11.16

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.8: Summary of SF-36 domain score 'general health perceptions' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Global Health Score (continued)							
End of Trial							
	N with data	41	26	21	41	26	21
	N missing	6	1	3	6	1	3
	Mean	51.74	52.31	50.41	2.29	4.37	1.70
	SD	6.008	6.089	7.035	5.961	6.101	5.197
	Min	32.43	37.21	35.62	-11.16	-7.97	-6.38
	25% quantile	49.01	52.20	47.42	0	0	-1.59
	Median	52.20	53.48	52.20	3.19	4.46	1.59
	75% quantile	56.35	56.35	53.79	4.78	7.33	4.78
	Max	59.53	59.53	59.53	15.94	18.18	11.16

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are analysed.

Table 14.2.8.2.9: Summary of SF-36 summary score 'physical component summary' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Physical Component Summary							
Baseline (Visit 2a)							
	N with data	46	26	24			
	N missing	1	1	0			
	Mean	39.49	38.98	38.35			
	SD	5.267	5.528	7.017			
	Min	29.93	30.03	25.77			
	25% quantile	34.88	34.81	31.70			
	Median	39.46	39.55	38.65			
	75% quantile	42.77	43.18	44.07			
	Max	50.47	52.00	50.01			
Visit 3a*							
	N with data	46	27	-	45	26	-
	N missing	1	0	-	2	1	-
	Mean	48.15	49.64	-	8.59	10.51	-
	SD	5.196	4.442	-	6.997	6.300	-
	Min	34.81	38.85	-	-8.20	-3.61	-
	25% quantile	46.08	46.74	-	2.54	7.24	-
	Median	48.40	51.02	-	8.01	10.42	-
	75% quantile	52.51	52.80	-	13.94	15.34	-
	Max	55.76	59.46	-	20.88	22.81	-
Visit 4							
	N with data	46	27	24	45	26	24
	N missing	1	0	0	2	1	0
	Mean	46.79	47.95	45.55	7.25	8.80	7.21
	SD	4.658	4.915	6.547	7.514	6.536	6.830
	Min	30.60	36.83	35.01	-10.90	-6.28	-10.45
	25% quantile	45.08	45.14	40.89	2.42	4.42	2.90
	Median	47.61	47.41	44.38	8.36	9.69	8.98
	75% quantile	49.75	52.40	48.17	10.93	13.10	11.89
	Max	53.59	55.19	59.26	20.60	21.12	17.61

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are used to calculate physical component summary (PCS).

Table 14.2.8.2.9: Summary of SF-36 summary score 'physical component summary' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Physical Component Summary (continued)							
Visit 5							
	N with data	45	27	22	44	26	22
	N missing	2	0	2	3	1	2
	Mean	47.91	49.19	46.28	8.80	10.05	7.89
	SD	4.600	5.591	4.008	7.338	7.521	6.439
	Min	30.86	32.20	38.70	-7.09	-5.12	-7.27
	25% quantile	46.12	47.68	43.34	4.02	5.42	4.97
	Median	48.79	49.52	46.38	7.79	9.57	7.24
	75% quantile	50.68	52.45	48.76	14.80	15.43	12.16
	Max	57.61	61.64	53.19	22.74	24.75	19.49
Visit 6							
	N with data	46	26	23	45	25	23
	N missing	1	1	1	2	2	1
	Mean	49.01	48.92	47.71	9.37	10.30	8.93
	SD	4.777	5.345	3.758	7.518	7.747	7.314
	Min	30.88	34.14	39.95	-10.62	-8.49	-7.37
	25% quantile	46.80	47.13	46.69	4.21	6.78	4.83
	Median	49.64	50.62	48.55	8.07	10.84	10.31
	75% quantile	52.52	52.59	50.15	14.45	14.72	13.48
	Max	55.32	55.91	53.35	25.39	25.12	22.78
Visit 7							
	N with data	46	26	20	45	25	20
	N missing	1	1	4	2	2	4
	Mean	48.87	48.65	47.86	9.19	9.99	8.52
	SD	3.965	3.943	6.176	6.893	5.842	7.396
	Min	37.02	40.11	30.93	-3.52	-3.07	-6.61
	25% quantile	46.88	46.62	45.56	4.90	6.60	4.18
	Median	48.50	49.55	49.47	7.03	10.15	8.79
	75% quantile	52.35	51.85	51.98	14.05	12.92	14.25
	Max	55.56	54.76	56.26	25.64	21.31	20.27

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are used to calculate physical component summary (PCS).

Table 14.2.8.2.9: Summary of SF-36 summary score 'physical component summary' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Physical Component Summary (continued)							
Visit 8							
	N with data	44	26	22	43	25	22
	N missing	3	1	2	4	2	2
	Mean	48.27	49.62	47.29	8.64	10.99	8.40
	SD	4.436	5.120	4.446	6.947	7.155	7.006
	Min	36.07	32.30	37.84	-7.05	-7.41	-3.88
	25% quantile	45.68	48.19	44.53	4.19	7.82	4.08
	Median	49.23	50.82	47.51	8.70	10.49	7.88
	75% quantile	51.82	52.59	51.56	13.65	15.20	13.27
	Max	54.86	55.46	52.79	20.01	24.18	21.84
Visit 9							
	N with data	42	25	21	42	24	21
	N missing	5	2	3	5	3	3
	Mean	48.06	48.17	47.10	8.04	9.57	7.59
	SD	5.066	4.228	4.525	6.769	6.426	6.773
	Min	32.59	39.30	38.42	-6.11	-2.40	-4.49
	25% quantile	46.50	45.92	44.23	3.56	5.18	3.01
	Median	49.36	48.44	47.03	7.01	8.49	7.32
	75% quantile	51.70	51.23	51.16	13.79	12.07	14.25
	Max	53.72	54.03	53.02	19.77	24.00	20.64
Visit 10							
	N with data	41	26	22	41	25	22
	N missing	6	1	2	6	2	2
	Mean	47.15	47.64	45.99	7.17	8.92	7.09
	SD	4.869	5.160	5.605	7.584	7.245	7.276
	Min	35.43	37.03	32.88	-12.08	-4.14	-7.01
	25% quantile	44.39	45.73	42.05	2.78	3.29	2.03
	Median	48.24	48.78	46.30	6.86	10.38	6.61
	75% quantile	50.32	51.46	50.11	11.68	12.79	12.86
	Max	55.67	54.16	53.85	21.65	23.07	18.59

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are used to calculate physical component summary (PCS).

Table 14.2.8.2.9: Summary of SF-36 summary score 'physical component summary' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Physical Component Summary (continued)							
End of Trial	N with data	40	26	21	40	25	21
	N missing	7	1	3	7	2	3
	Mean	48.57	48.70	47.15	8.52	10.08	7.63
	SD	4.505	5.816	5.205	6.984	7.293	5.760
	Min	37.26	28.61	30.66	-3.16	-8.71	-2.10
	25% quantile	46.56	47.08	46.11	3.84	6.77	3.35
	Median	49.62	48.95	47.28	8.80	9.41	6.99
	75% quantile	51.82	52.59	50.10	14.11	15.02	11.68
	Max	55.41	56.81	53.32	22.93	22.89	18.45

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are used to calculate physical component summary (PCS).

Clinipace: 14DEC21 / 7:41 / sf11.lst / hrql.sas

Table 14.2.8.2.10: Summary of SF-36 summary score 'mental component summary' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Mental Component Summary							
Baseline (Visit 2a)							
	N with data	46	26	24			
	N missing	1	1	0			
	Mean	36.32	36.61	35.58			
	SD	8.292	7.482	7.085			
	Min	19.57	24.59	25.63			
	25% quantile	31.68	29.94	29.65			
	Median	36.05	36.04	35.24			
	75% quantile	40.43	42.38	39.36			
	Max	54.73	49.92	52.29			
Visit 3a*							
	N with data	46	27	-	45	26	-
	N missing	1	0	-	2	1	-
	Mean	38.61	38.73	-	2.26	2.16	-
	SD	5.856	5.772	-	7.236	7.606	-
	Min	24.67	24.16	-	-12.38	-12.69	-
	25% quantile	34.32	34.74	-	-3.32	-1.81	-
	Median	39.16	40.90	-	3.78	1.53	-
	75% quantile	43.96	43.07	-	7.16	9.00	-
	Max	49.27	46.96	-	15.31	16.91	-
Visit 4							
	N with data	46	27	24	45	26	24
	N missing	1	0	0	2	1	0
	Mean	39.77	39.42	38.42	3.37	2.77	2.84
	SD	5.298	6.423	7.110	7.917	8.597	7.941
	Min	25.00	25.35	27.74	-13.65	-15.25	-14.96
	25% quantile	37.04	34.77	33.92	-2.38	-3.99	-1.32
	Median	40.52	40.30	38.21	4.07	3.25	2.42
	75% quantile	42.80	45.30	43.27	10.06	7.60	9.23
	Max	50.41	48.91	56.54	20.71	20.71	19.34

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are used to calculate mental component summary (MCS).

Table 14.2.8.2.10: Summary of SF-36 summary score 'mental component summary' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Mental Component Summary (continued)							
Visit 5							
	N with data	45	27	22	44	26	22
	N missing	2	0	2	3	1	2
	Mean	39.59	38.62	40.30	3.11	1.94	4.03
	SD	5.186	6.662	5.223	7.743	8.078	7.862
	Min	24.82	22.61	33.34	-12.47	-17.99	-14.62
	25% quantile	37.70	34.04	37.82	-2.86	-4.05	0.11
	Median	40.16	40.32	39.80	3.61	3.13	4.77
	75% quantile	43.49	43.39	41.89	8.35	6.22	9.03
	Max	46.45	47.77	52.36	18.42	21.29	18.83
Visit 6							
	N with data	46	26	23	45	25	23
	N missing	1	1	1	2	2	1
	Mean	38.14	39.80	38.40	1.92	2.80	2.55
	SD	5.433	6.350	6.033	7.596	8.136	7.581
	Min	25.10	21.91	24.20	-12.14	-18.69	-13.54
	25% quantile	34.65	36.92	33.97	-3.46	0.28	-0.70
	Median	39.77	41.87	40.35	0.75	2.22	2.78
	75% quantile	42.09	43.11	43.35	8.13	6.35	6.84
	Max	45.84	53.55	46.43	17.07	22.43	18.66
Visit 7							
	N with data	46	26	20	45	25	20
	N missing	1	1	4	2	2	4
	Mean	39.39	38.99	37.62	3.29	2.00	1.56
	SD	4.830	6.343	7.812	7.624	7.682	9.156
	Min	28.30	26.06	20.67	-13.88	-14.54	-16.59
	25% quantile	36.68	34.08	31.18	-1.34	-3.56	-2.12
	Median	39.85	40.31	41.39	4.24	2.13	1.60
	75% quantile	41.40	42.99	42.12	7.68	7.48	7.70
	Max	50.06	50.84	47.21	18.84	17.96	16.16

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are used to calculate mental component summary (MCS).

Table 14.2.8.2.10: Summary of SF-36 summary score 'mental component summary' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Mental Component Summary (continued)							
Visit 8							
	N with data	44	26	22	43	25	22
	N missing	3	1	2	4	2	2
	Mean	39.03	37.68	37.81	2.56	0.64	1.65
	SD	5.567	7.314	6.379	7.663	8.921	7.798
	Min	22.18	20.13	14.95	-12.11	-16.54	-12.32
	25% quantile	34.42	31.74	35.68	-2.87	-6.49	-2.45
	Median	40.46	40.04	38.95	2.41	-0.71	2.75
	75% quantile	43.25	42.38	41.64	8.51	8.16	5.82
	Max	50.22	47.59	44.66	17.48	18.71	14.77
Visit 9							
	N with data	42	25	21	42	24	21
	N missing	5	2	3	5	3	3
	Mean	38.29	37.35	36.67	2.16	-0.06	0.51
	SD	5.242	6.942	8.688	7.349	7.739	8.747
	Min	24.53	24.76	16.04	-16.52	-10.59	-12.81
	25% quantile	35.49	32.07	35.61	-2.91	-5.91	-6.76
	Median	38.88	38.34	38.19	3.49	-0.14	1.42
	75% quantile	42.56	42.32	43.11	7.18	4.92	4.99
	Max	46.39	46.92	46.92	17.04	19.62	18.05
Visit 10							
	N with data	41	26	22	41	25	22
	N missing	6	1	2	6	2	2
	Mean	38.57	37.73	37.76	2.36	0.87	1.60
	SD	5.130	6.804	7.523	6.808	7.458	9.833
	Min	27.86	21.81	23.76	-11.81	-14.52	-13.18
	25% quantile	36.28	34.11	31.13	-2.77	-3.43	-6.00
	Median	39.89	37.31	38.16	1.59	-0.10	0.10
	75% quantile	40.92	43.17	42.55	7.79	5.15	8.61
	Max	50.05	50.76	58.45	16.94	15.95	24.95

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are used to calculate mental component summary (MCS).

Table 14.2.8.2.10: Summary of SF-36 summary score 'mental component summary' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Mental Component Summary (continued)							
End of Trial							
	N with data	40	26	21	40	25	21
	N missing	7	1	3	7	2	3
	Mean	37.85	37.44	38.24	1.28	0.52	2.09
	SD	5.776	7.470	6.329	7.603	8.934	7.415
	Min	22.45	14.64	22.97	-14.64	-20.54	-17.09
	25% quantile	34.27	35.00	33.69	-3.95	-7.08	-0.46
	Median	38.72	38.06	40.18	1.54	1.61	0.87
	75% quantile	41.49	42.53	42.53	6.44	6.54	5.30
	Max	47.09	47.53	46.39	17.62	19.74	15.04

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are used to calculate mental component summary (MCS).

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Table 14.2.8.2.11: Summary of SF-36 question 'Reported Health Transition' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Reported Health Transition							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	2.00	1.74	1.71			
	SD	1.000	0.984	0.908			
	Min	1.00	1.00	1.00			
	25% quantile	1.00	1.00	1.00			
	Median	2.00	1.00	1.00			
	75% quantile	3.00	2.00	3.00			
	Max	5.00	4.00	3.00			
Visit 3a*							
	N with data	47	26	-	47	26	-
	N missing	0	1	-	0	1	-
	Mean	3.60	3.54	-	1.60	1.77	-
	SD	1.116	1.240	-	1.424	1.451	-
	Min	2.00	2.00	-	-1.00	-1.00	-
	25% quantile	3.00	2.00	-	0	1.00	-
	Median	3.00	3.00	-	2.00	2.00	-
	75% quantile	5.00	5.00	-	3.00	3.00	-
	Max	5.00	5.00	-	4.00	4.00	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	3.74	3.78	3.71	1.76	2.04	2.00
	SD	0.999	1.121	1.334	1.336	1.315	1.642
	Min	2.00	2.00	1.00	-1.00	-1.00	-1.00
	25% quantile	3.00	3.00	2.50	1.00	1.00	1.00
	Median	4.00	4.00	4.00	2.00	2.00	2.00
	75% quantile	5.00	5.00	5.00	3.00	3.00	3.50
	Max	5.00	5.00	5.00	4.00	4.00	4.00

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.8.2.11: Summary of SF-36 question 'Reported Health Transition' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Reported Health Transition (continued)							
Visit 5							
	N with data	46	27	23	46	27	23
	N missing	1	0	1	1	0	1
	Mean	3.96	3.93	3.87	1.96	2.19	2.13
	SD	1.115	1.072	1.254	1.646	1.415	1.424
	Min	2.00	2.00	2.00	-3.00	-1.00	-1.00
	25% quantile	3.00	3.00	3.00	1.00	1.00	1.00
	Median	4.00	4.00	4.00	2.00	2.00	2.00
	75% quantile	5.00	5.00	5.00	3.00	3.00	3.00
	Max	5.00	5.00	5.00	4.00	4.00	4.00
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	4.17	4.38	4.48	2.20	2.65	2.74
	SD	0.926	1.061	0.790	1.408	1.325	1.137
	Min	2.00	2.00	2.00	-2.00	0	0
	25% quantile	3.00	4.00	4.00	2.00	1.00	2.00
	Median	4.00	5.00	5.00	2.00	3.00	3.00
	75% quantile	5.00	5.00	5.00	3.00	4.00	4.00
	Max	5.00	5.00	5.00	4.00	4.00	4.00
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	4.41	4.12	4.60	2.43	2.38	2.85
	SD	0.909	1.211	0.821	1.544	1.602	1.137
	Min	1.00	1.00	2.00	-4.00	-1.00	1.00
	25% quantile	4.00	3.00	4.50	2.00	1.00	2.00
	Median	5.00	5.00	5.00	3.00	3.00	3.00
	75% quantile	5.00	5.00	5.00	4.00	4.00	4.00
	Max	5.00	5.00	5.00	4.00	4.00	4.00

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.8.2.11: Summary of SF-36 question 'Reported Health Transition' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Reported Health Transition (continued)							
Visit 8							
	N with data	44	25	22	44	25	22
	N missing	3	2	2	3	2	2
	Mean	3.27	3.44	3.27	1.30	1.68	1.50
	SD	0.899	1.121	0.985	1.340	1.464	1.439
	Min	2.00	1.00	2.00	-3.00	-1.00	0
	25% quantile	3.00	3.00	3.00	0.50	1.00	0
	Median	3.00	3.00	3.00	1.00	2.00	1.50
	75% quantile	4.00	4.00	4.00	2.00	3.00	2.00
	Max	5.00	5.00	5.00	4.00	4.00	4.00
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	3.21	3.19	3.05	1.24	1.46	1.24
	SD	0.951	0.939	0.740	1.445	1.363	1.091
	Min	1.00	2.00	2.00	-4.00	-1.00	-1.00
	25% quantile	3.00	2.00	3.00	0	1.00	0
	Median	3.00	3.00	3.00	1.00	1.00	2.00
	75% quantile	4.00	4.00	3.00	2.00	2.00	2.00
	Max	5.00	5.00	5.00	4.00	4.00	3.00
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	3.12	2.92	3.00	1.15	1.19	1.23
	SD	0.678	0.796	0.816	1.333	1.297	1.232
	Min	2.00	1.00	2.00	-3.00	-2.00	-1.00
	25% quantile	3.00	3.00	2.00	1.00	1.00	1.00
	Median	3.00	3.00	3.00	1.00	1.00	1.50
	75% quantile	3.00	3.00	3.00	2.00	2.00	2.00
	Max	5.00	5.00	5.00	3.00	4.00	3.00

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.8.2.11: Summary of SF-36 question 'Reported Health Transition' and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
Reported Health Transition (continued)							
End of Trial	N with data	41	26	21	41	26	21
	N missing	6	1	3	6	1	3
	Mean	3.15	3.38	3.00	1.20	1.65	1.19
	SD	0.727	0.898	0.707	1.209	1.413	1.030
	Min	1.00	2.00	2.00	-2.00	-1.00	-1.00
	25% quantile	3.00	3.00	3.00	1.00	1.00	0
	Median	3.00	3.00	3.00	1.00	2.00	1.00
	75% quantile	3.00	4.00	3.00	2.00	2.00	2.00
	Max	5.00	5.00	5.00	4.00	4.00	3.00

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.9.2.1: Summary of EQ-5D-3L utility index score and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
EQ-5D-3L Total Score							
Baseline (Visit 2a)							
	N with data	47	27	23			
	N missing	0	0	1			
	Mean	0.54	0.42	0.42			
	SD	0.402	0.475	0.596			
	Min	-0.70	-0.70	-1.09			
	25% quantile	0.26	0.17	0.17			
	Median	0.79	0.46	0.70			
	75% quantile	0.79	0.79	0.79			
	Max	0.89	0.89	1.00			
Visit 3a*							
	N with data	47	26	-	47	26	-
	N missing	0	1	-	0	1	-
	Mean	0.92	0.94	-	0.38	0.52	-
	SD	0.081	0.071	-	0.415	0.496	-
	Min	0.70	0.79	-	-0.10	0	-
	25% quantile	0.89	0.89	-	0.10	0.11	-
	Median	0.89	1.00	-	0.21	0.42	-
	75% quantile	1.00	1.00	-	0.62	0.74	-
	Max	1.00	1.00	-	1.70	1.70	-
Visit 4							
	N with data	46	27	24	46	27	23
	N missing	1	0	0	1	0	1
	Mean	0.90	0.93	0.86	0.36	0.51	0.44
	SD	0.116	0.080	0.131	0.425	0.483	0.538
	Min	0.36	0.79	0.38	-0.19	0	0
	25% quantile	0.89	0.89	0.79	0.10	0.10	0.09
	Median	0.89	0.90	0.89	0.21	0.32	0.21
	75% quantile	1.00	1.00	0.95	0.61	0.74	0.71
	Max	1.00	1.00	1.00	1.59	1.70	1.70

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:41 / sf12.lst / hrql.sas

Table 14.2.9.2.1: Summary of EQ-5D-3L utility index score and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
EQ-5D-3L Total Score (continued)							
Visit 5							
	N with data	46	27	23	46	27	22
	N missing	1	0	1	1	0	2
	Mean	0.92	0.94	0.86	0.38	0.52	0.45
	SD	0.081	0.167	0.171	0.433	0.516	0.623
	Min	0.70	0.17	0.17	-0.19	-0.61	-0.71
	25% quantile	0.89	1.00	0.89	0.10	0.11	0.10
	Median	0.89	1.00	0.89	0.21	0.51	0.21
	75% quantile	1.00	1.00	1.00	0.63	0.83	0.72
	Max	1.00	1.00	1.00	1.70	1.70	1.79
Visit 6							
	N with data	46	26	23	46	26	22
	N missing	1	1	1	1	1	2
	Mean	0.88	0.94	0.92	0.34	0.53	0.51
	SD	0.232	0.085	0.077	0.476	0.508	0.624
	Min	-0.15	0.70	0.79	-0.92	-0.10	-0.10
	25% quantile	0.89	0.89	0.89	0.10	0.11	0.10
	Median	0.89	1.00	0.89	0.21	0.47	0.21
	75% quantile	1.00	1.00	1.00	0.62	0.83	0.83
	Max	1.00	1.00	1.00	1.70	1.70	1.98
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	0.92	0.90	0.87	0.38	0.49	0.37
	SD	0.106	0.151	0.316	0.420	0.547	0.664
	Min	0.50	0.26	-0.45	-0.19	-0.52	-1.33
	25% quantile	0.89	0.89	0.89	0.10	0.10	0.10
	Median	1.00	0.89	0.89	0.21	0.47	0.21
	75% quantile	1.00	1.00	1.00	0.62	0.74	0.77
	Max	1.00	1.00	1.00	1.70	1.70	1.70

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.9.2.1: Summary of EQ-5D-3L utility index score and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
EQ-5D-3L Total Score (continued)							
Visit 8							
	N with data	44	25	22	44	25	21
	N missing	3	2	2	3	2	3
	Mean	0.91	0.89	0.89	0.37	0.50	0.47
	SD	0.188	0.232	0.138	0.472	0.588	0.610
	Min	-0.15	0.17	0.50	-1.04	-0.61	-0.39
	25% quantile	0.89	0.89	0.89	0.11	0.11	0.10
	Median	1.00	1.00	0.89	0.22	0.51	0.21
	75% quantile	1.00	1.00	1.00	0.63	0.83	0.83
	Max	1.00	1.00	1.00	1.70	1.70	1.70
Visit 9							
	N with data	42	26	21	42	26	20
	N missing	5	1	3	5	1	4
	Mean	0.89	0.85	0.86	0.36	0.44	0.36
	SD	0.193	0.259	0.196	0.450	0.602	0.560
	Min	-0.13	-0.22	0.26	-0.30	-1.00	-0.53
	25% quantile	0.89	0.79	0.89	0.10	0	0.09
	Median	0.94	0.89	0.89	0.21	0.41	0.15
	75% quantile	1.00	1.00	1.00	0.62	0.83	0.56
	Max	1.00	1.00	1.00	1.70	1.70	1.70
Visit 10							
	N with data	41	26	22	41	26	21
	N missing	6	1	2	6	1	3
	Mean	0.89	0.88	0.83	0.35	0.48	0.41
	SD	0.166	0.240	0.230	0.466	0.573	0.665
	Min	0.17	-0.22	0.26	-0.53	-1.00	-0.63
	25% quantile	0.89	0.89	0.79	0.10	0.11	0.09
	Median	0.89	0.94	0.89	0.21	0.41	0.11
	75% quantile	1.00	1.00	1.00	0.62	0.83	0.71
	Max	1.00	1.00	1.00	1.70	1.70	1.87

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

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Table 14.2.9.2.1: Summary of EQ-5D-3L utility index score and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
EQ-5D-3L Total Score (continued)							
End of Trial							
	N with data	41	26	21	41	26	20
	N missing	6	1	3	6	1	4
	Mean	0.91	0.92	0.92	0.36	0.51	0.43
	SD	0.120	0.148	0.078	0.456	0.533	0.543
	Min	0.46	0.31	0.79	-0.42	-0.48	0
	25% quantile	0.89	0.89	0.89	0.10	0.11	0.05
	Median	0.89	1.00	0.89	0.21	0.47	0.20
	75% quantile	1.00	1.00	1.00	0.62	0.83	0.77
	Max	1.00	1.00	1.00	1.70	1.70	1.70

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:41 / sf12.lst / hrql.sas

Table 14.2.9.2.2: Summary of EQ VAS score and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
EQ VAS score							
Baseline (Visit 2a)							
	N with data	47	27	24			
	N missing	0	0	0			
	Mean	52.47	52.87	48.38			
	SD	20.135	23.975	26.992			
	Min	19.00	10.00	5.00			
	25% quantile	31.00	40.00	27.50			
	Median	50.00	54.00	42.50			
	75% quantile	70.00	70.00	77.50			
	Max	90.00	95.00	90.00			
Visit 3a*							
	N with data	47	27	-	47	27	-
	Mean	77.81	72.44	-	25.34	19.57	-
	SD	15.376	24.184	-	22.559	33.535	-
	Min	30.00	10.00	-	-35.00	-85.00	-
	25% quantile	75.00	60.00	-	10.00	1.50	-
	Median	80.00	80.00	-	25.00	20.00	-
	75% quantile	88.00	90.00	-	42.00	39.00	-
	Max	100.00	97.00	-	68.00	84.00	-
Visit 4							
	N with data	46	27	24	46	27	24
	N missing	1	0	0	1	0	0
	Mean	79.35	79.33	67.79	26.61	26.46	19.42
	SD	18.760	18.149	22.110	25.955	33.252	26.600
	Min	10.00	35.00	14.00	-55.00	-60.00	-54.00
	25% quantile	77.00	69.00	60.00	10.00	10.00	1.50
	Median	85.00	80.00	72.50	25.00	25.00	19.50
	75% quantile	89.00	95.00	83.50	48.00	55.00	40.00
	Max	100.00	99.00	95.00	71.00	86.00	64.00

EQ VAS = EQ visual analog scale; SC = Standard Care.

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:41 / sf13.lst / hrql.sas

Table 14.2.9.2.2: Summary of EQ VAS score and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
EQ VAS score (continued)							
Visit 5							
	N with data	45	27	23	45	27	23
	N missing	2	0	1	2	0	1
	Mean	80.62	85.52	77.78	28.22	32.65	28.61
	SD	21.545	12.810	19.398	28.735	29.278	22.896
	Min	1.00	59.00	25.00	-61.00	-36.00	-6.00
	25% quantile	79.00	75.00	74.00	10.00	14.00	8.00
	Median	85.00	90.00	80.00	28.00	32.00	25.00
	75% quantile	93.00	97.00	91.00	51.00	54.00	50.00
	Max	100.00	100.00	98.00	71.00	90.00	70.00
Visit 6							
	N with data	46	26	23	46	26	23
	N missing	1	1	1	1	1	1
	Mean	83.96	84.19	71.35	31.22	31.40	22.17
	SD	14.709	16.798	30.283	23.225	33.459	33.455
	Min	30.00	29.00	4.00	-20.00	-43.00	-75.00
	25% quantile	83.00	77.00	68.00	10.00	12.50	3.00
	Median	87.00	89.50	85.00	29.00	32.00	21.00
	75% quantile	95.00	95.00	90.00	52.00	59.00	48.00
	Max	100.00	100.00	97.00	71.00	90.00	79.00
Visit 7							
	N with data	46	26	20	46	26	20
	N missing	1	1	4	1	1	4
	Mean	85.96	83.77	80.65	33.22	30.98	30.00
	SD	13.939	17.651	21.421	20.858	32.098	25.491
	Min	20.00	30.00	25.00	-2.00	-30.00	-1.00
	25% quantile	81.00	70.00	75.00	15.00	1.50	8.50
	Median	89.50	90.00	90.00	31.50	33.50	22.00
	75% quantile	95.00	98.00	94.50	50.00	50.00	50.00
	Max	100.00	100.00	100.00	71.00	89.00	80.00

EQ VAS = EQ visual analog scale; SC = Standard Care.

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:41 / sf13.lst / hrql.sas

Table 14.2.9.2.2: Summary of EQ VAS score and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
EQ VAS score (continued)							
Visit 8							
	N with data	43	25	22	43	25	22
	N missing	4	2	2	4	2	2
	Mean	84.19	82.04	73.86	30.88	27.54	23.36
	SD	16.276	21.721	25.146	23.733	32.999	35.515
	Min	28.00	19.00	4.00	-40.00	-53.00	-75.00
	25% quantile	85.00	79.00	69.00	11.00	10.00	5.00
	Median	89.00	89.00	78.50	27.00	28.00	27.00
	75% quantile	96.00	98.00	94.00	50.00	45.00	44.00
	Max	100.00	100.00	100.00	71.00	85.00	79.00
Visit 9							
	N with data	42	26	21	42	26	21
	N missing	5	1	3	5	1	3
	Mean	80.81	79.77	78.62	28.26	26.98	27.14
	SD	19.036	19.844	18.800	25.840	30.906	25.053
	Min	20.00	21.00	20.00	-41.00	-53.00	-1.00
	25% quantile	75.00	64.00	67.00	8.00	10.00	6.00
	Median	88.00	87.00	85.00	27.50	25.50	21.00
	75% quantile	92.00	95.00	92.00	48.00	55.00	42.00
	Max	100.00	99.00	96.00	71.00	79.00	74.00
Visit 10							
	N with data	41	26	22	41	26	22
	N missing	6	1	2	6	1	2
	Mean	78.41	77.50	74.00	25.56	24.71	23.50
	SD	21.606	19.723	20.183	28.708	30.277	28.135
	Min	19.00	19.00	22.00	-40.00	-36.00	-36.00
	25% quantile	74.00	70.00	62.00	8.00	9.00	2.00
	Median	86.00	81.50	76.50	25.00	28.00	21.00
	75% quantile	94.00	90.00	89.00	50.00	39.00	39.00
	Max	99.00	99.00	100.00	70.00	72.00	74.00

EQ VAS = EQ visual analog scale; SC = Standard Care.

* Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:41 / sf13.lst / hrql.sas

Table 14.2.9.2.2: Summary of EQ VAS score and changes from Baseline (Visit 2a) - full analysis set

Visit	Statistic	Observed			Change from Baseline		
		NDplus (N=47)	NDbasic (N=27)	SC (N=24)	NDplus (N=47)	NDbasic (N=27)	SC (N=24)
EQ VAS score (continued)							
End of Trial							
	N with data	41	25	21	41	25	21
	N missing	6	2	3	6	2	3
	Mean	80.66	78.40	78.14	27.15	23.90	26.67
	SD	20.991	23.543	18.128	27.216	34.912	23.455
	Min	0	21.00	30.00	-50.00	-45.00	-1.00
	25% quantile	80.00	75.00	73.00	11.00	11.00	10.00
	Median	85.00	84.00	81.00	25.00	30.00	19.00
	75% quantile	94.00	96.00	90.00	48.00	47.00	34.00
	Max	100.00	100.00	99.00	72.00	82.00	70.00

EQ VAS = EQ visual analog scale; SC = Standard Care.

* Visit 3a only applicable for patients in NDplus or NDbasic group

Table 14.3.1.1: Summary of adverse events - safety set

	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Number of subjects with Adverse Events	53 (91.4)	31 (83.8)	22 (88.0)	106 (88.3)
Number of subjects with				
TEAEs [1]	51 (87.9)	31 (83.8)	22 (88.0)	104 (86.7)
Pre-transplant TEAEs [2]	26 (44.8)	17 (45.9)	9 (36.0)	52 (43.3)
Post-transplant AEs [3]	46 (79.3)	26 (70.3)	22 (88.0)	94 (78.3)
Related* pre-transplant TEAEs	8 (13.8)	2 (5.4)	3 (12.0)	13 (10.8)
Related* post-transplant TEAEs	9 (15.5)	5 (13.5)	0 (0.0)	14 (11.7)
Serious TEAEs	22 (37.9)	12 (32.4)	6 (24.0)	40 (33.3)
Related* pre-transplant serious TEAEs	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Related* post-transplant serious TEAEs	4 (6.9)	1 (2.7)	0 (0.0)	5 (4.2)
TEAEs leading to death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

SC = Standard Care; [1] TEAE = any AE which started or worsened on or after the date of Visit 2b {sequestrectomy}

[2] Pre-transplant TEAE = any AE which started or worsened on or after the date of Visit 2b {sequestrectomy}, but before the date of Visit 3b {Transplant/Implant: 90 days after sequestrectomy} for patients of the NDplus and NDbasic groups and before Visit 5 {90 days after sequestrectomy} for patients of the SC group

[3] Post-transplant TEAE = any AE which started or worsened on or after the date of Visit 3b {Transplant/Implant} for patients of the NDplus and NDbasic groups and on or after the date of Visit 5 for patients of the SC group

* Pre-transplant TEAEs are related to medical intervention. Post-transplant TEAEs are related to medical intervention for patients in the SC group and to investigational product for patients of the NDplus and NDbasic group.

Table 14.3.1.2: TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Total number of subjects	58 (100)	37 (100)	25 (100)	120 (100)
Subjects with TEAEs [1]	51 (87.9)	31 (83.8)	22 (88.0)	104 (86.7)
Blood and lymphatic system disorders	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Anaemia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cardiac disorders	1 (1.7)	0 (0.0)	2 (8.0)	3 (2.5)
Arrhythmia	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Atrial fibrillation	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Diastolic dysfunction	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Ear and labyrinth disorders	2 (3.4)	1 (2.7)	0 (0.0)	3 (2.5)
Motion sickness	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Tinnitus	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Vertigo	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Endocrine disorders	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Autoimmune thyroiditis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Goitre	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Hypothyroidism	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Eye disorders	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Cataract	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Eye pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gastrointestinal disorders	13 (22.4)	4 (10.8)	4 (16.0)	21 (17.5)
Abdominal pain	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Colitis ulcerative	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Diarrhoea	1 (1.7)	2 (5.4)	0 (0.0)	3 (2.5)
Flatulence	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Gastric disorder	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gastritis	3 (5.2)	1 (2.7)	0 (0.0)	4 (3.3)
Gastrointestinal hypomotility	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Gastrointestinal motility disorder	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Gastroesophageal reflux disease	0 (0.0)	0 (0.0)	2 (8.0)	2 (1.7)
Haematochezia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Haemorrhoids	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Haemorrhoids thrombosed	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Nausea	3 (5.2)	0 (0.0)	1 (4.0)	4 (3.3)
Noninfective sialoadenitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)

Table 14.3.1.2: TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Toothache	3 (5.2)	0 (0.0)	1 (4.0)	4 (3.3)
Vomiting	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
General disorders and administration site conditions	2 (3.4)	0 (0.0)	1 (4.0)	3 (2.5)
Adverse drug reaction	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Chronic fatigue syndrome	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Pyrexia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Immune system disorders	1 (1.7)	1 (2.7)	4 (16.0)	6 (5.0)
Anaphylactic reaction	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Drug hypersensitivity	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Seasonal allergy	1 (1.7)	1 (2.7)	2 (8.0)	4 (3.3)
Infections and infestations	28 (48.3)	16 (43.2)	17 (68.0)	61 (50.8)
Abdominal infection	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Appendicitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Bacterial disease carrier	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Bacterial infection	1 (1.7)	1 (2.7)	3 (12.0)	5 (4.2)
Bronchitis	3 (5.2)	0 (0.0)	0 (0.0)	3 (2.5)
COVID-19	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Chronic sinusitis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Conjunctivitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Cystitis	2 (3.4)	1 (2.7)	0 (0.0)	3 (2.5)
Diverticulitis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Ear infection	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Erysipelas	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Erythema migrans	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Gastroenteritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gastrointestinal infection	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Helicobacter infection	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Herpes zoster	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Hordeolum	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Influenza	2 (3.4)	2 (5.4)	1 (4.0)	5 (4.2)
Intervertebral discitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Lymphangitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Nasopharyngitis	20 (34.5)	9 (24.3)	7 (28.0)	36 (30.0)
Pharyngitis	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Pharyngitis bacterial	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Pneumonia	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Pulpitis dental	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Respiratory tract infection	1 (1.7)	1 (2.7)	2 (8.0)	4 (3.3)

Table 14.3.1.2: TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Rhinitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Salpingitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sinusitis	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Staphylococcal infection	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Subcutaneous abscess	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Tonsillitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Tooth infection	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Upper respiratory tract infection	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Urinary tract infection	4 (6.9)	0 (0.0)	0 (0.0)	4 (3.3)
Vulvovaginal mycotic infection	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Injury, poisoning and procedural complications	13 (22.4)	14 (37.8)	5 (20.0)	32 (26.7)
Ankle fracture	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Arthropod bite	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Cartilage injury	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Contusion	2 (3.4)	2 (5.4)	0 (0.0)	4 (3.3)
Dural tear	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Fall	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Foot fracture	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Joint dislocation	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Ligament rupture	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Ligament sprain	2 (3.4)	2 (5.4)	0 (0.0)	4 (3.3)
Meniscus injury	3 (5.2)	1 (2.7)	0 (0.0)	4 (3.3)
Muscle rupture	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Perineal injury	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Post laminectomy syndrome	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Post procedural constipation	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Post procedural haemorrhage	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Procedural headache	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Procedural nausea	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Procedural pain	1 (1.7)	4 (10.8)	1 (4.0)	6 (5.0)
Procedural vomiting	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Road traffic accident	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Skin laceration	1 (1.7)	2 (5.4)	0 (0.0)	3 (2.5)
Tendon injury	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Thermal burn	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Investigations	2 (3.4)	0 (0.0)	1 (4.0)	3 (2.5)
Blood pressure increased	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
C-reactive protein increased	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Neurological examination	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)

Table 14.3.1.2: TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Metabolism and nutrition disorders	2 (3.4)	2 (5.4)	2 (8.0)	6 (5.0)
Diabetes mellitus	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Hypercholesterolaemia	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Type 1 diabetes mellitus	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Vitamin D deficiency	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	37 (63.8)	22 (59.5)	16 (64.0)	75 (62.5)
Arthralgia	5 (8.6)	3 (8.1)	1 (4.0)	9 (7.5)
Arthritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Back pain	16 (27.6)	9 (24.3)	12 (48.0)	37 (30.8)
Bursitis	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Cervical spinal stenosis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Chondritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Facet joint syndrome	2 (3.4)	2 (5.4)	1 (4.0)	5 (4.2)
Intervertebral disc protrusion	17 (29.3)	10 (27.0)	1 (4.0)	28 (23.3)
Lumbar spinal stenosis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Muscle spasms	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Muscle tightness	0 (0.0)	1 (2.7)	3 (12.0)	4 (3.3)
Muscular weakness	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Musculoskeletal pain	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Myalgia	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Neck pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Osteoarthritis	1 (1.7)	3 (8.1)	0 (0.0)	4 (3.3)
Pain in extremity	2 (3.4)	2 (5.4)	1 (4.0)	5 (4.2)
Periarthritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Rotator cuff syndrome	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Sacroiliac joint dysfunction	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Spinal osteoarthritis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Spinal pain	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Synovitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Tendon calcification	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Tendonitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Vertebral foraminal stenosis	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Basal cell carcinoma	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Prostate cancer	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Spinal cord neoplasm	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)

Table 14.3.1.2: TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Nervous system disorders	24 (41.4)	16 (43.2)	9 (36.0)	49 (40.8)
Areflexia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Carpal tunnel syndrome	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cervicobrachial syndrome	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Dizziness	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Dysaesthesia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Headache	5 (8.6)	4 (10.8)	2 (8.0)	11 (9.2)
Hyperaesthesia	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Hypersomnia	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Hypertonia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Hypoaesthesia	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Idiopathic generalised epilepsy	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Lumbar radiculopathy	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Migraine	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Monoparesis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Myasthenia gravis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Myelopathy	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Neuralgia	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Neuropathy peripheral	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Paraesthesia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Parkinson's disease	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Radicular pain	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Radiculopathy	3 (5.2)	1 (2.7)	0 (0.0)	4 (3.3)
Sacral radiculopathy	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sciatica	12 (20.7)	6 (16.2)	6 (24.0)	24 (20.0)
Seizure	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Syncope	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Tension headache	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Pregnancy, puerperium and perinatal conditions	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Abortion spontaneous	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Arrested labour	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cervical incompetence	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Psychiatric disorders	8 (13.8)	3 (8.1)	3 (12.0)	14 (11.7)
Anxiety disorder	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Depression	4 (6.9)	3 (8.1)	2 (8.0)	9 (7.5)
Insomnia	2 (3.4)	0 (0.0)	1 (4.0)	3 (2.5)
Mental disorder	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Panic attack	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sleep disorder	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)

Table 14.3.1.2: TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Renal and urinary disorders	2 (3.4)	2 (5.4)	0 (0.0)	4 (3.3)
Bladder irritation	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Dysuria	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Renal colic	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Renal infarct	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Ureteric stenosis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Reproductive system and breast disorders	2 (3.4)	2 (5.4)	0 (0.0)	4 (3.3)
Benign prostatic hyperplasia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Gynaecomastia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Postmenopausal haemorrhage	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Vulvovaginal pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Respiratory, thoracic and mediastinal disorders	6 (10.3)	3 (8.1)	2 (8.0)	11 (9.2)
Asthma	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Nasal polyps	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Oropharyngeal pain	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Pulmonary mass	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Respiration abnormal	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Rhinitis allergic	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Sleep apnoea syndrome	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Skin and subcutaneous tissue disorders	1 (1.7)	3 (8.1)	2 (8.0)	6 (5.0)
Eczema	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Erythema	1 (1.7)	2 (5.4)	1 (4.0)	4 (3.3)
Skin lesion	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Urticaria	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Surgical and medical procedures	3 (5.2)	3 (8.1)	4 (16.0)	10 (8.3)
Dental implantation	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Ear operation	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Endodontic procedure	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Immune tolerance induction	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Intraocular lens implant	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Nerve block	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Tooth extraction	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Wisdom teeth removal	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)

Table 14.3.1.2: TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Vascular disorders	3 (5.2)	4 (10.8)	3 (12.0)	10 (8.3)
Deep vein thrombosis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Hypertension	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Hypotension	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Thrombosis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Varicose vein	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)

Table 14.3.1.3: Serious TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Total number of subjects	58 (100)	37 (100)	25 (100)	120 (100)
Subjects with Serious TEAEs [1]	22 (37.9)	12 (32.4)	6 (24.0)	40 (33.3)
Cardiac disorders	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Diastolic dysfunction	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Endocrine disorders	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Goitre	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Gastrointestinal disorders	2 (3.4)	0 (0.0)	1 (4.0)	3 (2.5)
Colitis ulcerative	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gastritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Haemorrhoids thrombosed	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Infections and infestations	1 (1.7)	3 (8.1)	1 (4.0)	5 (4.2)
Appendicitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Erysipelas	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Intervertebral discitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Pneumonia	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Urinary tract infection	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Injury, poisoning and procedural complications	3 (5.2)	2 (5.4)	1 (4.0)	6 (5.0)
Contusion	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Foot fracture	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Meniscus injury	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Post laminectomy syndrome	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Post procedural haemorrhage	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Procedural pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Metabolism and nutrition disorders	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Type 1 diabetes mellitus	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	13 (22.4)	7 (18.9)	2 (8.0)	22 (18.3)
Back pain	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Bursitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Facet joint syndrome	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Intervertebral disc protrusion	11 (19.0)	4 (10.8)	1 (4.0)	16 (13.3)
Osteoarthritis	0 (0.0)	2 (5.4)	0 (0.0)	2 (1.7)
Rotator cuff syndrome	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Sacroiliac joint dysfunction	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)

Table 14.3.1.3: Serious TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Synovitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Tendon calcification	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Vertebral foraminal stenosis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Prostate cancer	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Nervous system disorders	5 (8.6)	0 (0.0)	1 (4.0)	6 (5.0)
Hyperaesthesia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Hypersomnia	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Idiopathic generalised epilepsy	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Parkinson's disease	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Radiculopathy	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sciatica	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Pregnancy, puerperium and perinatal conditions	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Arrested labour	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cervical incompetence	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Psychiatric disorders	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Depression	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Renal and urinary disorders	1 (1.7)	2 (5.4)	0 (0.0)	3 (2.5)
Dysuria	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Renal colic	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Renal infarct	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Ureteric stenosis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Reproductive system and breast disorders	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gynaecomastia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Respiratory, thoracic and mediastinal disorders	3 (5.2)	0 (0.0)	0 (0.0)	3 (2.5)
Nasal polyps	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Pulmonary mass	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sleep apnoea syndrome	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Surgical and medical procedures	0 (0.0)	0 (0.0)	2 (8.0)	2 (1.7)
Immune tolerance induction	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Intraocular lens implant	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)

Table 14.3.1.3: Serious TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Vascular disorders	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Deep vein thrombosis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Varicose vein	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)

Table 14.3.1.4: Pre-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Total number of subjects	58 (100)	37 (100)	25 (100)	120 (100)
Subjects with Pre-transplant TEAEs [1]	26 (44.8)	17 (45.9)	9 (36.0)	52 (43.3)
Cardiac disorders	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Atrial fibrillation	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Ear and labyrinth disorders	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Vertigo	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Eye disorders	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Eye pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gastrointestinal disorders	6 (10.3)	1 (2.7)	2 (8.0)	9 (7.5)
Diarrhoea	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Gastric disorder	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gastritis	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Haemorrhoids thrombosed	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Nausea	2 (3.4)	0 (0.0)	1 (4.0)	3 (2.5)
Vomiting	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
General disorders and administration site conditions	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Pyrexia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Immune system disorders	0 (0.0)	1 (2.7)	3 (12.0)	4 (3.3)
Drug hypersensitivity	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Seasonal allergy	0 (0.0)	1 (2.7)	2 (8.0)	3 (2.5)
Infections and infestations	6 (10.3)	2 (5.4)	1 (4.0)	9 (7.5)
Bacterial disease carrier	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cystitis	2 (3.4)	1 (2.7)	0 (0.0)	3 (2.5)
Lymphangitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Nasopharyngitis	2 (3.4)	0 (0.0)	1 (4.0)	3 (2.5)
Sinusitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Injury, poisoning and procedural complications	3 (5.2)	4 (10.8)	2 (8.0)	9 (7.5)
Dural tear	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Ligament sprain	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Meniscus injury	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Post procedural constipation	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)

SC = Standard Care; [1] Pre-transplant TEAE = any AE which started or worsened on or after the date of Visit 2b, but before the date of Visit 3b {NDplus/NDbasic} or before Visit 5 {SC}

Table 14.3.1.4: Pre-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Post procedural haemorrhage	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Procedural nausea	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Procedural pain	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Procedural vomiting	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Thermal burn	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Investigations	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
C-reactive protein increased	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Metabolism and nutrition disorders	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Diabetes mellitus	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Hypercholesterolaemia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	7 (12.1)	5 (13.5)	2 (8.0)	14 (11.7)
Arthralgia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Back pain	3 (5.2)	0 (0.0)	2 (8.0)	5 (4.2)
Bursitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Intervertebral disc protrusion	3 (5.2)	2 (5.4)	0 (0.0)	5 (4.2)
Muscle spasms	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Pain in extremity	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Nervous system disorders	4 (6.9)	5 (13.5)	1 (4.0)	10 (8.3)
Dizziness	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Dysaesthesia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Headache	1 (1.7)	2 (5.4)	0 (0.0)	3 (2.5)
Sciatica	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Seizure	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Psychiatric disorders	1 (1.7)	0 (0.0)	2 (8.0)	3 (2.5)
Depression	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Sleep disorder	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Reproductive system and breast disorders	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gynaecomastia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Respiratory, thoracic and mediastinal disorders	3 (5.2)	1 (2.7)	1 (4.0)	5 (4.2)
Oropharyngeal pain	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Respiration abnormal	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Rhinitis allergic	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Sleep apnoea syndrome	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)

SC = Standard Care; [1] Pre-transplant TEAE = any AE which started or worsened on or after the date of Visit 2b, but before the date of Visit 3b {NDplus/NDbasic} or before Visit 5 {SC}

Table 14.3.1.4: Pre-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Skin and subcutaneous tissue disorders	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Erythema	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Vascular disorders	2 (3.4)	3 (8.1)	1 (4.0)	6 (5.0)
Hypertension	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Hypotension	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Thrombosis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)

Table 14.3.1.5: Post-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Total number of subjects	58 (100)	37 (100)	25 (100)	120 (100)
Subjects with Post-transplant TEAEs [1]	46 (79.3)	26 (70.3)	22 (88.0)	94 (78.3)
Blood and lymphatic system disorders	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Anaemia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cardiac disorders	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Arrhythmia	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Diastolic dysfunction	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Ear and labyrinth disorders	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Motion sickness	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Tinnitus	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Endocrine disorders	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Autoimmune thyroiditis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Goitre	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Hypothyroidism	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Eye disorders	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cataract	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gastrointestinal disorders	8 (13.8)	3 (8.1)	3 (12.0)	14 (11.7)
Abdominal pain	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Colitis ulcerative	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Diarrhoea	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Flatulence	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Gastritis	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Gastrointestinal hypomotility	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Gastrointestinal motility disorder	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Gastroesophageal reflux disease	0 (0.0)	0 (0.0)	2 (8.0)	2 (1.7)
Haematochezia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Haemorrhoids	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Nausea	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Noninfective sialoadenitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Toothache	3 (5.2)	0 (0.0)	1 (4.0)	4 (3.3)

SC = Standard Care; [1] Post-transplant TEAE = any AE which started or worsened on or after the date of Visit 3b {NDplus/NDbasic} or the ddate of Visit 5 {SC}

Table 14.3.1.5: Post-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
General disorders and administration site conditions	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Adverse drug reaction	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Chronic fatigue syndrome	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Immune system disorders	1 (1.7)	0 (0.0)	3 (12.0)	4 (3.3)
Anaphylactic reaction	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Seasonal allergy	1 (1.7)	0 (0.0)	2 (8.0)	3 (2.5)
Infections and infestations	26 (44.8)	16 (43.2)	16 (64.0)	58 (48.3)
Abdominal infection	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Appendicitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Bacterial infection	1 (1.7)	1 (2.7)	3 (12.0)	5 (4.2)
Bronchitis	3 (5.2)	0 (0.0)	0 (0.0)	3 (2.5)
COVID-19	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Chronic sinusitis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Conjunctivitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Diverticulitis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Ear infection	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Erysipelas	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Erythema migrans	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Gastroenteritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Gastrointestinal infection	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Helicobacter infection	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Herpes zoster	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Hordeolum	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Influenza	2 (3.4)	2 (5.4)	1 (4.0)	5 (4.2)
Intervertebral discitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Nasopharyngitis	20 (34.5)	9 (24.3)	6 (24.0)	35 (29.2)
Pharyngitis	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Pharyngitis bacterial	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Pneumonia	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Pulpitis dental	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Respiratory tract infection	1 (1.7)	1 (2.7)	2 (8.0)	4 (3.3)
Rhinitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Salpingitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sinusitis	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Staphylococcal infection	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Subcutaneous abscess	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Tonsillitis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Tooth infection	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)

SC = Standard Care; [1] Post-transplant TEAE = any AE which started or worsened on or after the date of Visit 3b {NDplus/NDbasic} or the ddate of Visit 5 {SC}

Table 14.3.1.5: Post-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Upper respiratory tract infection	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Urinary tract infection	4 (6.9)	0 (0.0)	0 (0.0)	4 (3.3)
Vulvovaginal mycotic infection	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Injury, poisoning and procedural complications	10 (17.2)	11 (29.7)	3 (12.0)	24 (20.0)
Ankle fracture	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Arthropod bite	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Cartilage injury	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Contusion	2 (3.4)	2 (5.4)	0 (0.0)	4 (3.3)
Fall	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Foot fracture	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Joint dislocation	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Ligament rupture	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Ligament sprain	2 (3.4)	1 (2.7)	0 (0.0)	3 (2.5)
Meniscus injury	2 (3.4)	1 (2.7)	0 (0.0)	3 (2.5)
Muscle rupture	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Perineal injury	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Post laminectomy syndrome	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Procedural headache	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Procedural pain	1 (1.7)	3 (8.1)	0 (0.0)	4 (3.3)
Road traffic accident	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Skin laceration	1 (1.7)	2 (5.4)	0 (0.0)	3 (2.5)
Tendon injury	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Investigations	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Blood pressure increased	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Neurological examination	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Metabolism and nutrition disorders	1 (1.7)	2 (5.4)	1 (4.0)	4 (3.3)
Hypercholesterolaemia	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Type 1 diabetes mellitus	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Vitamin D deficiency	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	33 (56.9)	18 (48.6)	16 (64.0)	67 (55.8)
Arthralgia	4 (6.9)	3 (8.1)	1 (4.0)	8 (6.7)
Arthritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Back pain	14 (24.1)	9 (24.3)	12 (48.0)	35 (29.2)
Bursitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cervical spinal stenosis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Chondritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)

SC = Standard Care; [1] Post-transplant TEAE = any AE which started or worsened on or after the date of Visit 3b {NDplus/NDbasic} or the ddate of Visit 5 {SC}

Table 14.3.1.5: Post-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Facet joint syndrome	2 (3.4)	2 (5.4)	1 (4.0)	5 (4.2)
Intervertebral disc protrusion	14 (24.1)	8 (21.6)	1 (4.0)	23 (19.2)
Lumbar spinal stenosis	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Muscle spasms	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Muscle tightness	0 (0.0)	1 (2.7)	3 (12.0)	4 (3.3)
Muscular weakness	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Musculoskeletal pain	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Myalgia	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Neck pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Osteoarthritis	1 (1.7)	3 (8.1)	0 (0.0)	4 (3.3)
Pain in extremity	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Periarthritis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Rotator cuff syndrome	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Sacroiliac joint dysfunction	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Spinal osteoarthritis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Spinal pain	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Synovitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Tendon calcification	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Tendonitis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Vertebral foraminal stenosis	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Basal cell carcinoma	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Prostate cancer	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Spinal cord neoplasm	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Nervous system disorders	22 (37.9)	12 (32.4)	9 (36.0)	43 (35.8)
Areflexia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Carpal tunnel syndrome	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cervicobrachial syndrome	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Dizziness	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Headache	4 (6.9)	3 (8.1)	2 (8.0)	9 (7.5)
Hyperaesthesia	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Hypersomnia	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Hypertonia	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Hypoaesthesia	1 (1.7)	1 (2.7)	1 (4.0)	3 (2.5)
Idiopathic generalised epilepsy	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Lumbar radiculopathy	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Migraine	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Monoparesis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)

SC = Standard Care; [1] Post-transplant TEAE = any AE which started or worsened on or after the date of Visit 3b {NDplus/NDbasic} or the ddate of Visit 5 {SC}

Table 14.3.1.5: Post-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Myasthenia gravis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Myelopathy	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Neuralgia	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Neuropathy peripheral	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Paraesthesia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Parkinson's disease	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Radicular pain	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Radiculopathy	3 (5.2)	1 (2.7)	0 (0.0)	4 (3.3)
Sacral radiculopathy	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sciatica	11 (19.0)	5 (13.5)	5 (20.0)	21 (17.5)
Syncope	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Tension headache	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Pregnancy, puerperium and perinatal conditions	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Abortion spontaneous	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Arrested labour	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Cervical incompetence	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Psychiatric disorders	7 (12.1)	3 (8.1)	2 (8.0)	12 (10.0)
Anxiety disorder	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Depression	4 (6.9)	3 (8.1)	2 (8.0)	9 (7.5)
Insomnia	2 (3.4)	0 (0.0)	1 (4.0)	3 (2.5)
Mental disorder	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Panic attack	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Renal and urinary disorders	2 (3.4)	2 (5.4)	0 (0.0)	4 (3.3)
Bladder irritation	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Dysuria	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Renal colic	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Renal infarct	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Ureteric stenosis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Reproductive system and breast disorders	1 (1.7)	2 (5.4)	0 (0.0)	3 (2.5)
Benign prostatic hyperplasia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Postmenopausal haemorrhage	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Vulvovaginal pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)

SC = Standard Care; [1] Post-transplant TEAE = any AE which started or worsened on or after the date of Visit 3b {NDplus/NDbasic} or the ddate of Visit 5 {SC}

Table 14.3.1.5: Post-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Respiratory, thoracic and mediastinal disorders	3 (5.2)	2 (5.4)	1 (4.0)	6 (5.0)
Asthma	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Nasal polyps	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Oropharyngeal pain	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Pulmonary mass	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sleep apnoea syndrome	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Skin and subcutaneous tissue disorders	1 (1.7)	2 (5.4)	2 (8.0)	5 (4.2)
Eczema	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Erythema	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Skin lesion	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Urticaria	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Surgical and medical procedures	3 (5.2)	3 (8.1)	4 (16.0)	10 (8.3)
Dental implantation	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Ear operation	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Endodontic procedure	1 (1.7)	1 (2.7)	0 (0.0)	2 (1.7)
Immune tolerance induction	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Intraocular lens implant	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Nerve block	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Tooth extraction	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Wisdom teeth removal	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Vascular disorders	2 (3.4)	1 (2.7)	2 (8.0)	5 (4.2)
Deep vein thrombosis	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Hypertension	1 (1.7)	0 (0.0)	1 (4.0)	2 (1.7)
Varicose vein	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)

SC = Standard Care; [1] Post-transplant TEAE = any AE which started or worsened on or after the date of Visit 3b {NDplus/NDbasic} or the ddate of Visit 5 {SC}

Table 14.3.1.6: Related pre-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Total number of subjects	58 (100)	37 (100)	25 (100)	120 (100)
Subjects with Related pre-transplant TEAEs [1]	8 (13.8)	2 (5.4)	3 (12.0)	13 (10.8)
Injury, poisoning and procedural complications	2 (3.4)	2 (5.4)	2 (8.0)	6 (5.0)
Dural tear	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Post procedural constipation	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Post procedural haemorrhage	0 (0.0)	0 (0.0)	1 (4.0)	1 (0.8)
Procedural nausea	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Procedural pain	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Procedural vomiting	0 (0.0)	1 (2.7)	1 (4.0)	2 (1.7)
Investigations	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
C-reactive protein increased	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	3 (5.2)	0 (0.0)	0 (0.0)	3 (2.5)
Back pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Intervertebral disc protrusion	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.7)
Nervous system disorders	2 (3.4)	1 (2.7)	1 (4.0)	4 (3.3)
Dysaesthesia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Sciatica	2 (3.4)	0 (0.0)	1 (4.0)	3 (2.5)
Psychiatric disorders	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Sleep disorder	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)

Table 14.3.1.7: Related post-transplant TEAEs by system organ class and preferred term - safety set

Primary system organ class (SOC) Preferred term	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Total number of subjects	58 (100)	37 (100)	25 (100)	120 (100)
Subjects with Related post-transplant TEAEs [1]	9 (15.5)	5 (13.5)	0 (0.0)	14 (11.7)
Injury, poisoning and procedural complications	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Procedural pain	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	6 (10.3)	4 (10.8)	0 (0.0)	10 (8.3)
Back pain	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)
Intervertebral disc protrusion	5 (8.6)	3 (8.1)	0 (0.0)	8 (6.7)
Pain in extremity	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Spinal pain	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Nervous system disorders	4 (6.9)	2 (5.4)	0 (0.0)	6 (5.0)
Monoparesis	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Paraesthesia	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.8)
Sciatica	4 (6.9)	1 (2.7)	0 (0.0)	5 (4.2)

SC = Standard Care; [1] Post-transplant TEAE = any AE which started or worsened on or after the date of Visit 3b {NDplus/NDbasic} or the ddate of Visit 5 {SC}

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 1*					
Height (cm)	N with data	45	25	25	95
	Mean	174.8	177.5	177.3	176.2
	SD	9.72	10.59	9.45	9.87
	Min	158	158	158	158
	25% quantile	168.0	168.0	172.0	168.0
	Median	174.0	176.0	179.0	175.0
	75% quantile	182.0	189.0	185.0	185.0
	Max	198	193	191	198
	Weight (kg)	N with data	45	25	25
Mean		76.8	80.4	81.4	79.0
SD		15.81	13.88	13.04	14.63
Min		50	58	49	49
25% quantile		66.0	72.0	73.0	70.0
Median		75.0	75.0	82.0	78.0
75% quantile		86.0	90.0	86.0	88.0
Max		115	109	110	115
BMI (kg/m ²)		N with data	45	25	25
	Mean	25.0	25.4	25.9	25.3
	SD	3.45	3.14	4.16	3.56
	Min	19	19	19	19
	25% quantile	22.7	23.4	24.2	23.0
	Median	24.9	25.2	25.3	25.0
	75% quantile	27.2	27.8	28.4	27.9
	Max	33	33	35	35

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 1* (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	44	24	25	93
	Mean	131.7	132.3	128.2	130.9
	SD	17.89	16.92	14.41	16.67
	Min	90	100	100	90
	25% quantile	120.0	118.0	120.0	120.0
	Median	130.0	130.0	130.0	130.0
	75% quantile	142.0	140.0	140.0	140.0
	Max	170	174	154	174
Diastolic Blood Pressure (mmHg)					
	N with data	44	24	25	93
	Mean	84.1	83.4	82.2	83.4
	SD	11.67	12.78	10.54	11.58
	Min	60	60	60	60
	25% quantile	77.5	75.0	80.0	80.0
	Median	81.5	80.0	80.0	80.0
	75% quantile	90.0	90.0	86.0	90.0
	Max	110	109	102	110
Pulse Rate (beats/min)					
	N with data	44	24	25	93
	Mean	74.3	77.4	76.6	75.7
	SD	9.54	10.93	11.74	10.50
	Min	50	60	49	49
	25% quantile	70.0	70.0	71.0	70.0
	Median	74.0	76.0	78.0	76.0
	75% quantile	80.0	82.5	82.0	80.0
	Max	101	109	102	109

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Baseline (Visit 2a)					
Height (cm)	N with data	53	35	24	112
	Mean	176.4	177.9	177.0	177.0
	SD	9.73	9.73	9.51	9.62
	Min	158	157	158	157
	25% quantile	169.0	170.0	171.0	170.0
	Median	176.0	178.0	178.5	177.5
	75% quantile	184.0	188.0	185.0	185.0
	Max	198	193	191	198
Weight (kg)	N with data	53	34	24	111
	Mean	77.4	79.8	80.9	78.9
	SD	14.45	12.55	13.07	13.56
	Min	50	58	49	49
	25% quantile	67.0	71.0	72.5	70.0
	Median	75.0	78.0	82.0	78.0
	75% quantile	86.0	90.0	85.5	87.0
	Max	115	109	110	115
BMI (kg/m ²)	N with data	53	34	24	111
	Mean	24.7	25.1	25.9	25.1
	SD	3.10	2.84	4.24	3.31
	Min	18	19	19	18
	25% quantile	22.9	23.0	23.6	22.9
	Median	24.9	25.2	25.1	24.9
	75% quantile	26.9	27.7	28.7	27.2
	Max	33	30	35	35

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Baseline (Visit 2a) (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	53	34	24	111
	Mean	132.9	131.4	127.0	131.2
	SD	17.60	15.75	13.54	16.27
	Min	90	100	100	90
	25% quantile	120.0	120.0	120.0	120.0
	Median	130.0	130.0	130.0	130.0
	75% quantile	142.0	140.0	138.0	140.0
	Max	170	174	150	174
Diastolic Blood Pressure (mmHg)					
	N with data	53	34	24	111
	Mean	82.0	82.2	83.0	82.3
	SD	10.68	10.82	10.56	10.60
	Min	60	60	60	60
	25% quantile	78.0	78.0	80.0	78.0
	Median	81.0	80.0	80.0	80.0
	75% quantile	90.0	90.0	90.0	90.0
	Max	104	109	102	109
Pulse Rate (beats/min)					
	N with data	53	34	24	111
	Mean	72.9	73.7	75.8	73.8
	SD	8.84	10.54	11.94	10.07
	Min	50	55	49	49
	25% quantile	67.0	65.0	70.0	67.0
	Median	72.0	75.0	75.5	74.0
	75% quantile	80.0	80.0	81.0	80.0
	Max	100	96	102	102

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 3a					
Height (cm)					
	N with data	50	28	-	78
	Mean	175.9	177.8	-	176.6
	SD	10.12	9.81	-	9.99
	Min	158	158	-	158
	25% quantile	168.0	169.5	-	169.0
	Median	176.0	179.0	-	176.5
	75% quantile	184.0	188.0	-	185.0
	Max	198	193	-	198
Weight (kg)					
	N with data	50	28	-	78
	Mean	77.1	81.5	-	78.7
	SD	13.43	13.31	-	13.47
	Min	51	57	-	51
	25% quantile	67.0	72.0	-	70.0
	Median	75.5	80.0	-	78.0
	75% quantile	87.0	91.5	-	89.0
	Max	115	110	-	115
BMI (kg/m ²)					
	N with data	50	28	-	78
	Mean	24.8	25.7	-	25.1
	SD	2.78	3.08	-	2.91
	Min	19	20	-	19
	25% quantile	23.1	24.0	-	23.1
	Median	24.9	25.8	-	25.0
	75% quantile	26.7	27.7	-	27.2
	Max	31	33	-	33

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 3a (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	50	28	-	78
	Mean	129.1	132.5	-	130.3
	SD	15.20	20.23	-	17.13
	Min	100	100	-	100
	25% quantile	120.0	119.0	-	120.0
	Median	130.0	130.0	-	130.0
	75% quantile	140.0	141.5	-	140.0
	Max	168	207	-	207
Diastolic Blood Pressure (mmHg)					
	N with data	50	28	-	78
	Mean	81.1	82.9	-	81.8
	SD	11.14	10.83	-	10.99
	Min	60	65	-	60
	25% quantile	70.0	70.5	-	70.0
	Median	80.0	82.0	-	80.0
	75% quantile	90.0	90.0	-	90.0
	Max	107	106	-	107
Pulse Rate (beats/min)					
	N with data	49	26	-	75
	Mean	72.8	69.3	-	71.6
	SD	9.73	11.81	-	10.55
	Min	54	44	-	44
	25% quantile	66.0	60.0	-	65.0
	Median	72.0	72.0	-	72.0
	75% quantile	80.0	78.0	-	80.0
	Max	100	89	-	100

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 4					
Height (cm)	N with data	46	27	24	97
	Mean	176.1	177.3	177.4	176.8
	SD	10.30	9.59	9.59	9.85
	Min	158	158	158	158
	25% quantile	168.0	169.0	171.0	169.0
	Median	176.5	178.0	179.5	178.0
	75% quantile	185.0	188.0	185.0	185.0
	Max	198	192	191	198
Weight (kg)	N with data	46	27	24	97
	Mean	77.0	81.8	81.3	79.4
	SD	13.32	12.86	13.35	13.26
	Min	50	57	48	48
	25% quantile	69.0	72.0	74.0	71.0
	Median	75.0	80.0	81.0	78.0
	75% quantile	87.0	91.0	87.5	89.0
	Max	111	107	111	111
BMI (kg/m ²)	N with data	46	27	24	97
	Mean	24.7	25.9	25.9	25.3
	SD	2.86	2.78	4.41	3.31
	Min	18	22	19	18
	25% quantile	22.9	24.1	23.1	23.2
	Median	25.0	25.8	25.3	25.4
	75% quantile	26.9	27.7	28.2	27.1
	Max	30	33	36	36

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 4 (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	46	27	24	97
	Mean	129.5	127.8	126.2	128.2
	SD	15.07	13.11	14.25	14.27
	Min	100	110	100	100
	25% quantile	120.0	118.0	120.0	120.0
	Median	130.0	125.0	125.0	130.0
	75% quantile	140.0	140.0	130.0	138.0
	Max	161	160	170	170
Diastolic Blood Pressure (mmHg)					
	N with data	46	27	24	97
	Mean	82.2	82.6	83.5	82.6
	SD	11.22	9.44	9.87	10.33
	Min	60	64	70	60
	25% quantile	77.0	80.0	75.0	78.0
	Median	82.0	80.0	80.0	80.0
	75% quantile	90.0	88.0	89.5	89.0
	Max	113	109	102	113
Pulse Rate (beats/min)					
	N with data	46	26	24	96
	Mean	72.4	72.7	76.1	73.4
	SD	10.50	11.29	11.30	10.92
	Min	52	52	56	52
	25% quantile	64.0	66.0	66.0	64.0
	Median	73.0	72.0	76.0	72.5
	75% quantile	80.0	76.0	84.0	80.0
	Max	100	108	95	108

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 5					
Height (cm)					
	N with data	46	27	23	96
	Mean	176.3	177.4	177.1	176.8
	SD	10.08	9.54	9.70	9.75
	Min	158	158	158	158
	25% quantile	169.0	169.0	170.0	169.5
	Median	176.5	178.0	179.0	178.0
	75% quantile	185.0	188.0	185.0	185.0
	Max	198	192	191	198
Weight (kg)					
	N with data	46	27	23	96
	Mean	77.0	81.7	80.5	79.1
	SD	13.51	13.35	12.33	13.23
	Min	51	57	49	49
	25% quantile	68.0	72.0	74.0	70.0
	Median	76.0	80.0	80.0	78.5
	75% quantile	87.0	90.0	88.0	88.5
	Max	112	109	107	112
BMI (kg/m ²)					
	N with data	46	27	23	96
	Mean	24.6	25.8	25.7	25.2
	SD	2.85	2.94	4.27	3.28
	Min	19	21	19	19
	25% quantile	22.8	23.4	22.5	23.2
	Median	24.7	25.8	25.4	24.9
	75% quantile	26.6	27.8	27.8	27.0
	Max	30	33	36	36

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 5 (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	46	26	22	94
	Mean	132.2	125.4	126.0	128.9
	SD	16.26	10.46	9.42	13.72
	Min	110	110	110	110
	25% quantile	120.0	115.0	120.0	120.0
	Median	130.0	124.0	127.0	129.5
	75% quantile	140.0	135.0	130.0	135.0
	Max	175	147	146	175
Diastolic Blood Pressure (mmHg)					
	N with data	46	26	22	94
	Mean	84.1	81.7	81.6	82.8
	SD	10.71	9.71	8.61	9.96
	Min	65	64	70	64
	25% quantile	79.0	70.0	75.0	75.0
	Median	85.0	82.0	80.0	81.5
	75% quantile	90.0	90.0	90.0	90.0
	Max	113	100	97	113
Pulse Rate (beats/min)					
	N with data	46	26	22	94
	Mean	74.5	74.3	74.3	74.4
	SD	9.81	10.13	9.02	9.62
	Min	52	60	63	52
	25% quantile	68.0	67.0	64.0	67.0
	Median	76.0	74.0	73.0	76.0
	75% quantile	82.0	80.0	80.0	80.0
	Max	94	105	93	105

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 6					
Height (cm)					
	N with data	46	26	23	95
	Mean	175.9	176.8	177.5	176.5
	SD	10.43	9.26	10.39	10.03
	Min	158	158	158	158
	25% quantile	168.0	169.0	170.0	169.0
	Median	175.5	177.0	179.0	176.0
	75% quantile	185.0	182.0	185.0	185.0
	Max	198	190	199	199
Weight (kg)					
	N with data	46	26	23	95
	Mean	76.7	81.1	80.5	78.8
	SD	13.98	12.80	12.70	13.39
	Min	51	57	50	50
	25% quantile	66.0	72.0	76.0	70.0
	Median	76.0	80.0	81.0	78.0
	75% quantile	87.0	90.0	88.0	89.0
	Max	112	106	108	112
BMI (kg/m ²)					
	N with data	46	26	23	95
	Mean	24.6	25.8	25.6	25.2
	SD	2.83	2.80	4.44	3.30
	Min	18	21	20	18
	25% quantile	22.6	23.2	22.1	23.0
	Median	24.7	25.8	25.1	25.0
	75% quantile	26.6	27.7	28.1	26.9
	Max	31	33	37	37

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 6 (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	46	26	23	95
	Mean	130.9	130.0	125.3	129.3
	SD	14.98	10.20	11.87	13.17
	Min	100	110	109	100
	25% quantile	120.0	120.0	120.0	120.0
	Median	132.0	130.0	122.0	130.0
	75% quantile	141.0	139.0	132.0	140.0
	Max	161	145	153	161
Diastolic Blood Pressure (mmHg)					
	N with data	46	26	23	95
	Mean	84.3	82.8	78.6	82.5
	SD	11.50	7.55	10.85	10.55
	Min	60	70	58	58
	25% quantile	75.0	80.0	70.0	75.0
	Median	80.5	80.5	80.0	80.0
	75% quantile	93.0	88.0	85.0	90.0
	Max	109	98	98	109
Pulse Rate (beats/min)					
	N with data	46	26	23	95
	Mean	75.9	73.7	73.5	74.7
	SD	10.35	11.50	6.82	9.93
	Min	48	41	64	41
	25% quantile	68.0	65.0	66.0	68.0
	Median	77.0	76.0	72.0	76.0
	75% quantile	80.0	80.0	80.0	80.0
	Max	99	89	88	99

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 7					
Height (cm)					
	N with data	46	26	21	93
	Mean	176.0	176.8	177.5	176.6
	SD	10.35	9.29	10.00	9.90
	Min	158	158	158	158
	25% quantile	168.0	169.0	172.0	169.0
	Median	176.0	177.0	180.0	178.0
	75% quantile	185.0	182.0	185.0	185.0
	Max	198	190	191	198
Weight (kg)					
	N with data	46	26	21	93
	Mean	77.4	81.5	82.2	79.6
	SD	13.50	13.33	11.84	13.15
	Min	51	58	50	50
	25% quantile	67.0	72.0	80.0	71.0
	Median	75.5	81.0	82.0	80.0
	75% quantile	87.0	90.0	88.0	89.0
	Max	113	109	109	113
BMI (kg/m ²)					
	N with data	46	26	21	93
	Mean	24.8	26.0	26.2	25.5
	SD	2.73	3.02	4.20	3.22
	Min	19	21	20	19
	25% quantile	23.2	23.2	23.5	23.2
	Median	24.8	25.8	25.4	25.1
	75% quantile	26.6	28.4	28.1	27.5
	Max	30	33	36	36

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 7 (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	46	26	21	93
	Mean	133.7	135.7	127.8	132.9
	SD	16.18	16.85	10.53	15.42
	Min	102	110	110	102
	25% quantile	123.0	124.0	120.0	120.0
	Median	130.0	136.5	129.0	130.0
	75% quantile	141.0	146.0	130.0	140.0
	Max	169	182	150	182
Diastolic Blood Pressure (mmHg)					
	N with data	46	26	21	93
	Mean	84.5	83.5	82.9	83.8
	SD	11.60	10.75	10.15	10.96
	Min	60	69	70	60
	25% quantile	80.0	78.0	75.0	78.0
	Median	85.5	80.0	80.0	84.0
	75% quantile	93.0	90.0	90.0	90.0
	Max	115	114	105	115
Pulse Rate (beats/min)					
	N with data	46	26	21	93
	Mean	73.7	74.5	78.5	75.0
	SD	10.99	13.02	14.79	12.51
	Min	56	43	58	43
	25% quantile	67.0	65.0	68.0	66.0
	Median	72.5	74.5	80.0	73.0
	75% quantile	80.0	80.0	85.0	81.0
	Max	100	100	107	107

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 8					
Height (cm)					
	N with data	43	26	22	91
	Mean	176.3	176.7	177.1	176.6
	SD	10.39	9.21	9.86	9.83
	Min	158	158	158	158
	25% quantile	168.0	168.0	170.0	169.0
	Median	176.0	177.0	179.5	178.0
	75% quantile	186.0	182.0	185.0	185.0
	Max	198	190	191	198
Weight (kg)					
	N with data	43	26	22	91
	Mean	77.6	82.8	82.4	80.2
	SD	15.39	14.94	12.65	14.71
	Min	51	57	48	48
	25% quantile	67.0	73.0	77.0	70.0
	Median	75.0	80.0	84.0	80.0
	75% quantile	92.0	94.0	90.0	90.0
	Max	115	120	108	120
BMI (kg/m ²)					
	N with data	44	26	22	92
	Mean	25.9	26.4	26.4	26.1
	SD	7.97	3.26	4.57	6.15
	Min	19	22	19	19
	25% quantile	22.5	23.8	23.8	23.1
	Median	24.6	25.9	25.3	25.2
	75% quantile	27.1	28.4	28.4	27.8
	Max	73	34	37	73

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
Visit 8 (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	43	26	22	91
	Mean	131.3	130.7	126.8	130.0
	SD	15.97	11.06	11.84	13.75
	Min	100	110	110	100
	25% quantile	120.0	122.0	116.0	120.0
	Median	130.0	130.0	129.0	130.0
	75% quantile	143.0	138.0	131.0	140.0
	Max	166	155	149	166
Diastolic Blood Pressure (mmHg)					
	N with data	43	26	22	91
	Mean	85.5	82.3	80.5	83.4
	SD	11.06	10.04	10.23	10.68
	Min	60	68	64	60
	25% quantile	80.0	80.0	70.0	78.0
	Median	86.0	80.0	80.0	80.0
	75% quantile	93.0	87.0	86.0	89.0
	Max	110	113	102	113
Pulse Rate (beats/min)					
	N with data	43	26	22	91
	Mean	74.3	74.1	72.5	73.8
	SD	11.82	12.18	8.35	11.10
	Min	50	39	60	39
	25% quantile	64.0	68.0	68.0	66.0
	Median	73.0	72.0	71.5	72.0
	75% quantile	81.0	80.0	79.0	80.0
	Max	108	100	89	108

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
End of Trial					
Height (cm)	N with data	41	27	20	88
	Mean	175.9	176.0	177.5	176.3
	SD	10.42	9.94	10.33	10.16
	Min	158	157	158	157
	25% quantile	169.0	168.0	171.0	169.0
	Median	176.0	176.0	179.5	178.0
	75% quantile	184.0	182.0	185.0	185.0
	Max	198	190	191	198
Weight (kg)	N with data	40	27	20	87
	Mean	78.8	82.9	86.0	81.7
	SD	14.42	14.25	12.69	14.14
	Min	53	58	49	49
	25% quantile	70.3	74.0	83.0	74.0
	Median	76.5	84.0	87.5	83.0
	75% quantile	87.0	91.0	90.5	91.0
	Max	115	120	105	120
BMI (kg/m ²)	N with data	40	27	20	87
	Mean	25.3	26.7	27.4	26.2
	SD	2.98	3.44	4.61	3.62
	Min	20	21	19	19
	25% quantile	23.2	24.0	23.9	23.5
	Median	25.3	25.9	27.5	25.7
	75% quantile	27.0	29.7	30.4	28.7
	Max	33	34	38	38

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.2.1: Vital signs - safety set

Visit Parameter	Statistic	NDplus (N=58)	NDbasic (N=37)	SC (N=25)	Overall (N=120)
End of Trial (continued)					
Systolic Blood Pressure (mmHg)					
	N with data	39	26	19	84
	Mean	130.1	133.1	131.5	131.3
	SD	16.84	13.44	13.99	15.11
	Min	100	110	106	100
	25% quantile	115.0	125.0	122.0	120.0
	Median	130.0	130.0	131.0	130.0
	75% quantile	145.0	141.0	140.0	140.0
	Max	164	174	170	174
Diastolic Blood Pressure (mmHg)					
	N with data	39	26	19	84
	Mean	82.8	81.7	81.1	82.1
	SD	11.08	8.48	7.99	9.60
	Min	60	70	70	60
	25% quantile	78.0	75.0	75.0	76.5
	Median	82.0	80.0	80.0	80.0
	75% quantile	90.0	89.0	85.0	89.0
	Max	104	102	100	104
Pulse Rate (beats/min)					
	N with data	39	26	19	84
	Mean	75.1	76.6	73.8	75.3
	SD	11.91	9.89	11.46	11.14
	Min	55	60	49	49
	25% quantile	68.0	70.0	68.0	68.0
	Median	75.0	76.0	72.0	75.5
	75% quantile	86.0	84.0	80.0	84.0
	Max	110	100	100	110

SC = Standard Care

* Visit 1 applicable for Phase II subjects only.

Visit 3a only applicable for patients in NDplus or NDbasic group

Clinipace: 14DEC21 / 7:39 / vit.lst / vit.sas

Table 14.3.3.1: MRI parameters - change in extradiscal fluid collection from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Extradiscal fluid collection	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 1/Visit 2A**	ND plus (N=58)				
	No	58 (100)	0		58 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	58 (100)	0		58 (100)
	ND basic (N=37)				
	No	37 (100)	0		37 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	37 (100)	0		37 (100)
	SC (N=25)				
	No	25 (100)	0		25 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	25 (100)	0		25 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.1: MRI parameters - change in extradiscal fluid collection from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Extradiscal fluid collection	Number (%) of subjects				
		Screening (Visit 1)/Baseline (Visit 2A)**				
		No	Yes	Missing	Sum	
Visit 3a*	ND plus (N=50)					
	No	50 (100)	0		50 (100)	
	Yes	0	0		0 (0)	
	Missing	0	0		0 (0)	
	Sum	50 (100)	0		50 (100)	
	ND basic (N=28)					
	No	28 (100)	0		28 (100)	
	Yes	0	0		0 (0)	
	Missing	0	0		0 (0)	
	Sum	28 (100)	0		28 (100)	
	Visit 4	ND plus (N=47)				
		No	47 (100)	0		47 (100)
Yes		0	0		0 (0)	
Missing		0	0		0 (0)	
Sum		47 (100)	0		47 (100)	
ND basic (N=27)						
No		27 (100)	0		27 (100)	
Yes		0	0		0 (0)	
Missing		0	0		0 (0)	
Sum		27 (100)	0		27 (100)	
SC (N=24)						
No		24 (100)	0		24 (100)	
Yes		0	0		0 (0)	
Missing		0	0		0 (0)	
Sum		24 (100)	0		24 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.1: MRI parameters - change in extradiscal fluid collection from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Extradiscal fluid collection	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 5	ND plus (N=12)				
	No	12 (100)	0		12 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	12 (100)	0		12 (100)
	ND basic (N=8)				
	No	8 (100)	0		8 (100)
	Yes	0	0		0 (0)
Missing	0	0		0 (0)	
Sum	8 (100)	0		8 (100)	
Visit 6	ND plus (N=46)				
	No	45 (97.8)	0		45 (97.8)
	Yes	1 (2.2)	0		1 (2.2)
	Missing	0	0		0 (0)
	Sum	46 (100)	0		46 (100)
	ND basic (N=25)				
	No	25 (100)	0		25 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	25 (100)	0		25 (100)
	SC (N=23)				
	No	23 (100)	0		23 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	23 (100)	0		23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.1: MRI parameters - change in extradiscal fluid collection from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Extradiscal fluid collection	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 7	ND plus (N=46)				
	No	46 (100)	0		46 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	46 (100)	0		46 (100)
	ND basic (N=26)				
	No	26 (100)	0		26 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	26 (100)	0		26 (100)
	SC (N=21)				
	No	21 (100)	0		21 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	21 (100)	0		21 (100)	
Visit 8	ND plus (N=43)				
	No	43 (100)	0		43 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	43 (100)	0		43 (100)
	ND basic (N=25)				
	No	25 (100)	0		25 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	25 (100)	0		25 (100)
	SC (N=22)				
	No	22 (100)	0		22 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	22 (100)	0		22 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.1: MRI parameters - change in extradiscal fluid collection from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Extradiscal fluid collection	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
End of Trial	ND plus (N=39)				
	No	39 (100)	0		39 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	39 (100)	0		39 (100)
	ND basic (N=26)				
	No	26 (100)	0		26 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	26 (100)	0		26 (100)
	SC (N=20)				
	No	20 (100)	0		20 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	20 (100)	0		20 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.2: MRI parameters - change in fracture from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Fracture	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 1/Visit 2A**	ND plus (N=58)				
	No	58 (100)	0		58 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	58 (100)	0		58 (100)
	ND basic (N=37)				
	No	37 (100)	0		37 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	37 (100)	0		37 (100)
	SC (N=25)				
	No	25 (100)	0		25 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	25 (100)	0		25 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.2: MRI parameters - change in fracture from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Fracture	Number (%) of subjects				
		Screening (Visit 1)/Baseline (Visit 2A)**				
		No	Yes	Missing	Sum	
Visit 3a*	ND plus (N=50)					
	No	50 (100)	0		50 (100)	
	Yes	0	0		0 (0)	
	Missing	0	0		0 (0)	
	Sum	50 (100)	0		50 (100)	
	ND basic (N=28)					
	No	28 (100)	0		28 (100)	
	Yes	0	0		0 (0)	
	Missing	0	0		0 (0)	
	Sum	28 (100)	0		28 (100)	
	Visit 4	ND plus (N=47)				
		No	47 (100)	0		47 (100)
Yes		0	0		0 (0)	
Missing		0	0		0 (0)	
Sum		47 (100)	0		47 (100)	
ND basic (N=27)						
No		27 (100)	0		27 (100)	
Yes		0	0		0 (0)	
Missing		0	0		0 (0)	
Sum		27 (100)	0		27 (100)	
SC (N=24)						
No		24 (100)	0		24 (100)	
Yes		0	0		0 (0)	
Missing		0	0		0 (0)	
Sum		24 (100)	0		24 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.2: MRI parameters - change in fracture from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Fracture	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 5	ND plus (N=12)				
	No	12 (100)	0		12 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	12 (100)	0		12 (100)
	ND basic (N=8)				
	No	8 (100)	0		8 (100)
	Yes	0	0		0 (0)
Missing	0	0		0 (0)	
Sum	8 (100)	0		8 (100)	
Visit 6	ND plus (N=46)				
	No	46 (100)	0		46 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	46 (100)	0		46 (100)
	ND basic (N=25)				
	No	25 (100)	0		25 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	25 (100)	0		25 (100)
	SC (N=23)				
	No	23 (100)	0		23 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	23 (100)	0		23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.2: MRI parameters - change in fracture from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Fracture	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 7	ND plus (N=46)				
	No	46 (100)	0		46 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	46 (100)	0		46 (100)
	ND basic (N=26)				
	No	26 (100)	0		26 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	26 (100)	0		26 (100)
	SC (N=21)				
	No	21 (100)	0		21 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	21 (100)	0		21 (100)	
Visit 8	ND plus (N=43)				
	No	43 (100)	0		43 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	43 (100)	0		43 (100)
	ND basic (N=25)				
	No	25 (100)	0		25 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	25 (100)	0		25 (100)
	SC (N=22)				
	No	22 (100)	0		22 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	22 (100)	0		22 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.2: MRI parameters - change in fracture from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Fracture	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
End of Trial	ND plus (N=39)				
	No	39 (100)	0		39 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	39 (100)	0		39 (100)
	ND basic (N=26)				
	No	26 (100)	0		26 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	26 (100)	0		26 (100)
	SC (N=20)				
	No	20 (100)	0		20 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	20 (100)	0		20 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.3: MRI parameters - change in normal lordotic LS from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Normal lordotic LS	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 1/Visit 2A**	ND plus (N=58)				
	No	5 (8.6)	0		5 (8.6)
	Yes	0	53 (91.4)		53 (91.4)
	Missing	0	0		0 (0)
	Sum	5 (8.6)	53 (91.4)		58 (100)
	ND basic (N=37)				
	No	3 (8.1)	0		3 (8.1)
	Yes	0	34 (91.9)		34 (91.9)
	Missing	0	0		0 (0)
	Sum	3 (8.1)	34 (91.9)		37 (100)
	SC (N=25)				
	No	1 (4.0)	0		1 (4.0)
Yes	0	24 (96.0)		24 (96.0)	
Missing	0	0		0 (0)	
Sum	1 (4.0)	24 (96.0)		25 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.3: MRI parameters - change in normal lordotic LS from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Normal lordotic LS	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 3a*	ND plus (N=50)				
	No	3 (6.0)	0		3 (6.0)
	Yes	1 (2.0)	46 (92.0)		47 (94.0)
	Missing	0	0		0 (0)
	Sum	4 (8.0)	46 (92.0)		50 (100)
	ND basic (N=28)				
	No	2 (7.1)	0		2 (7.1)
	Yes	0	26 (92.9)		26 (92.9)
	Missing	0	0		0 (0)
	Sum	2 (7.1)	26 (92.9)		28 (100)
Visit 4	ND plus (N=47)				
	No	3 (6.4)	0		3 (6.4)
	Yes	1 (2.1)	43 (91.5)		44 (93.6)
	Missing	0	0		0 (0)
	Sum	4 (8.5)	43 (91.5)		47 (100)
	ND basic (N=27)				
	No	1 (3.7)	1 (3.7)		2 (7.4)
	Yes	0	25 (92.6)		25 (92.6)
	Missing	0	0		0 (0)
	Sum	1 (3.7)	26 (96.3)		27 (100)
	SC (N=24)				
	No	1 (4.2)	1 (4.2)		2 (8.3)
	Yes	0	22 (91.7)		22 (91.7)
	Missing	0	0		0 (0)
Sum	1 (4.2)	23 (95.8)		24 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.3: MRI parameters - change in normal lordotic LS from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Normal lordotic LS	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 5	ND plus (N=12)				
	No	0	0		0 (0)
	Yes	1 (8.3)	11 (91.7)		12 (100)
	Missing	0	0		0 (0)
	Sum	1 (8.3)	11 (91.7)		12 (100)
	ND basic (N=8)				
	No	0	0		0 (0)
	Yes	0	8 (100)		8 (100)
Missing	0	0		0 (0)	
Sum	0	8 (100)		8 (100)	
Visit 6	ND plus (N=46)				
	No	2 (4.3)	0		2 (4.3)
	Yes	2 (4.3)	42 (91.3)		44 (95.7)
	Missing	0	0		0 (0)
	Sum	4 (8.7)	42 (91.3)		46 (100)
	ND basic (N=25)				
	No	1 (4.0)	0		1 (4.0)
	Yes	0	24 (96.0)		24 (96.0)
	Missing	0	0		0 (0)
	Sum	1 (4.0)	24 (96.0)		25 (100)
	SC (N=23)				
	No	1 (4.3)	0		1 (4.3)
	Yes	0	22 (95.7)		22 (95.7)
	Missing	0	0		0 (0)
	Sum	1 (4.3)	22 (95.7)		23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.3: MRI parameters - change in normal lordotic LS from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Normal lordotic LS	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 7	ND plus (N=46)				
	No	3 (6.5)	1 (2.2)		4 (8.7)
	Yes	1 (2.2)	41 (89.1)		42 (91.3)
	Missing	0	0		0 (0)
	Sum	4 (8.7)	42 (91.3)		46 (100)
	ND basic (N=26)				
	No	1 (3.8)	0		1 (3.8)
	Yes	0	25 (96.2)		25 (96.2)
	Missing	0	0		0 (0)
	Sum	1 (3.8)	25 (96.2)		26 (100)
	SC (N=21)				
	No	0	0		0 (0)
Yes	1 (4.8)	20 (95.2)		21 (100)	
Missing	0	0		0 (0)	
Sum	1 (4.8)	20 (95.2)		21 (100)	
Visit 8	ND plus (N=43)				
	No	3 (7.0)	0		3 (7.0)
	Yes	1 (2.3)	39 (90.7)		40 (93.0)
	Missing	0	0		0 (0)
	Sum	4 (9.3)	39 (90.7)		43 (100)
	ND basic (N=25)				
	No	1 (4.0)	2 (8.0)		3 (12.0)
	Yes	0	22 (88.0)		22 (88.0)
	Missing	0	0		0 (0)
	Sum	1 (4.0)	24 (96.0)		25 (100)
	SC (N=22)				
	No	1 (4.5)	1 (4.5)		2 (9.1)
Yes	0	20 (90.9)		20 (90.9)	
Missing	0	0		0 (0)	
Sum	1 (4.5)	21 (95.5)		22 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.3: MRI parameters - change in normal lordotic LS from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Normal lordotic LS	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
End of Trial	ND plus (N=39)				
	No	3 (7.7)	1 (2.6)		4 (10.3)
	Yes	1 (2.6)	34 (87.2)		35 (89.7)
	Missing	0	0		0 (0)
	Sum	4 (10.3)	35 (89.7)		39 (100)
	ND basic (N=26)				
	No	1 (3.8)	2 (7.7)		3 (11.5)
	Yes	0	23 (88.5)		23 (88.5)
	Missing	0	0		0 (0)
	Sum	1 (3.8)	25 (96.2)		26 (100)
	SC (N=20)				
	No	1 (5.0)	2 (10.0)		3 (15.0)
Yes	0	17 (85.0)		17 (85.0)	
Missing	0	0		0 (0)	
Sum	1 (5.0)	19 (95.0)		20 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.4: MRI parameters - change in relevant scoliosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Relevant scoliosis	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 1/Visit 2A**	ND plus (N=58)				
	No	56 (96.6)	0		56 (96.6)
	Yes	0	2 (3.4)		2 (3.4)
	Missing	0	0		0 (0)
	Sum	56 (96.6)	2 (3.4)		58 (100)
	ND basic (N=37)				
	No	37 (100)	0		37 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	37 (100)	0		37 (100)
	SC (N=25)				
	No	25 (100)	0		25 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	25 (100)	0		25 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.4: MRI parameters - change in relevant scoliosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Relevant scoliosis	Number (%) of subjects				
		Screening (Visit 1)/Baseline (Visit 2A)**				
		No	Yes	Missing	Sum	
Visit 3a*	ND plus (N=50)					
	No	49 (98.0)	1 (2.0)		50 (100)	
	Yes	0	0		0 (0)	
	Missing	0	0		0 (0)	
	Sum	49 (98.0)	1 (2.0)		50 (100)	
	ND basic (N=28)					
	No	28 (100)	0		28 (100)	
	Yes	0	0		0 (0)	
	Missing	0	0		0 (0)	
	Sum	28 (100)	0		28 (100)	
	Visit 4	ND plus (N=47)				
		No	46 (97.9)	0		46 (97.9)
Yes		0	1 (2.1)		1 (2.1)	
Missing		0	0		0 (0)	
Sum		46 (97.9)	1 (2.1)		47 (100)	
ND basic (N=27)						
No		27 (100)	0		27 (100)	
Yes		0	0		0 (0)	
Missing		0	0		0 (0)	
Sum		27 (100)	0		27 (100)	
SC (N=24)						
No		24 (100)	0		24 (100)	
Yes		0	0		0 (0)	
Missing		0	0		0 (0)	
Sum		24 (100)	0		24 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.4: MRI parameters - change in relevant scoliosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Relevant scoliosis	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 5	ND plus (N=12)				
	No	12 (100)	0		12 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	12 (100)	0		12 (100)
	ND basic (N=8)				
	No	8 (100)	0		8 (100)
	Yes	0	0		0 (0)
Missing	0	0		0 (0)	
Sum	8 (100)	0		8 (100)	
Visit 6	ND plus (N=46)				
	No	45 (97.8)	0		45 (97.8)
	Yes	0	1 (2.2)		1 (2.2)
	Missing	0	0		0 (0)
	Sum	45 (97.8)	1 (2.2)		46 (100)
	ND basic (N=25)				
	No	24 (96.0)	0		24 (96.0)
	Yes	1 (4.0)	0		1 (4.0)
	Missing	0	0		0 (0)
	Sum	25 (100)	0		25 (100)
	SC (N=23)				
	No	23 (100)	0		23 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	23 (100)	0		23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.4: MRI parameters - change in relevant scoliosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Relevant scoliosis	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
Visit 7	ND plus (N=46)				
	No	45 (97.8)	0		45 (97.8)
	Yes	0	1 (2.2)		1 (2.2)
	Missing	0	0		0 (0)
	Sum	45 (97.8)	1 (2.2)		46 (100)
	ND basic (N=26)				
	No	25 (96.2)	0		25 (96.2)
	Yes	1 (3.8)	0		1 (3.8)
	Missing	0	0		0 (0)
	Sum	26 (100)	0		26 (100)
	SC (N=21)				
	No	21 (100)	0		21 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	21 (100)	0		21 (100)	
Visit 8	ND plus (N=43)				
	No	42 (97.7)	1 (2.3)		43 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	42 (97.7)	1 (2.3)		43 (100)
	ND basic (N=25)				
	No	25 (100)	0		25 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	25 (100)	0		25 (100)
	SC (N=22)				
	No	22 (100)	0		22 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	22 (100)	0		22 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.4: MRI parameters - change in relevant scoliosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Visit	Treatment group Relevant scoliosis	Number (%) of subjects			
		Screening (Visit 1)/Baseline (Visit 2A)**			
		No	Yes	Missing	Sum
End of Trial	ND plus (N=39)				
	No	38 (97.4)	1 (2.6)		39 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	38 (97.4)	1 (2.6)		39 (100)
	ND basic (N=26)				
	No	26 (100)	0		26 (100)
	Yes	0	0		0 (0)
	Missing	0	0		0 (0)
	Sum	26 (100)	0		26 (100)
	SC (N=20)				
	No	20 (100)	0		20 (100)
Yes	0	0		0 (0)	
Missing	0	0		0 (0)	
Sum	20 (100)	0		20 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	26 (44.8)	0	0	26 (44.8)
		Yes	0	1 (1.7)	0	1 (1.7)
		Missing	0	0	31 (53.4)	31 (53.4)
		Sum	26 (44.8)	1 (1.7)	31 (53.4)	58 (100)
		ND basic (N=37)				
		No	13 (35.1)	0	0	13 (35.1)
		Yes	0	1 (2.7)	0	1 (2.7)
		Missing	0	0	23 (62.2)	23 (62.2)
		Sum	13 (35.1)	1 (2.7)	23 (62.2)	37 (100)
		SC (N=25)				
		No	11 (44.0)	0	0	11 (44.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	14 (56.0)	14 (56.0)
		Sum	11 (44.0)	0	14 (56.0)	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	21 (42.0)	1 (2.0)	1 (2.0)	23 (46.0)
		Yes	2 (4.0)	0	0	2 (4.0)
		Missing	2 (4.0)	0	23 (46.0)	25 (50.0)
		Sum	25 (50.0)	1 (2.0)	24 (48.0)	50 (100)
		ND basic (N=28)				
		No	12 (42.9)	0	1 (3.6)	13 (46.4)
		Yes	0	1 (3.6)	0	1 (3.6)
		Missing	0	0	14 (50.0)	14 (50.0)
		Sum	12 (42.9)	1 (3.6)	15 (53.6)	28 (100)
	Visit 4	ND plus (N=47)				
		No	19 (40.4)	1 (2.1)	5 (10.6)	25 (53.2)
		Yes	2 (4.3)	0	0	2 (4.3)
		Missing	1 (2.1)	0	19 (40.4)	20 (42.6)
		Sum	22 (46.8)	1 (2.1)	24 (51.1)	47 (100)
		ND basic (N=27)				
		No	12 (44.4)	0	2 (7.4)	14 (51.9)
		Yes	0	1 (3.7)	0	1 (3.7)
		Missing	0	0	12 (44.4)	12 (44.4)
		Sum	12 (44.4)	1 (3.7)	14 (51.9)	27 (100)
SC (N=24)						
No	10 (41.7)	0	6 (25.0)	16 (66.7)		
Yes	0	0	0	0 (0)		
Missing	1 (4.2)	0	7 (29.2)	8 (33.3)		
Sum	11 (45.8)	0	13 (54.2)	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 5	ND plus (N=12)				
		No	3 (25.0)	0	2 (16.7)	5 (41.7)
		Yes	1 (8.3)	0	0	1 (8.3)
		Missing	0	0	6 (50.0)	6 (50.0)
		Sum	4 (33.3)	0	8 (66.7)	12 (100)
		ND basic (N=8)				
		No	3 (37.5)	0	0	3 (37.5)
		Yes	0	0	0	0 (0)
	Missing	0	0	5 (62.5)	5 (62.5)	
	Sum	3 (37.5)	0	5 (62.5)	8 (100)	
	Visit 6	ND plus (N=46)				
		No	18 (39.1)	1 (2.2)	3 (6.5)	22 (47.8)
		Yes	2 (4.3)	0	0	2 (4.3)
		Missing	2 (4.3)	0	20 (43.5)	22 (47.8)
		Sum	22 (47.8)	1 (2.2)	23 (50.0)	46 (100)
		ND basic (N=25)				
		No	11 (44.0)	0	1 (4.0)	12 (48.0)
		Yes	0	1 (4.0)	0	1 (4.0)
		Missing	0	0	12 (48.0)	12 (48.0)
		Sum	11 (44.0)	1 (4.0)	13 (52.0)	25 (100)
		SC (N=23)				
No		9 (39.1)	0	0	9 (39.1)	
Yes		0	0	0	0 (0)	
Missing	1 (4.3)	0	13 (56.5)	14 (60.9)		
Sum	10 (43.5)	0	13 (56.5)	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 7	ND plus (N=46)				
		No	18 (39.1)	1 (2.2)	0	19 (41.3)
		Yes	3 (6.5)	0	0	3 (6.5)
		Missing	1 (2.2)	0	23 (50.0)	24 (52.2)
		Sum	22 (47.8)	1 (2.2)	23 (50.0)	46 (100)
		ND basic (N=26)				
		No	12 (46.2)	0	1 (3.8)	13 (50.0)
		Yes	0	1 (3.8)	0	1 (3.8)
		Missing	0	0	12 (46.2)	12 (46.2)
		Sum	12 (46.2)	1 (3.8)	13 (50.0)	26 (100)
		SC (N=21)				
		No	8 (38.1)	0	1 (4.8)	9 (42.9)
	Yes	0	0	0	0 (0)	
	Missing	1 (4.8)	0	11 (52.4)	12 (57.1)	
	Sum	9 (42.9)	0	12 (57.1)	21 (100)	
	Visit 8	ND plus (N=43)				
		No	16 (37.2)	1 (2.3)	1 (2.3)	18 (41.9)
		Yes	2 (4.7)	0	0	2 (4.7)
		Missing	1 (2.3)	0	22 (51.2)	23 (53.5)
		Sum	19 (44.2)	1 (2.3)	23 (53.5)	43 (100)
		ND basic (N=25)				
		No	11 (44.0)	0	0	11 (44.0)
		Yes	1 (4.0)	1 (4.0)	0	2 (8.0)
		Missing	0	0	12 (48.0)	12 (48.0)
Sum		12 (48.0)	1 (4.0)	12 (48.0)	25 (100)	
SC (N=22)						
No		7 (31.8)	0	0	7 (31.8)	
Yes	1 (4.5)	0	0	1 (4.5)		
Missing	1 (4.5)	0	13 (59.1)	14 (63.6)		
Sum	9 (40.9)	0	13 (59.1)	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	End of Trial	ND plus (N=39)				
		No	16 (41.0)	1 (2.6)	0	17 (43.6)
		Yes	1 (2.6)	0	0	1 (2.6)
		Missing	1 (2.6)	0	20 (51.3)	21 (53.8)
		Sum	18 (46.2)	1 (2.6)	20 (51.3)	39 (100)
		ND basic (N=26)				
		No	12 (46.2)	1 (3.8)	0	13 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	13 (50.0)	13 (50.0)
		Sum	12 (46.2)	1 (3.8)	13 (50.0)	26 (100)
		SC (N=20)				
		No	6 (30.0)	0	0	6 (30.0)
		Yes	1 (5.0)	0	0	1 (5.0)
		Missing	1 (5.0)	0	12 (60.0)	13 (65.0)
		Sum	8 (40.0)	0	12 (60.0)	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	4 (6.9)	0	0	4 (6.9)
		Yes	0	54 (93.1)	0	54 (93.1)
		Missing	0	0	0	0 (0)
		Sum	4 (6.9)	54 (93.1)	0	58 (100)
		ND basic (N=37)				
		No	1 (2.7)	0	0	1 (2.7)
		Yes	0	36 (97.3)	0	36 (97.3)
		Missing	0	0	0	0 (0)
		Sum	1 (2.7)	36 (97.3)	0	37 (100)
		SC (N=25)				
		No	2 (8.0)	0	0	2 (8.0)
		Yes	0	23 (92.0)	0	23 (92.0)
		Missing	0	0	0	0 (0)
		Sum	2 (8.0)	23 (92.0)	0	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	4 (8.0)	19 (38.0)	0	23 (46.0)
		Yes	0	27 (54.0)	0	27 (54.0)
		Missing	0	0	0	0 (0)
		Sum	4 (8.0)	46 (92.0)	0	50 (100)
		ND basic (N=28)				
		No	1 (3.6)	11 (39.3)	0	12 (42.9)
		Yes	0	16 (57.1)	0	16 (57.1)
	Missing	0	0	0	0 (0)	
	Sum	1 (3.6)	27 (96.4)	0	28 (100)	
	Visit 4	ND plus (N=47)				
		No	3 (6.4)	10 (21.3)	0	13 (27.7)
		Yes	1 (2.1)	33 (70.2)	0	34 (72.3)
		Missing	0	0	0	0 (0)
		Sum	4 (8.5)	43 (91.5)	0	47 (100)
		ND basic (N=27)				
		No	1 (3.7)	7 (25.9)	0	8 (29.6)
		Yes	0	19 (70.4)	0	19 (70.4)
		Missing	0	0	0	0 (0)
		Sum	1 (3.7)	26 (96.3)	0	27 (100)
SC (N=24)						
No		1 (4.2)	9 (37.5)	0	10 (41.7)	
Yes	1 (4.2)	13 (54.2)	0	14 (58.3)		
Missing	0	0	0	0 (0)		
Sum	2 (8.3)	22 (91.7)	0	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2A)**				
			No	Yes	Missing	Sum	
Central Disc (continued)	Visit 5	ND plus (N=12)					
		No	2 (16.7)	1 (8.3)	0	3 (25.0)	
		Yes	1 (8.3)	8 (66.7)	0	9 (75.0)	
		Missing	0	0	0	0 (0)	
		Sum	3 (25.0)	9 (75.0)	0	12 (100)	
		ND basic (N=8)					
	No	0	1 (12.5)	0	1 (12.5)		
	Yes	0	7 (87.5)	0	7 (87.5)		
	Missing	0	0	0	0 (0)		
	Sum	0	8 (100)	0	8 (100)		
	Visit 6	ND plus (N=46)	No	3 (6.5)	12 (26.1)	0	15 (32.6)
			Yes	1 (2.2)	30 (65.2)	0	31 (67.4)
			Missing	0	0	0	0 (0)
			Sum	4 (8.7)	42 (91.3)	0	46 (100)
			ND basic (N=25)				
			No	1 (4.0)	4 (16.0)	0	5 (20.0)
		Yes	0	20 (80.0)	0	20 (80.0)	
		Missing	0	0	0	0 (0)	
Sum		1 (4.0)	24 (96.0)	0	25 (100)		
SC (N=23)		No	0	8 (34.8)	0	8 (34.8)	
		Yes	2 (8.7)	13 (56.5)	0	15 (65.2)	
		Missing	0	0	0	0 (0)	
	Sum	2 (8.7)	21 (91.3)	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 7	ND plus (N=46)				
		No	3 (6.5)	14 (30.4)	0	17 (37.0)
		Yes	1 (2.2)	28 (60.9)	0	29 (63.0)
		Missing	0	0	0	0 (0)
		Sum	4 (8.7)	42 (91.3)	0	46 (100)
		ND basic (N=26)				
		No	1 (3.8)	6 (23.1)	0	7 (26.9)
		Yes	0	19 (73.1)	0	19 (73.1)
		Missing	0	0	0	0 (0)
		Sum	1 (3.8)	25 (96.2)	0	26 (100)
		SC (N=21)				
		No	1 (4.8)	12 (57.1)	0	13 (61.9)
	Yes	1 (4.8)	7 (33.3)	0	8 (38.1)	
	Missing	0	0	0	0 (0)	
	Sum	2 (9.5)	19 (90.5)	0	21 (100)	
	Visit 8	ND plus (N=43)				
		No	3 (7.0)	18 (41.9)	0	21 (48.8)
		Yes	1 (2.3)	21 (48.8)	0	22 (51.2)
		Missing	0	0	0	0 (0)
		Sum	4 (9.3)	39 (90.7)	0	43 (100)
ND basic (N=25)						
No		1 (4.0)	6 (24.0)	0	7 (28.0)	
Yes		0	18 (72.0)	0	18 (72.0)	
Missing		0	0	0	0 (0)	
Sum		1 (4.0)	24 (96.0)	0	25 (100)	
SC (N=22)						
No		1 (4.5)	10 (45.5)	0	11 (50.0)	
Yes	1 (4.5)	10 (45.5)	0	11 (50.0)		
Missing	0	0	0	0 (0)		
Sum	2 (9.1)	20 (90.9)	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	End of Trial	ND plus (N=39)				
		No	2 (5.1)	16 (41.0)	0	18 (46.2)
		Yes	1 (2.6)	20 (51.3)	0	21 (53.8)
		Missing	0	0	0	0 (0)
		Sum	3 (7.7)	36 (92.3)	0	39 (100)
		ND basic (N=26)				
		No	1 (3.8)	10 (38.5)	0	11 (42.3)
		Yes	0	15 (57.7)	0	15 (57.7)
		Missing	0	0	0	0 (0)
		Sum	1 (3.8)	25 (96.2)	0	26 (100)
		SC (N=20)				
		No	1 (5.0)	13 (65.0)	0	14 (70.0)
		Yes	1 (5.0)	5 (25.0)	0	6 (30.0)
		Missing	0	0	0	0 (0)
		Sum	2 (10.0)	18 (90.0)	0	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated	Visit 1/Visit 2A**	ND plus (N=9)				
		No	8 (88.9)	0	0	8 (88.9)
		Yes	0	1 (11.1)	0	1 (11.1)
		Missing	0	0	0	0 (0)
		Sum	8 (88.9)	1 (11.1)	0	9 (100)
		ND basic (N=5)				
		No	5 (100)	0	0	5 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	5 (100)	0	0	5 (100)
		SC (N=2)				
		No	1 (50.0)	0	0	1 (50.0)
		Yes	0	1 (50.0)	0	1 (50.0)
		Missing	0	0	0	0 (0)
		Sum	1 (50.0)	1 (50.0)	0	2 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 3a*	ND plus (N=8)				
		No	6 (75.0)	1 (12.5)	0	7 (87.5)
		Yes	1 (12.5)	0	0	1 (12.5)
		Missing	0	0	0	0 (0)
		Sum	7 (87.5)	1 (12.5)	0	8 (100)
		ND basic (N=4)				
		No	3 (75.0)	0	0	3 (75.0)
		Yes	1 (25.0)	0	0	1 (25.0)
	Missing	0	0	0	0 (0)	
	Sum	4 (100)	0	0	4 (100)	
	Visit 4	ND plus (N=7)				
		No	4 (57.1)	0	0	4 (57.1)
		Yes	3 (42.9)	0	0	3 (42.9)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	3 (75.0)	0	0	3 (75.0)
		Yes	1 (25.0)	0	0	1 (25.0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
SC (N=2)						
No		1 (50.0)	1 (50.0)	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	1 (50.0)	1 (50.0)	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 5	ND plus (N=2)				
		No	2 (100)	0	0	2 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	2 (100)	0	0	2 (100)
		ND basic (N=3)				
	No	2 (66.7)	0	0	2 (66.7)	
	Yes	1 (33.3)	0	0	1 (33.3)	
	Missing	0	0	0	0 (0)	
	Sum	3 (100)	0	0	3 (100)	
	Visit 6	ND plus (N=7)				
		No	4 (57.1)	0	0	4 (57.1)
		Yes	3 (42.9)	0	0	3 (42.9)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	1 (25.0)	0	0	1 (25.0)
		Yes	3 (75.0)	0	0	3 (75.0)
Missing		0	0	0	0 (0)	
Sum		4 (100)	0	0	4 (100)	
SC (N=2)						
No		1 (50.0)	1 (50.0)	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	1 (50.0)	1 (50.0)	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2A)**				
			No	Yes	Missing	Sum	
Cranial Disc, add. treated (continued)	Visit 7	ND plus (N=7)					
		No	5 (71.4)	0	0	5 (71.4)	
		Yes	2 (28.6)	0	0	2 (28.6)	
		Missing	0	0	0	0 (0)	
		Sum	7 (100)	0	0	7 (100)	
		ND basic (N=4)					
		No	3 (75.0)	0	0	3 (75.0)	
		Yes	1 (25.0)	0	0	1 (25.0)	
		Missing	0	0	0	0 (0)	
		Sum	4 (100)	0	0	4 (100)	
		SC (N=2)					
		No	1 (50.0)	0	0	1 (50.0)	
	Yes	0	1 (50.0)	0	1 (50.0)		
	Missing	0	0	0	0 (0)		
	Sum	1 (50.0)	1 (50.0)	0	2 (100)		
	Visit 8	ND plus (N=6)	No	5 (83.3)	0	0	5 (83.3)
			Yes	1 (16.7)	0	0	1 (16.7)
			Missing	0	0	0	0 (0)
			Sum	6 (100)	0	0	6 (100)
			ND basic (N=4)	No	3 (75.0)	0	0
Yes				1 (25.0)	0	0	1 (25.0)
Missing		0		0	0	0 (0)	
Sum		4 (100)		0	0	4 (100)	
SC (N=2)		No	1 (50.0)	0	0	1 (50.0)	
		Yes	0	1 (50.0)	0	1 (50.0)	
		Missing	0	0	0	0 (0)	
		Sum	1 (50.0)	1 (50.0)	0	2 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	End of Trial	ND plus (N=6)				
		No	5 (83.3)	0	0	5 (83.3)
		Yes	1 (16.7)	0	0	1 (16.7)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
		ND basic (N=3)				
		No	2 (66.7)	0	0	2 (66.7)
		Yes	1 (33.3)	0	0	1 (33.3)
		Missing	0	0	0	0 (0)
		Sum	3 (100)	0	0	3 (100)
		SC (N=1)				
		No	1 (100)	0	0	1 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	1 (100)	0	0	1 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated	Visit 1/Visit 2A**	ND plus (N=49)				
		No	49 (100)	0	0	49 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	49 (100)	0	0	49 (100)
		ND basic (N=32)				
		No	31 (96.9)	0	0	31 (96.9)
		Yes	0	1 (3.1)	0	1 (3.1)
		Missing	0	0	0	0 (0)
		Sum	31 (96.9)	1 (3.1)	0	32 (100)
		SC (N=23)				
		No	22 (95.7)	0	0	22 (95.7)
		Yes	0	1 (4.3)	0	1 (4.3)
		Missing	0	0	0	0 (0)
		Sum	22 (95.7)	1 (4.3)	0	23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 3a*	ND plus (N=42)				
		No	42 (100)	0	0	42 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	42 (100)	0	0	42 (100)
		ND basic (N=24)				
	No	23 (95.8)	1 (4.2)	0	24 (100)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	23 (95.8)	1 (4.2)	0	24 (100)	
	Visit 4	ND plus (N=40)				
		No	39 (97.5)	0	0	39 (97.5)
		Yes	1 (2.5)	0	0	1 (2.5)
		Missing	0	0	0	0 (0)
		Sum	40 (100)	0	0	40 (100)
		ND basic (N=23)				
		No	20 (87.0)	0	0	20 (87.0)
		Yes	2 (8.7)	1 (4.3)	0	3 (13.0)
Missing		0	0	0	0 (0)	
Sum		22 (95.7)	1 (4.3)	0	23 (100)	
SC (N=22)						
No		20 (90.9)	0	0	20 (90.9)	
Yes	1 (4.5)	1 (4.5)	0	2 (9.1)		
Missing	0	0	0	0 (0)		
Sum	21 (95.5)	1 (4.5)	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Cranial Disc, not treated (continued)	Visit 5	ND plus (N=10)						
		No	10 (100)	0	0	10 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	10 (100)	0	0	10 (100)		
		ND basic (N=5)						
	No	5 (100)	0	0	5 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	5 (100)	0	0	5 (100)			
	Visit 6	ND plus (N=39)	No	38 (97.4)	0	0	38 (97.4)	
			Yes	1 (2.6)	0	0	1 (2.6)	
			Missing	0	0	0	0 (0)	
			Sum	39 (100)	0	0	39 (100)	
			ND basic (N=21)	No	18 (85.7)	0	0	18 (85.7)
				Yes	2 (9.5)	1 (4.8)	0	3 (14.3)
		Missing		0	0	0	0 (0)	
		Sum		20 (95.2)	1 (4.8)	0	21 (100)	
SC (N=21)		No		20 (95.2)	0	0	20 (95.2)	
		Yes		0	1 (4.8)	0	1 (4.8)	
		Missing	0	0	0	0 (0)		
		Sum	20 (95.2)	1 (4.8)	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 7	ND plus (N=39)				
		No	38 (97.4)	0	0	38 (97.4)
		Yes	1 (2.6)	0	0	1 (2.6)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=22)				
		No	21 (95.5)	0	0	21 (95.5)
		Yes	0	1 (4.5)	0	1 (4.5)
		Missing	0	0	0	0 (0)
		Sum	21 (95.5)	1 (4.5)	0	22 (100)
		SC (N=19)				
		No	17 (89.5)	1 (5.3)	0	18 (94.7)
	Yes	1 (5.3)	0	0	1 (5.3)	
	Missing	0	0	0	0 (0)	
	Sum	18 (94.7)	1 (5.3)	0	19 (100)	
	Visit 8	ND plus (N=37)				
		No	35 (94.6)	0	0	35 (94.6)
		Yes	2 (5.4)	0	0	2 (5.4)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
		ND basic (N=21)				
		No	17 (81.0)	0	0	17 (81.0)
		Yes	3 (14.3)	1 (4.8)	0	4 (19.0)
		Missing	0	0	0	0 (0)
Sum		20 (95.2)	1 (4.8)	0	21 (100)	
SC (N=20)						
No		18 (90.0)	0	0	18 (90.0)	
Yes	1 (5.0)	1 (5.0)	0	2 (10.0)		
Missing	0	0	0	0 (0)		
Sum	19 (95.0)	1 (5.0)	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.5: MRI parameters - change in dorsal disc extrusion from Baseline (Visit 2a) - safety set

Disc Type	Visit	Treatment group Dorsal disc extrusion	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	End of Trial	ND plus (N=33)				
		No	32 (97.0)	0	0	32 (97.0)
		Yes	1 (3.0)	0	0	1 (3.0)
		Missing	0	0	0	0 (0)
		Sum	33 (100)	0	0	33 (100)
		ND basic (N=23)				
		No	21 (91.3)	0	0	21 (91.3)
		Yes	1 (4.3)	1 (4.3)	0	2 (8.7)
		Missing	0	0	0	0 (0)
		Sum	22 (95.7)	1 (4.3)	0	23 (100)
		SC (N=19)				
		No	18 (94.7)	1 (5.3)	0	19 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	18 (94.7)	1 (5.3)	0	19 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	27 (46.6)	0	0	27 (46.6)
		Yes	0	0	0	0 (0)
		Missing	0	0	31 (53.4)	31 (53.4)
		Sum	27 (46.6)	0	31 (53.4)	58 (100)
		ND basic (N=37)				
		No	14 (37.8)	0	0	14 (37.8)
		Yes	0	0	0	0 (0)
		Missing	0	0	23 (62.2)	23 (62.2)
		Sum	14 (37.8)	0	23 (62.2)	37 (100)
		SC (N=25)				
		No	11 (44.0)	0	0	11 (44.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	14 (56.0)	14 (56.0)
		Sum	11 (44.0)	0	14 (56.0)	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	24 (48.0)	0	1 (2.0)	25 (50.0)
		Yes	0	0	0	0 (0)
		Missing	2 (4.0)	0	23 (46.0)	25 (50.0)
		Sum	26 (52.0)	0	24 (48.0)	50 (100)
		ND basic (N=28)				
	No	13 (46.4)	0	0	13 (46.4)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	15 (53.6)	15 (53.6)	
	Sum	13 (46.4)	0	15 (53.6)	28 (100)	
	Visit 4	ND plus (N=47)				
		No	22 (46.8)	0	5 (10.6)	27 (57.4)
		Yes	0	0	0	0 (0)
		Missing	1 (2.1)	0	19 (40.4)	20 (42.6)
		Sum	23 (48.9)	0	24 (51.1)	47 (100)
		ND basic (N=27)				
		No	13 (48.1)	0	2 (7.4)	15 (55.6)
		Yes	0	0	0	0 (0)
Missing		0	0	12 (44.4)	12 (44.4)	
Sum		13 (48.1)	0	14 (51.9)	27 (100)	
SC (N=24)						
No		10 (41.7)	0	6 (25.0)	16 (66.7)	
Yes	0	0	0	0 (0)		
Missing	1 (4.2)	0	7 (29.2)	8 (33.3)		
Sum	11 (45.8)	0	13 (54.2)	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 5	ND plus (N=12)				
		No	4 (33.3)	0	2 (16.7)	6 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	6 (50.0)	6 (50.0)
		Sum	4 (33.3)	0	8 (66.7)	12 (100)
		ND basic (N=8)				
		No	3 (37.5)	0	0	3 (37.5)
		Yes	0	0	0	0 (0)
	Missing	0	0	5 (62.5)	5 (62.5)	
	Sum	3 (37.5)	0	5 (62.5)	8 (100)	
	Visit 6	ND plus (N=46)				
		No	21 (45.7)	0	2 (4.3)	23 (50.0)
		Yes	0	0	0	0 (0)
		Missing	2 (4.3)	0	21 (45.7)	23 (50.0)
		Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=25)				
		No	12 (48.0)	0	1 (4.0)	13 (52.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	12 (48.0)	12 (48.0)
		Sum	12 (48.0)	0	13 (52.0)	25 (100)
SC (N=23)						
No		9 (39.1)	0	0	9 (39.1)	
Yes	0	0	0	0 (0)		
Missing	1 (4.3)	0	13 (56.5)	14 (60.9)		
Sum	10 (43.5)	0	13 (56.5)	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 7	ND plus (N=46)				
		No	22 (47.8)	0	0	22 (47.8)
		Yes	0	0	0	0 (0)
		Missing	1 (2.2)	0	23 (50.0)	24 (52.2)
		Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=26)				
		No	13 (50.0)	0	1 (3.8)	14 (53.8)
		Yes	0	0	0	0 (0)
		Missing	0	0	12 (46.2)	12 (46.2)
		Sum	13 (50.0)	0	13 (50.0)	26 (100)
		SC (N=21)				
		No	8 (38.1)	0	1 (4.8)	9 (42.9)
	Yes	0	0	0	0 (0)	
	Missing	1 (4.8)	0	11 (52.4)	12 (57.1)	
	Sum	9 (42.9)	0	12 (57.1)	21 (100)	
	Visit 8	ND plus (N=43)				
		No	19 (44.2)	0	1 (2.3)	20 (46.5)
		Yes	0	0	0	0 (0)
		Missing	1 (2.3)	0	22 (51.2)	23 (53.5)
		Sum	20 (46.5)	0	23 (53.5)	43 (100)
ND basic (N=25)						
No		13 (52.0)	0	0	13 (52.0)	
Yes		0	0	0	0 (0)	
Missing		0	0	12 (48.0)	12 (48.0)	
Sum		13 (52.0)	0	12 (48.0)	25 (100)	
SC (N=22)						
No		8 (36.4)	0	0	8 (36.4)	
Yes	0	0	0	0 (0)		
Missing	1 (4.5)	0	13 (59.1)	14 (63.6)		
Sum	9 (40.9)	0	13 (59.1)	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	End of Trial	ND plus (N=39)				
		No	18 (46.2)	0	0	18 (46.2)
		Yes	0	0	0	0 (0)
		Missing	1 (2.6)	0	20 (51.3)	21 (53.8)
		Sum	19 (48.7)	0	20 (51.3)	39 (100)
		ND basic (N=26)				
		No	13 (50.0)	0	0	13 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	13 (50.0)	13 (50.0)
		Sum	13 (50.0)	0	13 (50.0)	26 (100)
		SC (N=20)				
		No	7 (35.0)	0	0	7 (35.0)
		Yes	0	0	0	0 (0)
		Missing	1 (5.0)	0	12 (60.0)	13 (65.0)
		Sum	8 (40.0)	0	12 (60.0)	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	58 (100)	0	0	58 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	58 (100)	0	0	58 (100)
		ND basic (N=37)				
		No	37 (100)	0	0	37 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
		SC (N=25)				
		No	25 (100)	0	0	25 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	25 (100)	0	0	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	50 (100)	0	0	50 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	50 (100)	0	0	50 (100)
		ND basic (N=28)				
		No	28 (100)	0	0	28 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	28 (100)	0	0	28 (100)	
	Visit 4	ND plus (N=47)				
		No	47 (100)	0	0	47 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	47 (100)	0	0	47 (100)
		ND basic (N=27)				
		No	27 (100)	0	0	27 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	27 (100)	0	0	27 (100)
SC (N=24)						
No		24 (100)	0	0	24 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	24 (100)	0	0	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Central Disc (continued)	Visit 5	ND plus (N=12)						
		No	12 (100)	0	0	12 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	12 (100)	0	0	12 (100)		
		ND basic (N=8)						
	No	8 (100)	0	0	8 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	8 (100)	0	0	8 (100)			
	Visit 6	ND plus (N=46)	No	46 (100)	0	0	46 (100)	
			Yes	0	0	0	0 (0)	
			Missing	0	0	0	0 (0)	
			Sum	46 (100)	0	0	46 (100)	
			ND basic (N=25)	No	25 (100)	0	0	25 (100)
				Yes	0	0	0	0 (0)
		Missing		0	0	0	0 (0)	
		Sum		25 (100)	0	0	25 (100)	
SC (N=23)		No		23 (100)	0	0	23 (100)	
		Yes		0	0	0	0 (0)	
		Missing	0	0	0	0 (0)		
		Sum	23 (100)	0	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 7	ND plus (N=46)				
		No	46 (100)	0	0	46 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	46 (100)	0	0	46 (100)
		ND basic (N=26)				
		No	26 (100)	0	0	26 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	26 (100)	0	0	26 (100)
		SC (N=21)				
		No	21 (100)	0	0	21 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	21 (100)	0	0	21 (100)	
	Visit 8	ND plus (N=43)				
		No	43 (100)	0	0	43 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	43 (100)	0	0	43 (100)
ND basic (N=25)						
No		25 (100)	0	0	25 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		25 (100)	0	0	25 (100)	
SC (N=22)						
No		22 (100)	0	0	22 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	22 (100)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	End of Trial	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=26)				
		No	26 (100)	0	0	26 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	26 (100)	0	0	26 (100)
		SC (N=20)				
		No	20 (100)	0	0	20 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	20 (100)	0	0	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated	Visit 1/Visit 2A**	ND plus (N=9)				
		No	9 (100)	0	0	9 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	9 (100)	0	0	9 (100)
		ND basic (N=5)				
		No	5 (100)	0	0	5 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	5 (100)	0	0	5 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	2 (100)	0	0	2 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 3a*	ND plus (N=8)				
		No	8 (100)	0	0	8 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	8 (100)	0	0	8 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	4 (100)	0	0	4 (100)	
	Visit 4	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Cranial Disc, add. treated (continued)	Visit 5	ND plus (N=2)						
		No	2 (100)	0	0	2 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	2 (100)	0	0	2 (100)		
		ND basic (N=3)						
	No	3 (100)	0	0	3 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	3 (100)	0	0	3 (100)			
	Visit 6	ND plus (N=7)	No	7 (100)	0	0	7 (100)	
			Yes	0	0	0	0 (0)	
			Missing	0	0	0	0 (0)	
			Sum	7 (100)	0	0	7 (100)	
			ND basic (N=4)	No	4 (100)	0	0	4 (100)
				Yes	0	0	0	0 (0)
		Missing		0	0	0	0 (0)	
		Sum		4 (100)	0	0	4 (100)	
SC (N=2)		No		2 (100)	0	0	2 (100)	
		Yes		0	0	0	0 (0)	
		Missing	0	0	0	0 (0)		
		Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 7	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	2 (100)	0	0	2 (100)	
	Visit 8	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
ND basic (N=4)						
No		4 (100)	0	0	4 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		4 (100)	0	0	4 (100)	
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2a)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	End of Trial	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
		ND basic (N=3)				
		No	3 (100)	0	0	3 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	3 (100)	0	0	3 (100)
		SC (N=1)				
		No	1 (100)	0	0	1 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	1 (100)	0	0	1 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated	Visit 1/Visit 2A**	ND plus (N=49)				
		No	49 (100)	0	0	49 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	49 (100)	0	0	49 (100)
		ND basic (N=32)				
		No	32 (100)	0	0	32 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	32 (100)	0	0	32 (100)
		SC (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 3a*	ND plus (N=42)				
		No	42 (100)	0	0	42 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	42 (100)	0	0	42 (100)
		ND basic (N=24)				
		No	24 (100)	0	0	24 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	24 (100)	0	0	24 (100)	
	Visit 4	ND plus (N=40)				
		No	40 (100)	0	0	40 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	40 (100)	0	0	40 (100)
		ND basic (N=23)				
No		23 (100)	0	0	23 (100)	
Yes		0	0	0	0 (0)	
Missing	0	0	0	0 (0)		
Sum	23 (100)	0	0	23 (100)		
SC (N=22)	No	22 (100)	0	0	22 (100)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	22 (100)	0	0	22 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Cranial Disc, not treated (continued)	Visit 5	ND plus (N=10)						
		No	10 (100)	0	0	10 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	10 (100)	0	0	10 (100)		
		ND basic (N=5)						
	No	5 (100)	0	0	5 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	5 (100)	0	0	5 (100)			
	Visit 6	ND plus (N=39)	No	39 (100)	0	0	39 (100)	
			Yes	0	0	0	0 (0)	
			Missing	0	0	0	0 (0)	
			Sum	39 (100)	0	0	39 (100)	
			ND basic (N=21)	No	21 (100)	0	0	21 (100)
				Yes	0	0	0	0 (0)
		Missing		0	0	0	0 (0)	
		Sum		21 (100)	0	0	21 (100)	
SC (N=21)		No		21 (100)	0	0	21 (100)	
		Yes		0	0	0	0 (0)	
		Missing	0	0	0	0 (0)		
		Sum	21 (100)	0	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 7	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=22)				
		No	22 (100)	0	0	22 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	22 (100)	0	0	22 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	19 (100)	0	0	19 (100)	
	Visit 8	ND plus (N=37)				
		No	37 (100)	0	0	37 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
ND basic (N=21)						
No		21 (100)	0	0	21 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		21 (100)	0	0	21 (100)	
SC (N=20)						
No		20 (100)	0	0	20 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	20 (100)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.6: MRI parameters - change in spondylolisthesis > Meyerding grade I from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Spondylolisthesis > Meyerding grade I	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	End of Trial	ND plus (N=33)				
		No	33 (100)	0	0	33 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	33 (100)	0	0	33 (100)
		ND basic (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	19 (100)	0	0	19 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	27 (46.6)	0	0	27 (46.6)
		Yes	0	0	0	0 (0)
		Missing	0	0	31 (53.4)	31 (53.4)
		Sum	27 (46.6)	0	31 (53.4)	58 (100)
		ND basic (N=37)				
		No	14 (37.8)	0	0	14 (37.8)
		Yes	0	0	0	0 (0)
		Missing	0	0	23 (62.2)	23 (62.2)
		Sum	14 (37.8)	0	23 (62.2)	37 (100)
		SC (N=25)				
		No	10 (40.0)	0	0	10 (40.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	15 (60.0)	15 (60.0)
		Sum	10 (40.0)	0	15 (60.0)	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	24 (48.0)	0	2 (4.0)	26 (52.0)
		Yes	0	0	0	0 (0)
		Missing	2 (4.0)	0	22 (44.0)	24 (48.0)
		Sum	26 (52.0)	0	24 (48.0)	50 (100)
		ND basic (N=28)				
	No	13 (46.4)	0	0	13 (46.4)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	15 (53.6)	15 (53.6)	
	Sum	13 (46.4)	0	15 (53.6)	28 (100)	
	Visit 4	ND plus (N=47)				
		No	21 (44.7)	0	5 (10.6)	26 (55.3)
		Yes	1 (2.1)	0	0	1 (2.1)
		Missing	1 (2.1)	0	19 (40.4)	20 (42.6)
		Sum	23 (48.9)	0	24 (51.1)	47 (100)
		ND basic (N=27)				
		No	12 (44.4)	0	2 (7.4)	14 (51.9)
		Yes	1 (3.7)	0	0	1 (3.7)
Missing		0	0	12 (44.4)	12 (44.4)	
Sum		13 (48.1)	0	14 (51.9)	27 (100)	
SC (N=24)						
No		10 (41.7)	0	6 (25.0)	16 (66.7)	
Yes	0	0	0	0 (0)		
Missing	0	0	8 (33.3)	8 (33.3)		
Sum	10 (41.7)	0	14 (58.3)	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2a)**				
			No	Yes	Missing	Sum	
Caudal Disc (continued)	Visit 5	ND plus (N=12)					
		No	4 (33.3)	0	2 (16.7)	6 (50.0)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	6 (50.0)	6 (50.0)	
		Sum	4 (33.3)	0	8 (66.7)	12 (100)	
		ND basic (N=8)					
	No	3 (37.5)	0	1 (12.5)	4 (50.0)		
	Yes	0	0	0	0 (0)		
	Missing	0	0	4 (50.0)	4 (50.0)		
	Sum	3 (37.5)	0	5 (62.5)	8 (100)		
	Visit 6	ND plus (N=46)	No	20 (43.5)	0	3 (6.5)	23 (50.0)
			Yes	1 (2.2)	0	0	1 (2.2)
			Missing	2 (4.3)	0	20 (43.5)	22 (47.8)
			Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=25)	No	11 (44.0)	0	1 (4.0)	12 (48.0)
			Yes	1 (4.0)	0	0	1 (4.0)
			Missing	0	0	12 (48.0)	12 (48.0)
			Sum	12 (48.0)	0	13 (52.0)	25 (100)
SC (N=23)		No	9 (39.1)	0	0	9 (39.1)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	14 (60.9)	14 (60.9)	
		Sum	9 (39.1)	0	14 (60.9)	23 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 7	ND plus (N=46)				
		No	21 (45.7)	0	0	21 (45.7)
		Yes	1 (2.2)	0	0	1 (2.2)
		Missing	1 (2.2)	0	23 (50.0)	24 (52.2)
		Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=26)				
		No	12 (46.2)	0	1 (3.8)	13 (50.0)
		Yes	1 (3.8)	0	0	1 (3.8)
		Missing	0	0	12 (46.2)	12 (46.2)
		Sum	13 (50.0)	0	13 (50.0)	26 (100)
		SC (N=21)				
		No	8 (38.1)	0	1 (4.8)	9 (42.9)
	Yes	0	0	0	0 (0)	
	Missing	0	0	12 (57.1)	12 (57.1)	
	Sum	8 (38.1)	0	13 (61.9)	21 (100)	
	Visit 8	ND plus (N=43)				
		No	19 (44.2)	0	1 (2.3)	20 (46.5)
		Yes	0	0	0	0 (0)
		Missing	1 (2.3)	0	22 (51.2)	23 (53.5)
		Sum	20 (46.5)	0	23 (53.5)	43 (100)
ND basic (N=25)						
No		13 (52.0)	0	0	13 (52.0)	
Yes		0	0	0	0 (0)	
Missing		0	0	12 (48.0)	12 (48.0)	
Sum		13 (52.0)	0	12 (48.0)	25 (100)	
SC (N=22)						
No		8 (36.4)	0	0	8 (36.4)	
Yes	0	0	0	0 (0)		
Missing	0	0	14 (63.6)	14 (63.6)		
Sum	8 (36.4)	0	14 (63.6)	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	End of Trial	ND plus (N=39)				
		No	18 (46.2)	0	0	18 (46.2)
		Yes	0	0	0	0 (0)
		Missing	1 (2.6)	0	20 (51.3)	21 (53.8)
		Sum	19 (48.7)	0	20 (51.3)	39 (100)
		ND basic (N=26)				
		No	13 (50.0)	0	0	13 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	13 (50.0)	13 (50.0)
		Sum	13 (50.0)	0	13 (50.0)	26 (100)
		SC (N=20)				
		No	6 (30.0)	0	0	6 (30.0)
		Yes	1 (5.0)	0	0	1 (5.0)
		Missing	0	0	13 (65.0)	13 (65.0)
		Sum	7 (35.0)	0	13 (65.0)	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	58 (100)	0	0	58 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	58 (100)	0	0	58 (100)
		ND basic (N=37)				
		No	37 (100)	0	0	37 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
		SC (N=25)				
		No	25 (100)	0	0	25 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	25 (100)	0	0	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	50 (100)	0	0	50 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	50 (100)	0	0	50 (100)
		ND basic (N=28)				
	No	28 (100)	0	0	28 (100)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	28 (100)	0	0	28 (100)	
	Visit 4	ND plus (N=47)				
		No	44 (93.6)	0	0	44 (93.6)
		Yes	1 (2.1)	0	0	1 (2.1)
		Missing	2 (4.3)	0	0	2 (4.3)
		Sum	47 (100)	0	0	47 (100)
		ND basic (N=27)				
		No	26 (96.3)	0	0	26 (96.3)
		Yes	1 (3.7)	0	0	1 (3.7)
Missing		0	0	0	0 (0)	
Sum		27 (100)	0	0	27 (100)	
SC (N=24)						
No		24 (100)	0	0	24 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	24 (100)	0	0	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 5	ND plus (N=12)				
		No	12 (100)	0	0	12 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	12 (100)	0	0	12 (100)
		ND basic (N=8)				
		No	8 (100)	0	0	8 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	8 (100)	0	0	8 (100)	
	Visit 6	ND plus (N=46)				
		No	45 (97.8)	0	0	45 (97.8)
		Yes	1 (2.2)	0	0	1 (2.2)
		Missing	0	0	0	0 (0)
		Sum	46 (100)	0	0	46 (100)
		ND basic (N=25)				
		No	25 (100)	0	0	25 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	25 (100)	0	0	25 (100)
SC (N=23)						
No		23 (100)	0	0	23 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	23 (100)	0	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 7	ND plus (N=46)				
		No	45 (97.8)	0	0	45 (97.8)
		Yes	1 (2.2)	0	0	1 (2.2)
		Missing	0	0	0	0 (0)
		Sum	46 (100)	0	0	46 (100)
		ND basic (N=26)				
		No	26 (100)	0	0	26 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	26 (100)	0	0	26 (100)
		SC (N=21)				
		No	21 (100)	0	0	21 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	21 (100)	0	0	21 (100)	
	Visit 8	ND plus (N=43)				
		No	43 (100)	0	0	43 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	43 (100)	0	0	43 (100)
ND basic (N=25)						
No		25 (100)	0	0	25 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		25 (100)	0	0	25 (100)	
SC (N=22)						
No		22 (100)	0	0	22 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	22 (100)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	End of Trial	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=26)				
		No	24 (92.3)	0	0	24 (92.3)
		Yes	2 (7.7)	0	0	2 (7.7)
		Missing	0	0	0	0 (0)
		Sum	26 (100)	0	0	26 (100)
		SC (N=20)				
		No	19 (95.0)	0	0	19 (95.0)
		Yes	1 (5.0)	0	0	1 (5.0)
		Missing	0	0	0	0 (0)
		Sum	20 (100)	0	0	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated	Visit 1/Visit 2A**	ND plus (N=9)				
		No	9 (100)	0	0	9 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	9 (100)	0	0	9 (100)
		ND basic (N=5)				
		No	5 (100)	0	0	5 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	5 (100)	0	0	5 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	2 (100)	0	0	2 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 3a*	ND plus (N=8)				
		No	8 (100)	0	0	8 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	8 (100)	0	0	8 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	4 (100)	0	0	4 (100)	
	Visit 4	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2A)**				
			No	Yes	Missing	Sum	
Cranial Disc, add. treated (continued)	Visit 5	ND plus (N=2)					
		No	2 (100)	0	0	2 (100)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
		Sum	2 (100)	0	0	2 (100)	
		ND basic (N=3)					
	No	3 (100)	0	0	3 (100)		
	Yes	0	0	0	0 (0)		
	Missing	0	0	0	0 (0)		
	Sum	3 (100)	0	0	3 (100)		
	Visit 6	ND plus (N=7)	No	7 (100)	0	0	7 (100)
			Yes	0	0	0	0 (0)
			Missing	0	0	0	0 (0)
			Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)	No	4 (100)	0	0	4 (100)
			Yes	0	0	0	0 (0)
			Missing	0	0	0	0 (0)
			Sum	4 (100)	0	0	4 (100)
SC (N=2)		No	2 (100)	0	0	2 (100)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
		Sum	2 (100)	0	0	2 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 7	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	2 (100)	0	0	2 (100)	
	Visit 8	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
ND basic (N=4)						
No		4 (100)	0	0	4 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		4 (100)	0	0	4 (100)	
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2a)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	End of Trial	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
		ND basic (N=3)				
		No	3 (100)	0	0	3 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	3 (100)	0	0	3 (100)
		SC (N=1)				
		No	1 (100)	0	0	1 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	1 (100)	0	0	1 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated	Visit 1/Visit 2A**	ND plus (N=49)				
		No	49 (100)	0	0	49 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	49 (100)	0	0	49 (100)
		ND basic (N=32)				
		No	32 (100)	0	0	32 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	32 (100)	0	0	32 (100)
		SC (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 3a*	ND plus (N=42)				
		No	42 (100)	0	0	42 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	42 (100)	0	0	42 (100)
		ND basic (N=24)				
	No	24 (100)	0	0	24 (100)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	24 (100)	0	0	24 (100)	
	Visit 4	ND plus (N=40)				
		No	39 (97.5)	0	0	39 (97.5)
		Yes	1 (2.5)	0	0	1 (2.5)
		Missing	0	0	0	0 (0)
		Sum	40 (100)	0	0	40 (100)
		ND basic (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
Missing		0	0	0	0 (0)	
Sum		23 (100)	0	0	23 (100)	
SC (N=22)						
No		22 (100)	0	0	22 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	22 (100)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Cranial Disc, not treated (continued)	Visit 5	ND plus (N=10)						
		No	10 (100)	0	0	10 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	10 (100)	0	0	10 (100)		
		ND basic (N=5)						
	No	5 (100)	0	0	5 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	5 (100)	0	0	5 (100)			
	Visit 6	ND plus (N=39)	No	39 (100)	0	0	39 (100)	
			Yes	0	0	0	0 (0)	
			Missing	0	0	0	0 (0)	
			Sum	39 (100)	0	0	39 (100)	
			ND basic (N=21)	No	21 (100)	0	0	21 (100)
				Yes	0	0	0	0 (0)
		Missing		0	0	0	0 (0)	
		Sum		21 (100)	0	0	21 (100)	
SC (N=21)		No		21 (100)	0	0	21 (100)	
		Yes		0	0	0	0 (0)	
		Missing	0	0	0	0 (0)		
		Sum	21 (100)	0	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 7	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=22)				
		No	22 (100)	0	0	22 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	22 (100)	0	0	22 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	19 (100)	0	0	19 (100)	
	Visit 8	ND plus (N=37)				
		No	37 (100)	0	0	37 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
ND basic (N=21)						
No		21 (100)	0	0	21 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		21 (100)	0	0	21 (100)	
SC (N=20)						
No		20 (100)	0	0	20 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	20 (100)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.7: MRI parameters - change in protruding osteophyte from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Protruding osteophyte	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	End of Trial	ND plus (N=33)				
		No	33 (100)	0	0	33 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	33 (100)	0	0	33 (100)
		ND basic (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	19 (100)	0	0	19 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteochondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	27 (46.6)	0	0	27 (46.6)
		Yes	0	0	0	0 (0)
		Missing	0	0	31 (53.4)	31 (53.4)
		Sum	27 (46.6)	0	31 (53.4)	58 (100)
		ND basic (N=37)				
		No	14 (37.8)	0	0	14 (37.8)
		Yes	0	0	0	0 (0)
		Missing	0	0	23 (62.2)	23 (62.2)
		Sum	14 (37.8)	0	23 (62.2)	37 (100)
		SC (N=25)				
		No	11 (44.0)	0	0	11 (44.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	14 (56.0)	14 (56.0)
		Sum	11 (44.0)	0	14 (56.0)	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	24 (48.0)	0	1 (2.0)	25 (50.0)
		Yes	0	0	0	0 (0)
		Missing	2 (4.0)	0	23 (46.0)	25 (50.0)
		Sum	26 (52.0)	0	24 (48.0)	50 (100)
		ND basic (N=28)				
		No	13 (46.4)	0	0	13 (46.4)
		Yes	0	0	0	0 (0)
	Missing	0	0	15 (53.6)	15 (53.6)	
	Sum	13 (46.4)	0	15 (53.6)	28 (100)	
	Visit 4	ND plus (N=47)				
		No	22 (46.8)	0	5 (10.6)	27 (57.4)
		Yes	0	0	0	0 (0)
		Missing	1 (2.1)	0	19 (40.4)	20 (42.6)
		Sum	23 (48.9)	0	24 (51.1)	47 (100)
		ND basic (N=27)				
		No	13 (48.1)	0	2 (7.4)	15 (55.6)
		Yes	0	0	0	0 (0)
		Missing	0	0	12 (44.4)	12 (44.4)
		Sum	13 (48.1)	0	14 (51.9)	27 (100)
SC (N=24)						
No		10 (41.7)	0	6 (25.0)	16 (66.7)	
Yes	0	0	0	0 (0)		
Missing	1 (4.2)	0	7 (29.2)	8 (33.3)		
Sum	11 (45.8)	0	13 (54.2)	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2a)**				
			No	Yes	Missing	Sum	
Caudal Disc (continued)	Visit 5	ND plus (N=12)					
		No	4 (33.3)	0	2 (16.7)	6 (50.0)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	6 (50.0)	6 (50.0)	
		Sum	4 (33.3)	0	8 (66.7)	12 (100)	
		ND basic (N=8)					
	No	3 (37.5)	0	0	3 (37.5)		
	Yes	0	0	0	0 (0)		
	Missing	0	0	5 (62.5)	5 (62.5)		
	Sum	3 (37.5)	0	5 (62.5)	8 (100)		
	Visit 6	ND plus (N=46)	No	21 (45.7)	0	3 (6.5)	24 (52.2)
			Yes	0	0	0	0 (0)
			Missing	2 (4.3)	0	20 (43.5)	22 (47.8)
			Sum	23 (50.0)	0	23 (50.0)	46 (100)
			ND basic (N=25)				
			No	12 (48.0)	0	1 (4.0)	13 (52.0)
		Yes	0	0	0	0 (0)	
		Missing	0	0	12 (48.0)	12 (48.0)	
Sum		12 (48.0)	0	13 (52.0)	25 (100)		
SC (N=23)		No	9 (39.1)	0	0	9 (39.1)	
		Yes	0	0	0	0 (0)	
		Missing	1 (4.3)	0	13 (56.5)	14 (60.9)	
	Sum	10 (43.5)	0	13 (56.5)	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 7	ND plus (N=46)				
		No	22 (47.8)	0	0	22 (47.8)
		Yes	0	0	0	0 (0)
		Missing	1 (2.2)	0	23 (50.0)	24 (52.2)
		Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=26)				
		No	13 (50.0)	0	1 (3.8)	14 (53.8)
		Yes	0	0	0	0 (0)
		Missing	0	0	12 (46.2)	12 (46.2)
		Sum	13 (50.0)	0	13 (50.0)	26 (100)
		SC (N=21)				
		No	8 (38.1)	0	1 (4.8)	9 (42.9)
	Yes	0	0	0	0 (0)	
	Missing	1 (4.8)	0	11 (52.4)	12 (57.1)	
	Sum	9 (42.9)	0	12 (57.1)	21 (100)	
	Visit 8	ND plus (N=43)				
		No	19 (44.2)	0	1 (2.3)	20 (46.5)
		Yes	0	0	0	0 (0)
		Missing	1 (2.3)	0	22 (51.2)	23 (53.5)
		Sum	20 (46.5)	0	23 (53.5)	43 (100)
		ND basic (N=25)				
		No	13 (52.0)	0	0	13 (52.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	12 (48.0)	12 (48.0)
Sum		13 (52.0)	0	12 (48.0)	25 (100)	
SC (N=22)						
No		8 (36.4)	0	0	8 (36.4)	
Yes	0	0	0	0 (0)		
Missing	1 (4.5)	0	13 (59.1)	14 (63.6)		
Sum	9 (40.9)	0	13 (59.1)	22 (100)		

SC = Standard Care

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**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteochondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2a)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	End of Trial	ND plus (N=39)				
		No	18 (46.2)	0	0	18 (46.2)
		Yes	0	0	0	0 (0)
		Missing	1 (2.6)	0	20 (51.3)	21 (53.8)
		Sum	19 (48.7)	0	20 (51.3)	39 (100)
		ND basic (N=26)				
		No	13 (50.0)	0	0	13 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	13 (50.0)	13 (50.0)
		Sum	13 (50.0)	0	13 (50.0)	26 (100)
		SC (N=20)				
		No	7 (35.0)	0	0	7 (35.0)
		Yes	0	0	0	0 (0)
		Missing	1 (5.0)	0	12 (60.0)	13 (65.0)
		Sum	8 (40.0)	0	12 (60.0)	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	58 (100)	0	0	58 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	58 (100)	0	0	58 (100)
		ND basic (N=37)				
		No	36 (97.3)	0	0	36 (97.3)
		Yes	0	1 (2.7)	0	1 (2.7)
		Missing	0	0	0	0 (0)
		Sum	36 (97.3)	1 (2.7)	0	37 (100)
		SC (N=25)				
		No	25 (100)	0	0	25 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	25 (100)	0	0	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2a)**				
			No	Yes	Missing	Sum	
Central Disc (continued)	Visit 3a*	ND plus (N=50)					
		No	50 (100)	0	0	50 (100)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
		Sum	50 (100)	0	0	50 (100)	
		ND basic (N=28)					
	No	27 (96.4)	1 (3.6)	0	28 (100)		
	Yes	0	0	0	0 (0)		
	Missing	0	0	0	0 (0)		
	Sum	27 (96.4)	1 (3.6)	0	28 (100)		
	Visit 4	ND plus (N=47)	No	46 (97.9)	0	0	46 (97.9)
			Yes	1 (2.1)	0	0	1 (2.1)
			Missing	0	0	0	0 (0)
			Sum	47 (100)	0	0	47 (100)
			ND basic (N=27)				
			No	26 (96.3)	1 (3.7)	0	27 (100)
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
Sum		26 (96.3)	1 (3.7)	0	27 (100)		
SC (N=24)		No	24 (100)	0	0	24 (100)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
	Sum	24 (100)	0	0	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 5	ND plus (N=12)				
		No	12 (100)	0	0	12 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	12 (100)	0	0	12 (100)
		ND basic (N=8)				
		No	8 (100)	0	0	8 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	8 (100)	0	0	8 (100)	
	Visit 6	ND plus (N=46)				
		No	45 (97.8)	0	0	45 (97.8)
		Yes	1 (2.2)	0	0	1 (2.2)
		Missing	0	0	0	0 (0)
		Sum	46 (100)	0	0	46 (100)
		ND basic (N=25)				
		No	24 (96.0)	1 (4.0)	0	25 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	24 (96.0)	1 (4.0)	0	25 (100)
SC (N=23)						
No		23 (100)	0	0	23 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	23 (100)	0	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2A)**				
			No	Yes	Missing	Sum	
Central Disc (continued)	Visit 7	ND plus (N=46)					
		No	46 (100)	0	0	46 (100)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
		Sum	46 (100)	0	0	46 (100)	
		ND basic (N=26)					
		No	25 (96.2)	1 (3.8)	0	26 (100)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
		Sum	25 (96.2)	1 (3.8)	0	26 (100)	
		SC (N=21)					
		No	20 (95.2)	0	0	20 (95.2)	
	Yes	1 (4.8)	0	0	1 (4.8)		
	Missing	0	0	0	0 (0)		
	Sum	21 (100)	0	0	21 (100)		
	Visit 8	ND plus (N=43)	No	43 (100)	0	0	43 (100)
			Yes	0	0	0	0 (0)
			Missing	0	0	0	0 (0)
			Sum	43 (100)	0	0	43 (100)
			ND basic (N=25)	No	24 (96.0)	1 (4.0)	0
Yes				0	0	0	0 (0)
Missing		0		0	0	0 (0)	
Sum		24 (96.0)		1 (4.0)	0	25 (100)	
SC (N=22)		No		22 (100)	0	0	22 (100)
		Yes		0	0	0	0 (0)
		Missing	0	0	0	0 (0)	
		Sum	22 (100)	0	0	22 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	End of Trial	ND plus (N=39)				
		No	38 (97.4)	0	0	38 (97.4)
		Yes	0	0	0	0 (0)
		Missing	1 (2.6)	0	0	1 (2.6)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=26)				
		No	25 (96.2)	1 (3.8)	0	26 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	25 (96.2)	1 (3.8)	0	26 (100)
		SC (N=20)				
		No	20 (100)	0	0	20 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	20 (100)	0	0	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated	Visit 1/Visit 2A**	ND plus (N=9)				
		No	8 (88.9)	0	0	8 (88.9)
		Yes	0	1 (11.1)	0	1 (11.1)
		Missing	0	0	0	0 (0)
		Sum	8 (88.9)	1 (11.1)	0	9 (100)
		ND basic (N=5)				
		No	5 (100)	0	0	5 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	5 (100)	0	0	5 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	2 (100)	0	0	2 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 3a*	ND plus (N=8)				
		No	8 (100)	0	0	8 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	8 (100)	0	0	8 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	4 (100)	0	0	4 (100)	
	Visit 4	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Cranial Disc, add. treated (continued)	Visit 5	ND plus (N=2)						
		No	2 (100)	0	0	2 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	2 (100)	0	0	2 (100)		
		ND basic (N=3)						
	No	3 (100)	0	0	3 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	3 (100)	0	0	3 (100)			
	Visit 6	ND plus (N=7)	No	7 (100)	0	0	7 (100)	
			Yes	0	0	0	0 (0)	
			Missing	0	0	0	0 (0)	
			Sum	7 (100)	0	0	7 (100)	
			ND basic (N=4)	No	4 (100)	0	0	4 (100)
				Yes	0	0	0	0 (0)
		Missing		0	0	0	0 (0)	
		Sum		4 (100)	0	0	4 (100)	
SC (N=2)		No		2 (100)	0	0	2 (100)	
		Yes		0	0	0	0 (0)	
		Missing	0	0	0	0 (0)		
		Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 7	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	2 (100)	0	0	2 (100)	
	Visit 8	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
ND basic (N=4)						
No		4 (100)	0	0	4 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		4 (100)	0	0	4 (100)	
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		2 (100)	0	0	2 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	End of Trial	ND plus (N=6)				
		No	5 (83.3)	0	0	5 (83.3)
		Yes	0	0	0	0 (0)
		Missing	1 (16.7)	0	0	1 (16.7)
		Sum	6 (100)	0	0	6 (100)
		ND basic (N=3)				
		No	2 (66.7)	0	0	2 (66.7)
		Yes	1 (33.3)	0	0	1 (33.3)
		Missing	0	0	0	0 (0)
		Sum	3 (100)	0	0	3 (100)
		SC (N=1)				
		No	1 (100)	0	0	1 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	1 (100)	0	0	1 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated	Visit 1/Visit 2A**	ND plus (N=49)				
		No	49 (100)	0	0	49 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	49 (100)	0	0	49 (100)
		ND basic (N=32)				
		No	32 (100)	0	0	32 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	32 (100)	0	0	32 (100)
		SC (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 3a*	ND plus (N=42)				
		No	42 (100)	0	0	42 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	42 (100)	0	0	42 (100)
		ND basic (N=24)				
		No	24 (100)	0	0	24 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	24 (100)	0	0	24 (100)	
	Visit 4	ND plus (N=40)				
		No	40 (100)	0	0	40 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	40 (100)	0	0	40 (100)
		ND basic (N=23)				
No		23 (100)	0	0	23 (100)	
Yes		0	0	0	0 (0)	
Missing	0	0	0	0 (0)		
Sum	23 (100)	0	0	23 (100)		
SC (N=22)	No	22 (100)	0	0	22 (100)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	22 (100)	0	0	22 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Cranial Disc, not treated (continued)	Visit 5	ND plus (N=10)						
		No	10 (100)	0	0	10 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	10 (100)	0	0	10 (100)		
		ND basic (N=5)						
	No	5 (100)	0	0	5 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	5 (100)	0	0	5 (100)			
	Visit 6	ND plus (N=39)	No	39 (100)	0	0	39 (100)	
			Yes	0	0	0	0 (0)	
			Missing	0	0	0	0 (0)	
			Sum	39 (100)	0	0	39 (100)	
			ND basic (N=21)	No	21 (100)	0	0	21 (100)
				Yes	0	0	0	0 (0)
		Missing		0	0	0	0 (0)	
		Sum		21 (100)	0	0	21 (100)	
SC (N=21)		No		21 (100)	0	0	21 (100)	
		Yes		0	0	0	0 (0)	
		Missing	0	0	0	0 (0)		
		Sum	21 (100)	0	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteochondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 7	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=22)				
		No	22 (100)	0	0	22 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	22 (100)	0	0	22 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	19 (100)	0	0	19 (100)	
	Visit 8	ND plus (N=37)				
		No	37 (100)	0	0	37 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
ND basic (N=21)						
No		21 (100)	0	0	21 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		21 (100)	0	0	21 (100)	
SC (N=20)						
No		20 (100)	0	0	20 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	20 (100)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.8: Change in distinct sclerosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Distinct sclerosis of the osteocondral endplate	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2a)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	End of Trial	ND plus (N=33)				
		No	33 (100)	0	0	33 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	33 (100)	0	0	33 (100)
		ND basic (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	19 (100)	0	0	19 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	27 (46.6)	0	0	27 (46.6)
		Yes	0	0	0	0 (0)
		Missing	0	0	31 (53.4)	31 (53.4)
		Sum	27 (46.6)	0	31 (53.4)	58 (100)
		ND basic (N=37)				
		No	14 (37.8)	0	0	14 (37.8)
		Yes	0	0	0	0 (0)
		Missing	0	0	23 (62.2)	23 (62.2)
		Sum	14 (37.8)	0	23 (62.2)	37 (100)
		SC (N=25)				
		No	11 (44.0)	0	0	11 (44.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	14 (56.0)	14 (56.0)
		Sum	11 (44.0)	0	14 (56.0)	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2A)**				
			No	Yes	Missing	Sum	
Caudal Disc (continued)	Visit 3a*	ND plus (N=50)					
		No	24 (48.0)	0	1 (2.0)	25 (50.0)	
		Yes	0	0	0	0 (0)	
		Missing	2 (4.0)	0	23 (46.0)	25 (50.0)	
		Sum	26 (52.0)	0	24 (48.0)	50 (100)	
		ND basic (N=28)					
	No	13 (46.4)	0	0	13 (46.4)		
	Yes	0	0	0	0 (0)		
	Missing	0	0	15 (53.6)	15 (53.6)		
	Sum	13 (46.4)	0	15 (53.6)	28 (100)		
	Visit 4	ND plus (N=47)	No	22 (46.8)	0	5 (10.6)	27 (57.4)
			Yes	0	0	0	0 (0)
			Missing	1 (2.1)	0	19 (40.4)	20 (42.6)
			Sum	23 (48.9)	0	24 (51.1)	47 (100)
			ND basic (N=27)				
			No	13 (48.1)	0	3 (11.1)	16 (59.3)
		Yes	0	0	0	0 (0)	
		Missing	0	0	11 (40.7)	11 (40.7)	
Sum		13 (48.1)	0	14 (51.9)	27 (100)		
SC (N=24)		No	10 (41.7)	0	5 (20.8)	15 (62.5)	
		Yes	0	0	0	0 (0)	
		Missing	1 (4.2)	0	8 (33.3)	9 (37.5)	
	Sum	11 (45.8)	0	13 (54.2)	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 5	ND plus (N=12)				
		No	4 (33.3)	0	2 (16.7)	6 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	6 (50.0)	6 (50.0)
		Sum	4 (33.3)	0	8 (66.7)	12 (100)
		ND basic (N=8)				
		No	3 (37.5)	0	0	3 (37.5)
		Yes	0	0	0	0 (0)
	Missing	0	0	5 (62.5)	5 (62.5)	
	Sum	3 (37.5)	0	5 (62.5)	8 (100)	
	Visit 6	ND plus (N=46)				
		No	21 (45.7)	0	3 (6.5)	24 (52.2)
		Yes	0	0	0	0 (0)
		Missing	2 (4.3)	0	20 (43.5)	22 (47.8)
		Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=25)				
		No	12 (48.0)	0	1 (4.0)	13 (52.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	12 (48.0)	12 (48.0)
		Sum	12 (48.0)	0	13 (52.0)	25 (100)
SC (N=23)						
No		9 (39.1)	0	0	9 (39.1)	
Yes	0	0	0	0 (0)		
Missing	1 (4.3)	0	13 (56.5)	14 (60.9)		
Sum	10 (43.5)	0	13 (56.5)	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 7	ND plus (N=46)				
		No	22 (47.8)	0	0	22 (47.8)
		Yes	0	0	0	0 (0)
		Missing	1 (2.2)	0	23 (50.0)	24 (52.2)
		Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=26)				
		No	13 (50.0)	0	1 (3.8)	14 (53.8)
		Yes	0	0	0	0 (0)
		Missing	0	0	12 (46.2)	12 (46.2)
		Sum	13 (50.0)	0	13 (50.0)	26 (100)
		SC (N=21)				
		No	8 (38.1)	0	1 (4.8)	9 (42.9)
	Yes	0	0	0	0 (0)	
	Missing	1 (4.8)	0	11 (52.4)	12 (57.1)	
	Sum	9 (42.9)	0	12 (57.1)	21 (100)	
	Visit 8	ND plus (N=43)				
		No	19 (44.2)	0	0	19 (44.2)
		Yes	0	0	0	0 (0)
		Missing	1 (2.3)	0	23 (53.5)	24 (55.8)
		Sum	20 (46.5)	0	23 (53.5)	43 (100)
		ND basic (N=25)				
		No	13 (52.0)	0	0	13 (52.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	12 (48.0)	12 (48.0)
Sum		13 (52.0)	0	12 (48.0)	25 (100)	
SC (N=22)						
No		8 (36.4)	0	0	8 (36.4)	
Yes	0	0	0	0 (0)		
Missing	1 (4.5)	0	13 (59.1)	14 (63.6)		
Sum	9 (40.9)	0	13 (59.1)	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	End of Trial	ND plus (N=39)				
		No	18 (46.2)	0	0	18 (46.2)
		Yes	0	0	0	0 (0)
		Missing	1 (2.6)	0	20 (51.3)	21 (53.8)
		Sum	19 (48.7)	0	20 (51.3)	39 (100)
		ND basic (N=26)				
		No	13 (50.0)	0	0	13 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	13 (50.0)	13 (50.0)
		Sum	13 (50.0)	0	13 (50.0)	26 (100)
		SC (N=20)				
		No	7 (35.0)	0	0	7 (35.0)
		Yes	0	0	0	0 (0)
		Missing	1 (5.0)	0	12 (60.0)	13 (65.0)
		Sum	8 (40.0)	0	12 (60.0)	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	58 (100)	0	0	58 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	58 (100)	0	0	58 (100)
		ND basic (N=37)				
		No	37 (100)	0	0	37 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
		SC (N=25)				
		No	25 (100)	0	0	25 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	25 (100)	0	0	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	50 (100)	0	0	50 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	50 (100)	0	0	50 (100)
		ND basic (N=28)				
		No	28 (100)	0	0	28 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	28 (100)	0	0	28 (100)	
	Visit 4	ND plus (N=47)				
		No	47 (100)	0	0	47 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	47 (100)	0	0	47 (100)
		ND basic (N=27)				
No		26 (96.3)	0	0	26 (96.3)	
Yes		1 (3.7)	0	0	1 (3.7)	
Missing		0	0	0	0 (0)	
Sum		27 (100)	0	0	27 (100)	
SC (N=24)						
No		24 (100)	0	0	24 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	24 (100)	0	0	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects				
			Screening (Visit 1)/Baseline (Visit 2A)**				
			No	Yes	Missing	Sum	
Central Disc (continued)	Visit 5	ND plus (N=12)					
		No	12 (100)	0	0	12 (100)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
		Sum	12 (100)	0	0	12 (100)	
		ND basic (N=8)					
		No	8 (100)	0	0	8 (100)	
		Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)		
	Sum	8 (100)	0	0	8 (100)		
	Visit 6	ND plus (N=46)	No	46 (100)	0	0	46 (100)
			Yes	0	0	0	0 (0)
			Missing	0	0	0	0 (0)
			Sum	46 (100)	0	0	46 (100)
		ND basic (N=25)	No	25 (100)	0	0	25 (100)
			Yes	0	0	0	0 (0)
Missing			0	0	0	0 (0)	
Sum			25 (100)	0	0	25 (100)	
SC (N=23)		No	23 (100)	0	0	23 (100)	
		Yes	0	0	0	0 (0)	
		Missing	0	0	0	0 (0)	
		Sum	23 (100)	0	0	23 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 7	ND plus (N=46)				
		No	46 (100)	0	0	46 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	46 (100)	0	0	46 (100)
		ND basic (N=26)				
		No	26 (100)	0	0	26 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	26 (100)	0	0	26 (100)
		SC (N=21)				
		No	21 (100)	0	0	21 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	21 (100)	0	0	21 (100)	
	Visit 8	ND plus (N=43)				
		No	43 (100)	0	0	43 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	43 (100)	0	0	43 (100)
ND basic (N=25)						
No		25 (100)	0	0	25 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		25 (100)	0	0	25 (100)	
SC (N=22)						
No		22 (100)	0	0	22 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	22 (100)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	End of Trial	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=26)				
		No	26 (100)	0	0	26 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	26 (100)	0	0	26 (100)
		SC (N=20)				
		No	20 (100)	0	0	20 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	20 (100)	0	0	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated	Visit 1/Visit 2A**	ND plus (N=9)				
		No	9 (100)	0	0	9 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	9 (100)	0	0	9 (100)
		ND basic (N=5)				
		No	5 (100)	0	0	5 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	5 (100)	0	0	5 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	2 (100)	0	0	2 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 3a*	ND plus (N=8)				
		No	8 (100)	0	0	8 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	8 (100)	0	0	8 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	4 (100)	0	0	4 (100)	
	Visit 4	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Cranial Disc, add. treated (continued)	Visit 5	ND plus (N=2)						
		No	2 (100)	0	0	2 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	2 (100)	0	0	2 (100)		
		ND basic (N=3)						
	No	3 (100)	0	0	3 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	3 (100)	0	0	3 (100)			
	Visit 6	ND plus (N=7)	No	7 (100)	0	0	7 (100)	
			Yes	0	0	0	0 (0)	
			Missing	0	0	0	0 (0)	
			Sum	7 (100)	0	0	7 (100)	
			ND basic (N=4)	No	4 (100)	0	0	4 (100)
				Yes	0	0	0	0 (0)
		Missing		0	0	0	0 (0)	
		Sum		4 (100)	0	0	4 (100)	
SC (N=2)		No		2 (100)	0	0	2 (100)	
		Yes		0	0	0	0 (0)	
		Missing	0	0	0	0 (0)		
		Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 7	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	2 (100)	0	0	2 (100)	
	Visit 8	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
ND basic (N=4)						
No		4 (100)	0	0	4 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		4 (100)	0	0	4 (100)	
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	End of Trial	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
		ND basic (N=3)				
		No	3 (100)	0	0	3 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	3 (100)	0	0	3 (100)
		SC (N=1)				
		No	1 (100)	0	0	1 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	1 (100)	0	0	1 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated	Visit 1/Visit 2A**	ND plus (N=49)				
		No	49 (100)	0	0	49 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	49 (100)	0	0	49 (100)
		ND basic (N=32)				
		No	32 (100)	0	0	32 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	32 (100)	0	0	32 (100)
		SC (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 3a*	ND plus (N=42)				
		No	42 (100)	0	0	42 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	42 (100)	0	0	42 (100)
		ND basic (N=24)				
		No	24 (100)	0	0	24 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	24 (100)	0	0	24 (100)	
	Visit 4	ND plus (N=40)				
		No	40 (100)	0	0	40 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	40 (100)	0	0	40 (100)
		ND basic (N=23)				
No		23 (100)	0	0	23 (100)	
Yes		0	0	0	0 (0)	
Missing	0	0	0	0 (0)		
Sum	23 (100)	0	0	23 (100)		
SC (N=22)	No	22 (100)	0	0	22 (100)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	22 (100)	0	0	22 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 5	ND plus (N=10)				
		No	10 (100)	0	0	10 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	10 (100)	0	0	10 (100)
		ND basic (N=5)				
		No	5 (100)	0	0	5 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
	Sum	5 (100)	0	0	5 (100)	
	Visit 6	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=21)				
		No	21 (100)	0	0	21 (100)
		Yes	0	0	0	0 (0)
Missing		0	0	0	0 (0)	
Sum	21 (100)	0	0	21 (100)		
SC (N=21)						
No	21 (100)	0	0	21 (100)		
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	21 (100)	0	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 7	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=22)				
		No	22 (100)	0	0	22 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	22 (100)	0	0	22 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	19 (100)	0	0	19 (100)	
	Visit 8	ND plus (N=37)				
		No	37 (100)	0	0	37 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
ND basic (N=21)						
No		21 (100)	0	0	21 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		21 (100)	0	0	21 (100)	
SC (N=20)						
No		20 (100)	0	0	20 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	20 (100)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.9: Change in more than moderate degenerative spinal stenosis from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative spinal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	End of Trial	ND plus (N=33)				
		No	33 (100)	0	0	33 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	33 (100)	0	0	33 (100)
		ND basic (N=23)				
		No	22 (95.7)	0	0	22 (95.7)
		Yes	1 (4.3)	0	0	1 (4.3)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	19 (100)	0	0	19 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	27 (46.6)	0	0	27 (46.6)
		Yes	0	0	0	0 (0)
		Missing	0	0	31 (53.4)	31 (53.4)
		Sum	27 (46.6)	0	31 (53.4)	58 (100)
		ND basic (N=37)				
		No	13 (35.1)	0	0	13 (35.1)
		Yes	0	1 (2.7)	0	1 (2.7)
		Missing	0	0	23 (62.2)	23 (62.2)
		Sum	13 (35.1)	1 (2.7)	23 (62.2)	37 (100)
		SC (N=25)				
		No	11 (44.0)	0	0	11 (44.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	14 (56.0)	14 (56.0)
		Sum	11 (44.0)	0	14 (56.0)	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	24 (48.0)	0	2 (4.0)	26 (52.0)
		Yes	0	0	0	0 (0)
		Missing	2 (4.0)	0	22 (44.0)	24 (48.0)
		Sum	26 (52.0)	0	24 (48.0)	50 (100)
		ND basic (N=28)				
		No	12 (42.9)	1 (3.6)	0	13 (46.4)
		Yes	0	0	0	0 (0)
	Missing	0	0	15 (53.6)	15 (53.6)	
	Sum	12 (42.9)	1 (3.6)	15 (53.6)	28 (100)	
	Visit 4	ND plus (N=47)				
		No	22 (46.8)	0	5 (10.6)	27 (57.4)
		Yes	0	0	0	0 (0)
		Missing	1 (2.1)	0	19 (40.4)	20 (42.6)
		Sum	23 (48.9)	0	24 (51.1)	47 (100)
		ND basic (N=27)				
		No	12 (44.4)	0	2 (7.4)	14 (51.9)
		Yes	0	1 (3.7)	0	1 (3.7)
		Missing	0	0	12 (44.4)	12 (44.4)
		Sum	12 (44.4)	1 (3.7)	14 (51.9)	27 (100)
SC (N=24)						
No		10 (41.7)	0	5 (20.8)	15 (62.5)	
Yes	0	0	0	0 (0)		
Missing	1 (4.2)	0	8 (33.3)	9 (37.5)		
Sum	11 (45.8)	0	13 (54.2)	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 5	ND plus (N=12)				
		No	4 (33.3)	0	2 (16.7)	6 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	6 (50.0)	6 (50.0)
		Sum	4 (33.3)	0	8 (66.7)	12 (100)
		ND basic (N=8)				
		No	3 (37.5)	0	0	3 (37.5)
		Yes	0	0	0	0 (0)
	Missing	0	0	5 (62.5)	5 (62.5)	
	Sum	3 (37.5)	0	5 (62.5)	8 (100)	
	Visit 6	ND plus (N=46)				
		No	21 (45.7)	0	3 (6.5)	24 (52.2)
		Yes	0	0	0	0 (0)
		Missing	2 (4.3)	0	20 (43.5)	22 (47.8)
		Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=25)				
		No	11 (44.0)	0	1 (4.0)	12 (48.0)
		Yes	0	1 (4.0)	0	1 (4.0)
		Missing	0	0	12 (48.0)	12 (48.0)
		Sum	11 (44.0)	1 (4.0)	13 (52.0)	25 (100)
SC (N=23)						
No		9 (39.1)	0	0	9 (39.1)	
Yes	0	0	0	0 (0)		
Missing	1 (4.3)	0	13 (56.5)	14 (60.9)		
Sum	10 (43.5)	0	13 (56.5)	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	Visit 7	ND plus (N=46)				
		No	22 (47.8)	0	0	22 (47.8)
		Yes	0	0	0	0 (0)
		Missing	1 (2.2)	0	23 (50.0)	24 (52.2)
		Sum	23 (50.0)	0	23 (50.0)	46 (100)
		ND basic (N=26)				
		No	12 (46.2)	0	1 (3.8)	13 (50.0)
		Yes	0	1 (3.8)	0	1 (3.8)
		Missing	0	0	12 (46.2)	12 (46.2)
		Sum	12 (46.2)	1 (3.8)	13 (50.0)	26 (100)
		SC (N=21)				
		No	8 (38.1)	0	1 (4.8)	9 (42.9)
	Yes	0	0	0	0 (0)	
	Missing	1 (4.8)	0	11 (52.4)	12 (57.1)	
	Sum	9 (42.9)	0	12 (57.1)	21 (100)	
	Visit 8	ND plus (N=43)				
		No	19 (44.2)	0	0	19 (44.2)
		Yes	0	0	0	0 (0)
		Missing	1 (2.3)	0	23 (53.5)	24 (55.8)
		Sum	20 (46.5)	0	23 (53.5)	43 (100)
		ND basic (N=25)				
		No	12 (48.0)	0	0	12 (48.0)
		Yes	0	1 (4.0)	0	1 (4.0)
		Missing	0	0	12 (48.0)	12 (48.0)
Sum		12 (48.0)	1 (4.0)	12 (48.0)	25 (100)	
SC (N=22)						
No		8 (36.4)	0	0	8 (36.4)	
Yes	0	0	0	0 (0)		
Missing	1 (4.5)	0	13 (59.1)	14 (63.6)		
Sum	9 (40.9)	0	13 (59.1)	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Caudal Disc (continued)	End of Trial	ND plus (N=39)				
		No	18 (46.2)	0	0	18 (46.2)
		Yes	0	0	0	0 (0)
		Missing	1 (2.6)	0	20 (51.3)	21 (53.8)
		Sum	19 (48.7)	0	20 (51.3)	39 (100)
		ND basic (N=26)				
		No	12 (46.2)	1 (3.8)	0	13 (50.0)
		Yes	0	0	0	0 (0)
		Missing	0	0	13 (50.0)	13 (50.0)
		Sum	12 (46.2)	1 (3.8)	13 (50.0)	26 (100)
		SC (N=20)				
		No	7 (35.0)	0	0	7 (35.0)
		Yes	0	0	0	0 (0)
		Missing	1 (5.0)	0	12 (60.0)	13 (65.0)
		Sum	8 (40.0)	0	12 (60.0)	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc	Visit 1/Visit 2A**	ND plus (N=58)				
		No	58 (100)	0	0	58 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	58 (100)	0	0	58 (100)
		ND basic (N=37)				
		No	36 (97.3)	0	0	36 (97.3)
		Yes	0	1 (2.7)	0	1 (2.7)
		Missing	0	0	0	0 (0)
		Sum	36 (97.3)	1 (2.7)	0	37 (100)
		SC (N=25)				
		No	25 (100)	0	0	25 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	25 (100)	0	0	25 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 3a*	ND plus (N=50)				
		No	50 (100)	0	0	50 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	50 (100)	0	0	50 (100)
		ND basic (N=28)				
		No	27 (96.4)	1 (3.6)	0	28 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	27 (96.4)	1 (3.6)	0	28 (100)	
	Visit 4	ND plus (N=47)				
		No	47 (100)	0	0	47 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	47 (100)	0	0	47 (100)
		ND basic (N=27)				
		No	26 (96.3)	1 (3.7)	0	27 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	26 (96.3)	1 (3.7)	0	27 (100)
SC (N=24)						
No		24 (100)	0	0	24 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	24 (100)	0	0	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			No	Yes	Missing	Sum		
Central Disc (continued)	Visit 5	ND plus (N=12)						
		No	12 (100)	0	0	12 (100)		
		Yes	0	0	0	0 (0)		
		Missing	0	0	0	0 (0)		
		Sum	12 (100)	0	0	12 (100)		
		ND basic (N=8)						
	No	8 (100)	0	0	8 (100)			
	Yes	0	0	0	0 (0)			
	Missing	0	0	0	0 (0)			
	Sum	8 (100)	0	0	8 (100)			
	Visit 6	ND plus (N=46)	No	45 (97.8)	0	0	45 (97.8)	
			Yes	1 (2.2)	0	0	1 (2.2)	
			Missing	0	0	0	0 (0)	
			Sum	46 (100)	0	0	46 (100)	
			ND basic (N=25)	No	22 (88.0)	0	0	22 (88.0)
				Yes	2 (8.0)	1 (4.0)	0	3 (12.0)
		Missing		0	0	0	0 (0)	
		Sum		24 (96.0)	1 (4.0)	0	25 (100)	
SC (N=23)		No		23 (100)	0	0	23 (100)	
		Yes		0	0	0	0 (0)	
		Missing	0	0	0	0 (0)		
		Sum	23 (100)	0	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	Visit 7	ND plus (N=46)				
		No	45 (97.8)	0	0	45 (97.8)
		Yes	1 (2.2)	0	0	1 (2.2)
		Missing	0	0	0	0 (0)
		Sum	46 (100)	0	0	46 (100)
		ND basic (N=26)				
		No	25 (96.2)	0	0	25 (96.2)
		Yes	0	1 (3.8)	0	1 (3.8)
		Missing	0	0	0	0 (0)
		Sum	25 (96.2)	1 (3.8)	0	26 (100)
		SC (N=21)				
		No	21 (100)	0	0	21 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	21 (100)	0	0	21 (100)	
	Visit 8	ND plus (N=43)				
		No	43 (100)	0	0	43 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	43 (100)	0	0	43 (100)
ND basic (N=25)						
No		24 (96.0)	0	0	24 (96.0)	
Yes		0	1 (4.0)	0	1 (4.0)	
Missing		0	0	0	0 (0)	
Sum		24 (96.0)	1 (4.0)	0	25 (100)	
SC (N=22)						
No		22 (100)	0	0	22 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	22 (100)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Central Disc (continued)	End of Trial	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=26)				
		No	25 (96.2)	1 (3.8)	0	26 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	25 (96.2)	1 (3.8)	0	26 (100)
		SC (N=20)				
		No	20 (100)	0	0	20 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	20 (100)	0	0	20 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated	Visit 1/Visit 2A**	ND plus (N=9)				
		No	9 (100)	0	0	9 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	9 (100)	0	0	9 (100)
		ND basic (N=5)				
		No	5 (100)	0	0	5 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	5 (100)	0	0	5 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	2 (100)	0	0	2 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 3a*	ND plus (N=8)				
		No	8 (100)	0	0	8 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	8 (100)	0	0	8 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	4 (100)	0	0	4 (100)	
	Visit 4	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 5	ND plus (N=2)				
		No	2 (100)	0	0	2 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	2 (100)	0	0	2 (100)
		ND basic (N=3)				
	No	3 (100)	0	0	3 (100)	
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	3 (100)	0	0	3 (100)	
	Visit 6	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
Missing		0	0	0	0 (0)	
Sum		4 (100)	0	0	4 (100)	
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	2 (100)	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 7	ND plus (N=7)				
		No	7 (100)	0	0	7 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	7 (100)	0	0	7 (100)
		ND basic (N=4)				
		No	4 (100)	0	0	4 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	4 (100)	0	0	4 (100)
		SC (N=2)				
		No	2 (100)	0	0	2 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	2 (100)	0	0	2 (100)	
	Visit 8	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
ND basic (N=4)						
No		4 (100)	0	0	4 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		4 (100)	0	0	4 (100)	
SC (N=2)						
No		2 (100)	0	0	2 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		2 (100)	0	0	2 (100)	

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2a)**			
			No	Yes	Missing	Sum
Cranial Disc, add. treated (continued)	End of Trial	ND plus (N=6)				
		No	6 (100)	0	0	6 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	6 (100)	0	0	6 (100)
		ND basic (N=3)				
		No	3 (100)	0	0	3 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	3 (100)	0	0	3 (100)
		SC (N=1)				
		No	1 (100)	0	0	1 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	1 (100)	0	0	1 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated	Visit 1/Visit 2A**	ND plus (N=49)				
		No	49 (100)	0	0	49 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	49 (100)	0	0	49 (100)
		ND basic (N=32)				
		No	32 (100)	0	0	32 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	32 (100)	0	0	32 (100)
		SC (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 3a*	ND plus (N=42)				
		No	42 (100)	0	0	42 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	42 (100)	0	0	42 (100)
		ND basic (N=24)				
		No	24 (100)	0	0	24 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	24 (100)	0	0	24 (100)	
	Visit 4	ND plus (N=40)				
		No	40 (100)	0	0	40 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	40 (100)	0	0	40 (100)
		ND basic (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)
SC (N=22)						
No		22 (100)	0	0	22 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	22 (100)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 5	ND plus (N=10)				
		No	10 (100)	0	0	10 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	10 (100)	0	0	10 (100)
		ND basic (N=5)				
		No	5 (100)	0	0	5 (100)
		Yes	0	0	0	0 (0)
	Missing	0	0	0	0 (0)	
	Sum	5 (100)	0	0	5 (100)	
	Visit 6	ND plus (N=39)				
		No	39 (100)	0	0	39 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=21)				
		No	21 (100)	0	0	21 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	21 (100)	0	0	21 (100)
SC (N=21)						
No		21 (100)	0	0	21 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	21 (100)	0	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2A)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	Visit 7	ND plus (N=39)				
		No	38 (97.4)	0	0	38 (97.4)
		Yes	1 (2.6)	0	0	1 (2.6)
		Missing	0	0	0	0 (0)
		Sum	39 (100)	0	0	39 (100)
		ND basic (N=22)				
		No	22 (100)	0	0	22 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	22 (100)	0	0	22 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
	Yes	0	0	0	0 (0)	
	Missing	0	0	0	0 (0)	
	Sum	19 (100)	0	0	19 (100)	
	Visit 8	ND plus (N=37)				
		No	37 (100)	0	0	37 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	37 (100)	0	0	37 (100)
ND basic (N=21)						
No		21 (100)	0	0	21 (100)	
Yes		0	0	0	0 (0)	
Missing		0	0	0	0 (0)	
Sum		21 (100)	0	0	21 (100)	
SC (N=20)						
No		20 (100)	0	0	20 (100)	
Yes	0	0	0	0 (0)		
Missing	0	0	0	0 (0)		
Sum	20 (100)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.10: Change in more than moderate degenerative foraminal stenosis right or left from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group Degenerative foraminal stenosis	Number (%) of subjects			
			Screening (Visit 1)/Baseline (Visit 2a)**			
			No	Yes	Missing	Sum
Cranial Disc, not treated (continued)	End of Trial	ND plus (N=33)				
		No	33 (100)	0	0	33 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	33 (100)	0	0	33 (100)
		ND basic (N=23)				
		No	23 (100)	0	0	23 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	23 (100)	0	0	23 (100)
		SC (N=19)				
		No	19 (100)	0	0	19 (100)
		Yes	0	0	0	0 (0)
		Missing	0	0	0	0 (0)
		Sum	19 (100)	0	0	19 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Caudal Disc	Visit 1/Visit 2A**	ND plus (N=58)						
		0	24 (41.4)	0	0	0	0	24 (41.4)
		1	0	0	0	0	0	0 (0)
		2	0	0	3 (5.2)	0	0	3 (5.2)
		3	0	0	0	1 (1.7)	0	1 (1.7)
		Missing	0	0	0	0	30 (51.7)	30 (51.7)
		Sum	24 (41.4)	0	3 (5.2)	1 (1.7)	30 (51.7)	58 (100)
		ND basic (N=37)						
		0	14 (37.8)	0	0	0	0	14 (37.8)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	23 (62.2)	23 (62.2)
		Sum	14 (37.8)	0	0	0	23 (62.2)	37 (100)
		SC (N=25)						
		0	10 (40.0)	0	0	0	0	10 (40.0)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	15 (60.0)	15 (60.0)		
Sum	10 (40.0)	0	0	0	15 (60.0)	25 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Caudal Disc (continued)	Visit 3a*	ND plus (N=50)						
		0	20 (40.0)	0	1 (2.0)	1 (2.0)	2 (4.0)	24 (48.0)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (4.0)	0	0	2 (4.0)
		3	0	0	0	0	0	0 (0)
		Missing	3 (6.0)	0	0	0	21 (42.0)	24 (48.0)
		Sum	23 (46.0)	0	3 (6.0)	1 (2.0)	23 (46.0)	50 (100)
		ND basic (N=28)						
		0	13 (46.4)	0	0	0	0	13 (46.4)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	15 (53.6)	15 (53.6)
		Sum	13 (46.4)	0	0	0	15 (53.6)	28 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Caudal Disc (continued)	Visit 4	ND plus (N=47)						
		0	19 (40.4)	0	1 (2.1)	0	1 (2.1)	21 (44.7)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (4.3)	0	0	2 (4.3)
		3	0	0	0	0	0	0 (0)
		Missing	2 (4.3)	0	0	0	22 (46.8)	24 (51.1)
		Sum	21 (44.7)	0	3 (6.4)	0	23 (48.9)	47 (100)
		ND basic (N=27)						
		0	12 (44.4)	0	0	0	0	12 (44.4)
		1	0	0	0	0	0	0 (0)
		2	1 (3.7)	0	0	0	0	1 (3.7)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	14 (51.9)	14 (51.9)
		Sum	13 (48.1)	0	0	0	14 (51.9)	27 (100)
		SC (N=24)						
		0	9 (37.5)	0	0	0	5 (20.8)	14 (58.3)
		1	0	0	0	0	0	0 (0)
		2	1 (4.2)	0	0	0	0	1 (4.2)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	9 (37.5)	9 (37.5)		
Sum	10 (41.7)	0	0	0	14 (58.3)	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Caudal Disc (continued)	Visit 5	ND plus (N=12)						
		0	3 (25.0)	0	0	0	2 (16.7)	5 (41.7)
		1	0	0	0	0	0	0 (0)
		2	0	0	1 (8.3)	0	0	1 (8.3)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	6 (50.0)	6 (50.0)
		Sum	3 (25.0)	0	1 (8.3)	0	8 (66.7)	12 (100)
		ND basic (N=8)						
		0	3 (37.5)	0	0	0	0	3 (37.5)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	5 (62.5)	5 (62.5)
		Sum	3 (37.5)	0	0	0	5 (62.5)	8 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Caudal Disc (continued)	Visit 6	ND plus (N=46)						
		0	17 (37.0)	0	1 (2.2)	0	2 (4.3)	20 (43.5)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (4.3)	0	0	2 (4.3)
		3	1 (2.2)	0	0	0	0	1 (2.2)
		Missing	3 (6.5)	0	0	0	20 (43.5)	23 (50.0)
		Sum	21 (45.7)	0	3 (6.5)	0	22 (47.8)	46 (100)
		ND basic (N=25)						
		0	11 (44.0)	0	0	0	1 (4.0)	12 (48.0)
		1	0	0	0	0	0	0 (0)
		2	1 (4.0)	0	0	0	0	1 (4.0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	12 (48.0)	12 (48.0)
		Sum	12 (48.0)	0	0	0	13 (52.0)	25 (100)
		SC (N=23)						
		0	9 (39.1)	0	0	0	0	9 (39.1)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	14 (60.9)	14 (60.9)		
Sum	9 (39.1)	0	0	0	14 (60.9)	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Caudal Disc (continued)	Visit 7	ND plus (N=46)						
		0	19 (41.3)	0	1 (2.2)	0	0	20 (43.5)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (4.3)	0	0	2 (4.3)
		3	0	0	0	0	0	0 (0)
		Missing	2 (4.3)	0	0	0	22 (47.8)	24 (52.2)
		Sum	21 (45.7)	0	3 (6.5)	0	22 (47.8)	46 (100)
		ND basic (N=26)						
		0	13 (50.0)	0	0	0	1 (3.8)	14 (53.8)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	12 (46.2)	12 (46.2)
		Sum	13 (50.0)	0	0	0	13 (50.0)	26 (100)
		SC (N=21)						
		0	8 (38.1)	0	0	0	0	8 (38.1)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	13 (61.9)	13 (61.9)		
Sum	8 (38.1)	0	0	0	13 (61.9)	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Caudal Disc (continued)	Visit 8	ND plus (N=43)						
		0	16 (37.2)	0	1 (2.3)	0	0	17 (39.5)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (4.7)	0	0	2 (4.7)
		3	0	0	0	0	0	0 (0)
		Missing	2 (4.7)	0	0	0	22 (51.2)	24 (55.8)
		Sum	18 (41.9)	0	3 (7.0)	0	22 (51.2)	43 (100)
		ND basic (N=25)						
		0	12 (48.0)	0	0	0	0	12 (48.0)
		1	0	0	0	0	0	0 (0)
		2	1 (4.0)	0	0	0	0	1 (4.0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	12 (48.0)	12 (48.0)
		Sum	13 (52.0)	0	0	0	12 (48.0)	25 (100)
		SC (N=22)						
		0	7 (31.8)	0	0	0	0	7 (31.8)
		1	0	0	0	0	0	0 (0)
		2	1 (4.5)	0	0	0	0	1 (4.5)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	14 (63.6)	14 (63.6)		
Sum	8 (36.4)	0	0	0	14 (63.6)	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Caudal Disc (continued)	End of Trial	ND plus (N=39)						
		0	15 (38.5)	0	1 (2.6)	0	0	16 (41.0)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (5.1)	0	0	2 (5.1)
		3	0	0	0	0	0	0 (0)
		Missing	2 (5.1)	0	0	0	19 (48.7)	21 (53.8)
		Sum	17 (43.6)	0	3 (7.7)	0	19 (48.7)	39 (100)
		ND basic (N=26)						
		0	12 (46.2)	0	0	0	0	12 (46.2)
		1	0	0	0	0	0	0 (0)
		2	1 (3.8)	0	0	0	0	1 (3.8)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	13 (50.0)	13 (50.0)
		Sum	13 (50.0)	0	0	0	13 (50.0)	26 (100)
		SC (N=20)						
		0	7 (35.0)	0	0	0	0	7 (35.0)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	13 (65.0)	13 (65.0)		
Sum	7 (35.0)	0	0	0	13 (65.0)	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Central Disc	Visit 1/Visit 2A**	ND plus (N=58)						
		0	47 (81.0)	0	0	0	0	47 (81.0)
		1	0	1 (1.7)	0	0	0	1 (1.7)
		2	0	0	10 (17.2)	0	0	10 (17.2)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	47 (81.0)	1 (1.7)	10 (17.2)	0	0	58 (100)
		ND basic (N=37)						
		0	30 (81.1)	0	0	0	0	30 (81.1)
		1	0	3 (8.1)	0	0	0	3 (8.1)
		2	0	0	4 (10.8)	0	0	4 (10.8)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	30 (81.1)	3 (8.1)	4 (10.8)	0	0	37 (100)
		SC (N=25)						
0	22 (88.0)	0	0	0	0	22 (88.0)		
1	0	0	0	0	0	0 (0)		
2	0	0	3 (12.0)	0	0	3 (12.0)		
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0 (0)		
Sum	22 (88.0)	0	3 (12.0)	0	0	25 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Central Disc (continued)	Visit 3a*	ND plus (N=50)						
		0	35 (70.0)	0	4 (8.0)	0	0	39 (78.0)
		1	1 (2.0)	0	2 (4.0)	0	0	3 (6.0)
		2	3 (6.0)	0	4 (8.0)	0	0	7 (14.0)
		3	1 (2.0)	0	0	0	0	1 (2.0)
		Missing	0	0	0	0	0	0 (0)
		Sum	40 (80.0)	0	10 (20.0)	0	0	50 (100)
		ND basic (N=28)						
		0	23 (82.1)	2 (7.1)	0	0	0	25 (89.3)
		1	0	0	0	0	0	0 (0)
		2	0	1 (3.6)	2 (7.1)	0	0	3 (10.7)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	23 (82.1)	3 (10.7)	2 (7.1)	0	0	28 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					Sum
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	
Central Disc (continued)	Visit 4	ND plus (N=47)						
		0	31 (66.0)	0	1 (2.1)	0	0	32 (68.1)
		1	4 (8.5)	0	0	0	0	4 (8.5)
		2	3 (6.4)	0	8 (17.0)	0	0	11 (23.4)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	38 (80.9)	0	9 (19.1)	0	0	47 (100)
		ND basic (N=27)						
		0	20 (74.1)	1 (3.7)	1 (3.7)	0	0	22 (81.5)
		1	0	2 (7.4)	1 (3.7)	0	0	3 (11.1)
		2	2 (7.4)	0	0	0	0	2 (7.4)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	22 (81.5)	3 (11.1)	2 (7.4)	0	0	27 (100)
		SC (N=24)						
		0	17 (70.8)	0	1 (4.2)	0	0	18 (75.0)
		1	1 (4.2)	0	0	0	0	1 (4.2)
		2	2 (8.3)	0	2 (8.3)	0	0	4 (16.7)
		3	0	0	0	0	0	0 (0)
		Missing	1 (4.2)	0	0	0	0	1 (4.2)
		Sum	21 (87.5)	0	3 (12.5)	0	0	24 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Central Disc (continued)	Visit 5	ND plus (N=12)						
		0	6 (50.0)	0	3 (25.0)	0	0	9 (75.0)
		1	0	0	1 (8.3)	0	0	1 (8.3)
		2	1 (8.3)	0	1 (8.3)	0	0	2 (16.7)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	7 (58.3)	0	5 (41.7)	0	0	12 (100)
		ND basic (N=8)						
		0	6 (75.0)	0	0	0	0	6 (75.0)
		1	1 (12.5)	0	0	0	0	1 (12.5)
		2	0	1 (12.5)	0	0	0	1 (12.5)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	7 (87.5)	1 (12.5)	0	0	0	8 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Central Disc (continued)	Visit 6	ND plus (N=46)						
		0	27 (58.7)	0	5 (10.9)	0	0	32 (69.6)
		1	6 (13.0)	0	1 (2.2)	0	0	7 (15.2)
		2	4 (8.7)	0	3 (6.5)	0	0	7 (15.2)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	37 (80.4)	0	9 (19.6)	0	0	46 (100)
		ND basic (N=25)						
		0	16 (64.0)	2 (8.0)	0	0	0	18 (72.0)
		1	2 (8.0)	1 (4.0)	1 (4.0)	0	0	4 (16.0)
		2	2 (8.0)	0	1 (4.0)	0	0	3 (12.0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	20 (80.0)	3 (12.0)	2 (8.0)	0	0	25 (100)
		SC (N=23)						
		0	20 (87.0)	0	0	0	0	20 (87.0)
		1	0	0	2 (8.7)	0	0	2 (8.7)
		2	0	0	1 (4.3)	0	0	1 (4.3)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0 (0)		
Sum	20 (87.0)	0	3 (13.0)	0	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					Sum
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	
Central Disc (continued)	Visit 7	ND plus (N=46)						
		0	25 (54.3)	0	1 (2.2)	0	0	26 (56.5)
		1	10 (21.7)	0	2 (4.3)	0	0	12 (26.1)
		2	2 (4.3)	0	6 (13.0)	0	0	8 (17.4)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	37 (80.4)	0	9 (19.6)	0	0	46 (100)
		ND basic (N=26)						
		0	17 (65.4)	2 (7.7)	1 (3.8)	0	0	20 (76.9)
		1	2 (7.7)	1 (3.8)	1 (3.8)	0	0	4 (15.4)
		2	2 (7.7)	0	0	0	0	2 (7.7)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	21 (80.8)	3 (11.5)	2 (7.7)	0	0	26 (100)
		SC (N=21)						
0	17 (81.0)	0	1 (4.8)	0	0	18 (85.7)		
1	1 (4.8)	0	0	0	0	1 (4.8)		
2	0	0	2 (9.5)	0	0	2 (9.5)		
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0 (0)		
Sum	18 (85.7)	0	3 (14.3)	0	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					Sum
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	
Central Disc (continued)	Visit 8	ND plus (N=43)						
		0	19 (44.2)	0	1 (2.3)	0	0	20 (46.5)
		1	9 (20.9)	0	2 (4.7)	0	0	11 (25.6)
		2	6 (14.0)	0	6 (14.0)	0	0	12 (27.9)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	34 (79.1)	0	9 (20.9)	0	0	43 (100)
		ND basic (N=25)						
		0	16 (64.0)	1 (4.0)	0	0	0	17 (68.0)
		1	2 (8.0)	1 (4.0)	0	0	0	3 (12.0)
		2	2 (8.0)	1 (4.0)	2 (8.0)	0	0	5 (20.0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	20 (80.0)	3 (12.0)	2 (8.0)	0	0	25 (100)
		SC (N=22)						
0	17 (77.3)	0	0	0	0	17 (77.3)		
1	2 (9.1)	0	0	0	0	2 (9.1)		
2	0	0	3 (13.6)	0	0	3 (13.6)		
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0 (0)		
Sum	19 (86.4)	0	3 (13.6)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Central Disc (continued)	End of Trial	ND plus (N=39)						
		0	20 (51.3)	0	3 (7.7)	0	0	23 (59.0)
		1	5 (12.8)	0	1 (2.6)	0	0	6 (15.4)
		2	7 (17.9)	0	3 (7.7)	0	0	10 (25.6)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	32 (82.1)	0	7 (17.9)	0	0	39 (100)
		ND basic (N=26)						
		0	18 (69.2)	2 (7.7)	0	0	0	20 (76.9)
		1	0	1 (3.8)	0	0	0	1 (3.8)
		2	4 (15.4)	0	1 (3.8)	0	0	5 (19.2)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	22 (84.6)	3 (11.5)	1 (3.8)	0	0	26 (100)
		SC (N=20)						
0	15 (75.0)	0	1 (5.0)	0	0	16 (80.0)		
1	0	0	0	0	0	0 (0)		
2	2 (10.0)	0	2 (10.0)	0	0	4 (20.0)		
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0 (0)		
Sum	17 (85.0)	0	3 (15.0)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, add. treated	Visit 1/Visit 2A**	ND plus (N=9)						
		0	8 (88.9)	0	0	0	0	8 (88.9)
		1	0	1 (11.1)	0	0	0	1 (11.1)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	8 (88.9)	1 (11.1)	0	0	0	9 (100)
		ND basic (N=5)						
		0	5 (100)	0	0	0	0	5 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	5 (100)	0	0	0	0	5 (100)
		SC (N=2)						
		0	2 (100)	0	0	0	0	2 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0 (0)		
Sum	2 (100)	0	0	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					Sum
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	
Cranial Disc, add. treated (continued)	Visit 3a*	ND plus (N=8)						
		0	8 (100)	0	0	0	0	8 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	8 (100)	0	0	0	0	8 (100)
		ND basic (N=4)						
		0	4 (100)	0	0	0	0	4 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	4 (100)	0	0	0	0	4 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 4	ND plus (N=7)						
		0	7 (100)	0	0	0	0	7 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	7 (100)	0	0	0	0	7 (100)
		ND basic (N=4)						
		0	4 (100)	0	0	0	0	4 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	4 (100)	0	0	0	0	4 (100)
		SC (N=2)						
		0	2 (100)	0	0	0	0	2 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	2 (100)	0	0	0	0	2 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					Sum
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	
Cranial Disc, add. treated (continued)	Visit 5	ND plus (N=2)						
		0	2 (100)	0	0	0	0	2 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	2 (100)	0	0	0	0	2 (100)
		ND basic (N=3)						
		0	3 (100)	0	0	0	0	3 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	3 (100)	0	0	0	0	3 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					Sum
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	
Cranial Disc, add. treated (continued)	Visit 6	ND plus (N=7)						
		0	7 (100)	0	0	0	0	7 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	7 (100)	0	0	0	0	7 (100)
		ND basic (N=4)						
		0	4 (100)	0	0	0	0	4 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	4 (100)	0	0	0	0	4 (100)
		SC (N=2)						
		0	2 (100)	0	0	0	0	2 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	2 (100)	0	0	0	0	2 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 7	ND plus (N=7)						
		0	6 (85.7)	0	0	0	0	6 (85.7)
		1	0	0	0	0	0	0 (0)
		2	1 (14.3)	0	0	0	0	1 (14.3)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	7 (100)	0	0	0	0	7 (100)
		ND basic (N=4)						
		0	4 (100)	0	0	0	0	4 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	4 (100)	0	0	0	0	4 (100)
		SC (N=2)						
		0	2 (100)	0	0	0	0	2 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
Missing	0	0	0	0	0	0 (0)		
Sum	2 (100)	0	0	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 8	ND plus (N=6)						
		0	6 (100)	0	0	0	0	6 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	6 (100)	0	0	0	0	6 (100)
		ND basic (N=4)						
		0	4 (100)	0	0	0	0	4 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	4 (100)	0	0	0	0	4 (100)
		SC (N=2)						
		0	2 (100)	0	0	0	0	2 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0 (0)		
Sum	2 (100)	0	0	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, add. treated (continued)	End of Trial	ND plus (N=6)						
		0	6 (100)	0	0	0	0	6 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	6 (100)	0	0	0	0	6 (100)
		ND basic (N=3)						
		0	3 (100)	0	0	0	0	3 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	3 (100)	0	0	0	0	3 (100)
		SC (N=1)						
		0	1 (100)	0	0	0	0	1 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	1 (100)	0	0	0	0	1 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					Sum
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	
Cranial Disc, not treated	Visit 1/Visit 2A**	ND plus (N=49)						
		0	47 (95.9)	0	0	0	0	47 (95.9)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (4.1)	0	0	2 (4.1)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	47 (95.9)	0	2 (4.1)	0	0	49 (100)
		ND basic (N=32)						
		0	32 (100)	0	0	0	0	32 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	32 (100)	0	0	0	0	32 (100)
		SC (N=23)						
0	22 (95.7)	0	0	0	0	22 (95.7)		
1	0	0	0	0	0	0 (0)		
2	0	0	1 (4.3)	0	0	1 (4.3)		
3	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0 (0)		
Sum	22 (95.7)	0	1 (4.3)	0	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2a)**					
			0	1	2	3	Missing	Sum
Cranial Disc, not treated (continued)	Visit 3a*	ND plus (N=42)						
		0	40 (95.2)	0	0	0	0	40 (95.2)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (4.8)	0	0	2 (4.8)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	40 (95.2)	0	2 (4.8)	0	0	42 (100)
		ND basic (N=24)						
		0	24 (100)	0	0	0	0	24 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	24 (100)	0	0	0	0	24 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, not treated (continued)	Visit 4	ND plus (N=40)						
		0	37 (92.5)	0	0	0	0	37 (92.5)
		1	0	0	0	0	0	0 (0)
		2	1 (2.5)	0	2 (5.0)	0	0	3 (7.5)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	38 (95.0)	0	2 (5.0)	0	0	40 (100)
		ND basic (N=23)						
		0	22 (95.7)	0	0	0	0	22 (95.7)
		1	0	0	0	0	0	0 (0)
		2	1 (4.3)	0	0	0	0	1 (4.3)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	23 (100)	0	0	0	0	23 (100)
		SC (N=22)						
		0	19 (86.4)	0	0	0	0	19 (86.4)
		1	0	0	0	0	0	0 (0)
		2	1 (4.5)	0	1 (4.5)	0	0	2 (9.1)
		3	0	0	0	0	0	0 (0)
		Missing	1 (4.5)	0	0	0	0	1 (4.5)
		Sum	21 (95.5)	0	1 (4.5)	0	0	22 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, not treated (continued)	Visit 5	ND plus (N=10)						
		0	9 (90.0)	0	0	0	0	9 (90.0)
		1	0	0	0	0	0	0 (0)
		2	0	0	1 (10.0)	0	0	1 (10.0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	9 (90.0)	0	1 (10.0)	0	0	10 (100)
		ND basic (N=5)						
		0	5 (100)	0	0	0	0	5 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	5 (100)	0	0	0	0	5 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, not treated (continued)	Visit 6	ND plus (N=39)						
		0	37 (94.9)	0	0	0	0	37 (94.9)
		1	0	0	1 (2.6)	0	0	1 (2.6)
		2	0	0	1 (2.6)	0	0	1 (2.6)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	37 (94.9)	0	2 (5.1)	0	0	39 (100)
		ND basic (N=21)						
		0	21 (100)	0	0	0	0	21 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	21 (100)	0	0	0	0	21 (100)
		SC (N=21)						
		0	20 (95.2)	0	0	0	0	20 (95.2)
		1	0	0	0	0	0	0 (0)
		2	0	0	1 (4.8)	0	0	1 (4.8)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	20 (95.2)	0	1 (4.8)	0	0	21 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, not treated (continued)	Visit 7	ND plus (N=39)						
		0	37 (94.9)	0	0	0	0	37 (94.9)
		1	0	0	1 (2.6)	0	0	1 (2.6)
		2	0	0	1 (2.6)	0	0	1 (2.6)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	37 (94.9)	0	2 (5.1)	0	0	39 (100)
		ND basic (N=22)						
		0	22 (100)	0	0	0	0	22 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	22 (100)	0	0	0	0	22 (100)
		SC (N=19)						
		0	18 (94.7)	0	0	0	0	18 (94.7)
		1	0	0	0	0	0	0 (0)
		2	0	0	1 (5.3)	0	0	1 (5.3)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	18 (94.7)	0	1 (5.3)	0	0	19 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, not treated (continued)	Visit 8	ND plus (N=37)						
		0	35 (94.6)	0	1 (2.7)	0	0	36 (97.3)
		1	0	0	0	0	0	0 (0)
		2	0	0	1 (2.7)	0	0	1 (2.7)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	35 (94.6)	0	2 (5.4)	0	0	37 (100)
		ND basic (N=21)						
		0	21 (100)	0	0	0	0	21 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	21 (100)	0	0	0	0	21 (100)
		SC (N=20)						
		0	19 (95.0)	0	0	0	0	19 (95.0)
		1	0	0	0	0	0	0 (0)
		2	0	0	1 (5.0)	0	0	1 (5.0)
		3	0	0	0	0	0	0 (0)
Missing	0	0	0	0	0	0 (0)		
Sum	19 (95.0)	0	1 (5.0)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.11: MRI parameters - change in osteochondrosis grading (modic) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group osteochondrosis grading	Number (%) of subjects					
			Screening (Visit 1)/Baseline (Visit 2A)**					
			0	1	2	3	Missing	Sum
Cranial Disc, not treated (continued)	End of Trial	ND plus (N=33)						
		0	31 (93.9)	0	0	0	0	31 (93.9)
		1	0	0	0	0	0	0 (0)
		2	0	0	2 (6.1)	0	0	2 (6.1)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	31 (93.9)	0	2 (6.1)	0	0	33 (100)
		ND basic (N=23)						
		0	23 (100)	0	0	0	0	23 (100)
		1	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0 (0)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	23 (100)	0	0	0	0	23 (100)
		SC (N=19)						
		0	18 (94.7)	0	0	0	0	18 (94.7)
		1	0	0	0	0	0	0 (0)
		2	0	0	1 (5.3)	0	0	1 (5.3)
		3	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0 (0)
		Sum	18 (94.7)	0	1 (5.3)	0	0	19 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Caudal Disc	Visit 1/Visit 2A**	ND plus (N=58)							
		1	0	0	0	0	0	0	0 (0)
		2	0	8 (13.8)	0	0	0	0	8 (13.8)
		3	0	0	15 (25.9)	0	0	0	15 (25.9)
		4	0	0	0	3 (5.2)	0	0	3 (5.2)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	32 (55.2)	32 (55.2)
		Sum	0	8 (13.8)	15 (25.9)	3 (5.2)	0	32 (55.2)	58 (100)
		ND basic (N=37)							
		1	0	0	0	0	0	0	0 (0)
		2	0	10 (27.0)	0	0	0	0	10 (27.0)
		3	0	0	3 (8.1)	0	0	0	3 (8.1)
		4	0	0	0	1 (2.7)	0	0	1 (2.7)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	23 (62.2)	23 (62.2)
		Sum	0	10 (27.0)	3 (8.1)	1 (2.7)	0	23 (62.2)	37 (100)
		SC (N=25)							
		1	0	0	0	0	0	0	0 (0)
		2	0	3 (12.0)	0	0	0	0	3 (12.0)
		3	0	0	7 (28.0)	0	0	0	7 (28.0)
		4	0	0	0	0	0	0	0 (0)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	15 (60.0)	15 (60.0)		
Sum	0	3 (12.0)	7 (28.0)	0	0	15 (60.0)	25 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Caudal Disc (continued)	Visit 3a*	ND plus (N=50)							
		1	0	0	0	0	0	0	0 (0)
		2	0	5 (10.0)	2 (4.0)	0	0	0	7 (14.0)
		3	0	1 (2.0)	11 (22.0)	0	0	0	12 (24.0)
		4	0	0	2 (4.0)	3 (6.0)	0	0	5 (10.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	1 (2.0)	0	0	0	25 (50.0)	26 (52.0)
		Sum	0	7 (14.0)	15 (30.0)	3 (6.0)	0	25 (50.0)	50 (100)
		ND basic (N=28)							
		1	0	0	0	0	0	0	0 (0)
		2	0	7 (25.0)	0	0	0	0	7 (25.0)
		3	0	2 (7.1)	2 (7.1)	0	0	0	4 (14.3)
		4	0	0	1 (3.6)	1 (3.6)	0	0	2 (7.1)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	15 (53.6)	15 (53.6)
		Sum	0	9 (32.1)	3 (10.7)	1 (3.6)	0	15 (53.6)	28 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						Sum
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	
Caudal Disc (continued)	Visit 4	ND plus (N=47)							
		1	0	0	0	0	0	0	0 (0)
		2	0	4 (8.5)	1 (2.1)	0	0	0	5 (10.6)
		3	0	0	11 (23.4)	0	0	2 (4.3)	13 (27.7)
		4	0	0	2 (4.3)	3 (6.4)	0	0	5 (10.6)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	1 (2.1)	0	0	0	23 (48.9)	24 (51.1)
		Sum	0	5 (10.6)	14 (29.8)	3 (6.4)	0	25 (53.2)	47 (100)
		ND basic (N=27)							
		1	0	0	0	0	0	0	0 (0)
		2	0	8 (29.6)	1 (3.7)	0	0	0	9 (33.3)
		3	0	1 (3.7)	2 (7.4)	0	0	0	3 (11.1)
		4	0	0	0	1 (3.7)	0	0	1 (3.7)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	14 (51.9)	14 (51.9)
		Sum	0	9 (33.3)	3 (11.1)	1 (3.7)	0	14 (51.9)	27 (100)
		SC (N=24)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (8.3)	1 (4.2)	0	0	1 (4.2)	4 (16.7)
		3	0	1 (4.2)	5 (20.8)	0	0	0	6 (25.0)
		4	0	0	1 (4.2)	0	0	0	1 (4.2)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	13 (54.2)	13 (54.2)		
Sum	0	3 (12.5)	7 (29.2)	0	0	14 (58.3)	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Caudal Disc (continued)	Visit 5	ND plus (N=12)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	1 (8.3)	1 (8.3)
		3	0	0	3 (25.0)	0	0	0	3 (25.0)
		4	0	0	0	1 (8.3)	0	0	1 (8.3)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	7 (58.3)	7 (58.3)
		Sum	0	0	3 (25.0)	1 (8.3)	0	8 (66.7)	12 (100)
		ND basic (N=8)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (25.0)	1 (12.5)	0	0	0	3 (37.5)
		3	0	0	0	0	0	0	0 (0)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	5 (62.5)	5 (62.5)
		Sum	0	2 (25.0)	1 (12.5)	0	0	5 (62.5)	8 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Caudal Disc (continued)	Visit 6	ND plus (N=46)							
		1	0	0	0	0	0	0	0 (0)
		2	0	4 (8.7)	2 (4.3)	0	0	1 (2.2)	7 (15.2)
		3	0	0	10 (21.7)	1 (2.2)	0	1 (2.2)	12 (26.1)
		4	0	0	2 (4.3)	2 (4.3)	0	0	4 (8.7)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	1 (2.2)	0	0	0	22 (47.8)	23 (50.0)
		Sum	0	5 (10.9)	14 (30.4)	3 (6.5)	0	24 (52.2)	46 (100)
		ND basic (N=25)							
		1	0	0	0	0	0	0	0 (0)
		2	0	6 (24.0)	1 (4.0)	0	0	0	7 (28.0)
		3	0	2 (8.0)	2 (8.0)	0	0	0	4 (16.0)
		4	0	0	0	1 (4.0)	0	0	1 (4.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	13 (52.0)	13 (52.0)
		Sum	0	8 (32.0)	3 (12.0)	1 (4.0)	0	13 (52.0)	25 (100)
		SC (N=23)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (8.7)	1 (4.3)	0	0	0	3 (13.0)
3	0	1 (4.3)	3 (13.0)	0	0	0	4 (17.4)		
4	0	0	2 (8.7)	0	0	0	2 (8.7)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	14 (60.9)	14 (60.9)		
Sum	0	3 (13.0)	6 (26.1)	0	0	14 (60.9)	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Caudal Disc (continued)	Visit 7	ND plus (N=46)							
		1	0	0	0	0	0	0	0 (0)
		2	0	4 (8.7)	3 (6.5)	0	0	0	7 (15.2)
		3	0	0	9 (19.6)	0	0	1 (2.2)	10 (21.7)
		4	0	0	2 (4.3)	3 (6.5)	0	0	5 (10.9)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	1 (2.2)	0	0	0	23 (50.0)	24 (52.2)
		Sum	0	5 (10.9)	14 (30.4)	3 (6.5)	0	24 (52.2)	46 (100)
		ND basic (N=26)							
		1	0	0	0	0	0	0	0 (0)
		2	0	7 (26.9)	1 (3.8)	0	0	1 (3.8)	9 (34.6)
		3	0	2 (7.7)	2 (7.7)	0	0	0	4 (15.4)
		4	0	0	0	1 (3.8)	0	0	1 (3.8)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	12 (46.2)	12 (46.2)
		Sum	0	9 (34.6)	3 (11.5)	1 (3.8)	0	13 (50.0)	26 (100)
		SC (N=21)							
		1	0	0	0	0	0	0	0 (0)
		2	0	3 (14.3)	1 (4.8)	0	0	0	4 (19.0)
3	0	0	4 (19.0)	0	0	0	4 (19.0)		
4	0	0	0	0	0	0	0 (0)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	13 (61.9)	13 (61.9)		
Sum	0	3 (14.3)	5 (23.8)	0	0	13 (61.9)	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Caudal Disc (continued)	Visit 8	ND plus (N=43)							
		1	0	0	0	0	0	0	0 (0)
		2	0	3 (7.0)	2 (4.7)	0	0	0	5 (11.6)
		3	0	0	9 (20.9)	0	0	0	9 (20.9)
		4	0	0	2 (4.7)	3 (7.0)	0	0	5 (11.6)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	24 (55.8)	24 (55.8)
		Sum	0	3 (7.0)	13 (30.2)	3 (7.0)	0	24 (55.8)	43 (100)
		ND basic (N=25)							
		1	0	0	0	0	0	0	0 (0)
		2	0	8 (32.0)	1 (4.0)	0	0	0	9 (36.0)
		3	0	1 (4.0)	1 (4.0)	0	0	0	2 (8.0)
		4	0	0	1 (4.0)	1 (4.0)	0	0	2 (8.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	12 (48.0)	12 (48.0)
		Sum	0	9 (36.0)	3 (12.0)	1 (4.0)	0	12 (48.0)	25 (100)
		SC (N=22)							
		1	0	1 (4.5)	0	0	0	0	1 (4.5)
		2	0	2 (9.1)	1 (4.5)	0	0	0	3 (13.6)
		3	0	0	3 (13.6)	0	0	0	3 (13.6)
		4	0	0	1 (4.5)	0	0	0	1 (4.5)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	14 (63.6)	14 (63.6)		
Sum	0	3 (13.6)	5 (22.7)	0	0	14 (63.6)	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Caudal Disc (continued)	End of Trial	ND plus (N=39)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (5.1)	1 (2.6)	0	0	0	3 (7.7)
		3	0	0	12 (30.8)	0	0	0	12 (30.8)
		4	0	0	0	3 (7.7)	0	0	3 (7.7)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	21 (53.8)	21 (53.8)
		Sum	0	2 (5.1)	13 (33.3)	3 (7.7)	0	21 (53.8)	39 (100)
		ND basic (N=26)							
		1	0	0	0	0	0	0	0 (0)
		2	0	8 (30.8)	0	0	0	0	8 (30.8)
		3	0	1 (3.8)	3 (11.5)	1 (3.8)	0	0	5 (19.2)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	13 (50.0)	13 (50.0)
		Sum	0	9 (34.6)	3 (11.5)	1 (3.8)	0	13 (50.0)	26 (100)
		SC (N=20)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (10.0)	2 (10.0)	0	0	0	4 (20.0)
3	0	1 (5.0)	2 (10.0)	0	0	0	3 (15.0)		
4	0	0	0	0	0	0	0 (0)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	13 (65.0)	13 (65.0)		
Sum	0	3 (15.0)	4 (20.0)	0	0	13 (65.0)	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Central Disc	Visit 1/Visit 2A**	ND plus (N=58)							
		1	0	0	0	0	0	0	0 (0)
		2	0	5 (8.6)	0	0	0	0	5 (8.6)
		3	0	0	44 (75.9)	0	0	0	44 (75.9)
		4	0	0	0	9 (15.5)	0	0	9 (15.5)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	5 (8.6)	44 (75.9)	9 (15.5)	0	0	58 (100)
		ND basic (N=37)							
		1	0	0	0	0	0	0	0 (0)
		2	0	4 (10.8)	0	0	0	0	4 (10.8)
		3	0	0	22 (59.5)	0	0	0	22 (59.5)
		4	0	0	0	11 (29.7)	0	0	11 (29.7)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	4 (10.8)	22 (59.5)	11 (29.7)	0	0	37 (100)
		SC (N=25)							
		1	0	0	0	0	0	0	0 (0)
2	0	2 (8.0)	0	0	0	0	2 (8.0)		
3	0	0	19 (76.0)	0	0	0	19 (76.0)		
4	0	0	0	4 (16.0)	0	0	4 (16.0)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	2 (8.0)	19 (76.0)	4 (16.0)	0	0	25 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Central Disc (continued)	Visit 3a*	ND plus (N=50)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (4.0)	1 (2.0)	0	0	0	3 (6.0)
		3	0	2 (4.0)	29 (58.0)	3 (6.0)	0	0	34 (68.0)
		4	0	0	8 (16.0)	5 (10.0)	0	0	13 (26.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	4 (8.0)	38 (76.0)	8 (16.0)	0	0	50 (100)
		ND basic (N=28)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	3 (10.7)	14 (50.0)	1 (3.6)	0	0	18 (64.3)
		4	0	0	6 (21.4)	4 (14.3)	0	0	10 (35.7)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (10.7)	20 (71.4)	5 (17.9)	0	0	28 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Central Disc (continued)	Visit 4	ND plus (N=47)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (4.3)	2 (4.3)	1 (2.1)	0	0	5 (10.6)
		3	0	2 (4.3)	25 (53.2)	3 (6.4)	0	0	30 (63.8)
		4	0	0	8 (17.0)	4 (8.5)	0	0	12 (25.5)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	4 (8.5)	35 (74.5)	8 (17.0)	0	0	47 (100)
		ND basic (N=27)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	3 (11.1)	18 (66.7)	2 (7.4)	0	0	23 (85.2)
		4	0	0	1 (3.7)	3 (11.1)	0	0	4 (14.8)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (11.1)	19 (70.4)	5 (18.5)	0	0	27 (100)
		SC (N=24)							
		1	0	0	0	0	0	0	0 (0)
2	0	1 (4.2)	2 (8.3)	0	0	0	3 (12.5)		
3	0	1 (4.2)	15 (62.5)	1 (4.2)	0	0	17 (70.8)		
4	0	0	2 (8.3)	2 (8.3)	0	0	4 (16.7)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	2 (8.3)	19 (79.2)	3 (12.5)	0	0	24 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirrmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Central Disc (continued)	Visit 5	ND plus (N=12)							
		1	0	0	0	0	0	0	0 (0)
		2	0	1 (8.3)	0	0	0	0	1 (8.3)
		3	0	1 (8.3)	4 (33.3)	0	0	0	5 (41.7)
		4	0	0	5 (41.7)	1 (8.3)	0	0	6 (50.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	2 (16.7)	9 (75.0)	1 (8.3)	0	0	12 (100)
		ND basic (N=8)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	6 (75.0)	0	0	0	6 (75.0)
		4	0	0	1 (12.5)	1 (12.5)	0	0	2 (25.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	0	7 (87.5)	1 (12.5)	0	0	8 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Central Disc (continued)	Visit 6	ND plus (N=46)							
		1	0	0	0	0	0	0	0 (0)
		2	0	3 (6.5)	1 (2.2)	0	0	0	4 (8.7)
		3	0	1 (2.2)	21 (45.7)	1 (2.2)	0	0	23 (50.0)
		4	0	0	13 (28.3)	6 (13.0)	0	0	19 (41.3)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	4 (8.7)	35 (76.1)	7 (15.2)	0	0	46 (100)
		ND basic (N=25)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	3 (12.0)	12 (48.0)	0	0	0	15 (60.0)
		4	0	0	6 (24.0)	4 (16.0)	0	0	10 (40.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (12.0)	18 (72.0)	4 (16.0)	0	0	25 (100)
		SC (N=23)							
		1	0	0	0	0	0	0	0 (0)
2	0	0	0	0	0	0	0 (0)		
3	0	1 (4.3)	14 (60.9)	2 (8.7)	0	0	17 (73.9)		
4	0	1 (4.3)	4 (17.4)	1 (4.3)	0	0	6 (26.1)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	2 (8.7)	18 (78.3)	3 (13.0)	0	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Central Disc (continued)	Visit 7	ND plus (N=46)							
		1	0	0	0	0	0	0	0 (0)
		2	0	1 (2.2)	2 (4.3)	1 (2.2)	0	0	4 (8.7)
		3	0	3 (6.5)	22 (47.8)	0	0	0	25 (54.3)
		4	0	0	10 (21.7)	6 (13.0)	0	0	16 (34.8)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	1 (2.2)	0	0	0	1 (2.2)
		Sum	0	4 (8.7)	35 (76.1)	7 (15.2)	0	0	46 (100)
		ND basic (N=26)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	1 (3.8)	0	0	0	1 (3.8)
		3	0	3 (11.5)	12 (46.2)	1 (3.8)	0	0	16 (61.5)
		4	0	0	6 (23.1)	3 (11.5)	0	0	9 (34.6)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (11.5)	19 (73.1)	4 (15.4)	0	0	26 (100)
		SC (N=21)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	2 (9.5)	13 (61.9)	2 (9.5)	0	0	17 (81.0)
		4	0	0	3 (14.3)	1 (4.8)	0	0	4 (19.0)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	2 (9.5)	16 (76.2)	3 (14.3)	0	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Central Disc (continued)	Visit 8	ND plus (N=43)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (4.7)	1 (2.3)	0	0	0	3 (7.0)
		3	0	2 (4.7)	17 (39.5)	2 (4.7)	0	0	21 (48.8)
		4	0	0	13 (30.2)	5 (11.6)	0	0	18 (41.9)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	1 (2.3)	0	0	0	1 (2.3)
		Sum	0	4 (9.3)	32 (74.4)	7 (16.3)	0	0	43 (100)
		ND basic (N=25)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	1 (4.0)	0	0	0	1 (4.0)
		3	0	2 (8.0)	13 (52.0)	0	0	0	15 (60.0)
		4	0	1 (4.0)	5 (20.0)	3 (12.0)	0	0	9 (36.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (12.0)	19 (76.0)	3 (12.0)	0	0	25 (100)
		SC (N=22)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	1 (4.5)	15 (68.2)	2 (9.1)	0	0	18 (81.8)
		4	0	1 (4.5)	2 (9.1)	1 (4.5)	0	0	4 (18.2)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	2 (9.1)	17 (77.3)	3 (13.6)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Central Disc (continued)	End of Trial	ND plus (N=39)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	1 (2.6)	0	0	0	1 (2.6)
		3	0	3 (7.7)	18 (46.2)	0	0	0	21 (53.8)
		4	0	0	11 (28.2)	4 (10.3)	0	0	15 (38.5)
		5	0	0	0	1 (2.6)	0	0	1 (2.6)
		Missing	0	0	1 (2.6)	0	0	0	1 (2.6)
		Sum	0	3 (7.7)	31 (79.5)	5 (12.8)	0	0	39 (100)
		ND basic (N=26)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	3 (11.5)	15 (57.7)	1 (3.8)	0	0	19 (73.1)
		4	0	0	3 (11.5)	4 (15.4)	0	0	7 (26.9)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (11.5)	18 (69.2)	5 (19.2)	0	0	26 (100)
		SC (N=20)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	1 (5.0)	11 (55.0)	3 (15.0)	0	0	15 (75.0)
4	0	0	5 (25.0)	0	0	0	5 (25.0)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	1 (5.0)	16 (80.0)	3 (15.0)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, add. treated	Visit 1/Visit 2A**	ND plus (N=9)							
		1	0	0	0	0	0	0	0 (0)
		2	0	3 (33.3)	0	0	0	0	3 (33.3)
		3	0	0	4 (44.4)	0	0	0	4 (44.4)
		4	0	0	0	2 (22.2)	0	0	2 (22.2)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (33.3)	4 (44.4)	2 (22.2)	0	0	9 (100)
		ND basic (N=5)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	4 (80.0)	0	0	0	4 (80.0)
		4	0	0	0	1 (20.0)	0	0	1 (20.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	0	4 (80.0)	1 (20.0)	0	0	5 (100)
		SC (N=2)							
		1	1 (50.0)	0	0	0	0	0	1 (50.0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	1 (50.0)	0	0	0	1 (50.0)
		4	0	0	0	0	0	0	0 (0)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	1 (50.0)	0	1 (50.0)	0	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 3a*	ND plus (N=8)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (25.0)	0	0	0	0	2 (25.0)
		3	0	1 (12.5)	2 (25.0)	0	0	0	3 (37.5)
		4	0	0	2 (25.0)	1 (12.5)	0	0	3 (37.5)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (37.5)	4 (50.0)	1 (12.5)	0	0	8 (100)
		ND basic (N=4)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	2 (50.0)	0	0	0	2 (50.0)
		4	0	0	2 (50.0)	0	0	0	2 (50.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	0	4 (100)	0	0	0	4 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 4	ND plus (N=7)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (28.6)	0	0	0	0	2 (28.6)
		3	0	1 (14.3)	3 (42.9)	1 (14.3)	0	0	5 (71.4)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (42.9)	3 (42.9)	1 (14.3)	0	0	7 (100)
		ND basic (N=4)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	4 (100)	0	0	0	4 (100)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	0	4 (100)	0	0	0	4 (100)
		SC (N=2)							
		1	0	0	0	0	0	0	0 (0)
		2	1 (50.0)	0	1 (50.0)	0	0	0	2 (100)
		3	0	0	0	0	0	0	0 (0)
4	0	0	0	0	0	0	0 (0)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	1 (50.0)	0	1 (50.0)	0	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 5	ND plus (N=2)							
		1	0	0	0	0	0	0	0 (0)
		2	0	1 (50.0)	0	0	0	0	1 (50.0)
		3	0	0	1 (50.0)	0	0	0	1 (50.0)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	1 (50.0)	1 (50.0)	0	0	0	2 (100)
		ND basic (N=3)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	3 (100)	0	0	0	3 (100)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	0	3 (100)	0	0	0	3 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 6	ND plus (N=7)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (28.6)	0	0	0	0	2 (28.6)
		3	0	1 (14.3)	2 (28.6)	1 (14.3)	0	0	4 (57.1)
		4	0	0	1 (14.3)	0	0	0	1 (14.3)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	3 (42.9)	3 (42.9)	1 (14.3)	0	0	7 (100)
		ND basic (N=4)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	4 (100)	0	0	0	4 (100)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	0	4 (100)	0	0	0	4 (100)
		SC (N=2)							
		1	0	0	0	0	0	0	0 (0)
		2	1 (50.0)	0	0	0	0	0	1 (50.0)
		3	0	0	1 (50.0)	0	0	0	1 (50.0)
4	0	0	0	0	0	0	0 (0)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	1 (50.0)	0	1 (50.0)	0	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 7	ND plus (N=7)							
		1	0	0	0	0	0	0	0 (0)
		2	0	2 (28.6)	1 (14.3)	0	0	0	3 (42.9)
		3	0	1 (14.3)	1 (14.3)	0	0	0	2 (28.6)
		4	0	0	0	1 (14.3)	0	0	1 (14.3)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	1 (14.3)	0	0	0	1 (14.3)
		Sum	0	3 (42.9)	3 (42.9)	1 (14.3)	0	0	7 (100)
		ND basic (N=4)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	3 (75.0)	0	0	0	3 (75.0)
		4	0	0	1 (25.0)	0	0	0	1 (25.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	0	4 (100)	0	0	0	4 (100)
		SC (N=2)							
		1	0	0	0	0	0	0	0 (0)
		2	1 (50.0)	0	0	0	0	0	1 (50.0)
		3	0	0	1 (50.0)	0	0	0	1 (50.0)
4	0	0	0	0	0	0	0 (0)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	1 (50.0)	0	1 (50.0)	0	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, add. treated (continued)	Visit 8	ND plus (N=6)							
		1	0	0	0	0	0	0	0 (0)
		2	0	1 (16.7)	0	0	0	0	1 (16.7)
		3	0	1 (16.7)	2 (33.3)	1 (16.7)	0	0	4 (66.7)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	1 (16.7)	0	0	0	1 (16.7)
		Sum	0	2 (33.3)	3 (50.0)	1 (16.7)	0	0	6 (100)
		ND basic (N=4)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	0	0	0	0	0 (0)
		3	0	0	4 (100)	0	0	0	4 (100)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	0	4 (100)	0	0	0	4 (100)
		SC (N=2)							
		1	0	0	0	0	0	0	0 (0)
		2	1 (50.0)	0	0	0	0	0	1 (50.0)
		3	0	0	1 (50.0)	0	0	0	1 (50.0)
		4	0	0	0	0	0	0	0 (0)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	1 (50.0)	0	1 (50.0)	0	0	0	2 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, add. treated (continued)	End of Trial	ND plus (N=6)							
		1	0	0	0	0	0	0	0 (0)
		2	0	1 (16.7)	0	0	0	0	1 (16.7)
		3	0	1 (16.7)	2 (33.3)	1 (16.7)	0	0	4 (66.7)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	1 (16.7)	0	0	0	1 (16.7)
		Sum	0	2 (33.3)	3 (50.0)	1 (16.7)	0	0	6 (100)
		ND basic (N=3)							
		1	0	0	0	0	0	0	0 (0)
		2	0	0	2 (66.7)	0	0	0	2 (66.7)
		3	0	0	1 (33.3)	0	0	0	1 (33.3)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	0	3 (100)	0	0	0	3 (100)
		SC (N=1)							
		1	0	0	0	0	0	0	0 (0)
		2	1 (100)	0	0	0	0	0	1 (100)
		3	0	0	0	0	0	0	0 (0)
		4	0	0	0	0	0	0	0 (0)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	1 (100)	0	0	0	0	0	1 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, not treated	Visit 1/Visit 2A**	ND plus (N=49)							
		1	1 (2.0)	0	0	0	0	0	1 (2.0)
		2	0	24 (49.0)	0	0	0	0	24 (49.0)
		3	0	0	24 (49.0)	0	0	0	24 (49.0)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	1 (2.0)	24 (49.0)	24 (49.0)	0	0	0	49 (100)
		ND basic (N=32)							
		1	2 (6.3)	0	0	0	0	0	2 (6.3)
		2	0	13 (40.6)	0	0	0	0	13 (40.6)
		3	0	0	12 (37.5)	0	0	0	12 (37.5)
		4	0	0	0	5 (15.6)	0	0	5 (15.6)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	2 (6.3)	13 (40.6)	12 (37.5)	5 (15.6)	0	0	32 (100)
		SC (N=23)							
		1	0	0	0	0	0	0	0 (0)
2	0	16 (69.6)	0	0	0	0	16 (69.6)		
3	0	0	6 (26.1)	0	0	0	6 (26.1)		
4	0	0	0	1 (4.3)	0	0	1 (4.3)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	16 (69.6)	6 (26.1)	1 (4.3)	0	0	23 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, not treated (continued)	Visit 3a*	ND plus (N=42)							
		1	0	1 (2.4)	1 (2.4)	0	0	0	2 (4.8)
		2	0	19 (45.2)	1 (2.4)	0	0	0	20 (47.6)
		3	0	1 (2.4)	19 (45.2)	0	0	0	20 (47.6)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	21 (50.0)	21 (50.0)	0	0	0	42 (100)
		ND basic (N=24)							
		1	0	1 (4.2)	0	0	0	0	1 (4.2)
		2	2 (8.3)	8 (33.3)	1 (4.2)	0	0	0	11 (45.8)
		3	0	2 (8.3)	6 (25.0)	1 (4.2)	0	0	9 (37.5)
		4	0	0	2 (8.3)	1 (4.2)	0	0	3 (12.5)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	2 (8.3)	11 (45.8)	9 (37.5)	2 (8.3)	0	0	24 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						Sum
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	
Cranial Disc, not treated (continued)	Visit 4	ND plus (N=40)							
		1	0	1 (2.5)	0	0	0	0	1 (2.5)
		2	0	17 (42.5)	0	0	0	0	17 (42.5)
		3	0	2 (5.0)	16 (40.0)	0	0	0	18 (45.0)
		4	0	0	4 (10.0)	0	0	0	4 (10.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	20 (50.0)	20 (50.0)	0	0	0	40 (100)
		ND basic (N=23)							
		1	1 (4.3)	0	0	0	0	0	1 (4.3)
		2	1 (4.3)	8 (34.8)	1 (4.3)	0	0	0	10 (43.5)
		3	0	2 (8.7)	8 (34.8)	1 (4.3)	0	0	11 (47.8)
		4	0	0	0	1 (4.3)	0	0	1 (4.3)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	2 (8.7)	10 (43.5)	9 (39.1)	2 (8.7)	0	0	23 (100)
		SC (N=22)							
		1	0	0	0	0	0	0	0 (0)
		2	0	14 (63.6)	1 (4.5)	0	0	0	15 (68.2)
		3	0	2 (9.1)	4 (18.2)	0	0	0	6 (27.3)
		4	0	0	0	1 (4.5)	0	0	1 (4.5)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	16 (72.7)	5 (22.7)	1 (4.5)	0	0	22 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, not treated (continued)	Visit 5	ND plus (N=10)							
		1	0	0	0	0	0	0	0 (0)
		2	0	4 (40.0)	0	0	0	0	4 (40.0)
		3	0	0	6 (60.0)	0	0	0	6 (60.0)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	4 (40.0)	6 (60.0)	0	0	0	10 (100)
		ND basic (N=5)							
		1	0	0	0	0	0	0	0 (0)
		2	0	1 (20.0)	1 (20.0)	0	0	0	2 (40.0)
		3	0	1 (20.0)	2 (40.0)	0	0	0	3 (60.0)
		4	0	0	0	0	0	0	0 (0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	2 (40.0)	3 (60.0)	0	0	0	5 (100)

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, not treated (continued)	Visit 6	ND plus (N=39)							
		1	0	0	0	0	0	0	0 (0)
		2	0	18 (46.2)	0	0	0	0	18 (46.2)
		3	0	2 (5.1)	17 (43.6)	0	0	0	19 (48.7)
		4	0	0	2 (5.1)	0	0	0	2 (5.1)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	20 (51.3)	19 (48.7)	0	0	0	39 (100)
		ND basic (N=21)							
		1	0	1 (4.8)	0	0	0	0	1 (4.8)
		2	2 (9.5)	6 (28.6)	1 (4.8)	0	0	0	9 (42.9)
		3	0	2 (9.5)	7 (33.3)	1 (4.8)	0	0	10 (47.6)
		4	0	0	0	1 (4.8)	0	0	1 (4.8)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	2 (9.5)	9 (42.9)	8 (38.1)	2 (9.5)	0	0	21 (100)
		SC (N=21)							
		1	0	0	0	0	0	0	0 (0)
		2	0	13 (61.9)	0	0	0	0	13 (61.9)
		3	0	3 (14.3)	4 (19.0)	1 (4.8)	0	0	8 (38.1)
		4	0	0	0	0	0	0	0 (0)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	16 (76.2)	4 (19.0)	1 (4.8)	0	0	21 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						Sum
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	
Cranial Disc, not treated (continued)	Visit 7	ND plus (N=39)							
		1	0	1 (2.6)	0	0	0	0	1 (2.6)
		2	0	16 (41.0)	1 (2.6)	0	0	0	17 (43.6)
		3	0	3 (7.7)	15 (38.5)	0	0	0	18 (46.2)
		4	0	0	3 (7.7)	0	0	0	3 (7.7)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	20 (51.3)	19 (48.7)	0	0	0	39 (100)
		ND basic (N=22)							
		1	0	0	0	0	0	0	0 (0)
		2	2 (9.1)	8 (36.4)	1 (4.5)	0	0	0	11 (50.0)
		3	0	2 (9.1)	7 (31.8)	0	0	0	9 (40.9)
		4	0	0	0	2 (9.1)	0	0	2 (9.1)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	2 (9.1)	10 (45.5)	8 (36.4)	2 (9.1)	0	0	22 (100)
		SC (N=19)							
		1	0	1 (5.3)	0	0	0	0	1 (5.3)
		2	0	10 (52.6)	0	0	0	0	10 (52.6)
		3	0	3 (15.8)	4 (21.1)	1 (5.3)	0	0	8 (42.1)
		4	0	0	0	0	0	0	0 (0)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	14 (73.7)	4 (21.1)	1 (5.3)	0	0	19 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, not treated (continued)	Visit 8	ND plus (N=37)							
		1	0	1 (2.7)	0	0	0	0	1 (2.7)
		2	0	16 (43.2)	0	0	0	0	16 (43.2)
		3	0	1 (2.7)	14 (37.8)	0	0	0	15 (40.5)
		4	0	0	5 (13.5)	0	0	0	5 (13.5)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	18 (48.6)	19 (51.4)	0	0	0	37 (100)
		ND basic (N=21)							
		1	0	1 (4.8)	0	0	0	0	1 (4.8)
		2	2 (9.5)	7 (33.3)	0	0	0	0	9 (42.9)
		3	0	1 (4.8)	8 (38.1)	1 (4.8)	0	0	10 (47.6)
		4	0	0	0	1 (4.8)	0	0	1 (4.8)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	2 (9.5)	9 (42.9)	8 (38.1)	2 (9.5)	0	0	21 (100)
		SC (N=20)							
		1	0	1 (5.0)	0	0	0	0	1 (5.0)
		2	0	11 (55.0)	0	0	0	0	11 (55.0)
		3	0	3 (15.0)	3 (15.0)	1 (5.0)	0	0	7 (35.0)
		4	0	0	1 (5.0)	0	0	0	1 (5.0)
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	15 (75.0)	4 (20.0)	1 (5.0)	0	0	20 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.

Table 14.3.3.12: Change in disc degeneration grading (Pfirschmann) from Screening (Visit 1) or Baseline (Visit 2a)** - safety set

Disc Type	Visit	Treatment group disc generation grading	Number (%) of subjects						
			Screening (Visit 1)/Baseline (Visit 2A)**						
			1	2	3	4	5	Missing	Sum
Cranial Disc, not treated (continued)	End of Trial	ND plus (N=33)							
		1	0	0	0	0	0	0	0 (0)
		2	0	14 (42.4)	1 (3.0)	0	0	0	15 (45.5)
		3	0	4 (12.1)	10 (30.3)	0	0	0	14 (42.4)
		4	0	0	4 (12.1)	0	0	0	4 (12.1)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	0	18 (54.5)	15 (45.5)	0	0	0	33 (100)
		ND basic (N=23)							
		1	0	0	0	0	0	0	0 (0)
		2	2 (8.7)	8 (34.8)	1 (4.3)	0	0	0	11 (47.8)
		3	0	2 (8.7)	6 (26.1)	1 (4.3)	0	0	9 (39.1)
		4	0	0	1 (4.3)	2 (8.7)	0	0	3 (13.0)
		5	0	0	0	0	0	0	0 (0)
		Missing	0	0	0	0	0	0	0 (0)
		Sum	2 (8.7)	10 (43.5)	8 (34.8)	3 (13.0)	0	0	23 (100)
		SC (N=19)							
		1	0	0	0	0	0	0	0 (0)
2	0	12 (63.2)	0	0	0	0	12 (63.2)		
3	0	2 (10.5)	4 (21.1)	1 (5.3)	0	0	7 (36.8)		
4	0	0	0	0	0	0	0 (0)		
5	0	0	0	0	0	0	0 (0)		
Missing	0	0	0	0	0	0	0 (0)		
Sum	0	14 (73.7)	4 (21.1)	1 (5.3)	0	0	19 (100)		

SC = Standard Care

* Visit 3a only applicable for patients in NDplus or NDbasic group

**Screening (Visit 1) or Baseline (Visit 2a) used as baseline, whatever is available. If both visits are available, the latest one was taken into account.