

Table 14.2.9.1 Summary of Pure Tone Audiometric - by timepoint - FAS

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	Change from baseline	t-Test results		
					t-value (df)	p-value	95% CI
Bone conduction best ear (dbHL)							
Baseline							
n	32						
Mean (SD)	52.57(12.36)						
Median	51.90						
Min; Max	23.3; 75.0						
Month 6							
n	22	22	22	Absolute change	2.04 (21)	0.054	(-0.04, 4.15)
Mean (SD)	55.44(10.65)	2.05(4.72)	5.76(13.90)				
Median	56.15	2.35	3.88	% Change	1.94 (21)	0.066	(-0.41,11.92)
Min; Max	35.0; 74.0	-9.0; 11.7	-18.0; 50.2				
Month 12							
n	31	30	30	Absolute change	1.34 (29)	0.191	(-0.77, 3.71)
Mean (SD)	53.35(11.41)	1.47(6.00)	4.26(14.97)				
Median	55.00	0.10	0.17	% Change	1.56 (29)	0.130	(-1.33, 9.85)
Min; Max	28.8; 70.0	-15.0; 13.8	-30.0; 39.5				
Month 18							
n	11	11	11	Absolute change	-1.64 (10)	0.132	(-11.4, 1.73)
Mean (SD)	48.35(16.80)	-4.81(9.74)	-8.89(20.44)				
Median	51.30	-1.20	-2.53	% Change	-1.44 (10)	0.180	(-22.6, 4.84)
Min; Max	25.0; 73.8	-25.0; 5.0	-50.0; 14.6				
Month 24							
n	9	8	8	Absolute change	0.89 (7)	0.405	(-3.42, 7.52)
Mean (SD)	54.76(8.72)	2.05(6.55)	6.85(16.25)				
Median	55.00	1.90	3.26	% Change	1.19 (7)	0.272	(-6.73,20.43)
Min; Max	41.3; 66.3	-6.3; 11.3	-11.7; 37.7				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.

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Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	t-Test results			
				Change from baseline	t-value (df)	p-value	95% CI
Bone conduction best ear							
(dbHL) Month 36							
n	7	7	7	Absolute change	-0.23 (6)	0.827	(-8.88, 7.36)
Mean (SD)	56.16(12.86)	-0.76(8.78)	-1.71(16.90)				
Median	55.00	2.50	4.76	% Change	-0.27 (6)	0.798	(-17.3,13.92)
Min; Max	32.5; 73.0	-17.5; 6.7	-35.0; 13.3				
Month 48							
n	9	9	9	Absolute change	-1.80 (8)	0.109	(-8.51, 1.04)
Mean (SD)	47.62(13.76)	-3.73(6.21)	-8.08(12.81)				
Median	50.00	-5.00	-10.2	% Change	-1.89 (8)	0.095	(-17.9, 1.77)
Min; Max	18.0; 67.0	-11.2; 7.5	-22.7; 15.8				
Last Observation							
n	33	32	32	Absolute change	-0.42 (31)	0.674	(-2.86, 1.88)
Mean (SD)	52.16(13.13)	-0.49(6.58)	-0.72(14.54)				
Median	55.00	-1.20	-1.72	% Change	-0.28 (31)	0.782	(-5.96, 4.52)
Min; Max	18.0; 73.8	-17.5; 11.3	-36.8; 37.7				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.