

Table 18 Summary of Corneal Fluorescein Staining by NEI Scale (Full Analysis Set)

Visit		Pro-ocular 0.5% (N=29) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=89) n (%)
Baseline	n (missing)	29 (0)	30 (0)	30 (0)	89 (0)
	Mean (SD)	7.4 (3.00)	7.7 (2.88)	8.2 (3.47)	7.8 (3.11)
	Median	7.0	7.0	8.0	7.0
	Q1, Q3	5.0, 9.0	5.0, 10.0	5.0, 11.0	5.0, 10.0
	Min, Max	4, 15	4, 13	4, 15	4, 15
Week 12	n (missing)	24 (5)	28 (2)	27 (3)	79 (10)
	Mean (SD)	4.2 (2.63)	5.9 (3.83)	4.4 (3.23)	4.9 (3.35)
	Median	4.0	4.5	4.0	4.0
	Q1, Q3	2.0, 6.0	3.0, 9.5	1.0, 7.0	2.0, 7.0
	Min, Max	0, 11	1, 13	0, 11	0, 13
Week 12 change from Baseline	n (missing)	24 (5)	28 (2)	27 (3)	79 (10)
	Mean (SD)	-2.9 (3.81)	-2.0 (2.36)	-4.0 (3.45)	-2.9 (3.30)
	Median	-1.0	-1.5	-3.0	-2.0
	Q1, Q3	-4.5, 0.0	-4.0, 0.0	-6.0, -1.0	-4.0, -1.0
	Min, Max	-12, 1	-7, 2	-12, 1	-12, 2

Source: Table 14.2.2.1, Statistical Output in Appendix 16.2.

Abbreviations: N, total number of patients per group; n, number of non-missing observations; SD, standard deviation, Q1 / Q3, first and third quartile.

Table 19 Analysis of Corneal Fluorescein Staining by NEI Scale (Full Analysis Set)

Visit: Week 12	Adjusted Mean		P-value
	n	LS Mean (95% CI)	
1% Pro-ocular	28	-1.91 (-3.20;-0.61)	-
0.5% Pro-ocular	24	-3.19 (-4.60;-1.77)	-
Placebo	27	-3.64 (-5.02;-2.26)	-
LS Mean Difference, 1% Pro-ocular – Placebo (95% CI)		1.73 (0.14;3.32)	0.034
LS Mean Difference, 0.5% Pro-ocular – Placebo (95% CI)		0.45 (-1.23;2.13)	0.597

Source: Table 14.2.2.2, Statistical Output in Appendix 16.2.

Abbreviations: N, total number of patients per group; n, number of non-missing observations; CI, confidence interval.

The change from Baseline is analysed by means of an ANCOVA model by Visit with treatment as fixed effect and baseline measure and stratification factor (male, female: menopausal, female: non-menopausal) as covariates.