

Table 2. Changes in Eye Characteristics from Baseline by Treatment Group

Characteristic	Change* from Baseline						Between Group Difference		
	Active Eyes			Placebo Eyes			Mean	(95% CI)	P
	N	Mean	(SD)	N	Mean	(SD)			
Tear osmolarity, mOsm/L	424	-0.7	(21.5)	212	3.6	(18.3)	+4.3	(0.7, 7.8)	0.02
Keratograph tear break-up time, secs	290	-0.5	(6.7)	149	-0.5	(6.1)	0.0	(-1.3, 1.3)	0.97
Tear meniscus height, mm	317	0.00	(0.16)	162	-0.01	(0.14)	-0.01	(-0.04, 0.03)	0.71
Bulbar conjunctival redness score	273	-0.00	(0.34)	145	-0.01	(0.40)	-0.02	(-0.10,0.06)	0.66
		<u>(N=324)</u>			<u>(N=164)</u>				
Upper lid meibography - gland loss, n (%)							P		
Improved		81	(25%)		35	(21%)	0.34		
Same		92	(28%)		59	(36%)			
Worse		71	(22%)		34	(21%)			
Missing		80	(25%)		36	(22%)			
Lower lid meibography - gland loss, n (%)							P		
Improved		102	(31%)		38	(23%)	0.21		
Same		116	(36%)		64	(39%)			
Worse		82	(25%)		51	(31%)			
Missing		24	(7%)		11	(7%)			
		<u>(N= 611)</u>			<u>(N=320)</u>				
MMP-9 result, baseline to 3 months, n (%)							P		
Negative to Negative		351	(57%)		178	(56%)	0.69		
Negative to Positive		61	(10%)		43	(13%)			
Positive to Negative		82	(13%)		40	(13%)			
Positive to Positive		117	(19%)		59	(18%)			

*Changes are between baseline and 12 months except for MMP-9 results

SD is standard deviation

CI is confidence interval

p-values for upper/lower lid meibography and MMP-9 positivity are calculated without the missing category.