

Table 1.1.E.1-1: Key Safety and Efficacy Variables for All Eyes Treated

N	1 Month		3 Months		6 Months		12 Months	
	n/N	%	n/N	%	n/N	%	n/N	%
<b>EFFICACY VARIABLES</b>								
UCVA 20/20 or better	162	27.5	135	29.9	74	29.2	35	39.3
UCVA 20/25 to 20/40	288	48.9	210	46.6	119	47.0	38	42.7
(cumulative)	450	76.4	345	76.5	193	76.3	73	82.0
MRSE $\pm$ 0.50 D	261	44.3	200	44.3	125	49.4	53	59.6
MRSE $\pm$ 1.00 D	158	26.8	110	24.4	64	25.3	22	24.7
MRSE $\pm$ 2.00 D	123	20.9	98	21.7	48	19.0	10	11.2
MRSE $\pm$ 1.00 D (cumulative)	412	71.1	310	69.7	189	74.7	75	84.3
MRSE $\pm$ 2.00 D (cumulative)	342	59.0	268	59.5	137	53.7	45	50.0
Eyes Without Monovision								
# Non-Monovision (N)	339		260		140		51	
UCVA 20/20 or better	120	35.4	106	40.8	64	45.7	29	56.9
UCVA 20/25 to 20/40	163	48.1	116	44.6	55	39.3	17	33.3
(cumulative)	283	83.5	222	85.4	119	85.0	46	90.2
<b>SAFETY VARIABLES</b>								
Loss of $>$ 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/40	2	0.3	0	0.0	0	0.0	0	0.0
Increase $>$ 2 D cylinder	5	0.8	3	0.7	1	0.4	0	0.0
BSCVA worse than 20/25 if 20/20 or better preop	7	1.2	3	0.7	0	0.0	0	0.0