

and 6 months. Refractive stability is defined as a change in MRSE of 1 diopter or less in manifest spherical refractions that are performed at least 3 months apart (or at the specified interval). Table 1.1.E-2 summarizes the refractive stability for eyes that have postoperative visit data for the interval specified but not necessarily for the entire range of intervals (e.g., may have 1 and 3 month data but not 3 and 6 month data). These data are provided to show the refractive stability across the visit intervals for the entire set of eyes. Refractive stability for a subset of eyes that have sequential MRSE data at 1, 3, and 6 months is shown in Table 1.1.E-3.

Table 1.1.E-2: Stability of MRSE for all Eyes with Visit Data for the Specified Interval

Change in MRSE	1 and 3 Months		3 and 6 Months		6 and 9 Months	
	n/N	%	n/N	%	n/N	%
≤ 1.00 D	120/127	94.5%	67/73	91.8%	13/15	86.7%
Mean Difference	-0.201		-0.141		-0.667	
Std. Dev.	0.687		0.555		0.605	
C.I. (for the mean)	0.121		0.129		0.335	

Table 1.1.E-3: Stability of MRSE for All Eyes with Sequential Data at 1, 3 and 6 Months

	1 and 3 Months		3 and 6 Months	
	n/N	%	n/N	%
≤ 1.00 D	52/59	88.1%	54/59	91.5%
Mean Difference	-0.227		-0.137	
Std. Dev.	0.651		0.541	
C.I. (for the mean)	0.170		0.141	

For those eyes that have sequential data at 1, 3, and 6 months, approximately 88% are stable by 3 months and nearly 92% are stable at 6 months. These data are slightly below the FDA guidance which recommends that at least 95% of eyes reach refractive stability. In both the sequential data subset and the data for all eyes, the eyes that did not achieve stability were all high myopes that were treated for myopic astigmatism except for one eye in each group. These eyes all had an improvement