REGRESSION IN MYOPIC LASIK PATIENTS OVER THREE MONTHS

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ABSTRACT

PURPOSE: To determine the amount of regression in myopic LASIK patients over a three month period.

METHODS: This was a retrospective study of charts for 43 patients (85 eyes) who had myopic LASIK correction. Refractive errors were studied pre-operatively and at one week, one month, and three monthspost-operatively. Regression was determined for patients at one month and three months.

RESULTS: Mean regression at one month was -0.21D (spherical equivalent), with a standard deviation of 0.37D. At three months, the regression was still -0.21D. The standard deviation was 0.45D. Regression ranged from +0.50D to -1.21D at one month, and +1.00D to -1.75D at three months. The average pre-operative refractive error was -4.74D, and the standard deviation was 2.40D. Myopia was decreased in all patients. The average post-LASIK refractive errors were -0.19D (s.d. 0.58D) at one week, -0.29D (s.d. 0.61D) at one month, and -0.36D (s.d. 0.58D) at three months. After three months 92.5% of patients had a best corrected visual acuity (BVA) of 20/20 or better, and 100% of patients were correctable to 20/30 or better.

CONCLUSION: A small amount of regression occurs in most LASIK patients and appears to stabilize at one month. Longer studies will be helpful in determining a more precise estimate of the amount of regression and the time period before refractive stabilization.

The first myopic keratomileusis surgery was performed in 1964 by Joseph Barraquer M.D. using a prototype microkeratome to shave off a partial thickness cap. The cap was then frozen, lathe cut and sutured to the corneal interface.

Since then, many modifications have been made to the keratomileusis technique. The most recent, laser in situ keratomileusis (LASIK), uses an automated microkeratome and an excimer laser. This technique is gaining acceptance and popularity with ophthalmologists and optometrists.

LASIK has been found effective in reducing refractive error among myopic patients. However, there are differing opinions on the stability and regression apparent in LASIK patients. This paper will compare the results of patients who have had LASIK correction. It will evaluate manifest refractions and regression of post-operative patients over a three month period.

METHODS

PATIENT SELECTION

Patients included in the study must have had myopic LASIK surgery and a post-

operative visit at Eaton Rapids Optometry (ERO) before August 30, 1998. A retrospective review of charts was done for 43 patients (85 eyes) who fell into the above criteria. Women comprised 60% (52 eyes) of the total, while the remaining 40% (33 eyes) were male patients. The average age was 41.91 years, ranging from 20 to 68 years. All patients had myopia which ranged from -1.25D to -12.75D (spherical equivalent). None of the patients had previous refractive surgery. Patients were required to have a stable refractive error for at least one year prior to the LASIK surgery. Also, any patients wearing contact lenses discontinued their use at least one week before the pre-operative visit. All patients were free of any contraindications to LASIK, including herpes simplex, keratoconus, severe dry eye, anterior membrane dystrophy, thin corneas and active ocular diseases (ie. nuclear sclerosis, uveitis etc.).

PRE-OPERATIVE EXAMINATION

Pre-operative evaluations were performed on each patient at ERO prior to the surgery date. This included consultation, spectacle visual acuities, manifest refraction with best corrected visual acuity (BVA), corneal topography, slit lamp examination, intraocular pressure measurement (by NCT or applanation tonometry) and a dilated fundus examination. Depending on the surgery site, most patients were also required to have a cycloplegic refraction before the surgery. Also, pachymetry may have been performed at the surgery site.

SURGICAL TECHNIQUE

All surgeries were performed by three different ophthalmologist. Dr. Frank Rosenbaum, M.D. of Mid-Michigan Ophthalmology in Lansing, MI, performed 67.1% of the surgeries (57 eyes). Dr. Fouad Tayfour, M.D. of Windsor Laser Eye Institute in Windsor, ON operated on 23.5% of the cases (20 eyes). The remaining 9.4% (8 eyes) were done by Dr. Kevin Lavery, M.D. of The Laser Center in Jackson, MI. The technique, as performed by Dr. Rosenbaum, is briefly described below.

Prior to the surgery, 1% mydriacyl, 1% cyclogel and a topical anesthetic are instilled into the patient's eye. Patients are positioned in the operating room a least 35 minutes later and the eye is centered for surgery. The cornea is then marked for alignment purposes. The suction unit is applied over a wet cornea, and intraocular pressure is verified. A 160um flap is created with an Automated Corneal Shape (ACS) keratome. The suction is removed and the 8.5mm flap is laid back. The Visx Starr laser is pre-programmed for the least amount of minus to give the patient 20/20, combined with the most cylinder the patient will take. Ablation is then applied, drying the center every 30 seconds to avoid islands. Next, the flap is floated back into position and the interface is irrigated with saline. After the surgery, the patients are given Ocuflox and FML. They are instructed to use each four times per day for five days. They are also given shields to be worn at night for one week.

POST-OPERATIVE MANAGEMENT

Patients were seen one day post-operatively at their respective surgery sites. The remainder of the post-operative visits were done at ERO. All patients were to be seen at

one week, one month, and three months after surgery.

Uncorrected visual acuities and manifest refractions with BVA were done at all post-operative visits. In addition, auto-keratometry and NCT readings were taken. Slit lamp biomicroscopy was performed and any flap irregularities, debris, corneal haze or SPK was noted. Patient symptoms and medications (including the use of artificial tears) were also recorded. Additional procedures were performed as needed.

RESULTS

REFRACTIVE ERROR AND BVA

All refractions were converted to spherical equivalent form and rounded to the nearest hundredth. Manifest refractions with BVA pre-operatively, and at one week, one month, and three months post-operatively are listed in Table 1. Several patients chose to be undercorrected in one eye for the benefit of monovision. These eyes are marked with an asterisk in Table 1.

The average pre-operative refractive error was -4.74D, standard deviation was 2.40D, and the range was -1.25D to -12.75D. A pre-operative BVA of 20/20 or better was found in 83.53% of eyes. All eyes were 20/30 or better (best corrected) before LASIK.

Of the 43 patients (85 eyes) enrolled in the study, only 35 patients were required to have a one week follow-up as directed by their surgeon. For these patients, the mean refractive error was -0.19D with a standard deviation of 0.55D, and a range of +1.25D to -1.25D. After one week, 82.61% of eyes had a BVA of 20/20 or better. No patients had a BVA worse than 20/25.

All 43 patients (85 eyes) attended the one month post-operative check. At that time, refractions ranged from +1.50D to -1.75D, the average being -0.29D with a standard deviation of 0.61D. BVA's better than 20/20 were found in 87.06% of eyes. One hundred percent could see 20/25 or better with correction.

Only two patients (4 eyes) did not have a three month visit. One failed to keep the appointment, and the other had an enhancement between the one and three month appointments. Of the remaining 81 eyes, the mean refractive error at three months was -0.36D with a standard deviation of 0.58D. The range was +0.50D to -2.25D. Ninety-two and one half percent of eyes had a BVA of 20/20 or better, and all patients could be corrected to at least 20/30 at three months.

REGRESSION

The goal of the LASIK procedures was emmetropia for all patients, except those noted for monovision. Any residual refractive error at one week was considered an under or over correction. Regression was measured at one month and three months, each in comparison to the post-operative result at one week. Therefore, any patients that did not have a one week follow-up visit were dropped from this part of the study. Table 2 shows the regression of 69 eyes over a one month period, and 65 eyes over a three month period. Negative numbers indicate a regression (increase in myopia), while positive numbers indicate a decrease in myopia or an increase in hyperopia. The average regression from one

week to one month was -0.21D. The standard deviation was 0.37D. Regression at one month ranged from +0.50D to -1.12D. The mean regression calculated between one week and three months was -0.21D, with a standard deviation of 0.45D, and a range of +1.00D to -1.75D. Figure 1 shows the amount of regression patients had at one month, and again at three months.

DISCUSSION

Several studies have been done on the stability and regression of refractive error after myopic refractive surgery. Over 30 years ago, a 20% regression was noted by Barraquer in myopic keratomileusis patients. More recently, Saleh et al studied LASIK patients between three weeks and five months. He found a change of -0.61D in the mean spherical equivalent refractions (Chayet). In 1996, Augustine and Chester found a mean regression of -0.19D in spherical equivalent from one to twelve months post-LASIK (Augustine). In 1998, Chayet et al found a mean regression of -0.85D from week one to week four, and -0.22D from month one to month three (Chayet). Most studies observed a stabilization of refractive error between three and twelve months.

I observed a mean spherical equivalent regression of -0.21D between one week and one month, and -0.21D again from one week to three months. Since the value for the first month is equal to that over three months, it indicates the mean regression stabilized by one month (see Figure 2).

Some researchers, for example Guell and Muller, have found regression to be higher in patients with higher pre-operative refractive errors (Chayet). In this study, a significant increase in regression was not found in those patients with high pre-operative refractive errors. Figure 3 relates the pre-operative refractive errors to the amount of regression at three months. Regression appears to be fairly distributed among all pre-operative refractive errors.

In this study, the data shows a progressive increase in the mean refractive error over time, but the average amount of regression remains stable from one month to three months. This may be due to the differing amount of patients used at one week, one month and three months in the refractive error calculations. However, this may indicate the possibility that the regression measured in this study is not true regression, but an unstable refractive error over the first one to three months. Corneal topography, keratometry, and pachymetry results may have been helpful in determining true regression and refractive stability over the first three months. Also, it may be helpful to follow patients for a longer time period post-operatively (ie. six months to one year).

Several mechanisms have been proposed for the cause of regression in refractive surgery. These include nuclear sclerosis, corneal ectasia, corneal hydration, stromal synthesis and compensatory epithelial hyperplasia.

Research has been done to try to rule out several of these factors as the cause of regression in LASIK. Since LASIK spares the epithelium and Bowman's membrane, minimal haze formation is seen. Therefore, corneal hydration is not believed to be the cause for the increase in myopia seen in LASIK patients. Also, histological studies have shown

that stromal healing only takes place at the flap interface, and minimal extracellular matrix is produced here. Therefore, stromal synthesis is not thought to be a factor in LASIK regression.

Chayet et al believes that compensatory epithelial hyperplasia is the main mechanism responsible for regression in LASIK patients. They found a progressive increase in corneal thickness (without haze) which correlated with an increase in refractive error. Both stabilized between three and six months. Their belief is that an increase in corneal thickness (from CEH) causes an increase in the central corneal curvature, leading to a myopic shift. Keratometry readings follow the same pattern and support this theory (Chayet).

LASIK has been proven effective in reducing the amount of myopia, and is now becoming more favorable than other types of myopic refractive surgery. LASIK has several advantages, including increased patient comfort, reduced healing time, decreased need for post-operative steroid and antibiotic drops, decreased haze formation, and less regression than other types of refractive surgery.

A small amount of regression seems to occur in most LASIK patients. This regression appears to stabilize any time from one month to one year. Longer studies, with the help of topography and pachymetry results may aid in determining a more precise estimate of regression and refractive stability after LASIK. Regardless of the amount of post-operative regression, LASIK remains one of the most effective and predictable forms of refractive surgery available today.

Table 1: Refractive Errors of LASIK Patients

Number	Age	Dr.	Pre-Op	VA	1 Week	VA	1 Month	VA	3 Month	VA
* 1	44	R	-4.62	20/20	-1.00	20/20	-1.75	20/20	-1.50	20/20
2			-5.25	20/20	0.50	20/20	-0.25	20/20	-0.25	20/20
3	47	R	-9.50	20/20	-0.87	20/20	-1.75	20/20	-2.13	20/20
4			-8.50	20/20	-0.75	20/20	-0.88	20/20	-0.88	20/20
5	50	R	-5.25	20/20	-0.50	20/20	-0.38	20/15	-0.75	20/20
6			-3.50	20/20	0.38	20/20	0.00	20/15	0.00	20/20
* 7	55	T	-4.25	20/25		20/20	-0.75	20/20	-1.00	20/20
8			-5.00	20/25		20/20	-0.75	20/20	-0.50	20/20
9	40	R	-4.63	20/20	-0.38	20/20	-0.63	20/20	-0.50	20/20
10			-4.88	20/20	0.13	20/20	-0.13	20/20	-0.38	20/20
11	42	R	-8.13	20/20	0.00	20/20	0.25	20/20	-0.25	20/20
12			-7.88	20/25	-0.50	20/25	-0.38	20/20	-0.25	20/20
13	45	R	-8.63	20/30	-0.63	20/25	-1.75	20/20	-1.50	20/20
14			-8.25	20/25	-0.50	20/20	-0.75	20/20	-0.63	20/20
15	37	R	-2.63	20/20	0.00	20/20	0.00	20/20	0.00	20/20
16			-2.25	20/20	0.25	20/20	0.12	20/20	0.12	20/20
17	34	L	-1.62	20/20	0.00	20/15	0.00	20/15	0.00	20/20
18			-1.88	20/20	-0.25	20/15	0.00	20/15	0.00	20/20
19	45	T	-4.63	20/20		20/20	0.00	20/20	0.00	20/20
20			-4.75	20/20		20/20	0.00	20/20	0.00	20/20
21	40	R	-4.75	20/15	0.12	20/20	-0.12	20/20	-0.12	20/20
22			-3.13	20/15	-0.19	20/20	-0.25	20/20	-0.38	20/20
23	57	T	-3.38	20/20		20/20	0.13	20/20	-0.38	20/20
24			-3.75	20/20		20/20	0.50	20/20	0.00	20/20
25	38	R	-1.25	20/20	0.00	20/15	-0.38	20/20	-0.38	20/20
26			-1.25	20/20	0.00	20/15	-0.25	20/20	-0.25	20/20
27	22	R	-4.75	20/20	-0.25	20/25	0.25	20/15	0.00	20/15
28			-4.25	20/20	0.00	20/20	-0.13	20/15	0.00	20/15
29	48	R	-2.50	20/20	-0.13	20/15	-0.13	20/20	-0.75	20/20
30			-2.75	20/20	-0.50	20/15	-1.50	20/20	-2.25	20/20
31	50	R	-3.13	20/20	-0.38	20/20	-1.13	20/20	-1.00	20/20
32			-2.63	20/20	0.00	20/20	-0.75	20/20	-0.63	20/20
33	55	R	-2.00	20/20	0.50	20/20	0.25	20/20	0.50	20/20
34	28	T	-11.38	20/30		20/20	1.50	20/25	0.25	20/25
35			-12.75	20/30		20/20	1.50	20/25	0.38	20/20

Table 1: Refractive Errors of LASIK Patients

Number	Age	Dr.	Pre-Op	VA	1 Week	VA	1 Month	VA	3 Month	VA
36	27	R	-8.13	20/20	-0.13	20/20	-0.50	20/15	-0.50	20/15
37			-7.63	20/20	0.00	20/20	-0.25	20/15	-0.50	20/15
38	48	T	-4.00	20/20		20/20	0.00	20/20	0.00	20/20
39			-4.63	20/20		20/20	0.25	20/20	0.00	20/20
40	45	R	-7.00	20/20	-0.75	20/20	-1.13	20/25		20/20
41			-8.13	20/20	-1.25	20/20	-1.00	20/20		20/20
42	43	R	-3.50	20/20	0.00	20/20	-0.25	20/20	-0.25	20/20
43			-3.88	20/20	-0.63	20/20	-0.88	20/20	-1.13	20/20
44	48	L	-5.25	20/25	-0.75	20/25	-1.25	20/25	-1.13	20/25
45			-3.75	20/25	0.75	20/25	-0.25	20/25	-0.50	20/30
46	68	T	-6.00	20/20	0.50	20/20	0.38	20/20	-0.13	20/20
47			-6.13	20/25	-0.88	20/20	-1.63	20/25	-1.38	20/25
48	49	R	-8.75	20/25	-1.00	20/20	-1.13	20/20	-1.50	20/20
49			-8.25	20/30	-1.25	20/20	-1.00	20/20	-1.38	20/20
50	42	R	-5.00	20/25	-0.75	20/20	-0.63	20/20	-0.75	20/20
51			-5.00	20/25	-1.13	20/20	-0.88	20/20	-0.38	20/20
52	42	R	-2.63	20/20	-0.25	20/15	-0.38	20/20	-0.38	20/20
53			-2.88	20/20	-0.25	20/15	-0.63	20/20	-0.63	20/20
54	38	R	-4.25	20/20	-0.50	20/20	-0.25	20/20	-0.13	20/15
55			-4.38	20/20	-0.13	20/20	-0.13	20/20	-0.25	20/15
56	20	R	-3.00	20/20	0.00	20/15	-0.25	20/20	0.50	20/15
57			-3.50	20/20	-0.50	20/25	-0.25	20/20	0.50	20/15
58	51	R	-2.06	20/20	0.00	20/15	0.12	20/20	0.25	20/20
59			-1.94	20/20	0.13	20/15	0.13	20/20	-0.25	20/20
60	54	R	-5.13	20/20	-0.50	20/20	-0.25	20/20	-0.75	20/20
* 61			-5.50	20/20	-1.00	20/20	-1.25	20/20	-1.25	20/20
62	28	T	-7.13	20/15		20/20	-0.13	20/20	-0.25	20/20
63			-6.75	20/15		20/20	0.00	20/20	0.50	20/15
64	54	T	-4.00	20/20		20/20	0.00	20/15	-0.63	20/20
65			-2.25	20/20		20/20	0.13	20/15	0.00	20/20
66	52	R	-4.00	20/20	0.25	20/20	0.13	20/25	0.00	20/20
67			-4.13	20/20	1.13	20/20	1.00	20/20	0.38	20/20
68	36	R	-6.13	20/20	0.00	20/20	-0.13	20/20	0.00	20/20
69			-5.75	20/20	0.50	20/25	0.13	20/20	0.50	20/20
70	37	L	-3.63	20/15	-0.25	20/20	-0.13	20/20	0.00	20/15
71			-3.13	20/15	-0.50	20/25	-0.25	20/20	0.25	20/15

Table 1: Refractive Errors of LASIK Patients

Number	Age	Dr.	Pre-Op	VA	1 Week	VA	1 Month	VA	3 Month	VA
72	32	L	-2.75	20/20	-0.38	20/25	0.00	20/20	-0.25	20/20
73			-2.00	20/20	0.13	20/25	-0.25	20/25	-0.13	20/20
74	38	T	-8.88	20/20	0.75	20/25	0.25	20/25	-0.13	20/20
75			-9.38	20/20	1.25	20/25	0.25	20/25	0.50	20/25
76	41	T	-4.13	20/20		20/20	0.13	20/20	-0.13	20/20
77			-4.38	20/20		20/20	-0.50	20/20	-0.75	20/20
78	40	R	-3.13	20/20	0.25	20/20	0.25	20/20	0.00	20/20
79			-3.25	20/20	0.25	20/20	-0.25	20/20	-0.25	20/20
80	20	R	-2.25	20/20	0.25	20/20	-0.13	20/20	0.13	20/20
81			-1.75	20/20	0.50	20/20	0.25	20/20	0.25	20/20
82	39	R	-6.63	20/20	-1.00	20/20	-0.75	20/20	-0.63	20/20
83			-7.38	20/20	-0.88	20/20	-0.88	20/20	-1.00	20/20
84	33	R	-6.50	20/20	0.50	20/20	0.00	20/20		20/20
85			-6.50	20/20	0.63	20/20	-0.13	20/20		20/20
Average:	41.91		-4.74		-0.19		-0.29		-0.36	
Standard Deviation:			2.40		0.55		0.61		0.58	
Range	20-68		-1.25 to -12.75		1.25 to -1.25		1.50 to -1.75		0.50 to -2.25	
		20/20 or better		85.53%		82.61%		87.06%		92.50%
		20/30 or better		100%		100%		100%		100%
Total:	43 pts		R = 57 eyes							
	85 eyes		T = 20 eyes							
			L = 8 eyes							
Dr.	R - Dr. Frank Rosenbaum, M.D.									
	T - Dr. Fouad Tayfour, M.D.									
	L - Dr. Kevin Lavery, M.D.									
* indicates monovision										

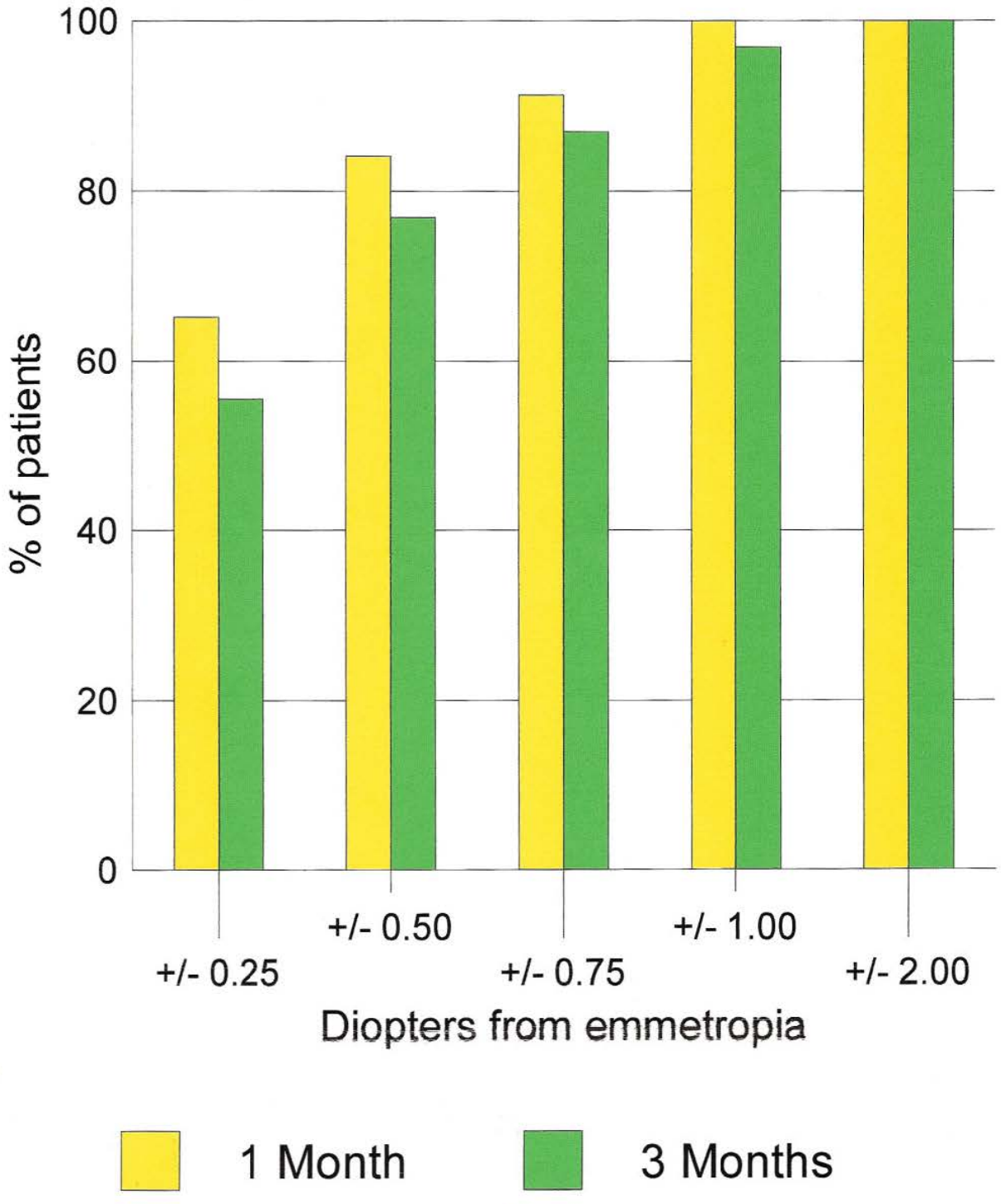
Table 2:
Regression in Myopic LASIK Patients

Number	1 Month	3 Month
1	-0.75	-0.50
2	-0.75	-0.75
3	-0.88	-1.26
4	-0.13	-0.13
5	0.12	-0.25
6	-0.38	-0.38
7	-0.25	0.13
8	-0.25	-0.51
9	0.25	-0.25
10	0.12	0.25
11	-1.12	-0.87
12	-0.25	-0.13
13	0.00	0.00
14	0.13	-0.13
15	0.00	0.00
16	0.25	0.25
17	-0.25	-0.25
18	-0.06	-0.19
19	-0.38	-0.38
20	-0.25	-0.25
21	0.50	0.25
22	-0.13	0.00
23	0.00	-0.62
24	-1.00	-1.75
25	-0.75	-0.62
26	-0.75	-0.63
27	-0.25	0.00
28	-0.37	-0.37
29	-0.25	-0.50
30	-0.38	enhance
31	0.25	enhance
32	-0.25	-0.25
33	-0.25	-0.50
34	-0.50	0.13
35	-1.00	-0.25
36	-0.12	-0.63
37	-0.75	-0.50
38	-0.13	-0.50
39	0.25	-0.13
40	-0.12	0.00

Number	1 Month	3 Month
41	0.25	0.75
42	-0.13	-0.13
43	-0.38	-0.38
44	0.25	0.37
45	0.00	-0.13
46	-0.25	0.50
47	0.25	1.00
48	0.12	0.25
49	0.00	-0.38
50	0.25	-0.25
51	-0.25	-0.25
52	-0.12	-0.25
53	-0.13	-0.75
54	-0.13	0.00
55	-0.37	0.00
56	0.12	0.25
57	0.25	0.75
58	0.38	0.13
59	-0.38	-0.25
60	-0.25	-0.88
61	-1.00	-0.75
62	0.00	-0.25
63	-0.50	-0.50
64	-0.38	0.13
65	-0.25	-0.25
66	0.25	0.37
67	0.00	-0.12
68	-0.50	
69	-0.76	
Avg.	-0.21	-0.21
Standard Deviation:	0.37	0.45
Range:		
Low:	-1.12	-1.75
High:	0.50	1.00

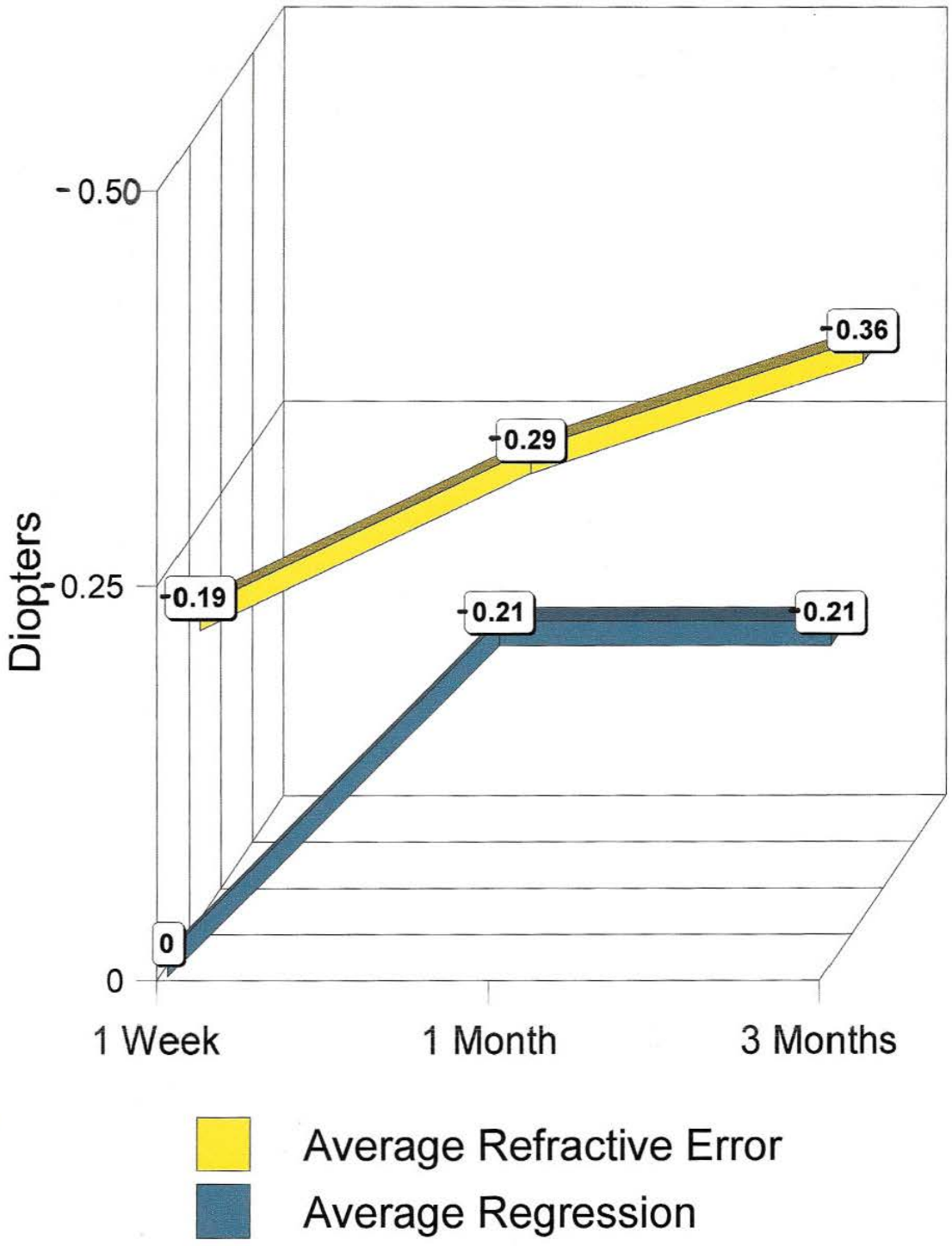
Post-op Results of Regression at 1 & 3 Months

Figure 1



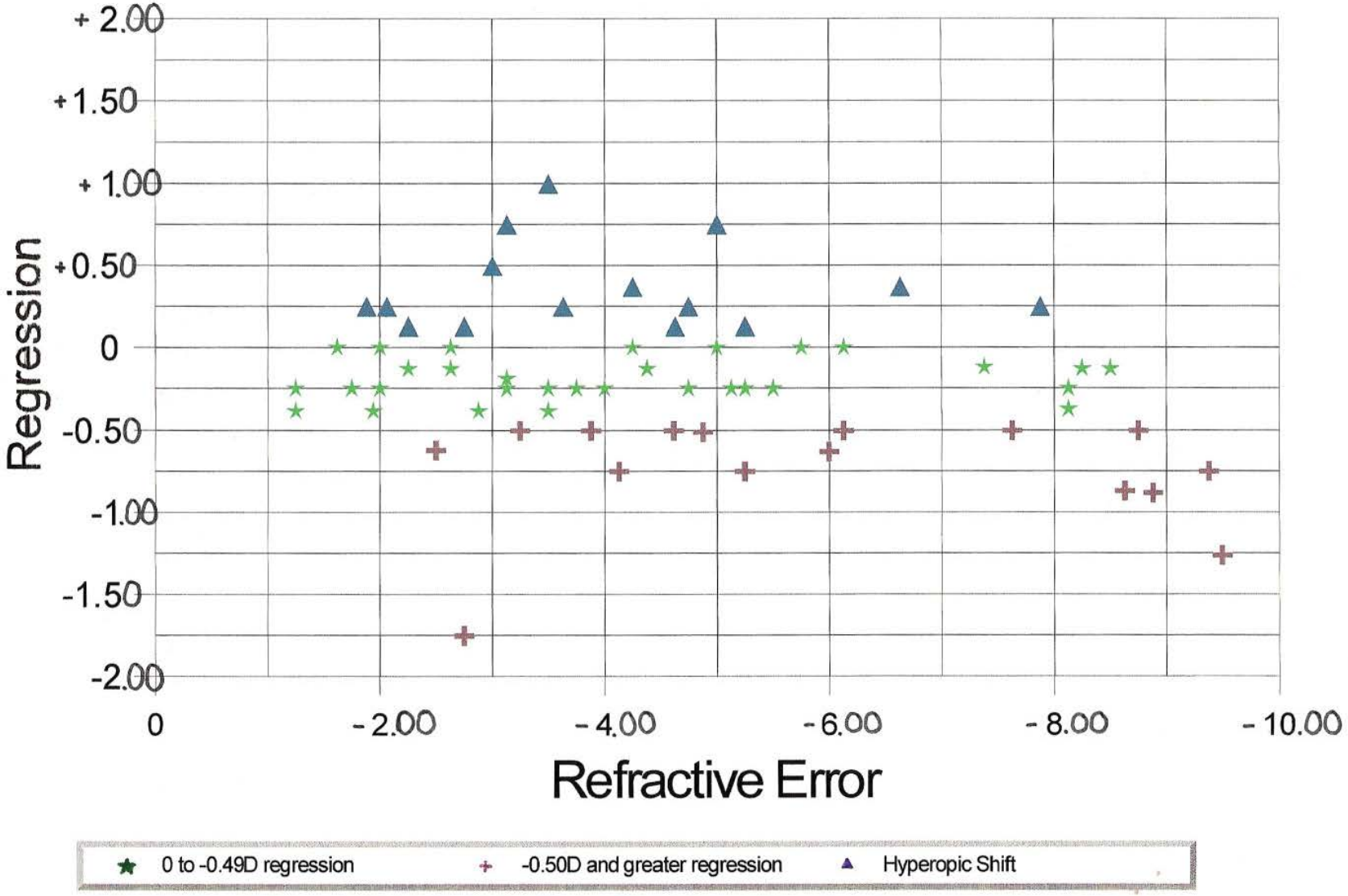
Refractive Error & Regression Over 3 Months

Figure 2



Pre-Op Refractive Error vs. Regression at 3 Months

Figure 3



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