Reoperations after myopic laser in situ keratomileusis

Jean-Luc Febbraro, MD, Kurt A. Buzard, MD, Miles H. Friedlander, MD

ABSTRACT

Purpose: To evaluate the results after enhancement of myopic laser in situ keratomileusis (LASIK) using the VISX Star excimer laser.

Setting: The Buzard Eye Institute, Las Vegas, Nevada, USA.

Methods: In this prospective study, 52 eyes of 40 patients had LASIK enhancernent. The existing flap was lifted and the excimer laser treatment reapplied for the residual refractive error, The VISX Star excimer laser was used for the primary LASIK and the enhancement procedure. Retreatments for undercorrection, regression, and overcorrection were performed after 6 weeks and up to 40 weeks after the primary LASIK. Follow-up was 96% at 1 month, 67% at 6 months, and 71% at 12 months.

Results: Mean pre-enhancement spherical equivalent was -0.77 diopters (D) ± 0.94 (SD) and mean uncorrected visual acuity (UCVA), 20/60. One year after the enhancement, mean spherical equivalent was -0.13 ± 0.33 D, and mean UCVA was 20/25. Refraction remained stable during the 1 year follow-up, with no retreatment required. After the enhancement, all patients had a UCVA of 20/40 or better. At 1 year, 3% of patients had lost 1 line of best corrected visual acuity and 32% had gained 1 line. No epithelial ingrowth was noted.

Conclusion: Retreatment for LASIK beginning 6 weeks after 'the initial procedure proved to be effective with minimal complications and good results. The technique to raise and reposition the flap appeared safe, and complications were few. *J Cataract Refract Surg 2000; 26:41-48* © *2000 ASCRS and ESCRS*

More than 30 years have passed since Barraquer [1,2] first described cryolathe keratomileusis to correct myopia. Laser in situ keratomileusis (LASIK) has proved effective for the correction of mild to severe myopia. [3-7] Myopic corrections as high as 29.00 diopters (D) have been reported,[8] although in our routine practice, maximum correction with LASIK is limited to 15.00 D for 2 reasons. First, we have performed LASIK for corrections as high as 22.00 D and have noted a loss of best corrected visual acuity (BCVA) that resolved slowly over a period of several months, illustrating the axiom first proposed by Barraquer[1]: Excessive flattening can result in decreased vision. Second, we have attempted to leave approximately half of the cornea1 thickness untouched at the conclusion of the case or to leave 250 μm in the bed or about 400 μm total for a typical 160 μm flap. On the lower end, we have treated refractive errors down to -0.75 D of myopia if they are disturbing the patient.

In most LASIK cases, some regression of the initial correction is noted. This regression is more significant in the first 6 weeks, with smaller changes in the first several

Accepted for publication August 9, 1999.

From the Departments of Ophthalmology, Tulane University Medical Center, New Orleans, Louisiana (Febbraro, Friedlander), and University of Nevada School of Medicine, Las Vegas, Nevada (Buzard), USA.

Reprint requests to Kurt A. Buzard, MD, The Buzard Eye Institute, 6020 Spring Mountain Road, Las Vegas, Nevada 89146, *USA.*

0886-3350/00/$-see matter
PII S0886-3350(99)00263-l

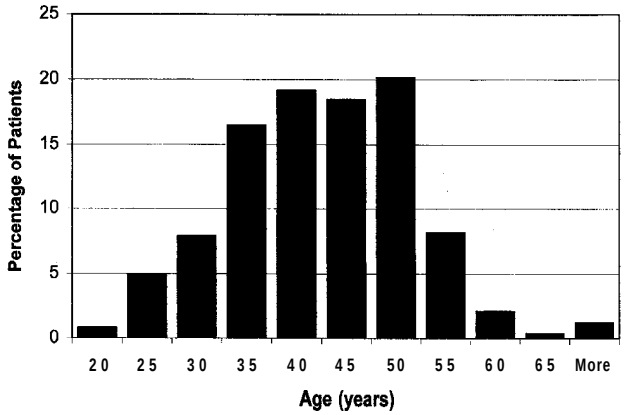

Figure 1. (Febbraro) Age distribution of patients before primary LASIK.

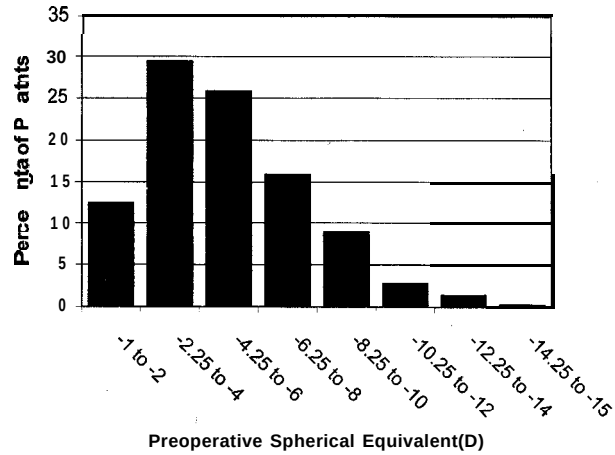

Figure 2. (Febbraro) Distribution of spherical equivalent before primary LASIK.

months. Regression is the most common complication of photorefractive keratectomy (PRK).[9,10] Retreatment of residual myopia with PRK is less successful than the primary PRK,[11,12] with the significant complications including loss of BCVA and corneal scarring. In contrast, retreatment of undercorrected PRK with LASIK is safer and more predictable[13]; however, even in these cases there is some loss of BCVA. The overall success rate of PRK is lower in cases of high myopia than in low to moderate myopia.[14,15] However, LASIK appears to have a more even rate of success across a broad range of refractive errors.[16]

The few published studies of regression and enhancement after LASIK often have poor follow-up and inconsistencies in nomogram construction. In this study, we evaluated enhancement in LASIK patients using the Buzard nomogram (K.A. Buzard, MD, "Advanced Techniques in LASIK," presented at the Symposium on Cataract, IOL and Refractive Surgery, Boston, Massachusetts, USA, April 1997).

Patients and Methods

Beginning in October 1997, 709 eyes of 399 patients, 194 men and 205 women, were prospectively studied. Patients were selected based on a desire to have surgery and having myopia or myopic astigmatism from -0.75 D to approximately 15.00 D. Inclusion criteria included a stable refraction for at least 2 years, age of at least 2 1 years, and absence of significant corneal disease or lenticular changes. Figure 1 shows the age distribution of the patients; mean age was 40.7 years ± 3.2 (SD) (range 2 1 to 76 years).

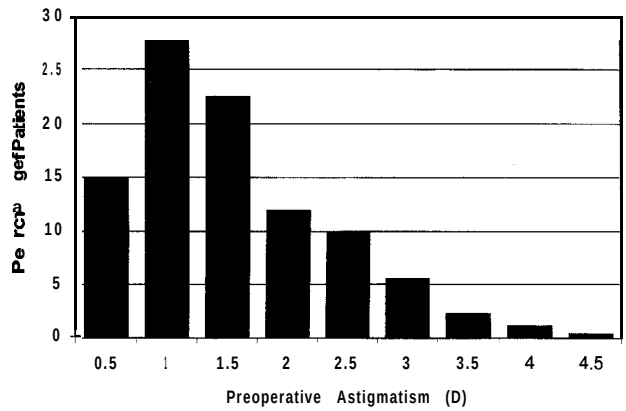

Figure 3. (Febbraro) Distribution of refractive astigmatism before primary LASIK.

The distribution of pre-LASIK spherical equivalents and astigmatism is shown in Figure 2 and Figure 3, respectively. Mean preoperative spherical equivalent was -4.86 ± 2.79 D (range – 1 .00 to – 15.00 D) and mean preoperative astigmatism, 1.43 ± 1.16 D. All primary LASIK procedures were based on dilated cyclopentolate hydrochloride (Cyclogyl®) refraction; additional treatment was based on the BCVA determined with the eye undilated. This approach of not dilating the eye after the first refractive procedure is consistent with a previous study of dilation after radial keratotomy (RK).[17]

Results of postoperative enhancement are reported for the subset of all patients who had the procedure. Patients were enrolled in the study sequentially; how-

ever, during this time, treatments were being performed on parients with keratoconus, previous cornea1 surgery (e.g., cornea1 transplantation and RK), and referrals. As these conditions would likely influence the results of this study, reoperations on these 46 eyes were excluded (Table 1).

Reoperations were performed in 52 eyes of 40 patients (23 men and 17 women) with a mean age of 43.4 ± 6.6 years (range 32 to 58 years). Mean time to retreatment was 4.5 ± 2.9 months (range 6 to 40 weeks) (Figure 4). Twenty percent had the enhancement at 2 months and 40% at 4 months. One patient (2 eyes) received more than 1 retreatment.

Nomogram

Most factories configure excimer lasers to provide correction for PRK on the surface of the cornea. In this study using the VISX Star excimer laser, the "entry dioptric numbers" were modified to provide better correction under the LASIK flap. It has been suggested that a standard 10% reduction in programmed value of the laser would result in an appropriate correction in LASIK. Early experience showed this 10% reduction resulted in progressive undercorrections under 7.00 D and progressive overcorrections above 7.00 D.

Thus, this study used a LASIK nomogram that varied in a linear manner according to preoperative myopia (Figure 5). Observation revealed no changes with less than 3.00 D of myopia and a linear reduction of effect to 10% at 7.00 D, increasing to 15% reduction at 15.00 D. The reductions occurred in the spherical portion of the plus cylinder refraction; the astigmatic portion of the plus cylinder refraction was unchanged with up to 3.00 D and then reduced in the same manner as myopia.

Table 1. Reasons for exclusion from enhancement surgery.

Reason	Number of Patients
No follow-up	7
Irregular astigmatism (referred)	6
Sands of Sahara	9
Keratoconus	10
Map dot fingerprint dystrophy	5
Previous radial keratotomy	5
Previous penetrating keratoplasty	3
Previous cataract	1

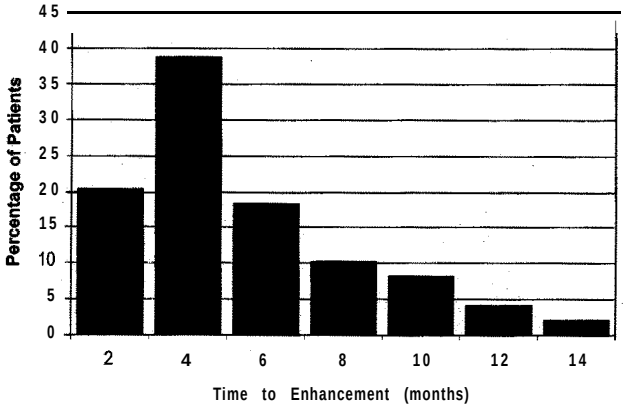

Figure 4. (Febbraro) Distribution of time between primary LASIK and enhancement.

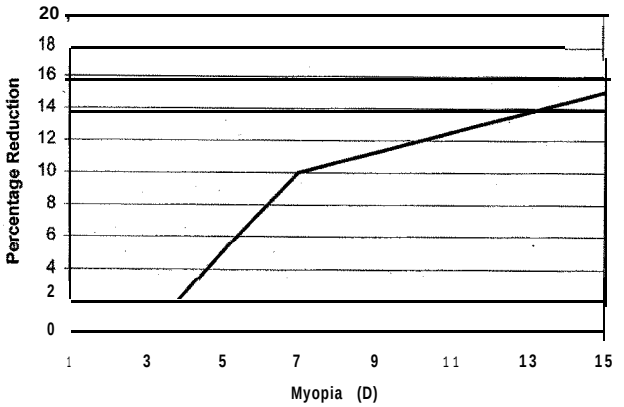

Figure 5. (Febbraro) Percentage of reduction with the linearly changing LASIK nomogram. The reduction goes up to 10% for myopia ranging from -3.10 to -7.00 D and up to 15% for myopia ranging from -7.10 to -15.00 D.

No adjustment was made for age or sex. The operating room temperature was kept at 68°F, humidity at 40%, and operating time a relatively consistent 10 minutes per case.

Primary LASIK Technique

All surgeries were performed by 1 surgeon (K.A.B.). Patients were given 5 mg of diazepam (Valium@) and then brought to the laser. The skin was prepared with 1 povidone-iodine (Betadine®) swab, and 4 cloth towels were used to drape the head.

The lids were drawn back with Steri-Strips and lashes were enclosed in Tegaderm (3M), which was wrapped around each lid margin. The lid was retracted with a stiff open Barraquer lid speculum. Tetracaine

drops were given, and the eye was flooded to provide topical anesthesia. Marking and creating the flap were done under a separate microscope (Topcon Instruments) equipped with a macular-to-macular centration light and circular illumination (Mastel Precision). The cornea was marked with an 8-cut radial marker, a 9.0 mm optical zone marker centered using the axime-ter, and an eccentric 3.0 mm optical zone marker, all stained with methylene blue.

The flap was created using the Automated Corneal Shaper #14l (Ch iron, Inc.) automated microkeratome with a nasal hinge and a 160 μm plate. Flap diameter was approximately 8.0 to 8.5 mm. All surgeries were performed with a VISX Star excimer laser with a standard 6.0 mm treatment zone. Most patients had bilateral surgery. Postoperatively, patients were given ciprofloxacin hydrochloride (Ciloxan®) 4 times a day for 1week and rimexolone (Vexol®) 4 times a day for 3 to 4 weeks.

Enhancements

Patients were evaluated postoperatively at 1 day, 2 and 6 weeks, 3 and 6 months, and 1 year. No enhancements were performed before 6 weeks after the primary LASIK. Indications for enhancement included residual myopia, hyperopia, or astigmatism greater than 0.75 D and evidence of refractive stability. Enhancements for myopia were usually done close to 6 weeks after the primary procedure; hyperopia and astigmatism were retreated at least 2 to 3 months postoperatively.

For retreatment, patients were given 1 drop of tetracaine. With the slitlamp and an I8 gauge needle, the edge of the previous flap was identified. With a lateral movement, the edge of the flap was disengaged from the bed along a short section of the flap. The patient was then taken to the operating room, where draping and marking were performed as above.

The surface was dried with a wet Merocel® sponge, and the flap was carefully dissected with a Castroviejo forceps and a cyclodialysis spatula without allowing the spatula to exit the flap. The flap was then gently lifted with the Castroviejo forceps and bent back, creating a sharp demarcation along the epithelial edge in a technique similar to that used for capsulorhexis in cataract surgery. In this series, no second microkeratome cut was required. A Merocel sponge was used to dry the bed, and the patient was rotated under the laser for retreatment. Retreatments were performed according to the standard nomogram and when hyperopia was present, according to the hyperopic Buzard nomogram." The flap was repositioned and dried for 5 minutes.

Results

The reoperation rate for the LASIK enhancement subgroup of 52 eyes was 7.3%. If the 7 eyes (1 .O%) that were retreated but did not return for follow-up were included, the rate would be 8.3%. If the entire group of 98 eyes were included, the retreatment rate would be 13.8%. Follow-up data were available for 96% eyes at 1 month, 67% at 3 months, 46% at 6 months, and 71% at 1 year.

Of the main group of 709 eyes, last follow-up was available for 96% at 1 month, 75% at 3 months, 38% at 6 months, and 21% at 1 year. At last follow-up, 80% were within $\pm$ 0.50 D, 87% within $\pm$ 1.00 D, and 100% within $\pm$2.00 D of enimetropia.

There was no statistical relationship between preoperative spherical equivalent and the need for enhancement (Figure 6). Thirty-five percent of the patients were within $\pm$ 1.00 D of emmetropia before enhancement and thus required a relatively small correction.

The efficacy of the procedure was considered to be the percentage of eyes that achieved each level of uncorrected visual acuity (UCVA) (Figure 7). The majority of the patients had a UCVA of 20/20 at 6 and 12 months; 20% had 20/25, and 20% had 20/30. In general, UCVA seemed to improve over time. It was 20/40 (20/50) or worse in 4 eyes (8%) at 1 month and in 1 eye (3%) at 3 months. At 12 months, 5% of patients had an UCVA of

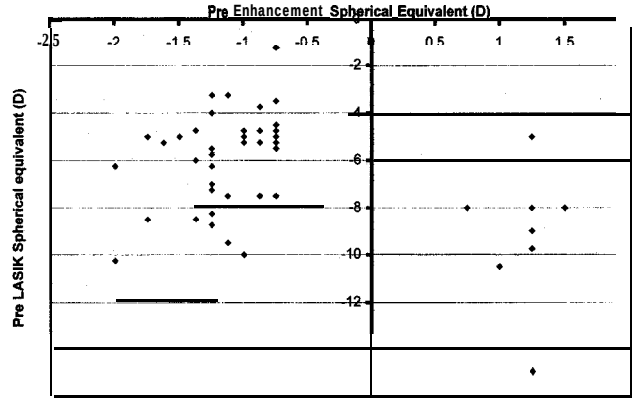

Figure 6. (Febbraro) Relationship between pre-LASIK and pre-enhancement spherical equivalents.

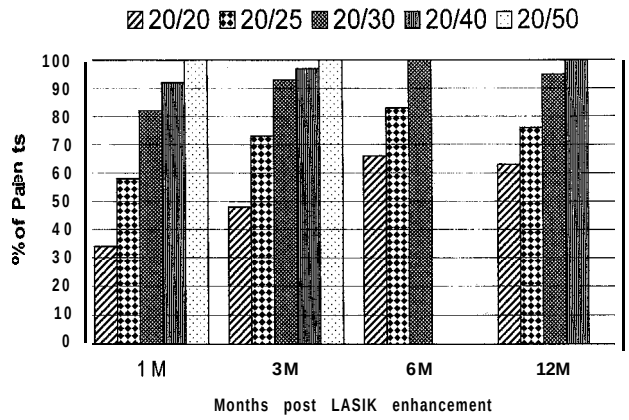

Figure 7 (Febbraro) Distribution of postenhancement UCVA at 1, 3, 6, and 12 months.

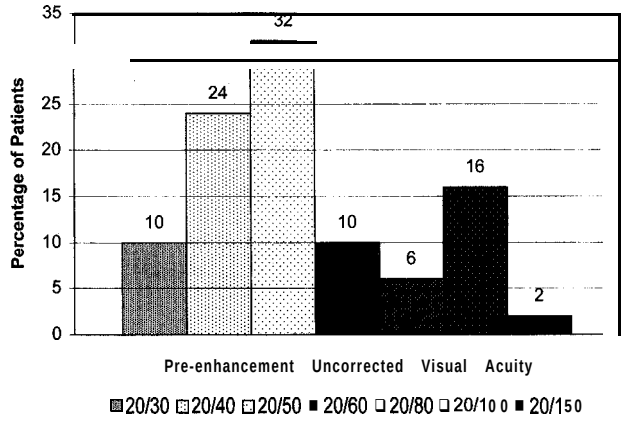

Figure 8. (Febbraro) Distribution of UCVA before LASIK enhancement.

20/40; none had a UCVA worse than 20/40. Before the enhancement, 66% of patients could not attain an acuity of 20/40 without correction (Figure 8).

The predictability of the enhancement procedure is shown in Figure 9. One hundred percent of patients were within ± 1.00 D of emmetropia at all stages of follow-up except 2 eyes in 1 patient at 1 month. This patient received a second enhancement for an overcorrection. At 1 year, 67% of the patients were within ±0.25 D of emmetropia.

Mean spherical equivalent refractive error (Figure 10) was 0.03 ± 0.44 D at 1 month, -0.02 ± 0.38 D at 3 months, -0.06 ± 0.27 D at 6 months, and -0.13 ± 0.33 D at 1 year. A Student *t* test found no statistical significance between 1, 3, 6, and 12 months despite the slight appearance of regression seen in Figure 10.

One measure of the safety of the LASIK enhancement was change in BCVA (Figure 11). In general, the patients had worse UCVA 1 day after the enhancement than after their primary LASIK procedure. One month after the enhancement, 14% of the patients had lost 1 line of BCVA; this decreased to 3% at 12 months. No patient lost more than 1 line of BCVA, and 5% gained 2 lines at 1 year. No patient had epitheliaI ingrowth, visually significant flap striae, sands of the Sahara syndrome, or other significant complications.

Discussion

Throughout the world, LASIK has become the standard treatment for myopia and myopic astigmatism of approximately – 1.00 to – 15.00 D. As found in this and other studies, the efficacy and predictability of

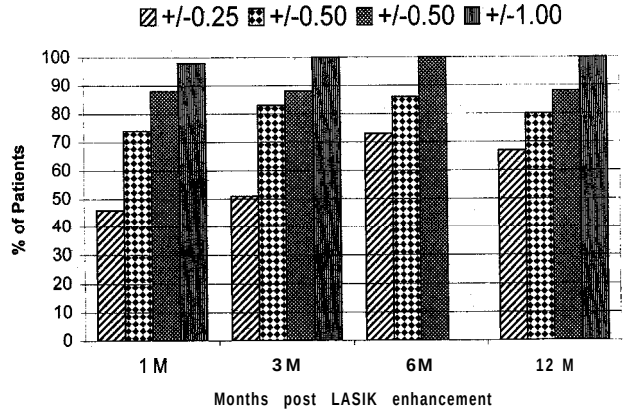

Figure 9. (Febbraro) Distribution of residual postenhancement spherical equivalent (D) at 1, 3, 6, and 12 months.

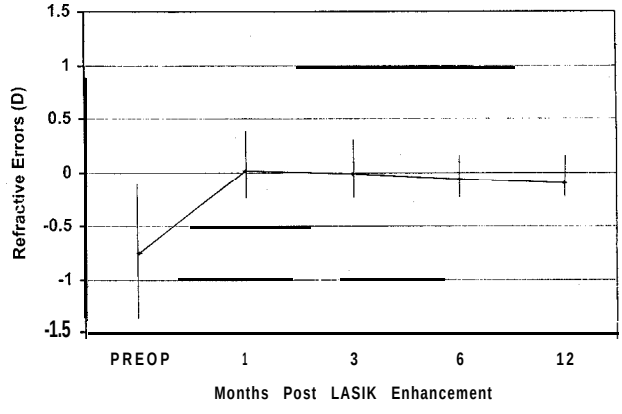

Figure 10. (Febbraro) Change in mean refractive errors before LASIK enhancement and during the first year after enhancement.

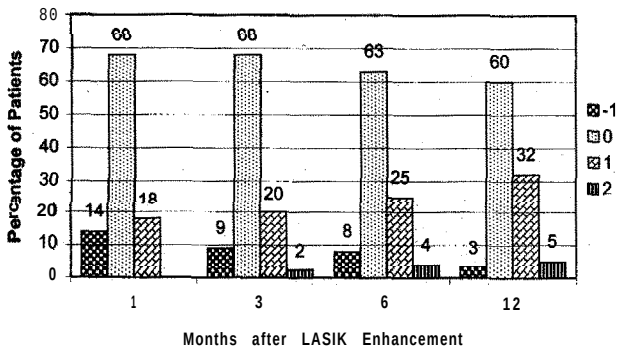

Figure 11. (Febbraro) Distribution of gain and loss of lines of BCVA 1, 3, 6, and 12 months after enhancement.

LASIK are remarkable over a range of refractive errors, with 95% having a UCVA of 20/40 or better and 35% having 20/20 after enhancement in the original group of 709 patients who had primary LASIK. In our study, 96% of eyes were within ± 1.00 D and 87% within ±0.50 D of emmetropia after enhancement. These results compare favorably with those in the literature.

The lack of a statistical trend with respect to initial myopia, the need for enhancement, and the relatively equal number of hyperopic and myopic enhancements suggest that the linearly increasing Buzard LASIK nomogram for the VISX Star laser is appropriate and accurate for both myopia. and hyperopia in terms of final results. This is in contrast to nomograms using a single percentage for all degrees of myopia.

In terms of LASIK enhancements, our results compare favorably with those of previous studies (Table 2).[19,20] They compared even more favorably considering efficacy and predictability results. In the other studies, a much larger range of refractive errors (up to 5.00 D) was noted before the enhancements, suggesting problems with the nomograms used. In addition, none of these studies seemed to include enhancements for hyperopia. There could also be a negative bias in the data because patients with satisfactory refractive outcome usually do not return for follow-up and were thus not represented in these studies.

Significant changes in the mean spherical equivalent during the follow-up were not noted in our study. Probst and Machat[18] found a significant refractive change from 1 to 3 months after enhancement but no significant regression from 3 to 6 or 12 months.

In terms of safety, the incidence of loss of 1 line of BCVA at 3 months (8% to 9%) in our study was similar to that of Gutierrez[19] but slightly superior to that of Probst and Machat[18] at 6 months. The percentage of lost lines of BCVA in our study decreased with time; at 12 months, 3% had lost 1 line of Snellen acuity and 32% had gamed 1 line of BCVA.

The lack of epithelial ingrowth and striae and the low percentage of a 1 line loss of BCVA demonstrate the advantages of the technique we describe. Lifting a previous LASIK flap by first identifying and opening the flap edge at the slitlamp and then using blunt dissection with a tearing technique enabIes one to achieve a sharp epithelial boundary. A technique we consider less advantageous involves using a hook on the cornea1 surface to identify the flap and lifting the edge in the operating room. We believe a rough epithelium leads to more flap complications and an increased loss of BCVA. Our success using this flap technique after several years without having to recut is additional proof of its safety. This method prevents such complications as folding or loss of thin stromal lamellae.

These observations are in keeping with the experience of Barraquer, who made the same observation with respect to freezing keratomileusis flaps many years ago. An important exception to lifting LASIK flaps without recutting are patients who have had previous incisional keratotomy and some cornea1 transplantation cases in which an attempt to bluntly dissect the flap after 2 months can result in a torn flap. Also, larger flaps are more difficult to lift over time.

Given the safety and good results, with 67% of the patients having 20/20 UCVA after 1 year, retreatment can be small. In this study, 35% of patients were at or below ± 1.00 D of emmetropia when retreated. The excellent results with these small corrections suggest that equally small corrections can be applied as a primary procedure with good predictability and safety. Thus, the suggestion by some surgeons that small myopic corrections (less than 1.00 or 2.00 D) might more safely be performed with PRK does not seem to be borne out.

Although it is often suggested that age might be an active variable in the LASIK nomogram, no evidence of correlation between age and results was found in the primary LASIK group in our study. It appears that in some patients, retreatment at 6 weeks is safe and effective if sequential follow-up shows no changes in refraction. In addition, retreatment can be performed with the original nomogram, unlike in previous studies”

Table 2. Comparison of studies of LASIK enhancements.

Study	Preoperative	Postoperative 1 Month	3 Months	6 Months	12 Months
Probst & Machat[19]					
Number of eyes	209	159	122	51	9
SE (D)					
Mean ± SD	-1.95 ± 0.78	-0.33 ± 0.84	-0.63 ± 0.92	-0.69 ± 1.10	-0.67 ± 0.90
Range	-4.50 to -0.38	–	–	–	–
Emmetropia (%)					
Within ±0.50 D	–	–	51.6	58.8	77.8
Within ±1.00 D	–	57.7	76.2	83.3	77.8
Within ±2.00 D	–	88.4	–	–	–
BCVA (%)					
≥20/40	–		71.3	88.2	66.7
Lost lines	–	–	–	14.0	
Gained lines	–	–	–	15.0	–
Gutiérrez[20]					
Number of eyes	80	78	39		–
Mean SE ± SD (D)	-3.25 ± 1.74	–	-0.15 ± 1.29		–
Sphere/cylinder	−2.60/−1.03	–	0.26/−0.57	–	–
UCVA	0.21	–	0.54	–	–
BCVA	0.78	–	0.76	–	–
Lost lines BCVA (%)	–	–	7.6		–
Gained lines BCVA (%)	–	–	30.0	–	–
Salah[21]					
Number of eyes	20	–	–	–	20
SE (D)					
Mean	-2.50		–	–	-0.16
Range	– 1 .oo to -5.50	–	–	–	1.00 to +1.00
Cylinder (D)	-0.55	–		–	-0.40
UCVA	20/80	–		–	–
BCVA	20/35		–	–	–
UCVA ≥20/40 (%)	–	–	–	–	85.0
Emmetropia (%)					
Within ±0.50 D		–	–	–	75.0
Within ± 1 .OO D		–	–	–	100.0
Current					
Number of eyes	52	50	35	25	37
SE (D)					
Mean ± SD	-0.77 ± 0.94	0.03 ± 0.44	-0.02 ± 0.38	-0.60 ± 0.27	-0.13 ± 0.33
Range	-2.00 to +1.50		–	–	–
UCVA	20/60	–	–	–	–
BCVA	20/22	–	–	–	–
UCVA ≥20/40 (%)	–	92.0	97.0	100.0	100.0
Within 1 .00 D emmetropia (%)	–	98.0	1.00.0	100.0	100.0
Lost lines BCVA (%)	–	14.0	9.0	8.0	3.0
Gained lines BCVA (%)	–	18.0	20.0	25.0	32.0

SE = spherical equivalent; BCVA = best corrected visual acuity; UCVA = uncorrected visual acuity

that reduced the retreatment nomogram by a fixed percentage.

In conclusion, the use of LASIK to enhance primary myopic LASIK procedures is safe and effective in eyes with even a relatively small amount of residual myopia.

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