ABSTRACT

A prospective, nonrandomized, unmasked, 1-year clinical trial was performed in 2482 eyes to evaluate the safety and efficacy of laser in situ keratomileusis (LASIK) for myopia and myopic astigmatism using a new excimer laser system. The study found that LASIK was a safe and effective method for correcting myopia and myopic astigmatism in patients with sphere to –15 diopters (D) and cylinder to 5 D.

ORIGINAL ARTICLE

Prospective LASIK Trial for Myopia and Myopic Astigmatism: 1-Year Results

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In North America alone, myopia affects an estimated 75 million people, and the prevalence is increasing.[1-5] The recent population-based survey in Beaver Dam, Wis, showed that 14.4% of phakic adults older than 75 years had myopia, but 42.9% of phakic adults aged 43 to 54 years had myopia greater than or equal to 0.5 diopters (D).[6] Several other population-based studies suggest that this rise in myopia prevalence is largely due to an adaptive lengthening of the eye that results from a significant increase in close-up work.[1,7,8] The shape of the lens may also change as the tone of the ciliary muscle and zonular fibers relaxes with age, and this may also affect refraction.[9]

More than 90% of myopes have low to moderate myopia (to –6 D), and about two-thirds also have some degree of astigmatism. In 1993, we began offering laser in situ keratomileusis (LASIK) for myopes and individuals with myopic astigmatism who desired surgical correction. We used a new excimer laser and performed the procedures initially under Institutional Review Board (IRB) approval and subsequently under a slightly modified protocol approved for an investigational device exemption (IDE). We studied this procedure in an effort to validate the theory that LASIK promotes rapid visual recovery with minimal or no postoperative pain, haze, or regression. We also assessed the incidence and clinical significance of complications, especially those unique to the LASIK

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procedure, such as lost flaps, astigmatism caused by flap folds or irregularities, and "melted" flaps resulting from an infiltration of white blood cells into the stroma-flap interface.

Patients & Methods

A prospective, nonrandomized, unmasked, clinical trial was conducted initially under IRB approval (cohort 1) and subsequently, starting July 1, 1996, under a slightly modified IDE-approved protocol (cohort 2). Patients who came to one of our laser eye centers beginning May 1, 1993, seeking surgical correction of myopia were eligible for the study if they were 18 years old or older, had primary myopia between –1.0 D and –15.0 D with or without astigmatism up to 5.0 D, and had stable refraction defined as less than 0.5 D shift for the 30 days before surgery. Subjects also needed to want to be free of spectacles or contact lenses and be willing to comply with all postoperative follow-up visits. Patients refrained from soft contact lens wear for 2 weeks before the preoperative evaluation or hard contact lens wear for 3 weeks before the preoperative evaluation.

Patients not meeting these criteria, as well as patients with any of the following conditions, were excluded from the study: active ocular or systemic infection, severe dry eye syndrome, Fuchs dystrophy, anterior basement membrane dystrophy, keratoconus associated with thinning, and/or central corneal scars that affected visual acuity. Patients receiving chronic topical steroid therapy and those with corneas too thin to permit the desired correction also were excluded.

Preoperatively, complete ocular and medical histories were taken. Best-corrected visual acuity (BCVA) and uncorrected visual acuity (UCVA) measurements and manifest and cycloplegic refractions were obtained. Dilated fundus examinations, brightness acuity testing, pupillary examinations, keratometry, tonometry, pachymetry, and topography were performed. Refractive and ocular stability was documented.

On every operative day, we calibrated the laser and tested beam quality. Each patient was prepared with a povidone-iodine (Betadine) eyelid scrub before surgical draping. We then administered approximately 5 tetracaine drops, placed a lid speculum, and simultaneously vacuumed and irrigated the eye with balanced salt solution. After placing the keratome suction ring on the eye, we used a microkeratome (Chiron Automated Corneal Shaper, Bausch & Lomb Surgical, Claremont, Calif) to create a nasally hinged corneal flap 160 µm thick and approximately 8 mm in diameter. The incision began at the temporal side and stopped 90% of the way across. After swinging the cap nasally to expose the stromal bed, the patient fixated on a light coaxial with the laser beam, and the stromal bed was ablated with a 193-nm wavelength excimer laser (Kremer Excimer Laser, Kremer Laser Center, King of Prussia, Pa), using a typical fluence of about 140 mJ/cm.^{2}

This laser has a computer-controlled aperture assembly that shapes the laser beam as it passes through tissue. This aperture assembly consists of an adjustable iris for the spherical (myopic) correction and a slot with adjustable width and angle for the oblong (astigmatic) correction, which affects just one meridian of the eye. This laser differs from other lasers of its type in several ways. Its operating microscope has a fully automated foot control that enables the surgeon to zoom in and out during cap manipulation and ablation, the software was developed specifically for LASIK, and the laser allows astigmatic ablations within a full 6-mm optical zone.

Following ablation, the operating surgeon irrigated the bed and interface and replaced the flap without any sutures. A clear shield was then placed over the eye. To prevent trauma to the eyes and potential cap displacement, the patient was instructed to wear the shield and keep the eye closed for the first day. Thereafter, patients wore the eye shield for 1 week while sleeping. We also prescribed 1% prednisolone acetate sterile ophthalmic solution twice a day and a broad-spectrum topical antibiotic 4 times a day, both for 4 days.

Patients were evaluated on postoperative day 1, week 1, and months 1, 3, 6, and 12 at the Kremer Laser Eye Centers and qualified comanaging sites. Qualified sites performed standardized postoperative evaluations and completed standardized follow-up forms. Postoperative evaluations included keratometry, uncorrected and best spectacle-corrected visual acuities, manifest refraction, and a thorough slit-lamp examination for assessment of corneal clarity and the anterior chamber and lens status. All patient complaints, complications, and adverse reactions were recorded. Cycloplegic refractions were performed at 12 months. All measurements were taken by optometrists or ophthalmologists other than the authors and were entered into a computer database. The database was closed for purposes of this analysis on November 20, 1997.

We evaluated the effectiveness of the procedure based on the absolute manifest refraction over time (sphere and cylinder); improvement in UCVA; reduction in the spherical equivalent refraction, including independent analyses of both the spherical and cylindrical components; and accuracy of the achieved spherical equivalent. We evaluated the predictability of the procedure and device by assessing the proportion of eyes experiencing deviations from the intended correction within ±0.5 D, ±1.0 D, and ±2.0 D. Stability was defined as a change of 1.0 D or more for 2 consecutive visits spaced 3 months apart.

We evaluated safety in terms of a loss in BCVA of greater than 2 lines, a BCVA worse than 20/40, BCVA worse than 20/25 in eyes that were 20/20 or better preoperatively, and all symptoms and complications. We asked patients to describe their symptoms as bothersome or not bothersome, and we also recorded this information. We recorded the results of all eyes retreated for undercorrection. Per instruction from the

Food and Drug Administration (FDA), all eyes treated for overcorrection were excluded from the analysis.

The protocol for cohort 1 differed from that of cohort 2 in 2 primary ways. Initially, the intended correction typically was calculated by subtracting 20% from the theoretical correction, but with time and experience we reduced and ultimately eliminated this safety factor. All patients in cohort 2 were treated using an intended correction equivalent to the ideal correction. Also, a second investigator (G.P.) joined the study during the IDE phase (cohort 2).

To determine whether the protocol, degree of correction (less than 7 D preoperative spherical equivalent v greater than or equal to 7 D spherical equivalent), or type of correction (myopia only v myopic astigmatism) influenced the visual outcome, we performed statistical comparisons of the key safety and efficacy outcome measures at the 0.05 significance level at the point of stability (the 6-month interval). Depending on the analysis, we used either the χ^2 or Cochran-Mantel-Haenszel statistic, controlling for protocol or preoperative refraction when appropriate. To determine whether the visual results remained stable over time, key 6- and 12-month outcome measures were also compared using the Cochran-Mantel-Haenszel statistic, controlling for protocol. So that we could independently assess both the position (axis) and magnitude of any residual astigmatism, we performed vector analysis using the widely accepted Holladay method.[10] Finally, we also compared the accuracy of the surgical correction in a series of eyes with both manifest and cycloplegic refractive data at 12 months using the McNemar test. This enabled us to determine whether we induced any significant refractive changes in the cornea that were masked by the patient's natural accommodation.

Monovision eyes were excluded from all analyses. In patients with monovision, the goal of LASIK is to achieve slightly different visual acuities in each eye—1 for near (reading) and 1 for far vision—to accommodate for presbyopia.

Results

Demographics. A total of 2482 eyes were treated under both protocols. We treated slightly more males than females and more eyes for myopic astigmatism than for myopia only. Table 1 summarizes the key demographic characteristics, which were similar for both cohorts. There were 1402 eyes with 6 months of follow-up and 957 eyes with 12 months of follow-up.

Preoperatively, 58.5% and 72% of eyes in cohorts 1 and 2, respectively, had myopia (sphere) less than –7 D, and 96% and 94% of eyes in these cohorts also had astigmatism (cylinder) less than 3 D. Less than 1% of all eyes combined had UCVA of 20/40 or better.

Efficacy. Mean sphere went from –6.03 D preoperatively to –0.40 D at 6 months; mean cylinder went from 0.87 D to 0.53 D, respectively. Figures 1 and 2 show the absolute sphere and cylinder (±SD) at all intervals.

Six months after LASIK, 88% of all eyes had UCVA of 20/40 or better. The UCVA was statistically better in eyes from cohort 2 (Table 2) because cohort 1 eyes were intentionally undercorrected. The manifest refraction spherical equivalent was accurate to within ±1.0 D of the intended correction in 86.7% of all eyes (Table 2). Table 2 shows that refractive outcomes remained sta-

TABLE 1

Key Demographic and Visual Characteristics

Characteristic	Cohort 1 (n = 616)	Cohort 2 (n = 704)
Male, No. (%)	329 (53.4)	359 (51.0)
Mean age, y	38.1	36.3
Myopia, No. (%) of eyes	487/1140 (42.7)	630/1342 (46.9)
Myopic astigmatism, No. (%) of eyes	653/1140 (57.3)	712/1342 (53.1)

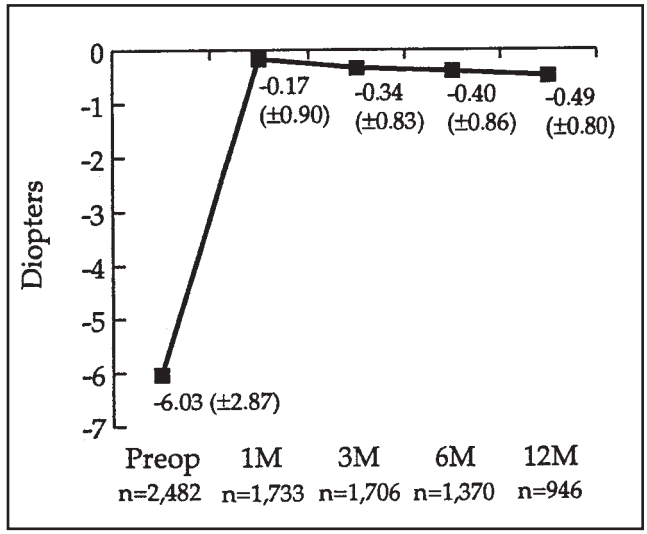

Fig 1.—Mean manifest sphere over time, before LASIK and 1, 3, 6, and 12 months after the procedure. Parenthetical values are the SD.

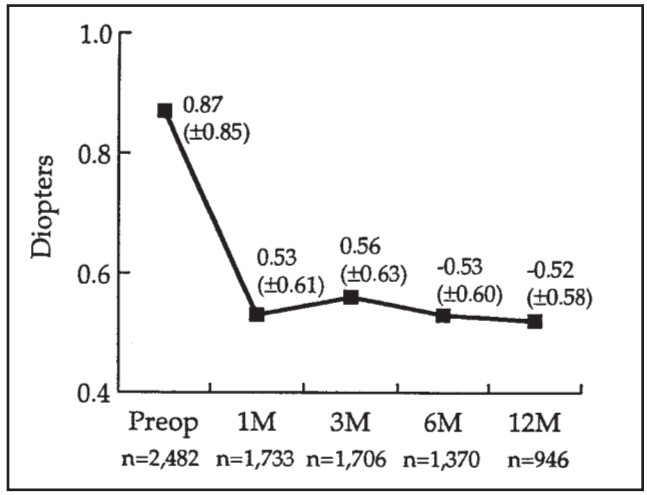

Fig 2.—Mean manifest cylinder over time, before LASIK and 1, 3, 6, and 12 months after the procedure. Parenthetical values are the SD.

TABLE 2

Key Efficacy Results 6 and 12 Months after LASIK in All Eyes*

Efficacy Measure	Cohort 1, No. (%)		Cohort 2, No. (%)		*P*†	
	6 mo	12 mo	6 mo	12 mo	Cohort Comparison	6- and 12-mo Comparison
UCVA: ‡						
≥ 20/20	212/668 (31.7)	202/612 (32.7)	199/491 (40.5)	87/218 (39.9)	.002	.840
≥ 20/40	579/668 (86.7)	535/612 (87.4)	446/491 (90.3)	201/218 (92.2)	.029	.523
MRSE: §						
±0.5 D	494/737 (67.0)	431/688 (62.6)	472/665 (71.0)	199/269 (74.0)	.111	.401
±1 D	631/737 (85.6)	588/688 (85.5)	584/665 (87.8)	249/269 (92.6)	.226	.231
±2 D	710/737 (96.3)	669/688 (97.2)	650/665 (97.7)	266/269 (98.9)	.123	.091

*Includes re-treated eyes.

†Comparison between cohorts at the point of stability (6 months) used the χ^2 statistic, and comparison between 6- and 12-month results used the Cochran-Mantel-Haenszel statistic, controlling for protocol.

‡All eyes treated for monovision were excluded from the analysis for uncorrected visual acuity (UCVA), since undercorrection is intentional in this subpopulation.

§MRSE indicates manifest refraction spherical equivalent and indicates percentage of eyes corrected to within ±0.5 diopters (D), ±1.0 D, and ±2.0 D of the intended correction.

ble over time, as there were no statistically significant differences between the 6- and 12-month key efficacy results when controlled for protocol.

The LASIK surgery was most effective in eyes with low to moderate myopia. Both UCVA and the accuracy of the correction were significantly better in eyes with less than 7 D of preoperative spherical equivalent (Table 3). When we assessed cohort 2 eyes to determine whether the type of correction (myopia only v myopic astigmatism) influenced the refractive and visual outcomes, there was one statistically significant difference. Eyes with preoperative spherical equivalent of 7 D or greater treated for myopic astigmatism were less likely to achieve 20/20 UCVA than were eyes with preoperative spherical equivalent greater than or equal to 7 D that were treated for myopia only ($P = .057$, Cochran-Mantel-Haenszel statistic controlling for preoperative spherical equivalent). However, there was no statistically significant difference between the proportions of these eyes achieving 20/40 uncorrected vision ($P = .808$, Cochran-Mantel-Haenszel statistic controlling for preoperative spherical equivalent).

When we assessed the spherical and cylindrical components of the 6-month postoperative refraction separately, we found that eyes treated for myopia only had the most residual cylinder. In all eyes treated for myopia only (both cohorts), mean cylinder overcorrection at 6 months was approximately 0.75 D (cohort 1: 0.71 D ± 0.68, n = 657; cohort 2: 0.72 D ± 0.64, n = 713). By 12 months, less than 1% of eyes (4/414) treated for myopia only had cylinder increases greater than 2 D. The median shift in cylinder axis in all eyes was 25° and 35° for cohorts 2 and 1, respectively. However, the highest shifts in astigmatic axes tended to occur in eyes with the lowest degrees of residual cylinder; 68.8% and 70.9% of eyes treated for myopia only in cohorts 2 and 1, respectively, had residual cylinder from 0 to less than 1 D at 6 months. This is clinically important because measurements of the astigmatic axis in eyes with small amounts of astigmatism are highly inaccurate and tend to fluctuate widely.

To determine whether surgery induced any significant refractive changes in the cornea that were masked by the patient's natural accommodation, we compared the accuracy of the spherical equivalent based on manifest v cycloplegic refractions. As Table 4 shows, a greater proportion of eyes achieved manifest refractions within ±1.0 D than cycloplegic refractions within ±1.0 D of the intended correction. However, there was no difference in the proportions of eyes achieving within ±0.5 D or ±2.0 D of the intended correction, regardless of the method of refraction.

Safety. In this study, 2.3% of all eyes (22/957) lost 2 or more lines of BCVA 12 months after surgery. Only 1.6% of eyes (n = 15) had BCVA worse than 20/40. There were no statistically significant differences in rates of BCVA losses greater than 2 lines or BCVA worse than 20/40 between cohorts or between the 6- and 12-month results. As Table 5 shows, most eyes that lost BCVA had higher refractive errors (7 D or greater) and required a greater degree of laser correction.

As expected, symptoms were most prevalent in

TABLE 3

Key Efficacy Results at 6 Months Stratified by Preoperative Manifest Refraction

Efficacy Measure	Cohort 1, No. (%)		Cohort 2, No. (%)		*P**
	<7 D	≥ 7 D	<7 D	≥ 7 D	
UCVA: †					
≥ 20/20	176/447 (39.4)	36/221 (16.3)	185/371 (49.9)	14/120 (11.7)	.001
≥ 20/40	407/447 (91.1)	172/221 (77.8)	358/371 (96.5)	88/120 (73.3)	.001
MRSE: ‡					
±0.5 D	356/483 (73.7)	138/254 (54.3)	374/477 (78.4)	98/188 (52.1)	.001
±1 D	439/483 (90.9)	192/254 (75.6)	446/477 (93/5)	138/188 (73.4)	.001
±2 D	480/483 (99.4)	230/254 (90.6)	475/477 (99.6)	175/188 (93.1)	.001

*P values are identical for the comparisons between eyes with <7 diopters (D) of preoperative spherical equivalent and ≥ 7 D eyes within each protocol population. Cochran-Mantel-Haenszel statistic comparing outcomes by preoperative spherical equivalent, controlling protocol.

†All eyes treated for monovision were excluded from the analysis for uncorrected visual acuity (UCVA), since undercorrection is intentional in this subpopulation.

‡MRSE indicates manifest refraction spherical equivalent and indicates percentage of eyes corrected to within ±0.5 D, ±1.0 D, and ±2.0 D of the intended correction.

TABLE 4

Accuracy of Correction: Manifest v Cycloplegic Refraction

Spherical Equivalent (diopters)	Manifest Refraction, No. (%)*	Cycloplegic Refraction, No. (%)*	*P*†
±0.5 D	158/224 (70.5)	160/224 (71.4)	.7440
±1.0 D	211/224 (94.2)	199/224 (88.8)	.0075
±2.0 D	222/224 (99.1)	221/224 (98.7)	1.000

*224 eyes had both manifest and cycloplegic refractive data at 12 months.

†Derived from the McNemar test.

eyes with high spherical equivalents (7 D or greater) and in eyes with residual refractive errors. The incidence of symptoms that patients considered bothersome ranged from 0.1% to 4.1% for both cohorts and included glare, halos, trouble with night driving, double vision/ghost images, foreign body sensation, anxiety, and pain. The most frequent, bothersome symptom was difficulty with right driving. However, as with all other symptoms, this symptom was reported much less frequently by cohort 2 patients than by those in cohort 1. We also anecdotally observed that foreign body sensations were more prevalent in patients with prior dry eye syndrome. The study did not measure the extent to which the symptoms may have resolved in the presence of spectacle correction, as we would expect.

There were 2 types of intraoperative complications: incomplete flaps and hingeless flaps. In 5 cases, we aborted the LASIK procedure; 4 of these cases were due to a microkeratome gear malfunction that developed gradually. We later treated all of these eyes without sequelae. In 29 cases, the microkeratome cut all the way through and rendered the flap hingeless; there were no associated sequelae.

We noted one malaligned cap during the first 24 postoperative hours and were able to reposition it without sequelae. Corneal edema was present between week 1 and month 1 in 73 eyes, and all of these cases later resolved.

Additional complications noted at 1, 3, 6, and 12 months postoperatively are shown in Table 6. Overall, there was a lower incidence of epithelium in the inter-

TABLE 5

Loss of BCVA at 6 Months in Eyes with Low-to-Moderate and High Preoperative Spherical Equivalent*

BCVA Measure	Cohort 1, No. (%)		Cohort 2, No. (%)		*P*†
	<7 D	≥ 7 D	<7 D	≥ 7 D	
Loss of ≥ 2 lines	2/483 (0.4)	18/254 (7.1)	2/477 (0.4)	12/188 (6.3)	<.001
<20/40	0/483 (0)	11/254 (4.3)	1/477 (0.2)	3/188 (1.6)	<.001
<20/25 with ≥ 20/20 preop	8/469 (2.0)	17/183 (9.0)	9/477 (2.0)	17/188 (9.0)	<.001

*BCVA indicates best-corrected visual acuity; D, diopters; and preop, preoperatively.

†Cochran-Mantel-Haenszel statistic was used to compare preoperative spherical equivalent groups, controlling for protocol.

TABLE 6

Incidence of Postoperative Complications

Complication	Cohort 2, No. (%)				Cohort 1, No. (%)			
	Mo 1	Mo 3	Mo 6	Mo 12	Mo 1	Mo 3	Mo 6	Mo 12
Corneal edema ≥ 1 mo	2/873 (0.2)	1/814 (0.1)	0/657 (0)	0/308 (0)	14/804 (1.7)	4/910 (0.4)	0/788 (0)	0/752 (0)
Corneal infiltrate	0/873 (0)	0/814 (0)	0/657 (0)	0/308 (0)	0/804 (0)	0/910 (0)	1/788 (0.1)	0/752 (0)
Epithelium in interface, central	1/873 (0.1)	1/814 (0.1)	0/657 (0)	0/308 (0)	2/741 (0.3)	0/859 (0)	1/750 (0.1)	0/687 (0)
Epithelium in interface, peripheral	1/873 (0.1)	0/814 (0)	1/657 (0.2)	0/308 (0)	8/741 (1.1)	12/859 (1.4)	15/750 (2)	10/687 (1.5)
Epithelial defect, central	1/873 (0.1)	1/814 (0.1)	0/657 (0)	0/308 (0)	2/741 (0.3)	1/859 (0.1)	2/750 (0.3)	0/687 (0)
Epithelial defect, peripheral	1/873 (0.1)	0/814 (0)	1/657 (0.2)	0/308 (0)	1/741 (0.1)	1/859 (0.1)	0/750 (0)	2/687 (0.3)
Interface foreign bodies	126/873 (14)	128/814 (14)	95/657 (15)	27/308 (9)	71/741 (9.6)	78/859 (9.1)	50/750 (6.7)	43/687 (6.3)
Cap striae	9/873 (1.0)	6/814 (0.7)	5/657 (0.8)	1/308 (0.3)	3/741 (0.4)	7/859 (0.8)	5/750 (0.7)	3/687 (0.4)
Pain	4/873 (0.5)	4/814 (0.5)	3/657 (0.5)	2/308 (0.7)	4/741 (0.5)	1/859 (0.1)	3/750 (0.4)	2/687 (0.3)
Retinal detachment	0/873 (0)	0/814 (0)	0/657 (0)	1/308 (0.3)	0/804 (0)	0/910 (0)	0/788 (0)	1/752 (0.1)

face of the stromal bed and the underside of the flap in cohort 2 eyes, as compared with cohort 1 eyes. We believe this was due to our increased surgical experience. When the epithelium was in the periphery of the interface, it did not influence vision and we did not remove it. When the epithelium was central in the interface, we removed it. The foreign bodies in the interface were observed under slit-lamp examination

and had no clinical sequelae. In some instances, cap striae (at least 1% incidence at all intervals) was associated with small BCVA decreases. Two retinal detachments occurred at 11 months and more than 1 year after surgery, suggesting that they were unrelated to surgery. Several patients also had early cataracts, but these cataracts were noted before surgery and were therefore not iatrogenic.

Re-treatments. The re-treatment rate for undercorrections in the cohort 2 population was 3.5% (47/1342). This re-treatment rate was higher in cohort 1 eyes due to the intentional undercorrection planned under this earlier protocol. In cohort 1, 14.2% of eyes (162/1140) were re-treated for undercorrection. We also re-treated 19 eyes in cohort 2 and 25 eyes in cohort 1 for overcorrection, although as stated earlier, these eyes were excluded from the data analysis.

Discussion

The results of this study demonstrate that LASIK is an effective and safe alternative for correcting myopia with or without astigmatism. Based on these data, the FDA granted the first approval of an excimer laser system for performing the LASIK procedure.

With LASIK, the surgeon can avoid the need to invade the corneal epithelium, Bowman membrane, and the basal nerve plexus. In our study, LASIK appeared to benefit patients in a number of ways. First, patients in this study did not require extensive pain management. Second, none of the patients in this study required extension of their short-term steroid regimen, because the corrections were accurate and stable. Even though we conservatively determined that stability (defined as a change in spherical equivalent less than l D from visit to visit) occurred between the 3- and 6-month follow-up intervals, stability was achieved in 90.6% of cohort 2 eyes between the 1- and 3-month visits. Although anecdotal, most of our patients were able to see well enough to pass the driver's test on the first or second postoperative day. Third, although the eyes in this study with higher preoperative refractive errors (7 D or greater) were somewhat less likely to achieve UCVA of 20/40 or better and were slightly more likely to experience BCVA loss and complications, the procedure is effective and predictable enough to warrant FDA approval for correcting myopia as high as –15 D and astigmatism to 5 D.

A number of recent studies directly comparing LASIK with PRK in eyes with moderate to high myopia found that LASIK produced superior early results.[11-16] In all of these studies, LASIK-treated eyes had better early UCVA and were associated with less postoperative pain. In several of the studies, LASIK was also associated with a more rapid recovery of BCVA (due to lack of haze) and caused less glare, halos, and diplopia than did PRK.[11-16] One 80-eye trial of eyes with average myopia (–9.25 D)[11] showed that some grade of haze developed in more than one-fourth of PRK-treated patients, whereas no LASIK-treated patient experienced haze. In that study, mean postoperative myopia was –1.5 D ± 0.42 and –0.88 D ± 0.70 in the PRK and LASIK groups, respectively. In addition, 3 of the trials[14-16] showed that efficacy outcomes are generally similar between PRK and LASIK after 6 months and up to 12 months, although additional controlled comparisons are needed to determine the long-term outcomes of the 2 procedures.

In this series, there were no vision-threatening complications; there were no corneal infections, lost or melted caps, anterior chamber perforations, or retinal vascular accidents. Nevertheless, it is important to realize that the potential for serious complications exists, and each stage of the LASIK procedure must be performed with care and control. We learned that one of the critical and sometimes limiting factors is microkeratome function. In addition, lack of fixation during ablation can lead to decentered ablations, which can induce astigmatism and ultimately cause glare, ghost images, and diplopia. With time, we improved our centering strategy, and this may be the reason why the incidence of glare, halos, and problems with night driving were lower in the second cohort.

It should be noted that, in this study population, there was a loss of patients with time. At 6 months, 1402 eyes were evaluated, representing an accountability of 81.1% for cohort 2 and a somewhat lower accountability for cohort 1. To determine whether this affected the validity of the data, we performed 24 additional intra-data-set statistical comparisons. We compared safety and efficacy variables resulting from assessments at 6 months, at the last visit for eyes of patients who did not return for follow-up before the 6-month visit, and at the last visit for eyes not yet due for a 6-month evaluation. Similar comparisons were performed at the 12-month interval. These analyses demonstrated that the data are reliable.

We did observe that, at the upper end of the refractive range (–10 to –13 D), refraction took longer to stabilize. We have since improved the homogeneity of the excimer laser beam and decreased the tolerance of some of the laser calibrations to improve results in these eyes. In addition, while we used a 200-µm postablation corneal thickness as a minimum for this study, we observed that some eyes with ablations to 200 µm had slower visual recoveries. We have since increased this required minimum. For certain patients with thin corneas and with spherical equivalents greater than –10 D, we now consider alternative treatments including phakic lens implants.

In sum, these data demonstrate that, for most patients with myopia or myopic astigmatism who seek and qualify for surgical correction, LASIK is both safe and effective.

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