
200 Hz flying-spot technology of the LaserSight LSX excimer laser in the treatment of myopic astigmatism

Six and 12 month outcomes of laser in situ keratomileusis and photorefractive keratectomy

Aleksandar Stojanovic, MD, Tore A. Nitter, MD

ABSTRACT

Purpose: To evaluate safety, efficacy, predictability, and stability in the treatment of myopic astigmatism with laser in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) using the 200 Hz flying-spot technology of the LaserSight LSX excimer laser.

Setting: SynsLaser Clinic, Tromsø, Norway.

Methods: This retrospective study included 110 eyes treated with LASIK and 87 eyes treated with PRK that were available for evaluation at 6 and 12 months, respectively. The mean preoperative spherical equivalent (SE) was -5.35 diopters (D) ± 2.50 (SD) (range -1.13 to -11.88 D) in the LASIK eyes and -4.72 ± 2.82 D (range -1.00 to -15.50 D) in the PRK eyes. The treated cylinder was 4.00 D in both groups. Eleven (8.5%) LASIK eyes and 8 (7.4%) PRK eyes had secondary surgical procedures before 6 and 12 months, respectively, and were excluded when the 6 and 12 month outcomes were analyzed.

Results: None of the eyes lost 2 or more lines of best spectacle-corrected visual acuity. Seventy-seven percent of the LASIK eyes and 78% of the PRK eyes achieved an uncorrected visual acuity of 20/20 or better; 98% in both groups achieved 20/40 or better. The SE was within ± 0.5 D of the desired refraction in 83% of the LASIK eyes and 77% of the PRK eyes; it was within ± 1.0 D in 97% and 98%, respectively. The cylinder correction had a mean magnitude of error of 0.04 ± 0.31 D (range -0.96 to $+0.85$ D) in the LASIK eyes and 0.02 ± 0.37 D (range -1.44 to $+0.72$ D) in the PRK eyes. Refractive stability was achieved at 1 month and beyond in the LASIK eyes and at 3 months and beyond in the PRK eyes.

Conclusion: The outcomes of this study are comparable to those achieved with lasers that use small-beam technology with a lower frequency, as well as with other types of delivery systems. They suggest that the 200 Hz technology used in the LaserSight LSX excimer laser is safe, effective, and predictable and that with LASIK and PRK the results are stable when treating low to moderate myopia and astigmatism up to 4.0 D. *J Cataract Refract Surg* 2001; 27:1263–1277 © 2001 ASCRS and ESCRS

Photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) have become the main procedures in refractive surgery. The excimer laser technology used in performing PRK and LASIK has evolved from broad-beam, low-frequency, hardware-based systems to small-beam, high-frequency, software-driven systems. Smooth ablations¹ and complex ablation patterns, which are features of the latter technology, are necessary for customized ablation. Customized ablation has become a more realistic treatment approach as a result of recent developments in sophisticated diagnostics such as elevation corneal topography² and wavefront aberrometry.³

There are relatively few studies analyzing the results of PRK and LASIK using excimer lasers with a 1.0 mm or smaller spot delivered at up to 100 Hz⁴⁻⁸; to our knowledge, only 1 study (reporting 3 eyes)³ involves a 200 Hz delivery system.

The purpose of this study was to evaluate safety, efficacy, stability, and predictability in the treatment of myopic astigmatism with LASIK and PRK using the 200 Hz flying-spot technology of the LaserSight LSX excimer laser. The laser features a pair of galvanometric computer-controlled mirrors delivering a 0.84 mm, low fluence (89 mJcm⁻²) Gaussian profile beam in a software-programmed randomized pattern at 200 Hz. It was used in a traditional manner without its eye-tracking device.

Patients and Methods

This retrospective noncomparative study comprised 238 consecutive eyes treated for myopic astigmatism with PRK and LASIK from November 1998 through September 1999 at the SynsLaser Clinic in Tromsø, Norway. The follow-up was 6 months in the LASIK eyes and 12 months in the PRK eyes.

One hundred thirty eyes of 78 patients were treated with LASIK, and 108 eyes of 65 patients were treated with PRK. Only LASIK eyes with complete data at the 1, 3, and 6 month examinations and PRK eyes with complete data at the 1, 3, 6, and 12 month examinations were included in the outcomes analysis. For this reason, 9 LASIK eyes (6.9%) and 13 PRK eyes (12.0%) were excluded. The preoperative demographic data of the excluded eyes were comparable to those of the rest of the group. The preoperative mean manifest spherical equivalent (SE) was -4.24 diopters (D) \pm 1.17 (SD) (range -2.25 to -6.50 D) in the LASIK eyes and -2.83 ± 1.29 D (range -1.00 to -4.88 D) in the PRK eyes, with mean astigmatism of up to 1.00 D in both groups.

Eleven LASIK eyes (8.5%) and 8 PRK eyes (7.4%) had secondary surgical procedures before 6 and 12 months, respectively, and were excluded when these outcomes were analyzed. Their preoperative, preenhancement, and postenhancement data are presented separately. Consequently, 110 LASIK eyes were analyzed at 6 months and 87 PRK eyes were analyzed at 12 months.

The mean patient age was 28.8 ± 9.5 years (range 19 to 52 years) in the LASIK group and 32.5 ± 8.7 years (range 19 to 57 years) in the PRK group. There were 41 men (37.3%) and 69 women (62.7%) in the LASIK group and 32 (36.8%) and 55 (63.2%), respectively, in the PRK group. Patients were at least 18 years old, were free of ocular diseases, and had a stable refraction for the past 2 years. Patients were excluded if they took oral or topical eye medication, were pregnant, or had had eye surgery or disease. Soft contact lenses were discontinued 1 week preoperatively and hard contact lenses, 4 weeks preoperatively. Two surgeons (A.S., A.L.) performed the procedures.

Baseline Refractive Error

The preoperative SE was -5.35 ± 2.50 D (range -1.13 to -11.88 D) in the LASIK group and -4.72 ± 2.82 D (range -1.00 to -15.50 D) in the PRK group. Table 1 shows the distribution of low, moderate, high, and extreme myopia in the 2 groups.

The preoperative cylinder was -1.07 ± 1.01 D (range 0.00 to -5.00 D) in the LASIK group and -0.95 ± 0.93 D (range 0.00 to -4.00 D) in the PRK group. The preoperative cylinder was greater than

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Reprint requests to Alesandar Stojanovic, MD, Fløyvn. 32, 9020 Tromsødalen, Norway. E-mail: aleks@online.no.

Table 1. Distribution of baseline SE.

SE Range (D)	LASIK		PRK	
	Number	(%)	Number	(%)
-0.12 to -3.00	23	(20.91)	31	(35.63)
-3.12 to -6.00	47	(42.73)	31	(35.63)
-6.12 to -10.00	39	(36.37)	21	(28.74)
-10.12 to -16.00	1	(0.91)	4	(4.59)

SE = spherical equivalent; LASIK = laser in situ keratomileusis; PRK = photorefractive keratectomy

2.00 D in 20 LASIK eyes (18.18%) and 11 (12.64%) PRK eyes.

Procedures

The preoperative evaluation included measurement of uncorrected (UCVA) and best spectacle-corrected (BSCVA) visual acuity, cycloplegic refraction, applanation tonometry, corneal topography, ultrasonic pachymetry, slitlamp and dilated fundus examinations, scotopic pupillometry, and tear-film-function assessment. The preoperative corneal thickness and the calculated depth of the excimer laser ablation were evaluated to ensure that 250 μm of posterior corneal stroma were preserved. In these calculations, the treatment zone diameter had to match or exceed the patients' preoperative scotopic pupil size. Approximately 20% of the LASIK candidates were rejected because of insufficient calculated residual stromal depth. The preoperative mean keratometry and the planned refraction change were evaluated in both groups to ensure that the postoperative values were within the 39.0 to 49.0 D range.

Alprazolam (Xanor[®]), 1 mg, was given orally 30 minutes preoperatively; ciprofloxacin 0.3% (Cilox[®]) as well as unpreserved diclofenac 0.1% (Voltaren[®]) eye-drops were applied 30, 15, and 5 minutes preoperatively for both PRK and LASIK.

Photorefractive Keratectomy

All PRK procedures were done sequentially, starting in the nondominant eye and operating on the second eye after 1 to 3 months. Unpreserved oxybuprocaine 0.4% (Oxibuprokain[®]) drops were applied before the epithelium was removed with the Amoils epithelial scrubber (Innovative Excimer Solutions, Inc.). The epithelium was removed to a diameter of 8.0 mm, exposing Bowman's layer. After the laser ablation, the cornea was hy-

drated with 2.5 mL of chilled balanced salt solution (BSS[®]) and a bandage contact lens (Biomedics 55, American Hydron) was applied.

Unpreserved Voltaren was used 4 times the first postoperative day, while the mixture of dexamethasone 0.1% and chloramphenicol 0.5% drops (Spersadex[®] med kloramfenikol) was used 4 times a day during the first month. Dexamethasone drops were used between 1 and 3 months, tapered in each patient depending on the amount of myopia corrected and the amount of postoperative regression and/or haze. In patients with preoperative myopia of -6.0 D or more, dexamethasone drops were tapered from 4 times a day during the first month to 1 to 2 times a day through the third month even if there was no haze. Patients with less myopia were treated the same way if the haze grade was greater than 0.5, if regression was diagnosed at 1 month, or both; otherwise dexamethasone drops were tapered to zero within 2 weeks after the 1 month examination. The bandage contact lens was removed after 3 to 5 days upon confirmation of reepithelialization by biomicroscopy.

Use of ultraviolet (UV)-protective eyewear was strongly recommended during the first year after PRK, especially if there was a danger of high UV exposure (reflection from snow or water, high altitudes, low latitudes, thinning in the ozone layer). Vitamin C, 1000 mg daily, was used 2 weeks preoperatively and 2 weeks postoperatively. The same daily dose was used when the threat of abundant UV radiation was present.⁹

Laser in Situ Keratomileusis

Bilateral simultaneous surgery was performed in 102 eyes (93%). The skin was prepared with a povidone-iodine swab, and the lids were enclosed with a "LASIK drape" (1022, 3M). An adjustable aspiration speculum (Geuder) was used for eyelid retraction. Proparacaine

hydrochloride 0.5% (Alcaine®) drops were applied and fornices swabbed with a microsurgical sponge. The cornea was marked with a Dulane LASIK marker (Katena) dipped in methylene blue. A superior-hinge-type microkeratome (Hansatome, Bausch & Lomb) was used. The suction ring was placed on the eye with approximately 0.5 mm superior decentration relative to the pupil to accommodate larger flaps.

A 9.5 or 8.5 mm ring diameter was used, based on the preoperative keratometry as well as the white-to-white diameter. For K-values between 40.0 and 45.0 D, a 9.5 mm ring was used unless the white-to-white diameter was less than 11.5 mm, in which case an 8.5 mm ring was used. It was not used if the K-values were lower than 42.0 D. For K-values above 45.0 D, an 8.5 mm ring was always used. After the suction was activated, an IOP of >65 mm Hg was verified using the Barraquer tonometer.

The cornea was moistened using a "dripping wet" microsurgical sponge soaked in Alcaine. The microkeratome head with a 180 μm fixed plate was engaged, and a superior hinge lamellar flap was created during the forward motion of the microkeratome. Once the microkeratome reached the stop, the suction was turned off, the microkeratome head reversed, and the microkeratome lifted. A Chayet LASIK drain (Visitec), lightly moistened with BSS, was applied, covering a 2.0 mm wide circular zone around the limbus, preventing reflux toward the cornea. The completed flap was reflected using the Mendez LASIK forceps (Katena). The stromal bed was dried with a microsurgical sponge prior to the laser ablation in case fluid accumulation was noticed under the hinge.

The oblique laser microscope lights were dimmed during the laser ablation to help patients fixate. After the ablation, a single drop of unpreserved chloramphenicol 0.1% was applied and evenly distributed on the stromal bed; after 2 seconds, it was wiped off with a Meroce® sponge (Solan) before the flap was repositioned using the Rubenstein LASIK multiport cannula (ASICO). The laser microscope magnification was increased from 1.6 to 2.4, and the interface was inspected under the laser system's dual oblique illumination. Interface irrigation was performed with the Rubenstein cannula. The flap was then gently stroked with the same cannula, squeezing out the excess fluid. One drop of Cilox and 1 drop of Voltaren were applied to the corneal surface.

According to a protocol proposed by Jack Holladay, MD, 1 drop of unpreserved sodium chloride 5% was applied for 30 seconds (M. Lipner, "Trolling for Lamellar Pearls," *EyeWorld*, October 1999, pages 47–48). After the eyelid retractor and the draping were removed, the patient was examined with a slit-lamp microscope and placed in a supine position for 20 to 30 minutes, blinking normally to help remove any superficial edema by evaporation.

In both LASIK and PRK, the ablated optical zone was maximized to match or exceed the patient's preoperative scotopic pupil size, ranging from 5.5 to 7.5 mm, with a tapering transition zone of 6.5 to 8.5 mm. The desired spherical and cylinder corrections were entered into the laser system with no adjustments to the desired treatment. When astigmatism was treated, the laser software would automatically match the shortest axis length of the oval ablation to the desired optical zone.

All ablations were centered on the entrance pupil, while the patient fixated coaxially, by targeting the laser fixation light. The operating room was maintained at a constant temperature of 20°C to 22°C and humidity of 35% to 40%.

Follow-up examinations were performed by the surgeon 1 day, 1 week, and 1, 3, 6, and 12 months postoperatively. Patients were encouraged to report any loss of quality or quantity of vision as soon they noticed it.

Data Analysis

To calculate the mean visual acuity and changes, all visual acuity measurements were converted from Snellen to the logarithm of the minimum angle of resolution (logMAR) using the following equation: $\log\text{MAR} = \log_{10}(\text{Snellen VA})^{-1}$.¹⁰ Vector analysis was used to analyze the changes in spherocylinders according to the Alpins method.¹¹ Targeted induced astigmatism (vector of intended change in cylinder) and surgically induced astigmatism (SIA) (vector of the actual change in cylinder) were evaluated. Cylinder values were kept in minus format throughout the study. The refractive outcome of astigmatism was represented as the magnitude of error and angle of error. Positive and negative values of the magnitude of error represent overcorrections and undercorrections, respectively. Positive and negative values of the angles of error represent clockwise and anticlockwise deviations, respectively.

A scale of 0 to 4 was used to quantify haze: 0 = clear cornea; 0.5 = trace of opacity; 1 = mild not affecting refraction; 2 = moderate with difficult refraction; 3 = opacity that prevents refraction; 4 = unable to view anterior chamber.¹²

Centration of the ablation was measured as the distance between the center of the entrance pupil and the center of the ablation zone, registered on a difference map of the preoperative and postoperative topographies. The Tomey TMS-2 cornea topographer was used. Measurements and calculations were done according to the methodology described by Cooper et al.⁸

The safety index (mean postoperative BSCVA/mean preoperative BSCVA), efficacy index (mean postoperative UCVA/mean postoperative BSCVA), and other results are presented in accordance with the recommended format.¹³ Surgically induced refractive change was calculated by use of vector analysis.^{11,14}

Double angle plots were used to represent the magnitudes and angles of error for SIA. The angles of error are doubled so 180 degrees of astigmatism are stretched over 360 degrees of the polar diagram. The undercorrections and overcorrections are shown to the left and right of the vertical axis, respectively. Undercorrections and overcorrections with zero angles of error are shown along the horizontal axis. Results with no zero angles of error are shown above or below the horizontal axis, with maximum angles of error along the vertical axis. For the same magnitude of error (same distance from the center), the points closest to the horizontal axis represent the best results.

Results

Safety

Figures 1 and 2 show the change in Snellen lines of BSCVA. No eye in the LASIK or PRK group lost 2 or more lines at 6 and 12 months, respectively.

Among the LASIK eyes, 6.4% lost 1 line of BSCVA, and among the PRK eyes, 14.9% lost 1 line. The difference was not statistically significant ($P = .09$, 2-tailed Fisher exact test). Table 2 shows the distribution of eyes that lost 1 line of BSCVA, grouped by the level of preoperative myopia. The difference between LASIK and PRK eyes was not statistically significant in any range.

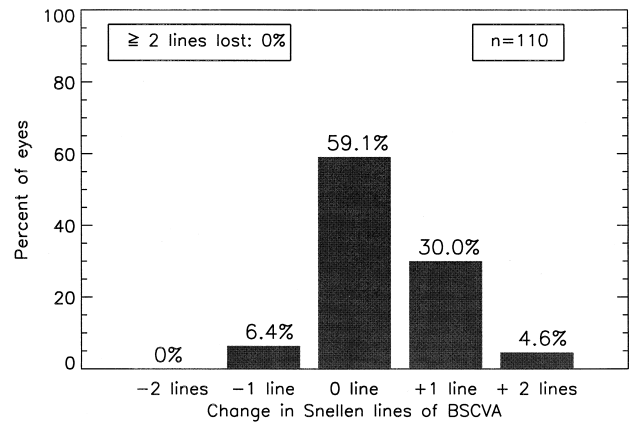


Figure 1. (Stojanovic) Change in BSCVA in the LASIK group at 6 months.

The safety index was 1.07 in the LASIK group and 1.06 in the PRK group.

Efficacy

Eyes targeted for myopia, as well as eyes with a preoperative BSCVA worse than 20/20, were excluded when efficacy was analyzed. Thirty LASIK eyes and 23 PRK eyes were targeted for myopia; 29 LASIK eyes and 18 PRK eyes had a preoperative BSCVA worse than 20/20. Efficacy was analyzed in 64 LASIK eyes and 54 PRK eyes.

At 6 and 12 months, the UCVA was 20/20 or better in 76.6% ($n = 49$) of the LASIK eyes and 77.7% ($n = 42$) of the PRK eyes, respectively; it was 20/40 or better in 98.4% ($n = 63$) and 98.1% ($n = 53$), respectively.

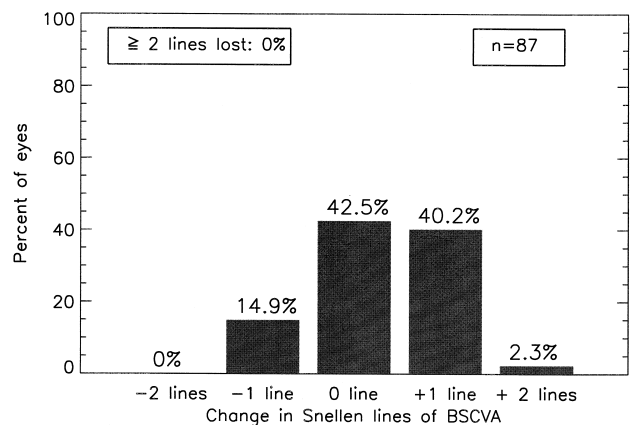


Figure 2. (Stojanovic) Change in BSCVA in the PRK group at 12 months.

Table 2. Eyes with loss of 1 line of BSCVA.

Range (D)	Treatment	Number of Eyes	Lost 1 Line of BSCVA	
			Number	(%)
-0.12 to -3.00	LASIK	23	1	(4)
	PRK	31	1	(3)
-3.12 to -6.00	LASIK	47	3	(6)
	PRK	31	7	(22)
-6.12 to -10.00	LASIK	39	3	(8)
	PRK	21	5	(23)
-10.12 to -16.00	LASIK	1	0	(0)
	PRK	4	0	(0)

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis; PRK = photorefractive keratectomy

The efficacy index was 0.93 (n = 80) in the LASIK group and 0.90 (n = 64) in the PRK group at 6 and 12 months, respectively (eyes with a preoperative BSCVA worse than 20/20 included in this calculation). Figures 3 and 4 show the UCVA in the LASIK and PRK groups at the 6 month and 12 month examinations, respectively.

When eyes that had enhancement procedures before the evaluation points were added to the cohort above, using the same inclusion criteria, the number of cases evaluated for efficacy increased by 5 LASIK eyes and 4 PRK eyes. Preenhancement UCVA in these additional cases was used for the new calculation. In this new cohort, consisting of 69 LASIK eyes and 58 PRK eyes, the UCVA was 20/20 or better in 71.0% (n = 49) of LASIK eyes and 72.4% (n = 42) of PRK eyes and 20/40 or better in 95.6% (n = 66) and 96.6% (n = 56), respectively.

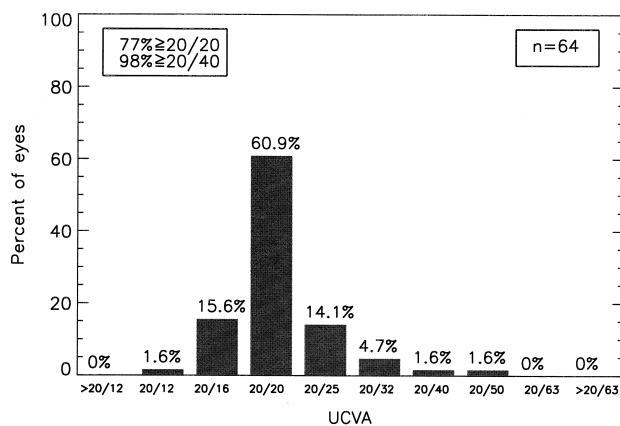


Figure 3. (Stojanovic) Distribution of in LASIK eyes at 6 months.

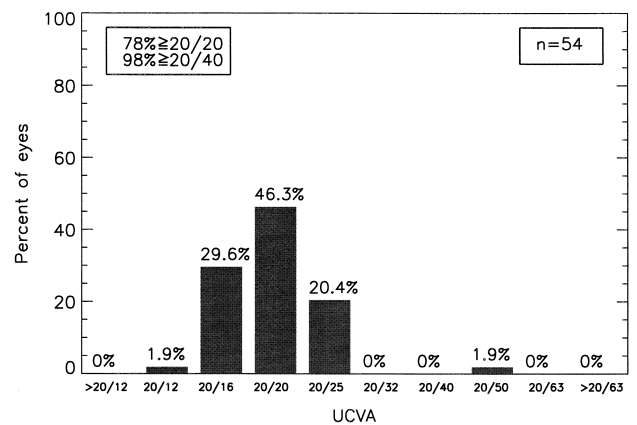


Figure 4. (Stojanovic) Distribution of UCVA in PRK eyes at 12 months.

Predictability

The mean manifest SE was -0.11 ± 0.49 D (range -2.0 to $+1.0$ D) in the LASIK group and -0.02 ± 0.44 D (range -1.1 to $+1.0$ D) in the PRK group at 6 and 12 months, respectively. In the LASIK group, 82.7% (91 of 110 eyes) were within ± 0.5 D of the intended SE refraction and 97.3% (107/110 eyes) were within ± 1.0 D after 6 months. In the PRK group, 77.0% (67/87 eyes) were within ± 0.5 D and 97.7% (85/87 eyes) were within ± 1.0 D after 12 months.

Figures 5 and 6 are scatter diagrams showing the attempted versus achieved SE in the LASIK and PRK groups at 6 and 12 months, respectively.

Table 3 shows the refractive outcome in the LASIK and PRK groups according to the attempted SE correc-

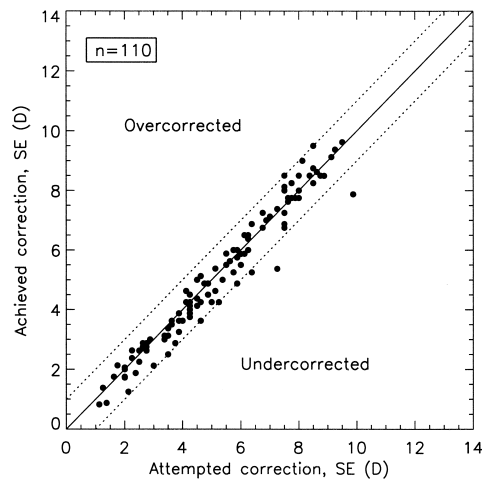


Figure 5. (Stojanovic) Attempted versus achieved SE in LASIK eyes at 6 months (solid diagonal line indicates zero error; dotted lines indicate ± 1.0 D).

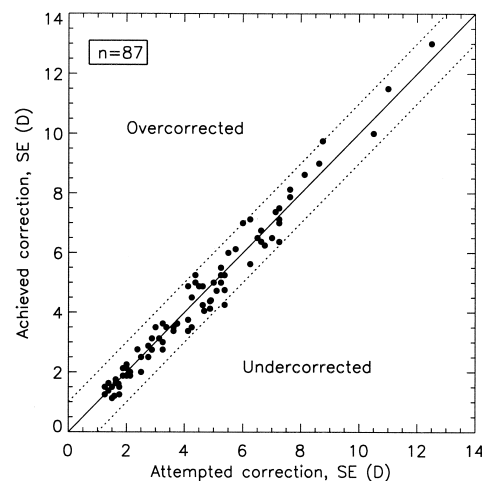


Figure 6. (Stojanovic) Attempted versus achieved SE in PRK eyes at 12 months (solid diagonal line indicates zero error; dotted lines indicate ± 1.0 D).

tion. Figures 7 and 8 show the refractive outcome according to the postoperative SE in the LASIK and PRK groups at 6 and 12 months, respectively.

Two LASIK eyes (1.8%) and 1 PRK eye (1.1%) were overcorrected by 1.0 D (SE) at 6 and 12 months, respectively.

When cases that had enhancement procedures before the evaluation points were added to the cohorts above, the number of eyes for evaluation of predictability increased by 11 LASIK eyes and 8 PRK eyes. Preenhancement refractive outcomes in these additional eyes were used for calculations. In the new cohort

(121 LASIK eyes and 95 PRK eyes), 76.9% ($n = 93$) of the LASIK eyes and 70.5% ($n = 67$) of the PRK eyes were within ± 0.5 D of the intended SE refraction and 92.6% ($n = 112$) and 90.5% ($n = 86$), respectively, were within ± 1.0 D.

Predictability of the Astigmatic Correction

Eleven LASIK eyes and 12 PRK eyes with zero preoperative astigmatism had no astigmatic correction and were excluded from analysis of the astigmatic correction. Ninety-nine LASIK eyes and 75 PRK eyes were analyzed. The mean magnitude of error was 0.03 ± 0.31 D (range -0.96 to $+0.85$ D) in the LASIK eyes and 0.05 ± 0.38 D (range -1.44 to $+0.72$ D) in the PRK eyes at 6 and 12 months, respectively. The angle of error was 1.8 ± 11.3 degrees (range -42.3 to $+37.5$ degrees) in the LASIK eyes and 1.3 ± 12.5 degrees (range -40.0 to $+42.5$ degrees) in the PRK eyes at 6 and 12 months, respectively. When the 40 LASIK and 33 PRK eyes with preoperative astigmatism greater than 0 D and less than 0.5 D were excluded, the mean magnitude of error was 0.00 ± 0.35 D (range -0.96 to $+0.85$ D) in the LASIK eyes and -0.15 ± 0.42 D (range -1.44 to $+0.72$ D) in the PRK eyes at 6 and 12 months, respectively; the angle of error was 1.0 ± 6.0 degrees (range -15.7 to $+16.8$ degrees) in the LASIK eyes and 0.2 ± 4.9 degrees (range -9.0 to $+14.5$ degrees) in the PRK eyes at 6 and 12 months, respectively.

Figures 9 and 10 show the magnitudes and angles of error in the LASIK and PRK groups at 6 and 12 months, respectively.

Stability

Table 4 summarizes the stability of the manifest SE refraction from 1 to 3 months, 3 to 6 months, and 6 to 12 months. The refractive stability was evident at 1 month and beyond in LASIK eyes and at 3 months and beyond in PRK eyes. The requirement for refractive stability was that at least 95% of eyes must have a change of 1.0 D or greater between 2 examinations at least 1 month apart. Figures 11 and 12 show the change over time of the manifest SE refraction in LASIK and PRK eyes.

Centration Analysis

The preoperative topography maps and the maps from the 6 month examination in LASIK eyes and the

Table 3. Refractive outcomes in LASIK eyes at 6 months and in PRK eyes at 12 months postoperatively.

Attempted SE (D)	Within ±0.5 D				Within ±1.0 D				Within ±2.0 D			
	LASIK		PRK		LASIK		PRK		LASIK		PRK	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
-0.12 to -3.00	18	(78)	27	(87)	23	(100)	31	(100)	23	(100)	31	(100)
-3.12 to -6.00	38	(81)	25	(81)	46	(98)	31	(100)	47	(100)	31	(100)
-6.12 to -10.00	35	(87)	13	(62)	38	(95)	20	(95)	40	(100)	21	(100)
-10.12 to -12.50	0		2	(50)	0		3	(75)	0		4	(100)

LASIK = laser in situ keratomileusis; PRK = photorefractive keratectomy; SE = spherical equivalent

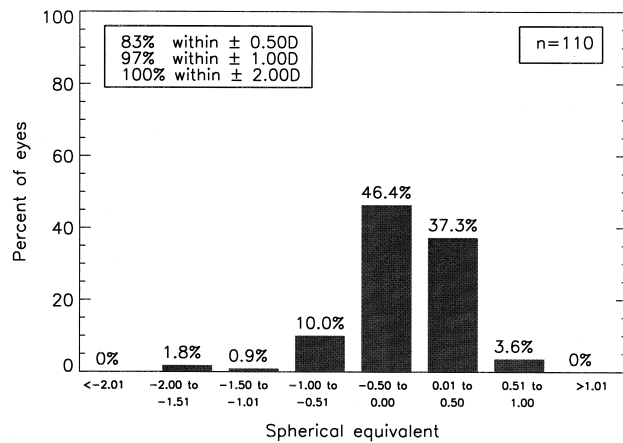


Figure 7. (Stojanovic) Distribution of refractive outcomes in LASIK eyes at 6 months.

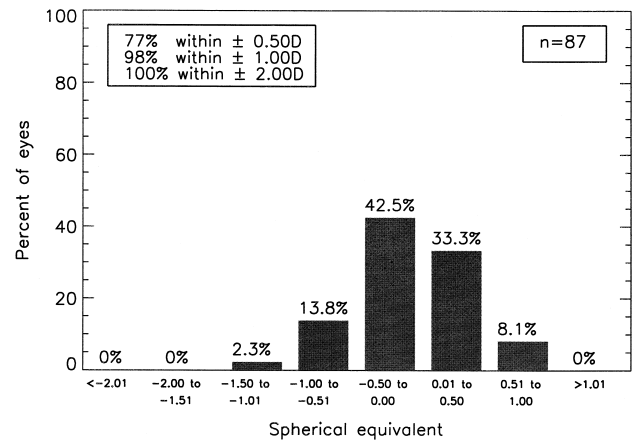


Figure 8. (Stojanovic) Distribution of refractive outcomes in PRK eyes at 12 months.

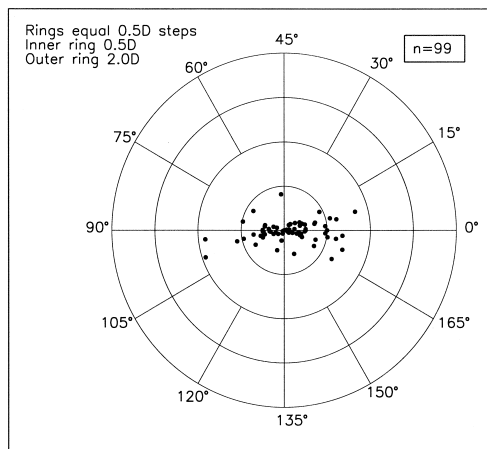


Figure 9. (Stojanovic) Double-angle plot representing the magnitude of error and angle of error for SIA in LASIK eyes at 6 months.

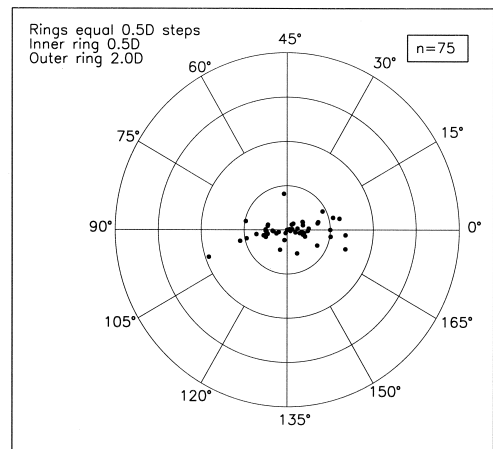


Figure 10. (Stojanovic) Double-angle plot representing the magnitude of error and angle of error for SIA in PRK eyes at 12 months.

12 month examination in PRK eyes were available for 82 LASIK eyes (74.5%) and 61 PRK eyes (70.1%) and were used to measure the ablation centration.

The mean decentration was 0.57 ± 0.28 mm (range 0.12 to 1.45 mm) in LASIK eyes and 0.49 ± 0.26 mm (range 0.18 to 1.23 mm) in PRK eyes. The decentration was less than 0.50 mm in 39 LASIK eyes (47.6%) and

Table 4. Stability of MRSE.

Change in MRSE (D)	Between 1 and 3 Months				Between 3 and 6 Months				Between 6 and 12 Months	
	LASIK (n = 110)		PRK (n = 87)		LASIK (n = 110)		PRK (n = 87)		PRK (n = 87)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
≤0.50	103	(94)	65	(75)	105	(95)	72	(83)	84	(97)
≤1.00	108	(98)	81	(93)	110	(100)	86	(99)	85	(98)

MRSE = manifest refraction spherical equivalent; LASIK = laser in situ keratomileusis; PRK = photorefractive keratectomy

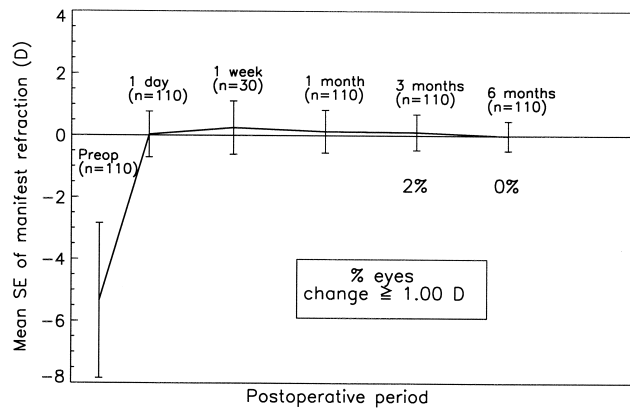


Figure 11. (Stojanovic) Stability of refraction in LASIK eyes. The graph depicts the change in the mean SE manifest refraction during the observation period. Error bars represent 1 standard deviation. The number of eyes examined at each interval is in parentheses. The percentages of eyes changing the mean SE manifest refraction by 1.00 D or more from the previous point are placed under the error bars.

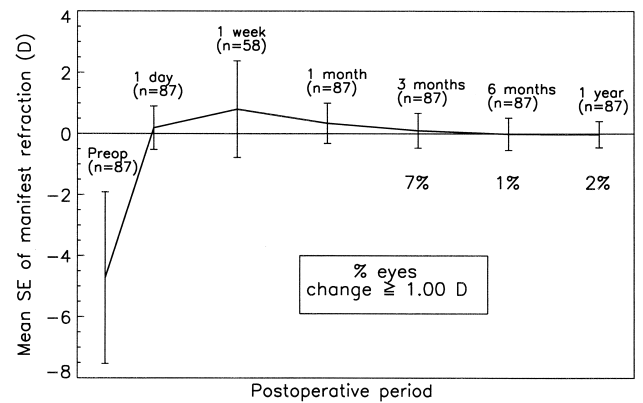


Figure 12. (Stojanovic) Stability of refraction in PRK eyes. The graph depicts the change in the mean SE manifest refraction during the observation period. Error bars represent 1 standard deviation. The number of eyes examined at each interval is in parentheses. The percentages of eyes changing the mean SE manifest refraction by 1.00 D or more from the previous point are placed under the error bars.

36 PRK eyes (59.0%), between 0.50 and 1.00 mm in 40 LASIK eyes (48.7%) and 23 PRK eyes (37.7%), and over 1.00 mm in 3 LASIK eyes (3.7%) and 2 PRK eyes (3.3%). Table 5 shows the direction and amount of decentration. Decentration was defined as inferior if it occurred between semimeridians of 225 degrees and 315 degrees, superior; between 45 degrees and 135 degrees, nasal (for right eyes) and temporal (for left eyes); between 315 degrees and 45 degrees and temporal (for right eyes) and nasal (for left eyes); between 135 degrees and 225 degrees.

Secondary Surgical Modifications

Eleven LASIK eyes (8.5%) and 8 PRK eyes (7.4%) had secondary surgical procedures. Indications were undercorrections or overcorrections of more than 0.5 D when desired by patients. The secondary surgical proce-

dures were performed between 2 and 5 months postoperatively in LASIK eyes and between 4 and 8 months postoperatively in PRK eyes. The preenhancement mean manifest SE was -1.56 ± 0.49 D (range -1.00 to -2.50 D) in the LASIK group and -1.36 ± 0.51 D (range -0.38 to -2.13 D) in the PRK group; the original preoperative mean manifest SE was -6.58 ± 1.88 D (range -3.50 to -9.25 D) in the LASIK group and -4.91 ± 0.99 D (range -3.75 to -6.75 D) in the PRK group.

Outcomes analysis 3 months after the secondary surgery showed a mean manifest SE of $+0.16 \pm 0.29$ D (range -0.50 to $+0.50$ D) in the LASIK group and $+0.45 \pm 0.28$ D (range 0.00 to $+0.88$ D) in the PRK group. In the LASIK group, 100% (all 11 eyes) were within ± 0.5 D of the desired SE. In the PRK group, 62.5% (5 of 8 eyes) were within ± 0.5 D of the desired

Table 5. Centration outcomes in LASIK eyes (n = 82) and PRK eyes (n = 61) distributed over 4 quadrants.

Decentration (mm)	Inferior				Superior				Nasal				Temporal			
	LASIK (n = 40)		PRK (n = 30)		LASIK (n = 1)		PRK (n = 1)		LASIK (n = 22)		PRK (n = 15)		LASIK (n = 19)		PRK (n = 15)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
<0.50	17	(21)	18	(31)	0	0			11	(13)	10	(16)	11	(13)	7	(12)
0.50 to 1.00	20	(24)	10	(16)	1	(1)	1	(2)	11	(13)	5	(9)	8	(10)	8	(13)
>1.00	3	(4)	2	(3)	0	0			0		0		0		0	

LASIK = laser in situ keratomileusis; PRK = photorefractive keratectomy

SE and all 8 eyes were within ± 1.0 D. The safety index was 1.00 in the LASIK group and 1.06 in the PRK group, and the efficacy index was 0.93 and 0.89, respectively.

Complications

No significant sight-threatening complications occurred in either group. A free cap occurred in 1 eye (0.9%) in the LASIK group. The cap was replaced after ablation, and the postoperative course was uneventful.

In 2 eyes (1.8%) in the LASIK group, both treated for moderate myopia with astigmatism of 0.5 D, epithelial ingrowths developed and were diagnosed at the 1 month examination. At that time, the patients complained about a foreign-body sensation. The eyes were treated by lifting the flap and removing the epithelium, after which they had an uneventful postoperative course. Before the enhancement and at 3 and 6 months, the SE in both eyes was within ± 0.5 D of the attempted outcome.

One eye with a preoperative manifest refraction of $-7.25 -0.25 \times 10$ and a BSCVA of 20/15 that had uneventful LASIK developed striae. One day postoperatively, a light stromal edema and folds in Descemet's membrane were noted; the BSCVA was 20/30, with a manifest refraction of $-0.50 -0.75 \times 20$. The patient did not show up at the 1 week examination; he complained of a reduction in visual acuity at the 1 month examination. Horizontal striae in the ablation area were diagnosed, and the BSCVA was reduced to 20/40, with a manifest refraction of $-1.25 -1.25 \times 15$. The epithelium over the area with striae was removed, and the flap was lifted, hydrated, and stretched before it was repositioned. A bandage contact lens was placed and remained for 4 days after the treatment. Most of the striae had

disappeared when the contact lens was removed, and the BSCVA improved to 20/20, corrected with $-0.50 -0.25 \times 10$. At 6 months, there were no striae noticeable at the slitlamp examination; the UCVA was 20/25 and the BSCVA 20/20, corrected with $-0.50 -0.25 \times 15$.

Complaints of moderate night-vision problems with glare and/or halos were reported in 4 LASIK eyes (3.6%) and 3 PRK eyes (3.4%). The preoperative SE in all these eyes was between -6.12 and -16.00 D. The night-vision problems were noted as answers to questions about patients' complaints in general; the patients were not questioned specifically about their night vision.

An increase in intraocular pressure (IOP) did not occur in the LASIK group and was uncommon in the PRK group, in which 3 eyes (3.4%) had readings above 25 mm Hg at 3 months. The eyes reached their preoperative IOP levels after the topical steroid treatment was discontinued.

One eye with a preoperative manifest refraction of $-4.25 -0.25 \times 10$ and an uneventful PRK showed delayed epithelial healing; reepithelialization was completed 7 days postoperatively. At 1 month, the UCVA was 20/50 and the BSCVA 20/30, with a refraction of $-0.75 -0.50 \times 0$ and a haze grade of 1. At 3 months, the UCVA decreased to 20/60, the BSCVA remained 20/30, and regression to $-1.25 -0.50 \times 0$ occurred; the haze peaked to grade 1.5. Dexamethasone drops were used 4 times a day through the fourth month and tapered to 3 times a day and 2 times a day during the fifth and sixth months, after which time they were discontinued. With this treatment, haze decreased to grade 1 at 6 months and spontaneously decreased further to grade 0.5 at 12 months. This eye had a UCVA of

20/25 and a BSCVA of 20/20 with a refraction of $-0.50 -0.50 \times 5$ at 12 months.

Postoperative haze was absent in the LASIK eyes, but it occurred in the PRK group (grade 0.5 to 1.5), reaching a peak at 3 months. It was graded higher than trace in only 3% of PRK eyes, and it occurred only in eyes whose SE ranged between -6.12 and -10.00 D. The mean haze score and grade at 1, 3, 6, and 12 months postoperatively is shown in Table 6. No haze was associated with a loss of BSCVA. Eyes with late-onset corneal haze were not observed in this cohort.

Discussion

A 6 month follow-up for LASIK and a 12 month follow-up for PRK were chosen because postoperative stability of these procedures is considered to be reached well before these points. Polunin and coauthors¹⁵ suggest that corneal optical density increases during the first postoperative month and returns to normal 2 to 3 months after PRK and 3 to 4 weeks after LASIK. Our LASIK cases reached refractive stability at 1 month and our PRK cases, at 3 months.

Controlled trials of LASIK versus PRK show that outcomes in these 2 groups at 6 and 12 months, respectively, are very similar.¹⁶⁻²³ The same conclusion can be drawn from the results of this study, but LASIK has the advantages of minimal postoperative discomfort,^{20,24} rapid recovery of clear vision, and stabilization of the refractive change,^{20,22,25} as well as the absence of haze.²⁴ These factors make LASIK the patients' preferred procedure.²¹ However, Oshika et al.²⁶ show that both PRK and LASIK increase the wavefront aberrations and with a large pupil, LASIK induces more spherical aberrations than PRK.

The results of our study can be compared to the results with a 60 Hz, 1.0 mm flying-spot Autonomous laser,⁴ as well as to those with a scanning-slit Nidek laser.¹⁷ Table 7 compares the predictability and efficacy of the 3 systems. As in our study, the studies with the other 2 platforms show 12 month PRK outcomes that do not include the retreated eyes in their calculation of efficacy and predictability. Their retreatment rates are similar to ours, 10.9% in the Autonomous study and 9.3% in the Nidek study.

Attempts to reduce optical aberrations by enlarging the ablation zone size lead to significantly increased ablation volume, which places greater demands on ablation smoothness since the surface irregularities increase with the ablation depth.²⁷ All the factors affecting corneal smoothness after excimer laser ablation have not been identified, and to our knowledge there is only 1 study that establishes a connection between the ablation smoothness and the quality of outcomes. In that study, Vinciguerra et al.²⁸ observe that eyes with the most postoperative ablation regularity had a "sharply" lower incidence of haze and a better refractive outcome. According to O'Donnell and coauthors,¹ galvanometric scanning delivery systems produce ablations approximately 3 times smoother than the iris diaphragm with a beam homogenizer, which produces ablations about twice as smooth as the iris diaphragm without a beam homogenizer. However, Krueger⁶ suggests that eye tracking is necessary for accurate placement of each laser pulse on the ablation zone to achieve a smooth treatment with a small scanning-spot laser. To our knowledge, this assertion is not supported by an in vitro or clinical study that analyzes and compares the ablation smoothness in comparable systems with and without eye tracking.

Table 6. Postoperative haze in PRK eyes.

Time (Month)	Mean Score \pm SD	Grade of Haze, Number of Eyes (%)			
		0.0	0.5	1.0	1.5
1	0.16 \pm 0.28	59 (68)	26 (30)	1 (1)	1 (1)
3	0.16 \pm 0.31	61 (70)	23 (26)	1 (1)	2 (2)
6	0.10 \pm 0.25	70 (80)	15 (17)	1 (1)	1 (1)
12	0.10 \pm 0.21	71 (82)	15 (17)	1 (1)	0

Scale 0-4: 0 = clear cornea; 0.5 = trace of opacity; 1 = mild not affecting refraction; 2 = moderate with difficult refraction; 3 = opacity that prevents refraction; 4 = unable to view anterior chamber

Table 7. Twelve month outcomes with PRK for low-to-moderate myopia with astigmatism.

Outcomes	Laser System		
	LaserSight LSX (n = 54/87)	Autonomous (n = 116/119) ⁴	Nidek EC (n = 82/82) ²⁹
UCVA, n (%)			
≥20/20	68 (78)	80 (62)	70 (85)
>20/40	85 (98)	113 (97)	80 (98)
Achieved correction, n (%)			
Within ±0.5 D	67 (77)	88 (74)	68 (83)
Within ±1.0 D	85 (98)	113 (95)	77 (94)

UCVA = uncorrected visual acuity

Numbers in parentheses beneath laser name represent the size of the group for UCVA and achieved correction, respectively.

Another commonly expressed view is that treatments with 1.0 mm scanning-spot lasers carry an increased risk for decentration.⁸ We agree with this view as long as the use of this technology implies a prolonged ablation time. However, ablation times with a 200 Hz LaserSight LSX system are comparable to the ablation times with scanning-slit and 2.0 mm scanning-spot lasers.

To achieve optimal ablation centration, 2 conditions must be met throughout the procedure: The laser's aiming beam must be centered on the entrance pupil, and the patient's fixation must be coaxial with the laser beam. Centration of the laser is achieved manually or through the use of an eye tracker. Fixation is maintained by the patient's active observation of a targeting light that is coaxial with the laser beam. A certain amount of decentration of the ablation will occur whenever a patient loses fixation irrespective of the surgeon or the eye tracker maintaining the centration perfectly on the entrance pupil. This decentration will, in our opinion, occur because of the parallax between the real pupil and its projection on the corneal surface—entrance pupil. In cases lacking perfect coaxiality, which occurs whenever a patient's fixation is lost, displacement of the pupillary projection on the corneal surface will also occur and the surgeon or the eye tracker will then aim at the wrong target. Figure 13 illustrates a decentered ablation in a nonfixating eye despite the surgeon's/eye tracker's centration on the entrance pupil.

The mean decentration in the PRK-treated eyes in our study was comparable to the decentration results in the PRK eyes (n = 49) treated with the Autonomous system (0.42 ± 0.28 mm; range 0.05 to 1.30 mm).⁸

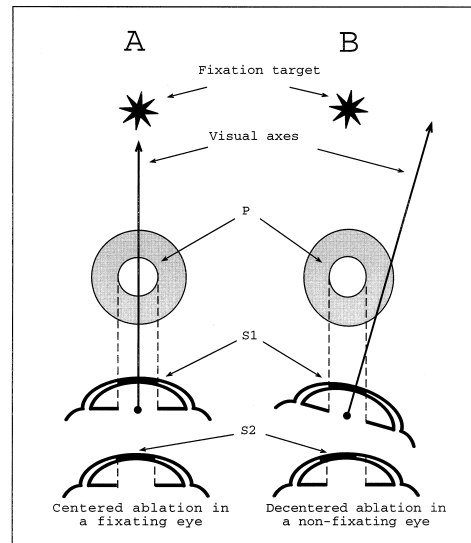


Figure 13. (Stojanovic) Relationship between the patient's fixation and the ablation centration. *A*: When the patient is fixating. *B*: When the patient is not fixating. In both cases, the surgeon and/or the eye tracker is centering on the entrance pupil (P). The side view (S1) shows the pupillary projection on the corneal surface in a fixating and a nonfixating eye, while the side view (S2) shows that the ablation is decentered in the nonfixating eye.

Both are comparable to the reported mean decentrations of the broad-beam lasers that did not use an eye-tracker—0.52 mm,²⁹ 0.40 mm,³⁰ 0.47 mm,³¹ 0.46 mm,³² 0.62 mm,³³ 0.46 mm,³⁴ 0.48 mm,³⁵ 0.34 mm,³⁶ and 0.43 mm.³⁷

Decentration of the ablation in our study, similar to those in several other studies^{32,35,36,38} occurred most often inferiorly. Table 6 shows that in our study, inferior decentration occurred in 49% of cases. In nearly half of our cases, nasal (25%) or temporal (25%) decentrations occurred; in a few cases (1%), superior decentration oc-

curred. An inferior decentration might be explained by Bell's phenomenon, in which the globe rotates upward because of attempted eye closure. In this case, the center of the entrance pupil, as seen by a surgeon or by an eye tracker, projects on the cornea with an inferior displacement. Temporal, nasal, and superior decentrations can be explained in a similar way, by esophoria, exophoria, and hypophoria. In all these situations, the patient loses fixation and the eye slowly drifts,³⁶ causing a global tilt, while the surgeon (or the eye tracker) follows the entrance pupil "assuming that the ablation centration is still perfect."

Assurance of the patient's fixation during the entire ablation time is crucial if good ablation centration is to be achieved manually or through the use of an eye tracker. An eye tracker is an excellent device that ensures that the laser pulses are centered around the pupil as seen from the eye tracker's imaging device, thereby improving on the surgeon's manual centration and catching the saccadic movements of the eye.

An eye tracker, however, cannot compensate for the lack of patient fixation. According to Kim et al.,³⁹ the lack of fixation can occur because of haziness of the dried ablated corneal surface, which may compromise the patient's view of the targeting light, Bell's phenomenon, heart pulsation, or voluntary movements. These factors should be considered when we try to explain why the centration outcomes of the Autonomous laser,⁸ which presumably has the most sophisticated eye-tracking system currently available, are not better than the published outcomes of other eye-tracking⁴⁰ or non-eye-tracking systems^{29-32,34,35} currently available. Tsai and Lin,⁴⁰ who analyzed centration of a Schwind laser with eye-tracking, conclude that a tracking system alone cannot ensure good centration and that the influence of patient-related factors is significant. The true value of eye tracking in the treatment of myopia with low to moderate astigmatism has to be shown by a comparative study of outcomes with and without the use of an eye tracker.

In our study, the small number of eyes with postoperative PRK haze graded >0.5 might be the result of the smooth ablation achieved with our laser, combined with the operative and postoperative protocols that involved the use of the Amoils epithelial scrubber, chilled BSS, bandage contact lenses, vitamin C, and tapering steroids and the meticulous use of UV-protective eyewear with every exposure to sunlight during the first postoperative

year. No cases of late-onset corneal haze were registered, presumably because our study concerns relatively small groups and late-onset corneal haze occurs with a relatively low incidence of 1% to 4%.⁴¹⁻⁴³ This complication is nevertheless considered one of the main disadvantages of PRK.

The relatively small percentage of patients who complained of night-vision problems can be explained by the use of large treatment zones that matched the preoperative scotopic pupil size by the rejection of LASIK candidates with large pupils whose preoperative pachymetry would not allow the use of the appropriate treatment zones. Several investigators have suggested that using an ablation zone that matches or exceeds the scotopic pupil size might reduce symptoms such as glare and halos.^{32, 44, 45} With a large optical zone, optical edge effects might be reduced and when the entrance pupil is large, the surface area of the cornea focusing light properly is much greater.

A high-frequency, small, flying-spot excimer laser delivery approach has been available since the early 1990s,⁴⁶ but only recently has this approach become popular because of the smooth ablation¹ and flexibility in ablation patterns. Some originally wide beam lasers adapted their delivery systems by decreasing the spot size and introducing galvanometric mirrors. By using their original large laser chambers (constructed for broad-beam ablations), they have limited their delivery frequency to approximately 50 Hz. Consequently, their spot size could not be decreased below 2.0 mm if reasonable treatment durations were to be maintained. Broad-beam lasers that break the beam into smaller beam components or use a slit do not achieve greater resolution than 2.0 mm either. One millimeter spot lasers provide a resolution 4 times greater than lasers with a 2.0 mm spot. This, along with the ablation pattern versatility, which is limited by software design only, makes them a logical choice for providing customized ablation. We can therefore expect an increasing number of excimer lasers with a 1.0 mm or smaller beam and repetition rates even greater than 200 Hz.

The outcomes of this study suggest that the 200 Hz technology used in the LaserSight LSX excimer laser system is safe, effective, and predictable and that the results are stable when treating low to moderate myopia with astigmatism up to 4.0 D with both LASIK and PRK.

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