Photorefractive Keratectomy versus Laser In Situ Keratomileusis for Moderate to High Myopia

A Randomized Prospective Study

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Objective: This report presents the results of a randomized clinical trial of photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK).

Design: A randomized, prospective, multicenter clinical trial.

Participants: A total of 220 eyes of 220 patients entered the study cohort: 105 randomized to PRK and 115 to LASIK. The mean preoperative manifest refraction spherical equivalent was −9.23 diopters (D) in the PRK group and −9.30 D in the LASIK group.

Intervention: All patients received a one-pass, multizone excimer laser ablation as part of either a PRK or LASIK procedure using the Summit Apex excimer laser. Attempted corrections ranged from 6.00 to 15.00 D.

Main Outcome Measures: Data on uncorrected and spectacle-corrected visual acuity, predictability, and stability of refraction, corneal haze, and flap complications were analyzed. Patients were observed for up to 6 months.

Results: One day after surgery, 0 (0.0%) and 3 (4.5%) eyes in the PRK group saw 20/20 and 20/40 or better uncorrected, respectively, while 7 (10%) and 48 (68.6%) eyes in the LASIK group saw 20/20 and 20/40 or better, respectively. At 6 months after PRK, 13 (19.1%) and 45 (66.2%) eyes saw 20/20 and 20/40 or better, respectively, while after LASIK, 16 (26.2%) and 34 (55.7%) eyes saw 20/20 and 20/40 or better, respectively (odds ratio = 0.56 for likelihood of uncorrected visual acuity <20/40 for PRK vs. LASIK, 95% confidence interval [CI] = 0.31–1.19). After PRK, 39 eyes (57.4%) were within 1.0 D of attempted correction compared with 24 eyes (40.7%) in the LASIK group (odds ratio = 0.50 for likelihood of undercorrection 1.0 D for PRK vs. LASIK, 95% CI = 0.24–1.04); however, the standard deviation of the predictability was similar between groups: 1.01 D for PRK and 1.22 D for LASIK. From months 1 to 6, there was an average regression of 0.89 D in the PRK group and 0.55 D in the LASIK group. After PRK, eight eyes (11.8%) had a decrease in spectacle-corrected visual acuity of two Snellen lines or more; after LASIK, two eyes (3.2%) had a decrease of two lines or more (odds ratio = 3.89 for risk of loss of spectacle-corrected visual acuity for PRK vs. LASIK, 95% CI = 0.71–21.30). Only two eyes had postoperative spectacle-corrected visual acuity less than 20/32, however.

Conclusions: Although improvement in uncorrected visual acuity is more rapid in LASIK than in PRK, efficacy outcomes in the longer term generally are similar between the two procedures. There is a greater tendency toward undercorrection in LASIK eyes using the specific laser and nomogram in this study, but the scatter in achieved versus attempted correction is similar, suggesting little difference in the accuracy of the two procedures. A suggestion of decreased propensity for loss of spectacle-corrected visual acuity in LASIK eyes requires further investigation. *Ophthalmology 1998;105:1512–1523*
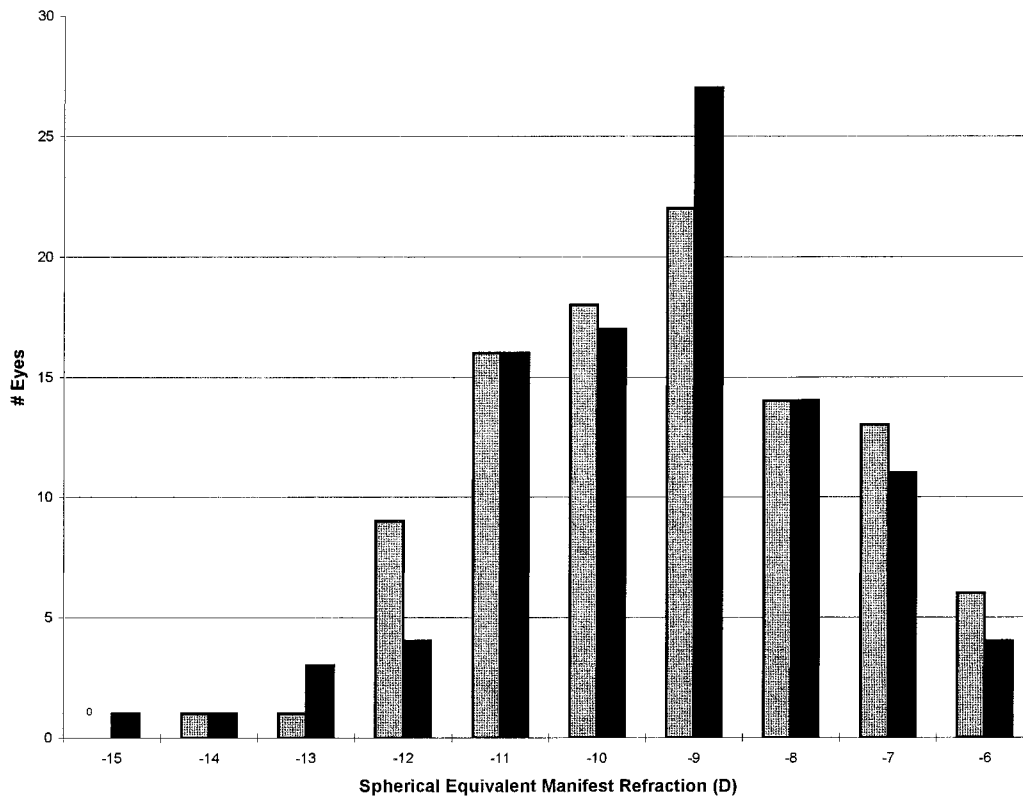
Figure 1. Spherical equivalent refraction of patient cohort stratified to 1.0-diopter subgroups. Photorefractive keratectomy = gray columns; laser in situ keratomileusis = black columns.

Although there have been a number of well-designed published studies reporting the results of excimer laser photorefractive keratectomy (PRK),[1–12] as yet, few controlled trials of laser in situ keratomileusis (LASIK) and no direct comparisons of LASIK to PRK are available. With increased interest in LASIK and reported success in early studies,[13–20] it is thus important to assiduously investigate the relative advantages and risks of each procedure. The randomized, controlled clinical trial presents the strongest methodology to compare the two procedures accurately.

In this article, therefore, we report the results of a randomized, multicenter, clinical study of PRK versus LASIK in 220 myopic eyes of 220 patients with moderate-to-high myopia using the Summit Apex excimer laser ™(Summit Technology, Inc, Waltham, MA).

Patients and Methods

Study Design

As part of a phase III multicenter clinical study of the Summit Technology excimer laser (Waltham, MA) conducted in accordance with U.S. Food and Drug Administration (FDA) regulations, a randomized, prospective study was performed to assess the comparative safety and efficacy of PRK and LASIK for the treatment of myopia.[17] Treatments were performed at seven clinical centers. Two hundred twenty eyes of 220 patients were entered in the cohort reported in this study; follow-up time was 6 months.

All study centers conformed to standardized patient entry criteria under an FDA Investigational Device Exemption granted to Summit Technology.[21] Approvals from appropriate institutional review boards were obtained, and all patients gave their informed consent.

Patient Selection

All patients entered in the study were 21 years of age or older and had between −6.0 and −15.0 diopters (D) of myopia (manifest refraction spherical equivalent) (Fig 1). Less than or equal to 2.00 D of refractive astigmatism was allowed. The study protocol allowed planned undercorrections or overcorrections of 1.0 D or less. Patients were excluded if they had spectacle-corrected visual acuity less than 20/32 or were functionally monocular. Other exclusion criteria were previous ocular surgery, previous or current ocular disease including clinical or topographic evidence of keratoconus, and systemic diseases that might influence wound healing. In addition, corneal thickness of between 500 and 700 μm and a normal endothelial cell count were required.

Photorefractive Keratectomy and Laser In Situ Keratomileusis Procedure

Eyes were assigned randomly to either PRK or LASIK procedure after patient registration and communication with the study's coordinating center. The eye to be first treated was determined by the principal investigator. Laser treatments were performed with the

Summit Apex excimer laser system (Summit Technology, Inc). Laser parameters included a repetition rate of 10 Hz, radiant exposure at the corneal plane of 180 mJ/cm[2], and pulse duration of 14 nsec, resulting in an ablation rate of corneal stromal tissue of approximately 0.25 μm/pulse. Treatment zone diameter was 6.0 mm in all cases. A two-zone laser ablation program with a spherical 5.0-mm central zone and blend zone to 6.0 mm was used in both the PRK and LASIK procedures.

The standardized PRK procedure used is explained in detail elsewhere.[22] In brief, to ensure appropriate laser energy and beam homogeneity, ablation and beam profile characteristics were tested at the beginning of each treatment day by the rate and pattern of ablation of a 100-μm-thick gelatin filter (Kodak #1497890; Eastman Kodak, Rochester, NY) and standardized ablations on a polymethylmethacrylate disc. The operative eye received two drops of pilocarpine 1% approximately 30 minutes before the procedure to facilitate centration, and topical anesthetic drops. With the patient in the supine position, the laser was focused on the cornea by adjusting the position of the patient in the vertical direction until the two converging helium–neon aiming beams were coincident on the anterior corneal surface. The ablation was centered over the entrance pupil as suggested by Uozato and Guyton.[23] The centration procedure and its accuracy in general are published elsewhere.[24]

Two training sessions were performed to familiarize the patient with the procedure and to ensure proper fixation subsequently. The first training session involved the application of methylcellulose 1% to the cornea before ablation to block the incoming laser beam. The second session was performed on dry epithelium using 25 pulses of the laser at its maximum aperture. The optical zone then was marked around the entrance pupil with a 7.0-mm optical zone marker, the epithelium within this area was removed with a microsurgical blade, and the laser ablation was performed.

For the LASIK procedure, the Automatic Corneal Shaper microkeratome (Chiron Vision, Inc, Claremont, CA) using the LASIK ring was used to prepare a corneal flap of 8.5-mm diameter and 160-μm thickness. The flap then was positioned to the side and laser ablation was performed. Filtered balanced salt solution was placed on the flap and stromal bed, and the corneal flap was then repositioned. Approximately 5 minutes was allowed to ensure proper adherence of the flap.

Postoperative Management

After surgery, in the PRK eyes, a combination tobramycin–dexamethasone ointment was applied five times daily until the cornea had re-epithelialized. Per the study protocol, prednisolone acetate 1% was then applied four times daily for 1 month. Steroid taper after 1 month was at the surgeon's discretion. In the LASIK eyes, antibiotic and corticosteroid drops (tobramycin or ofloxacin, and prednisolone acetate 1%) were administered five times daily for 1 week and then discontinued.

Patient Examinations

Patients were seen before surgery and after surgery on days 1 and 3 and at 1 week if slit-lamp examination on day 3 showed that the cornea had not re-epithelialized completely. Patients were again examined at 1, 3, and 6 months.

Preoperative and follow-up visits included a detailed ophthalmologic examination with manifest refraction by two independent observers at each visit. Per the study protocol, refractions needed to be within 1.0 D of each other; if not, refractions were repeated until the differences were reconciled. Visual acuity was measured under controlled lighting conditions by trained technicians using a back-illuminated Early Treatment Diabetic Retinopathy Study chart (Lighthouse for the Blind, New York, NY). Manual keratometry[25] and computer-assisted videokeratography (EyeSys Laboratories, Houston, TX) were also performed at designated examinations. Contact lens wear was discontinued at least 2 weeks before the preoperative examination for rigid lens wearers and at least 1 week for soft contact lens wearers.

Anterior stromal haze was graded subjectively during slit-lamp biomicroscopy and reported as one of five standardized categories: clear, trace (haze seen only with broad-beam illumination), mild (haze visible by slit-beam illumination), moderate (haze somewhat obscuring iris detail), and marked (haze markedly obscuring iris detail).[5] Corneal topography maps were reviewed by two masked observers and placed into qualitative patterns described elsewhere.[26] Any other complications or adverse reactions were noted by the investigator.

Data Acquisition and Analysis

All visual acuity measurements were reported on the logarithm of the minimum angle of resolution (logMAR) scale. To ensure consistency in visual acuity measurement, the total number of letters read was counted and divided by five to determine visual acuity.[27] Outcome of predictability was defined as achieved minus attempted correction. Stability of the postoperative refraction was assessed by comparing the manifest refraction spherical equivalent at different follow-up examinations.

Data were entered from uniform study forms submitted from each investigational site. Bivariate analyses were performed initially to test for individual associations between the preoperative characteristics and the outcomes measured. Contingency tables were constructed for categoric variables. For continuous variables, mean values were compared across groups. A significance level of 0.05 was used for subsequent inclusion in the multivariate models. Multivariate models were constructed using the variables found to be significant in the bivariate analyses and additional variables thought to be of demographic or clinical significance. Odds ratios, indicating the strength of the independent association, were calculated and are presented with their 95% confidence interval (CI) for associations of both preoperative characteristics and treatment group (PRK or LASIK) with outcomes of uncorrected visual acuity, loss of spectacle-corrected visual acuity of two or more Snellen lines, and undercorrections and overcorrections greater than 1.0 D. Statistical analysis was performed using the Statistical Analysis System 6.07 (SAS Institute, Inc, Cary, NC).

Results

Preoperative Characteristics

A total of 220 eyes of 220 patients entered the study cohort reported in this study. One hundred five were assigned to the PRK procedure and 115 to LASIK. The mean age was 39 years (range, 21–58 years) in the PRK group and 38 years (range, 21–64 years) in the LASIK group. Fifty-six patients (53%) were male and 49 (47%) were female in the PRK group; 48 (42%) were male and 67 (58%) were female in the LASIK group.

Preoperative manifest spherical equivalent refraction ranged from −6.00 to −14.38 D (mean = −9.23 D, standard deviation = 1.76 D) in the PRK group and from −6.00 to −13.88 D (mean = −9.30 D, standard deviation = 1.70 D) in the LASIK group.

Table 1. Uncorrected Visual Acuity (UCVA) following PRK and LASIK: No. (%) of Eyes

UCVA	1 day PRK (n = 67)	1 day LASIK (n = 70)	3 days PRK (n = 71)	3 days LASIK (n = 67)	1 mo PRK (n = 99)	1 mo LASIK (n = 105)	3 mos PRK (n = 90)	3 mos LASIK (n = 94)	6 mos PRK (n = 68)	6 mos LASIK (n = 61)
≥20/20	0 (0.0)	7 (10.0)	0 (0.0)	9 (13.4)	9 (9.1)	19 (18.1)	14 (15.6)	20 (21.3)	13 (19.1)	16 (26.2)
20/25 to 20/40	3 (4.50)	41 (58.5)	15 (21.1)	40 (59.7)	53 (53.5)	57 (54.3)	51 (56.7)	45 (47.9)	32 (47.1)	18 (29.5)
20/50 to 20/80	8 (11.9)	20 (28.6)	30 (42.3)	13 (19.4)	36 (36.4)	18 (17.1)	19 (21.1)	22 (23.4)	14 (20.6)	15 (24.6)
20/100 to 20/200	30 (44.8)	2 (2.9)	23 (32.4)	5 (7.5)	1 (1.0)	11 (10.5)	6 (6.7)	7 (7.4)	9 (30.2)	12 (19.7)
≤20/200	26 (38.8)	0 (0.0)	3 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Patients Lost to Follow-up

Two hundred five patients were observed at 1 month, 184 at 3 months, and 129 at 6 months. To investigate the potential bias that those patients lost to follow-up at each timepoint differed from those patients examined, preoperative characteristics of potential importance were analyzed for each group by follow-up status. There were no differences at baseline in age, gender, preoperative uncorrected or spectacle-corrected visual acuity, manifest refraction spherical equivalent, or intraocular pressure between the initial patient cohorts and those observed at the timepoints studied.

Laser Procedure Characteristics

Total time for the PRK procedures from insertion to removal of the lid speculum averaged 5.74 minutes. Total time for the LASIK procedures averaged 15.88 minutes. One PRK procedure was interrupted, and three LASIK procedures were interrupted.

Uncorrected Visual Acuity

Comparison of Photorefractive Keratectomy and Laser-assisted In Situ Keratomileusis. Uncorrected visual acuity data are presented in Table 1 and Figure 2. An early advantage was seen in the LASIK group; at 1 day after PRK, 3 eyes (4.5%) saw 20/40 or better compared with 48 eyes (68.6%) after LASIK. However, at 1 month and thereafter, this difference disappeared. At 6 months after PRK, 45 eyes (66.2%) saw 20/40 or better compared with 34 eyes (55.7%) in the LASIK group; 13 eyes (19.1%) in the PRK group saw 20/20 or better compared with 16 eyes (26.2%) after LASIK. Overall, for the outcome of uncorrected visual acuity worse than 20/40 at the 6-month follow-up visit, a trend toward superior outcome for PRK was seen (adjusted odds ratio = 0.56 for likelihood of uncorrected visual acuity <20/40 for PRK vs. LASIK, 95% CI = 0.31–1.19). However, this finding was not statistically significant.

Stability. Stability of uncorrected visual acuity was analyzed by comparing changes at different timepoints after PRK and LASIK using a definition of stability of one Snellen line. From the 1-month to 3-month examination, all eyes in both groups gained more than 1 Snellen line of uncorrected visual acuity. From the 3-month to 6-month examination, 13 (19.4%) PRK eyes gained more than 1 Snellen line compared with 5 (8.8%) LASIK eyes. Over the same interval, 24 (35.8%) of 67 PRK eyes and 16 (28.1%) of 57 LASIK eyes lost more than 1 Snellen line of uncorrected visual acuity. The other eyes remained stable within one Snellen line of their preoperative visual acuity.
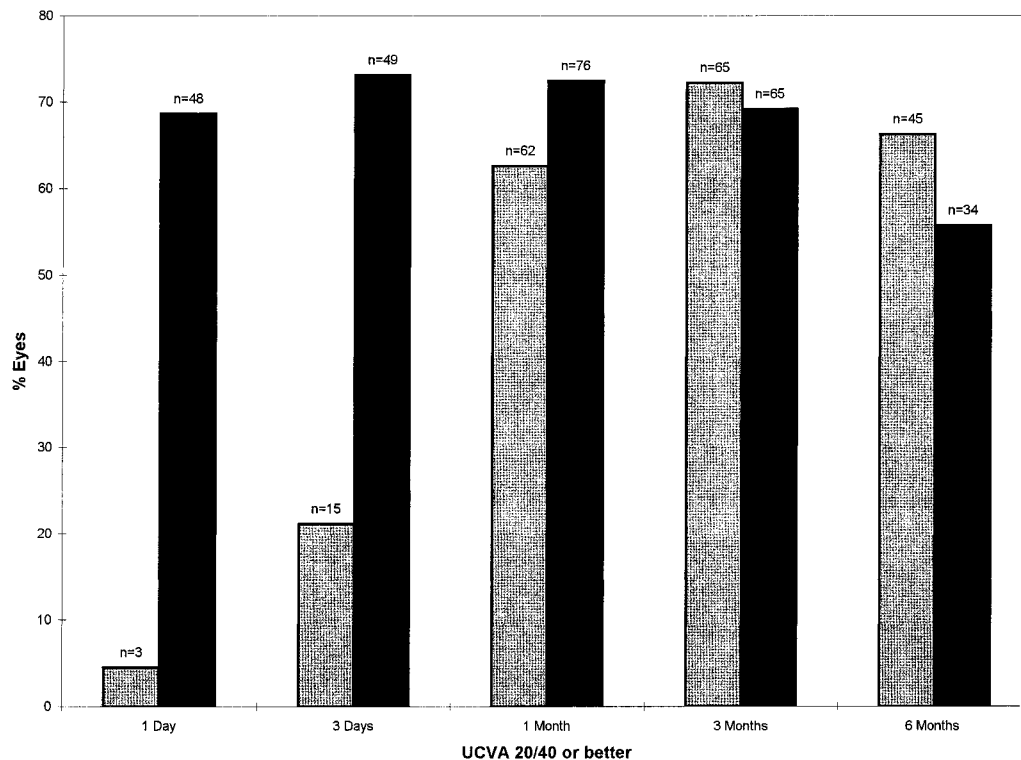

Figure 2. Percentage of patients with uncorrected visual acuity of 20/40 or better after photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) at different timepoints. PRK = gray columns; LASIK = black columns.

Table 2. Multiple Logistic Regression Model of Preoperative Characteristics Associated with Uncorrected Visual Acuity <20/40 6 Months after PRK and LASIK

	PRK		LASIK	
Characteristic	Odds Ratio	95% CI	Odds Ratio	95% CI
Age (per year)	1.08*	1.01–1.16	1.07	0.99–1.14
Gender (F relative to M)	1.50	0.49–4.63	1.22	0.39–3.78
Intraocular pressure	1.22*	1.01–1.49	0.85	0.68–1.05
Manifest refraction Spherical equivalent (per D)	0.92	0.68–1.25	0.85	0.48–1.50

CI = confidence interval.
* Statistically significant.

Preoperative Predictors. Table 2 presents the multiple logistic regression model of preoperative characteristics associated with uncorrected visual acuity worse than 20/40 at the 6-month follow-up visit. For the PRK subgroup, this analysis indicated an independent association of increased age (odds ratio = 1.08/year, 95% CI = 1.01–1.16) and increased intraocular pressure (odds ratio = 1.22/mmHg, 95% CI = 1.01–1.49) with less likelihood of achieving uncorrected visual acuity of 20/40 or better. There were no independent risk factors in the LASIK group, although age approached statistical significance.

Predictability, Accuracy, and Stability of Refractive Change

Predictability and Accuracy of Photorefractive Keratectomy and Laser In Situ Keratomileusis. The predictability and accuracy of the procedure, as defined by the achieved minus attempted correction, are seen in Table 3 and Figure 3. At 6 months after PRK, 20 eyes (29.4%) were within 0.5 D, 39 eyes (57.4%) were within 1.0 D, and 61 eyes (89.7%) were within 2.0 D of attempted correction; after LASIK, 16 eyes (27.1%) were within 0.5 D, 24 eyes (40.7%) were within 1.0 D, and 42 eyes (71.2%) were within 2.0 D of attempted correction. The mean predictability for the PRK group was −0.77 D undercorrection with a standard deviation of 1.01, and the mean predictability for the LASIK group was −1.43 undercorrection with a standard deviation of 1.22.

Overall, for the outcome of undercorrections greater than 1.0 D at the 6-month follow-up visit, a trend for lesser likelihood of undercorrection in PRK was seen (adjusted odds ratio = 0.50 for likelihood of undercorrection 1.0 D for PRK vs. LASIK, 95% CI = 0.24–1.04). However, this finding was not statistically significant. Multivariate analysis of overcorrections could not be done because of the small number of patients who were overcorrected in this study.

Preoperative Predictors. Table 4 presents the multiple logistic regression model of preoperative characteristics associated with undercorrection greater than 1 D at the 6-month follow-up visit. This analysis indicated no statistically significant predictors in the PRK group. However, an independent association of greater preoperative spherical equivalent refraction with undercorrections in the LASIK group was found (odds ratio = 0.65 D, 95% CI = 0.44–0.95). In addition, women in the LASIK group were more likely to be undercorrected by 1.0 D or more (odds ratio = 4.16, 95% CI = 1.19–14.52). Multivariate analysis of overcorrections could not be done because of the small number of patients who were overcorrected in this study.

Stability. The change in refraction over time is illustrated in Figure 4. At 1 month after PRK, the mean manifest refraction was −0.14 D (standard deviation = 1.29 D, range = −3.25 to +4.0 D), at 3 months −0.71 D (standard deviation = 1.05 D, range = −3.25 to +2.0 D), and at 6 months −1.03 D (standard deviation = 0.99 D, range = −3.25 to +1.38). In comparison, at 1 month after LASIK, the mean manifest refraction was −0.74 D (standard deviation = 1.11 D, range = −3.38 to +4.0 D), at 3 months −0.96 D (standard deviation = 1.15 D, range = −3.5 to +2.25 D), and at 6 months −1.29 D (standard deviation = 1.21 D, range = −5.0 to +1.13 D).

Table 5 further quantifies the stability of postoperative refraction by comparing spherical equivalent refraction at different timepoints after PRK and LASIK using a definition of stability of 1.0-D difference in manifest refraction spherical equivalent between follow-up visits. From the 1-month to 3-month examination, 53 (59.6%) PRK eyes were stable within 1.0 D and 67 (74.4%) LASIK eyes were stable within 1.0 D. From the 3-month to 6-month examination, 58 (86.6%) PRK eyes were stable within 1.0 D, and 52 (92.9%) LASIK eyes were stable within 1.0 D. For both procedures, there were more myopic than hyperopic changes from 1 to 3 months; this decreased with time. At both intervals, a greater proportion of PRK eyes than LASIK eyes showed myopic shifts (i.e., regression of effect).

Loss of Spectacle-corrected Visual Acuity

Comparison of Photorefractive Keratectomy and Laser In Situ Keratomileusis. At 1 month after PRK, 35 eyes (35%) had a decrease in spectacle-corrected visual acuity of 2 Snellen lines or more compared with 15 eyes (14.3%) in the LASIK group (Table 6). At 3 months after PRK, 18 eyes (19.8%) had a decrease in spectacle-corrected visual acuity of 2 Snellen lines or more compared with 6 eyes (6.5%) after LASIK. At 6 months after PRK, eight eyes (11.8%) had a decrease in spectacle-corrected visual acuity of two Snellen lines or more compared with two eyes (3.2%) in the LASIK group. Of these eight eyes in the PRK group, four decreased from a preoperative spectacle-corrected visual acuity of 20/16 to a postoperative acuity of 20/25, one decreased from 20/12.5 to 20/20, and one each decreased from 20/20 and 20/25 to 20/62.5, respectively. Of the two eyes in the LASIK group, one decreased from 20/12.5 to 20/25 and the other decreased from 20/20 to 20/32.

Regarding the outcome of loss of spectacle-corrected visual acuity of two Snellen lines or more at 6 months, no statistically significant difference between the two procedures was found (odds ratio = 3.89 for PRK vs. LASIK, 95% CI = 0.71–21.30). However, the odds ratio of 3.89 suggests a trend toward a lesser likelihood of loss of spectacle-corrected visual acuity with LASIK compared with that of PRK.

Preoperative Predictors. The multiple logistic regression model of preoperative characteristics associated with a decrease in spectacle-corrected visual acuity of two Snellen lines or more showed that neither age, gender, manifest refraction, nor intraocular pressure were statistically significant predictors of this outcome in the PRK group. There were too few cases in the LASIK group to perform multivariate analysis.

Corneal Haze

Generally, there was progressive clearing of the corneas during the 6 months after PRK (Table 7). At 6 months, 31 (45.6%) corneas were clear (0+), 30 (44.1%) showed trace haze (1+), 4 (5.9%) showed mild haze (2+), and 3 (4.4%) showed moderate haze (3+). No eyes were ranked 4+. Subepithelial haze was not seen in LASIK-treated eyes.

Table 3. Predictability (Achieved − Attempted Correction) Following PRK and LASIK: No. (%) of Eyes

	1 mo		3 mos		6 mos	
	PRK (n = 100)	*LASIK (n = 102)*	*PRK (n = 90)*	*LASIK (n = 86)*	*PRK (n = 68)*	*LASIK (n = 59)*
Range						
+3.1 to 4.0 D	2 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
+2.1 to 3.0 D	3 (3.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
+1.1 to 2.0 D	16 (16.0)	2 (2.0)	5 (5.6)	2 (2.3)	2 (2.9)	1 (1.7)
+0.51 to 1.0 D	15 (15.0)	4 (3.9)	9 (10.0)	5 (5.8)	5 (7.4)	1 (1.7)
±0.5 D	30 (30.0)	28 (27.5)	27 (30.0)	17 (19.8)	20 (29.4)	16 (27.1)
−0.51 to −1.0 D	13 (13.0)	15 (14.7)	22 (24.4)	15 (17.4)	14 (20.6)	7 (11.9)
−1.1 to −2.0 D	16 (16.0)	36 (35.3)	22 (24.4)	25 (29.1)	20 (29.4)	17 (28.8)
−2.1 to −3.0 D	4 (4.0)	15 (14.7)	4 (4.4)	15 (17.4)	7 (10.3)	12 (20.3)
−3.1 to −4.0 D	1 (1.0)	1 (1.0)	1 (1.1)	5 (5.8)	0 (0.0)	3 (5.1)
−4.1 to −5.0 D	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.3)	0 (0.0)	2 (3.4)
Overcorrected >1.0 D	21 (21.0)	3 (2.9)	5 (5.6)	2 (2.3)	2 (2.9)	1 (1.7)
Undercorrected >1.0 D	21 (21.0)	52 (51.0)	27 (30.0)	47 (54.7)	27 (39.7)	34 (57.6)
Mean	+0.02	−0.98	−0.51	−1.23	−0.77	−1.43
Range	−3.1 to +3.5	−3.7 to +3.0	−3.3 to +1.6	−4.3 to +1.8	−2.9 to +1.4	−4.8 to +0.7
SD	1.26	1.08	0.97	1.23	1.01	1.22

Adverse Reactions

There were three flap-related complications in the LASIK group. In the first case, the microkeratome stopped in the middle of the pass. The procedure was stopped, and the patient received uncomplicated LASIK treatment 3 months later. In the second case, the flap was completely cut off. The excimer ablation was completed without complication, and the corneal lenticule was replaced. In the third case, the flap was extremely thin. It was replaced without laser ablation. The procedure was completed without complication 1 month later.

No other unanticipated adverse reactions such as microbial keratitis, endophthalmitis, corneal melting or perforation, corneal decompensation, hyphema, hypopyon, cataract, or retinal lesions were found in this study.
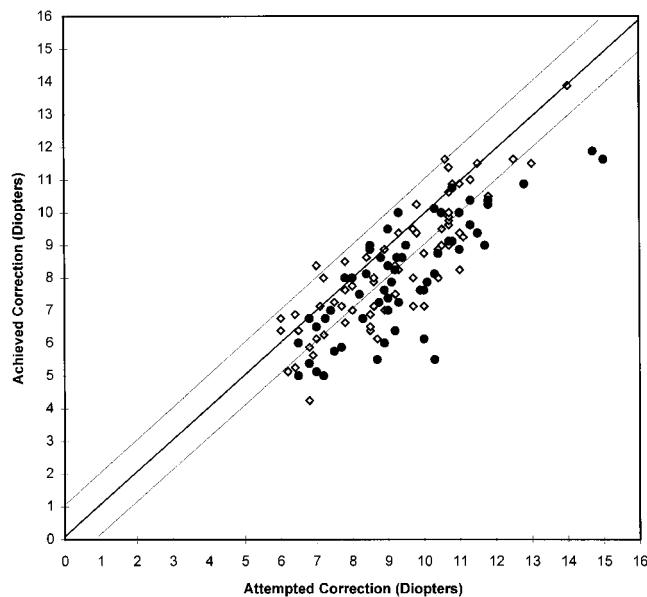
Discussion

To advise patients properly regarding refractive surgery, it is essential to clearly understand the relative advantages and risks of different procedures. Recently, it has been suggested that LASIK may be a procedure preferred to PRK, especially for higher degrees of myopia. However, neither anecdotal reports nor case series of a single procedure can compare two different surgical techniques properly. The randomized, controlled clinical trial is the most appropriate methodology to obtain this information. This report thus presents results of PRK versus LASIK for the correction of moderate-to-high myopia and affords the strength of a prospective, randomized multicenter design with rigorous control of case selection, examination methodologies, surgical technique, postoperative care, and patient follow-up.

In general, although LASIK showed clear superiority in improvement of uncorrected visual acuity in the early postoperative period, this study showed little difference in efficacy outcomes between PRK and LASIK at 6 months. With regard to long-term safety of the two procedures, the small number of poor outcomes in both groups and relatively short follow-up does not allow for definitive conclusions;

Figure 3. Scattergram showing achieved vs. attempted refractive correction at 6 months (n = 68 for photorefractive keratectomy [PRK] and 61 for laser in situ keratomileusis [LASIK]). Dashed lines indicate 1.0-diopter boundaries of predictability. Open diamonds (◇) indicate PRK eyes; black circles (●) indicate LASIK eyes.

Table 4. Multiple Logistic Regression Model of Preoperative Characteristics Associated with Undercorrection of >1 D 6 Months after PRK and LASIK

	PRK		LASIK	
Characteristic	*Odds Ratio*	*95% CI*	*Odds Ratio*	*95% CI*
Age (per year)	0.99	0.93–1.04	1.05	0.98–1.12
Gender (F relative to M)	0.82	0.30–2.23	4.16*	1.19–14.52
Intraocular pressure	1.14	0.84–1.36	0.85	0.67–1.08
Manifest refraction Spherical equivalent (per D)	0.93	0.71–1.22	0.65*	0.44–0.90

CI = confidence interval.

* Statistically significant.

Figure 4. Change in refraction over time for (A) photorefractive keratectomy and (B) laser in situ keratomileusis. Each black square (■) represents the mean spherical equivalent refraction, and vertical bars indicate the standard deviation.
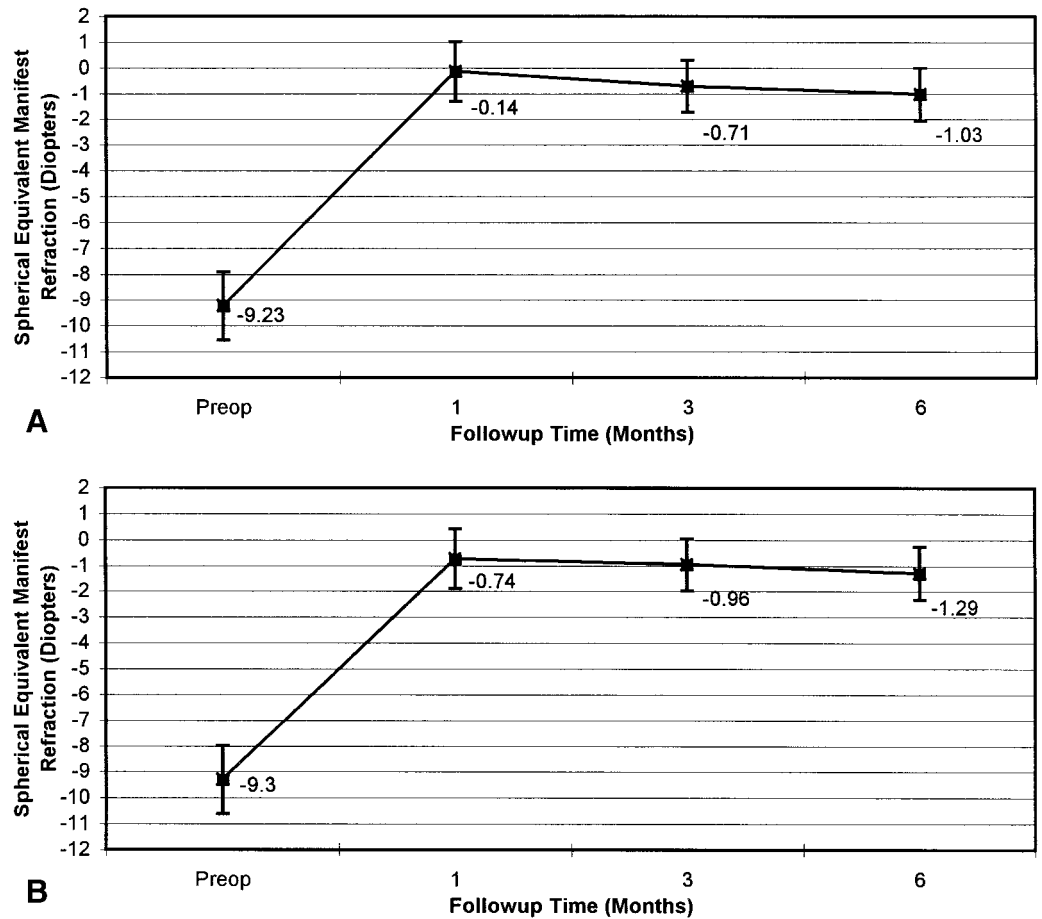
however, our findings do suggest some issues for further investigation.

Efficacy of Photorefractive Keratectomy versus Laser In Situ Keratomileusis

Uncorrected Visual Acuity. Return of good uncorrected visual acuity was more rapid in the LASIK group. This result was expected since LASIK in general preserves an intact epithelium, obviating the initial surface healing phase implicit in PRK. Early attainment of good uncorrected visual acuity, thus seems to be one of the major advantages of the LASIK procedure. By the 1-month follow-up, however, the PRK group in general had caught up to the LASIK group. Indeed, there was even a trend toward better uncorrected visual acuity in the PRK group at 6 months, although this was not statistically significant. This finding may possibly be attributed to the greater number of undercorrections in the LASIK-treated eyes. Furthermore, its significance is further mitigated by the fact that, contrary to the 20/40 or better outcome, more patients who underwent LASIK were 20/20 or better uncorrected than were those who underwent PRK.

A more rapid visual recovery in LASIK is also supported by the data on stability of uncorrected visual acuity. From 3 to 6 months, 19% of PRK eyes gained more than one line of uncorrected visual acuity compared with only 9% of LASIK eyes. Again, this finding would be expected since surface epithelial remodeling over time is likely more important in PRK.[28,29]

Table 5. Stability of Refraction after PRK and LASIK between Examinations: No. (%)

| | Time of Examinations | | | |
| | 1–3 mos | | 3–6 mos | |
Change (D)	PRK	LASIK	PRK	LASIK
Hyperopic shift >1.0 D	7/89 (7.9)	9/90 (10)	4/67 (6.0)	1/56 (1.8)
Stable (±1.0 D)	53/89 (59.6)	67/90 (74.4)	58/67 (86.6)	52/56 (92.9)
Myopic shift >1.0 D	29/89 (32.6)	14/90 (15.6)	5/67 (7.5)	3/56 (5.4)

Table 6. Change in Spectacle-corrected Visual Acuity following PRK and LASIK: No. (%) of Eyes

	Time after PRK or LASIK					
	1 mo		3 mos		6 mos	
	PRK (n = 100)	LASIK (n = 105)	PRK (n = 91)	LASIK (n = 93)	PRK (n = 68)	LASIK (n = 62)
Change in Snellen lines						
+3	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)
+2	0 (0.0)	6 (5.7)	3 (3.3)	6 (6.5)	2 (2.9)	3 (4.8)
+1	11 (11.0)	9 (8.6)	10 (11.0)	31 (33.3)	14 (20.6)	15 (24.2)
No change	25 (25.0)	46 (43.8)	46 (50.5)	28 (30.1)	30 (44.1)	27 (43.6)
−1	29 (29.0)	29 (27.6)	14 (15.4)	22 (23.6)	14 (20.6)	14 (22.6)
−2	23 (23.0)	6 (5.7)	14 (15.4)	6 (6.5)	6 (8.8)	1 (1.6)
−3	7 (7.0)	5 (4.8)	2 (2.2)	0 (0.0)	0 (0.0)	1 (1.6)
−4	4 (4.0)	3 (2.9)	2 (2.2)	0 (0.0)	1 (1.5)	0 (0.0)
−5	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
−6	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
−7	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

In past analysis of PRK for myopia of 1.5 to 6.0 D,[30] we found that older age was independently associated with less likelihood of achieving 20/40 or better uncorrected visual acuity. Similarly, in our current study, age was a preoperative predictor of uncorrected visual acuity in the PRK group but not in the LASIK group. This may possibly be explained by a greater influence of wound healing, which, in turn, may be influenced by patient age on outcomes of PRK compared with LASIK. In addition, in other work,[31] we have found more irregular topography patterns in PRK than in LASIK-treated eyes. Age-related changes of the eye, such as lenticular and macular changes, may not allow an older eye to compensate for corneal topographic irregularities as well as younger eyes and thus may lead to worse postoperative uncorrected visual acuity with increasing age in PRK.

Unlike our previous study of PRK for lower myopia,[30] there was no independent association of preoperative refractive error with uncorrected visual acuity outcome for either the PRK or LASIK group. There was an association of higher intraocular pressure with a greater likelihood of uncorrected visual acuity of 20/40 or better in the PRK group in the current study. The reason for this last finding is unclear.

Predictability, Accuracy, and Stability. Predictability, accuracy, and long-term stability of refractive correction are other important outcomes of a refractive surgical procedure. Because an identical ablation algorithm was used for a given attempted correction in both the PRK and LASIK groups, this study presents a unique opportunity to understand the variables in refractive outcome between the two techniques.

Although this finding was not statistically significant, there was an estimated twofold greater likelihood of undercorrection in patients who underwent LASIK than in those who underwent PRK. The average eye receiving LASIK was undercorrected by −1.43 D compared with the attempted correction, whereas there was an average undercorrection of −0.77 D in the PRK group. The reasons for the relative undercorrections in the LASIK group may include the following:

1. The ablation rate may be less on the internal corneal stromal lamellae beneath the LASIK flap compared with the surface ablation of PRK.

2. Circumferential flap retraction, noted intraoperatively as a peripheral gutter, may cause a relative steepening of the flap and hence predispose toward undercorrection.

3. The corneal flap may not parallel the treatment zone perfectly, thus mitigating the corneal sculpting effect of the ablation.[31]

This may result from both a *masking* and *vaulting* effect of the flap. Masking would be analogous to the effect of a soft contact lens over an irregular corneal surface. Vaulting would be secondary to a tendency of the flap to retain its original curvature, a function of the elastic modulus (i.e., the amount of force required per unit deformation) of the corneal flap. Theoretically, this tendency would be greater for higher degrees of correction, in which the sagittal distance between the flap's preoperative position and the stromal bed would be greater; thus, the flap may not deform sufficiently to conform to the new stromal curvature. This hypothesis is supported by our finding of an association of higher refractive error with more undercorrections in the LASIK group.

Although there was, indeed, a greater incidence of undercorrection in the LASIK group, it has been suggested[32] that the outcome of predictability (i.e., the difference between achieved and attempted correction) is an inadequate

Table 7. Anterior Stromal Haze following PRK: No. (%) of Eyes

	Time after PRK		
Haze Grade	1 mo (n = 100)	3 mos (n = 90)	6 mos (n = 68)
Clear	18 (18.0)	27 (30.0)	31 (45.6)
Trace	68 (68.0)	51 (56.7)	30 (44.1)
Mild	10 (10.0)	11 (12.2)	4 (5.9)
Moderate	4 (4.0)	1 (1.1)	3 (4.4)
Marked	0 (0.0)	0 (0.0)	0 (0.0)

measure of the actual variability in refractive outcome of a procedure since it is influenced by mean error as well as scatter in the outcome. Rather, these investigators emphasize that the standard deviation of the difference between the achieved and attempted correction may be a more important indicator of the variability in outcome from a procedure. Therefore, although the mean predictability in this study differs between PRK and LASIK, the standard deviations, and thus variability in refractive outcome, are similar. This would suggest that a simple change in ablation nomogram when using the two-zone algorithm used in this study (i.e., adding a small amount of ablation to LASIK for a given correction) could make the predictability as well as the accuracy of the two procedures similar.

Regarding stability of refraction, it has been suggested that wound-healing responses may lead to refractive regression after PRK for higher degrees of myopia[33–38] and that LASIK may both reduce this response and achieve earlier stability.[39] This notion is supported in this study. There was a mean refractive regression in the PRK group of 0.89 D from the 1-month to 6-month examinations compared with regression of 0.55 D over the same period in the LASIK group. In addition, whereas 33% of PRK-treated eyes regressed more than 1.0 D from postoperative months 1 to 3, only 16% of LASIK-treated eyes regressed over this same period. However, the overall refractive regression in this study up to 6 months, in general, was relatively small and does not seem to be a substantial problem for either procedure. Longer term follow-up is necessary to determine whether refractive regression continues beyond the 6-month timepoint for both PRK and LASIK.

Safety of Photorefractive Keratectomy and Laser In Situ Keratomileusis

Loss of Spectacle-corrected Visual Acuity. Spectacle-corrected visual acuity is a general indicator of a variety of changes in the optics of the cornea and visual function after refractive surgical procedures. Because spectacle-corrected visual acuity would actually be expected to increase slightly after refractive surgery due to the image magnification inherent in correcting myopia at the corneal rather than the spectacle plane,[40] a loss of visual acuity of two Snellen lines or more might be expected to have clinical impact.

At all timepoints studied, relatively more patients in the PRK group lost two Snellen lines or more of spectacle-corrected visual acuity. Although not statistically significant, there was a trend toward a greater likelihood of loss of two or more lines at the 6-month follow-up examination in the PRK- compared with the LASIK-treated patients. What might account for these differences? Loss of spectacle-corrected visual acuity may arise from two general causes: (1) loss of corneal clarity secondary to haze and scar formation and (2) corneal topography irregularities resulting in unfocused "noise" light degrading the focused image.[31,41,42] Regarding the first cause, performing ablation under a corneal flap seems to mitigate against haze formation.[39] In the LASIK group in this study, the typical subepithelial reticular haze seen in PRK was avoided. However, even in the PRK group, haze did not seem to be a substantial

problem. There was progressive clearing of the corneas with time after treatment, and at 6 months, only 4% of eyes had haze graded as more than mild. However, even if mild, haze may have accounted for loss of spectacle-corrected visual acuity in some patients. Indeed, haze was found in five of the eight patients losing spectacle-corrected visual acuity in the PRK group.

Irregularities in postoperative corneal topography is the second potential cause of spectacle-corrected visual acuity loss.[26,43,44] An irregular corneal topography pattern, intuitively, would be expected to decrease a patient's spectacle-corrected visual acuity since the focused "signal" may be disturbed by optical noise resulting from nonfocused light rays.[41] In separate work analyzing corneal topography of the patients in the current study,[31] we found differences in topography pattern between the PRK- and LASIK-treated eyes at months 1 and 3; eyes after PRK were more likely to have an irregular topography pattern than LASIK-treated eyes. In addition, eyes with irregular topography patterns in general were associated with a greater tendency toward loss of spectacle-corrected visual acuity. Therefore, the lower propensity toward, and quicker return of, spectacle-corrected visual acuity in patients who underwent LASIK may be a result of a smoother optical surface. This, in turn, may be a result of either masking of underlying topography perturbations by the lamellar corneal flap, thus mitigating induced topography changes, or moderated epithelial and stromal wound healing in LASIK. In this study, induced astigmatism was implicated in four of the eight eyes in the PRK group losing spectacle-corrected visual acuity.

Although differences in lost spectacle-corrected visual acuity between the PRK and LASIK groups were found at 1, 3, and 6 months' follow-up, this finding was not statistically significant. Furthermore, there was a tendency for fewer patients to lose spectacle-corrected visual acuity with time, and the difference in this outcome between the two treatment groups diminished with time. At 6 months, only a small number of patients actually lost spectacle-corrected visual acuity. In addition, of those who did lose spectacle-corrected visual acuity, all but two patients had 20/32 visual acuity or better. Thus, it remains to be seen whether the difference between the PRK and LASIK eyes remains beyond 6 months or simply is a result of the lengthier healing time of the PRK-treated eye.

Other Complications. Epithelialization was complete by 3 days in most eyes after PRK, and there was no incidence of persistent epithelial defect, recurrent epithelial dysadhesion within the treatment zone, sterile stromal ulceration, or corneal infection.[45] Because epithelium is not removed in LASIK, postoperative epithelial defects are usually not a problem and were not seen in this study.

Complications related to the corneal flap, however, are inherent to the LASIK procedure alone. Thin flaps, incomplete flaps, and completely removed corneal lamellar discs were all seen in this study. However, all procedures ultimately were completed without adverse outcomes. Whether advantages of early visual recovery and diminished corneal haze outweigh potential flap complications remains for further study.

The essential outcomes of both PRK and LASIK in this study show no substantial differences in efficacy at 6-month follow-up. Both PRK and LASIK seem to be relatively safe and effective procedures for the correction of moderate-to-high myopia. Photorefractive keratomileusis has the advantage of greater ease of surgery without complications associated with a corneal flap. Laser in situ keratomileusis has advantages of faster visual recovery and possibly less likelihood of loss of spectacle-corrected visual acuity. It should be stressed that this study assessed one laser using a particular ablation algorithm and looked only at the correction of higher degrees of myopia. The relative results of PRK and LASIK using other lasers and for lower degrees of myopia await future clinical investigation.

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Discussion
by
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The authors present results from an ongoing study to prospectively evaluate photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) for moderate and high myopia in the context of a phase III U.S. Food and Drug Administration-sanctioned clinical trial.

The data indicate that fairly good results comparable to those published in the literature can be achieved with either procedure.[1–6] The most notable differences in outcome between the two techniques are faster visual recovery but greater mean undercorrection in the LASIK group and greater best spectacle-corrected visual acuity loss in the PRK group at all timepoints. In addition, it should be emphasized that neither group came close to achieving the levels of predictability reported after PRK for low myopia. Specifically, at 6 months, 57.4% of PRK cases and 40.7% of LASIK cases were within ± 1.0 diopter (D) of intended correction.

Although intraoperative complications of PRK are rare and seldom visually significant, microkeratome-related complications remain a significant theoretical concern during LASIK procedures. The flap-related complication rate of 2.9% (3 of 102) and the good visual acuity results in this study suggest that LASIK in the hands of refractive surgeons experienced in lamellar corneal surgery is safer than some published studies indicate.[6] The results presented here, however, reflect not only meticulous technique but also good surgical judgment when complications were encountered, which dictated that two cases be aborted and postponed when the quality of the corneal flap was unacceptable. Much like phacoemulsification procedures, there often is a significant learning curve associated with mastering microkeratome usage. Beginning LASIK surgeons should be mindful of this issue and obtain appropriate training as well as exercise conservative judgment in the selection and management of initial cases.

Despite being from a prospective, randomized clinical trial, one should be cognizant of the data's limitations as presented. These include:

1. Limited follow-up. Six-month follow-up is only available for 68% and 58% of PRK and LASIK patients, respectively. Although 6 months may be an adequate period of time to achieve refractive stability after LASIK, studies of PRK for high myopia recently published by Krueger et al[3] and others suggest that refractive regression may continue well beyond 6 months in some instances.

2. The PRK epithelial removal technique. Although definitive data have not yet been published in the peer-reviewed literature, some investigators have reported results suggesting that less-traumatic epithelial removal techniques (e.g., transepithelial, laser scrape) yield better and more stable visual results after PRK for high myopia (Johnson D, Pop M, personal communication, 1996).

3. Steroid regimen after PRK. Data from Tengroth et al[7] suggest that a more prolonged course of topical corticosteroids may influence the refractive outcome positively after PRK. Although the steroid regimen after surgery was left up to the individual surgeons in this study, it would be helpful to know how long and how intensively topical steroids were used after PRK.

4. Ablation algorithms. Although ablation parameters have been optimized for low and moderate myopic corrections with PRK, refinement clearly is necessary and possible for the correction of high myopia using either PRK or LASIK. Modifications will most likely include multiple ablation zone diameters and passes for PRK and downward adjustment of the estimated ablation rate per pulse for LASIK, at least for software used by the Summit Apex UV200 laser system in this study. It is not unreasonable to expect improved results from such adjustments.

In summary, this ongoing, carefully controlled, prospective clinical trial of PRK and LASIK for high myopia has and will

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continue to provide valuable information about both procedures. Although they do not and cannot allow for constant technical innovation, investigations of this nature represent the best means of achieving systematic advances in the field of refractive surgery.

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