Comparison of Laser in situ Keratomileusis and Photorefractive Keratectomy for the Correction of Myopia of -6.00 Diopters or Less

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ABSTRACT

PURPOSE: To evaluate the safety and efficacy of laser in situ keratomileusis (LASIK) compared to photorefractive keratectomy (PRK) for the correction of low or moderate myopia (-0.50 to -6.00 D) at 6 months after surgery.

METHODS: The study population comprised a non-randomized consecutive series of 622 eyes of 392 patients who were treated with the Nidek EC-5000 excimer laser. LASIK was performed using the ACS Chiron microkeratome on 314 eyes and surface PRK on 308 eyes. All patients were treated using a standard protocol, then assessed at 1, 3, and 6 months postoperatively.

RESULTS: Forty-four percent of the LASIK group and 67% of the PRK group attended their 6-month examination. Eighty percent of patients (111 eyes) after LASIK and 65% (136 eyes) after PRK had an uncorrected visual acuity of 20/20 or better. Spherical equivalent refraction was within ±0.50 D of intended refraction in 78% (109 eyes) for LASIK and 82% (170 eyes) for PRK. Loss of two more lines of best spectacle-corrected visual acuity at 6 months occurred in 1.4% (2 eyes) of the LASIK group and 1.0% (2 eyes) of the PRK group.

CONCLUSION: At 1 month follow-up, the percentage of eyes that achieved 20/20 uncorrected visual acuity was greater in the LASIK group than in the PRK group. At 6 months, visual and refractive outcomes of LASIK and PRK were similar. Although flap related complications occurred only after LASIK, the overall risk of loss of best spectacle-corrected visual acuity was not significantly greater than for PRK. [*J Refract Surg* 2001;17:46-54]

A number of well-designed studies have reported the outcomes of surface photorefractive keratectomy (PRK) for low myopia (-0.50 to -6.00 diopters [D]).[1-7] However, as yet there are few controlled studies of laser in situ keratomileusis (LASIK) for treating this range of myopia and still fewer direct comparisons between the two procedures.[8-11] With increasing assurances regarding the efficacy and safety of LASIK due to better nomograms, and improvements in the currently available microkeratomes and surgical technique, this procedure is today considered by many as the technique of choice for correction of myopia greater than -6.00 D.[12-14] Many refractive surgeons also choose LASIK for the treatment of low myopia[15], therefore it is important to compare the relative outcomes and efficacy of the two procedures.

We report the results from a single center of a large consecutive series of LASIK and surface PRK procedures to correct myopia of -6.00 D or less.

PATIENTS AND METHODS

Patient Characteristics

The study population comprised a non-randomized consecutive series of 622 eyes of 392 patients, from which 314 eyes underwent LASIK and 308 eyes had PRK. Because LASIK is a newer procedure than PRK, the PRK procedures tended to be performed earlier in the series than the LASIK procedures. Patients were eligible for inclusion in this study if they were 18 years or older and had given informed consent; had stable myopia ranging from -0.50 to -6.00 D spherical equivalent refraction

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Table 1
Characteristics of 392 Patients by Amount of Preoperative Myopia and Surgical Treatment

	Low Myopia (-0.50 to -3.00 D)			Moderate Myopia (-3.10 to -6.00 D)		
	LASIK	PRK	*P* value	LASIK	PRK	*P* value
Eyes treated (n)	97	155		217	153	
Mean age years, ±SD	37 ± 9.1	37.4 ± 10.4	.720	38.2 ± 9.5	37.5 ± 9.9	.510
Mean preoperative spherical equivalent ± SD (range) (D)	-2.26 ± 0.48 (-1.25 to -3.00)	-2.10 ± 0.58 (-0.50 to -3.00)	.025	-4.61 ± 0.85 (-3.13 to -6.00)	-4.10 ± 0.75 (-3.12 to -6.00)	<.001
Astigmatic correction (%)	56.7	49.7	.277	70.5	67.3	.513
Preoperative best spectacle corrected visual acuity (%)						
20/20 or better	94.8	86.5	.030	89.4	84.3	.148
20/25 or better	100	94.2	.014*	97.2	92.8	.045
20/40 or better	100	100	--	100	99.3	.414*

**Fisher's Exact Test*

at the spectacle plane for at least 12 months, a best spectacle-corrected visual acuity (BSCVA) of at least 20/60 in both eyes, and stable keratometry after not wearing soft contact lenses for at least 2 weeks and hard lenses for 1 month. Patients were excluded if they did not meet these criteria or had a history of keratoconus, ocular surgery or trauma, or therapy likely to interfere with corneal healing. The study protocol and informed consent were approved by the Human Research Ethics Committee of the Royal Victorian Eye and Ear Hospital, Melbourne.

Unilateral LASIK was performed in 67 patients; bilateral in 120 patients. Unilateral PRK was performed in 95 patients and bilateral PRK in 103 patients. Seven patients had LASIK in one eye and PRK in the fellow eye. Twenty-five surgeons performed the procedures. The median number of LASIK eyes per surgeon was 10 (range, 0 to 82 eyes), and for PRK, 5 eyes (range, 0 to 69 eyes).

Selected patient characteristics are shown in Table 1. The mean age of the patients was 37.5 years with no significant differences between the LASIK and PRK treatments. The mean preoperative spherical equivalent refraction was statistically significantly lower among those patients having PRK compared to LASIK for low myopes (-2.11 D for PRK and -2.27 D for LASIK, *t*-test = 2.26, $P = .025$) and for moderate myopes (-4.10 D for PRK and -4.62 D for LASIK, *t*-test = 6.11, $P < .001$). The percentage of eyes with astigmatic correction was not significantly different between the LASIK or PRK treatments in the low myopia group (56.7% for LASIK, 49.7% for PRK) or in the moderate myopia group (70.5% for LASIK, 67.3% for PRK). In both the low and moderate myopia groups, LASIK eyes had a higher preoperative BSCVA of 20/25 or better compared to PRK eyes.

Surgical Technique

The Nidek EC-5000 excimer laser (Nidek Co, Gamagori, Japan) with a scanning slit beam in the delivery system was used to treat all eyes. Single zone treatments were used for PRK with a 6.5-mm ablation zone and a 7.5-mm transition zone, and for LASIK, a 6.0-mm ablation zone with a 6.5-mm transition zone. The Nidek EC-5000 defaults were used at a 30 Hz repetition rate with a 0.215 cylindrical compensation factor and a rate of 0.285 for the cylindrical shift to sphere.

The LASIK flap was created using the Automatic Corneal Shaper (Chiron Vision, Claremont, CA). After application of topical oxybuprocaine hydrochloride 0.4%, a lid speculum was inserted. The optical zone was outlined with a 7-mm marker using gentian violet dye decentered nasally with the eye fixing on a coaxial fixation target within the operating microscope. A 3-mm zone marker was used to make three circles straddling the edge of the proposed flap to assist in postoperative alignment. The suction ring was aligned with the 7-mm zone circle.

The adequacy of suction was checked with the Chiron applanation lens. Balanced salt solution was applied to the cornea and suction ring of the keratome. The keratome was inserted into the suction ring and a nasally hinged lamellar flap of 160 µm was created. The suction ring and keratome were removed and the corneal flap reflected nasally to lie on a cellulose sponge. The laser ablation was

then performed on the exposed stroma. The corneal bed was irrigated with balanced salt solution and the flap replaced, ensuring precise alignment. The 360° striae test was performed after 5 minutes to ensure flap adhesion. The speculum was removed, and chloramphenicol 0.5% and fluoromethalone 0.1% drops were instilled into the lower fornix. A clear shield was taped over the eye immediately postoperatively for the first 24 hours and then worn at night for 5 nights. Postoperatively, topical antibiotics and corticosteroids were continued at four times per day for 1 week.

A standard technique was used for PRK.[16] Briefly, after the application of amethocaine 1%, a lid speculum was inserted and mechanical debridement of the corneal epithelium was performed within a 7.5-mm central zone with either a blunt Beaver blade or Paton spatula. Surface ablation was then performed using a 6.5-mm ablation zone with a 7.5-mm transition zone and the Nidek EC-5000 laser default settings for cylinder compensation and shift rate as used for LASIK. After surgery, diclofenac sodium 0.1%, fluoromethalone 0.1%, homatropine hydrobromide 5%, and chloramphenicol ointment were instilled into the eye. A semipressure patch was applied and patients were asked to leave this in place for 24 hours. Topical antibiotics were continued four times daily until the epithelium had healed. Fluoromethalone 0.1% was tapered over 2 to 4 weeks. Patients were given codeine phosphate (30 mg)/paracetamol (500 mg) and instructed to take two tablets every 4 hours for the first 24 to 28 hours.

Both groups of patients were examined using a standardized protocol at 1, 3, 6, and 12 months following excimer ablation.[15] Data were entered into a customized version of Microsoft Access for Windows '95 Version 7 and the data were analyzed using the Statistical Program for Social Sciences (SPSS for Windows, Version 8.0).[17] Statistical analysis included the Pearson chi-square statistic (X^2) for proportions and Student's *t*-test for continuous data.[18] All chi-square values presented had two degrees of freedom. Fisher's exact test or the Yates correction was employed for determining the statistical significance for a single 2 x 2 table when a cell count was $\leqslant 5$.[18]

RESULTS

Patients Lost to Follow-up

Of the original 314 eyes treated with LASIK, 274 eyes (87.2%) were observed at 1 month, 191 eyes (60.8%) at 3 months, and 139 eyes (44.2%) at 6 months. Of the 308 original eyes treated with PRK, 281 eyes (91.2%) were observed at 1 month, 250 eyes (81.1%) at 3 months, and 209 eyes (67.8%) at 6 months.

To investigate if there was a surveillance bias associated with attendance to follow-up examinations, we examined the uncorrected visual acuity (UCVA) at the preceding examination for those who attended the examination compared to those who did not (Table 2). In general, those who failed to attend a scheduled examination (for example, the 3-month examination), had a better UCVA in the previous scheduled examination (in this example, the 1-month examination) than those who did attend the scheduled examination. This suggests that patients who failed to attend a follow-up examination had at least as good uncorrected visual acuity as those who did.

Uncorrected Visual Acuity

Figure 1 shows the uncorrected visual acuity at 1, 3, and 6 months by treatment and amount of preoperative myopia. In low myopes, a higher percentage of LASIK compared to PRK eyes had an UCVA of 20/20 or better at 1 month (80% for LASIK, 53% for PRK, $X^2 = 16.63$, $P = <.001$), and at 6 months (89% for LASIK, 69% for PRK, $X^2 = 5.59$, $P = .03$). In the moderate myopia group, more eyes could see 20/20 or better after LASIK than after PRK at 1 month (62% for LASIK, 29% for PRK, $X^2 = 35.96$, $P < .001$), at 3 months (65% for LASIK, 53% for PRK, $X^2 = 4.16$, $P = .04$), and at 6 months (77% for LASIK, 61% for PRK, $X^2 = 5.70$, $P = .02$). In general, the percentage of eyes achieving UCVA of 20/40 or better was similar for LASIK and PRK. However, a statistically significant difference was observed among LASIK and PRK eyes that achieved an UCVA of 20/40 or better at 1 month in the moderate myopia group (96% for LASIK, 89% for PRK, $X^2 = 6.04$, $P = .01$).

Predictability and Accuracy

For low myopes, significantly more LASIK eyes than PRK eyes were within ±0.50 D of attempted correction at 1 month (81% for LASIK, 67% for PRK, $X^2 = 4.61$, $P = .03$), but no significant differences were observed at 3 months (82% for LASIK, 83% for PRK, $X^2 = 0.44$, $P = .82$), and at 6 months (94% for LASIK, 87% for PRK, $X^2 = 1.01$, $P = .31$) (Table 3). A similar trend was seen in the moderate myopes; the percentage of LASIK and PRK treated eyes within ±0.50 D of attempted correction at 1 month was 72% for LASIK, 62% for PRK ($X^2 = 3.82$, $P = .05$); at 3 months, 77% for LASIK, 75% for PRK ($X^2 = 0.14$,

Table 2
Attendance and Uncorrected Visual Acuity at Follow-up Examinations After PRK or LASIK

Follow-up Examination of Those Examined at Previous Examination	Attended Previous Exam (n)	Uncorrected Visual Acuity at Previous Scheduled Examination — 20/20 or Better %	P-value	— 20/25 or Better %	P-value	— 20/40 or Better %	P-value
3-month PRK							
Attended	233	38.4	.02	59.2	.12	89.7	.58
Did not attend	40	57.5		80.0		92.5	
3-month LASIK							
Attended	174	63.8	.04	78.7	.12	96.0	--
Did not attend	71	77.5		87.3		98.6	
6-month PRK							
Attended	187	56.1	.16	73.3	.07	94.1	1.00*
Did not attend	49	67.3		85.7		93.9	
6-month LASIK							
Attended	109	71.6	.06	85.3	.004	94.5	--
Did not attend	56	57.1		66.1		100.0	
12-month PRK							
Attended	135	61.5	.33	80.7	.57	95.6	.26
Did not attend	43	69.8		76.7		90.7	
12-month LASIK							
Attended	51	66.7	.77	76.5	1.00*	92.2	1.00*
Did not attend	17	70.6		76.5		94.1	

**Fisher's Exact Test*

Table 3
Baseline Myopia and Refractive Error at 1,3, and 6 Months Following LASIK or PRK

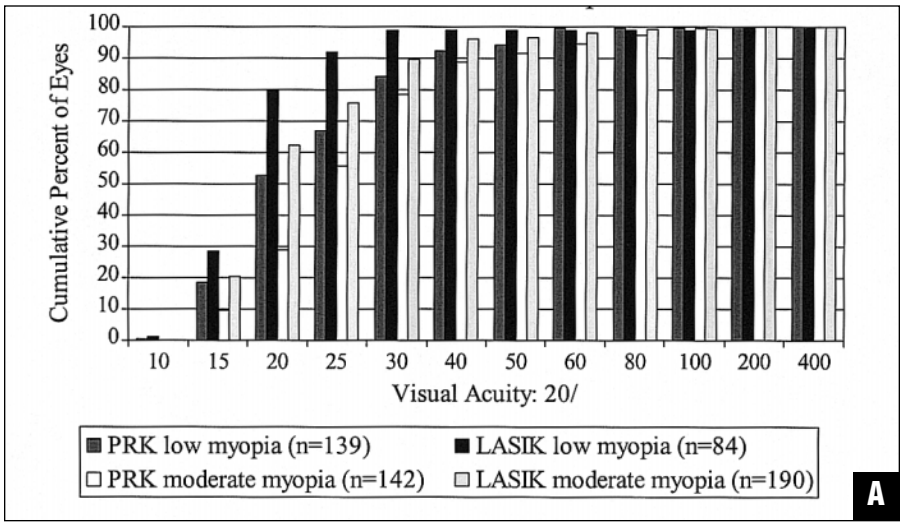
Myopia Group	Refractive Error After Surgery (D)	Follow-up — 1 month LASIK n	(%)	PRK n	(%)	3 months LASIK n	(%)	PRK n	(%)	6 months LASIK n	(%)	PRK n	(%)
Low Myopia	<-1.00	0	(0)	2	(1.4)	0	(0)	3	(2.5)	0	(0)	1	(1)
(-0.50 to -3.00 D)	-1.00 to -0.51	4	(4.8)	2	(1.4)	5	(10)	9	(7.5)	0	(0)	5	(5.2)
	-0.50 to +0.50	67	(80)	93	(67)	41	(82)	100	(84)	35	(94)	84	(87)
	+0.51 to +1.00	11	(13)	35	(25)	3	(6)	6	(5)	2	(5.4)	4	(4.1)
	>+1.00	1	(1.2)	6	(4.3)	1	(2)	2	(1.7)	0	(0)	3	(3.1)
	total	83	(100)	138	(100)	50	(100)	120	(100)	37	(100)	97	(100)
Moderate Myopia	<-1.00	6	(3.2)	2	(1.4)	5	(3.5)	2	(1.5)	4	(3.9)	3	(2.7)
(-3.10 to -6.00 D)	-1.00 to -0.51	16	(8.4)	4	(2.8)	8	(5.7)	8	(6.2)	7	(6.9)	6	(5.4)
	-0.50 to +0.50	137	(72)	88	(62)	108	(77)	97	(75)	74	(73)	86	(77)
	+0.51 to +1.00	20	(11)	30	(21)	13	(9.2)	17	(13)	11	(11)	13	(12)
	>+1.00	11	(5.8)	18	(13)	7	(5)	6	(4.6)	6	(5.9)	3	(2.7)
	total	190	(100)	142	(100)	141	(100)	130	(100)	102	(100)	111	(100)

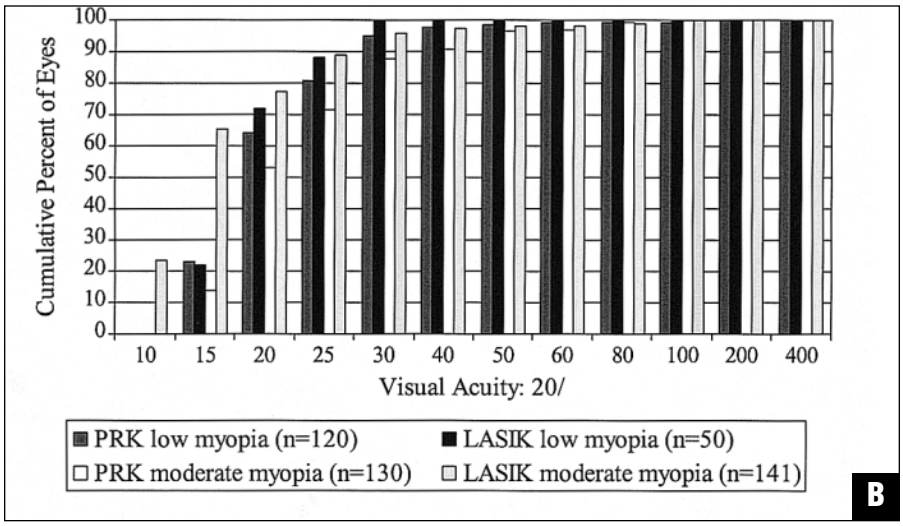
P = .70); and at 6 months, 73% for LASIK, 78% for PRK (X^2 = 0.69, P = .40).

Refractive error at 6 months after PRK or LASIK treatment is shown in Figure 2. In the low myopia group, 96% of the PRK eyes and 100% of the LASIK eyes were within ±1.00 D (Fisher's Exact test, P = .06). In the moderate myopic eyes, 95% of PRK eyes and 90% of LASIK eyes were within ±1.00 D (X^2 = 1.48, P = .22).

Stability of Refractive Correction

In this study there was no evidence of significant regression for either procedure across the range of myopia (Fig 3). There was no significant change in mean spherical equivalent refraction after 1 month for LASIK in both groups, but for PRK there was some overcorrection at 1 month and then stability from 3 months onward.





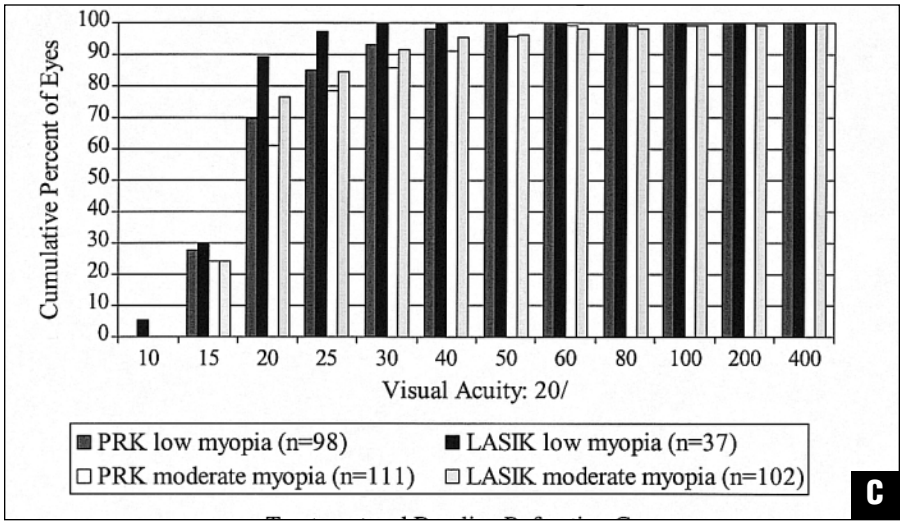


Figure 1. Uncorrected visual acuity after PRK or LASIK at **A)** 1 month, **B)** 3 months, and **C)** 6 months.

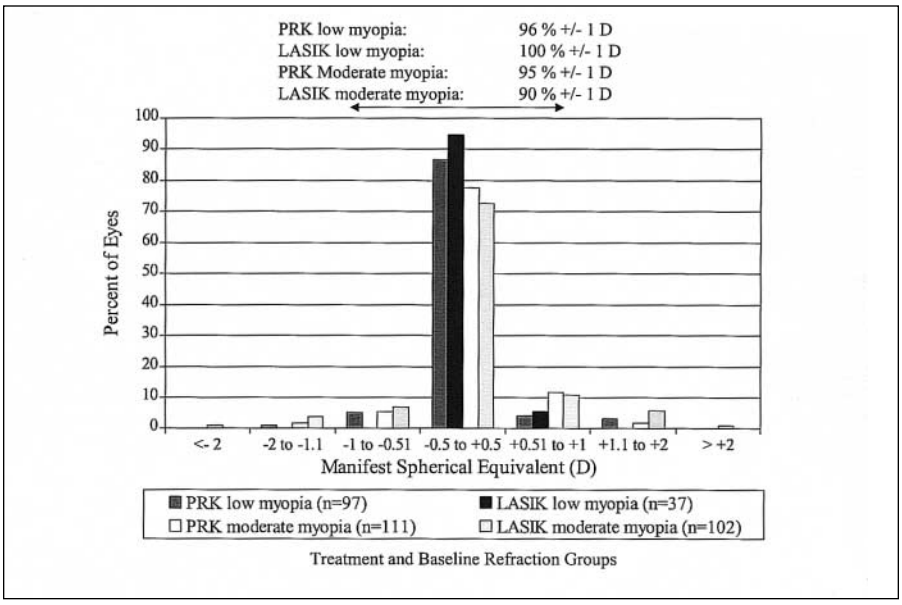


Figure 2. Refractive error after PRK or LASIK.

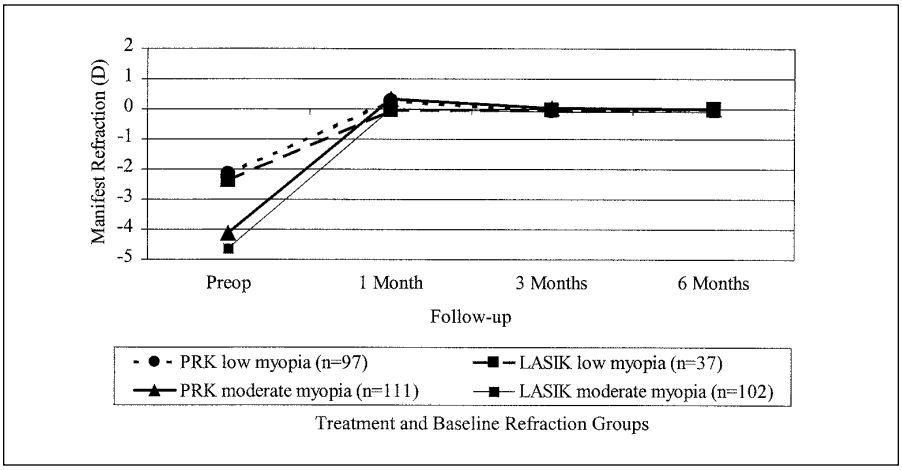


Figure 3. Change in refraction after PRK or LASIK.

Loss of Best Spectacle-corrected Visual Acuity

At 6 months, the distribution of lines of BSCVA lost was similar between LASIK and PRK eyes (Fig 4). For low myopic eyes, five (5.1%) PRK eyes and one LASIK eye (2.7%) lost one line of BSCVA (Fisher's Exact P = .47), but no eyes lost more than two lines. For moderately myopic eyes, one line of BSCVA was lost in seven (6.3%) PRK eyes and nine (8.8%) LASIK eyes (X^2 = 0.48, P = .48). In the moderately myopic group, two lines were lost in two (1.8%) PRK eyes and one (1.0%) LASIK eye. One of the PRK eyes that lost two lines of BSCVA had a preoperative BSCVA of 20/16 and a 6-month BSCVA of 20/25. By 12 months, vision had improved in this eye and BSCVA was 20/20. The other PRK eye that lost two lines of BSCVA was 20/32 preoperatively and 20/50 BSCVA at 6 months. Unfortunately, 12-month visual acuity data are unavailable for this eye.

One LASIK eye in the moderately myopic group lost four lines of BSCVA. This patient had a dislocated flap at day one and after replacement, was left with significant folds and then went on to a partial flap necrosis requiring amputation of the flap.

Corneal Haze

Significant corneal haze was not seen for LASIK or PRK eyes. The mean haze score using a standard photographic grading chart[3] was less than 0.5 in each group (data not shown).

Retreatment

Five (1.6%) of the LASIK eyes and 11 (3.6%) of the PRK eyes required retreatment (X^2 = 2.43, P = .12). Of the LASIK retreated eyes, final UCVA was 20/20 in two eyes, 20/25 in two eyes, and 20/32 in one eye. Final BSCVA among the retreated LASIK eyes was 20/20 in four eyes and 20/25 in one eye.

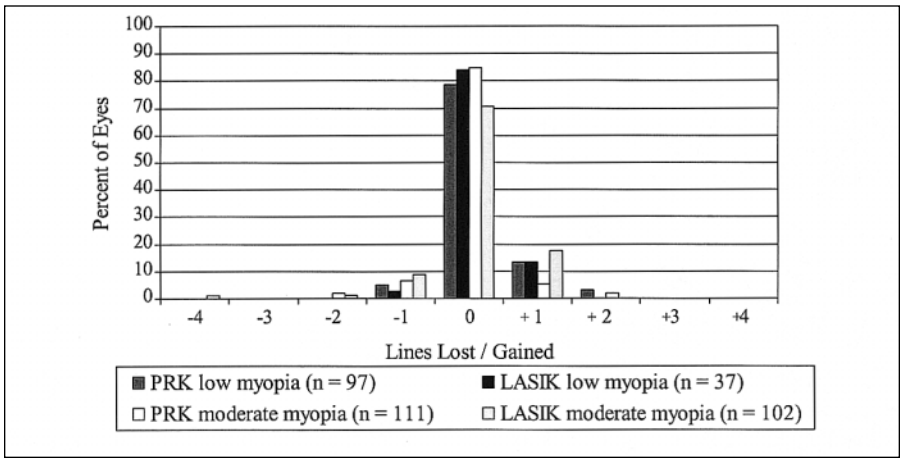


Figure 4. Change in spectacle-corrected visual acuity (lines lost or gained) after PRK or LASIK.

The latter eye lost one line of best spectacle-corrected visual acuity. Among the PRK retreated eyes, final UCVA was 20/20 or better in five eyes, 20/25 in three eyes, 20/32 in one eye, 20/50 in one eye, and 20/80 in one eye. Final BSCVA among the PRK retreated eyes was 20/20 or better in seven eyes, 20/25 in three eyes, and 20/32 in one eye. In the PRK retreated group, two eyes lost one line of best spectacle-corrected visual acuity and one eye lost two lines of best spectacle-corrected visual acuity.

Adverse Reactions

Flap complications occurred in 6% of the LASIK group (Table 4). No other unanticipated adverse reactions such as microbial keratitis, endophthalmitis, corneal decompensation, hyphema, hypopyon, cataract, or retinal lesions were found in this study. Two eyes had a loss of two or more lines of BSCVA as a direct result of a flap complication, as indicated in Figure 4. None of the eyes that had flap complications required retreatment.

DISCUSSION

To adequately advise patients who are considering refractive surgery, it is essential to present clearly the relative advantages and risks of the different procedures. It has been suggested that LASIK is the procedure of choice for myopia greater than 6.00 D spherical equivalent refraction.[12] Our study showed that LASIK is a safe, efficient, and predictable method when compared to PRK to surgically correct low or moderate myopia (≤-6.00 D). In general, LASIK showed a slight advantage in improvement of UCVA up to 6 months, but thereafter there was no significant difference between the two procedures.

Patients undergoing LASIK and PRK achieved similar good outcomes for UCVA for the treatment of their low or moderate myopia, and this is comparable to other studies.[8,11,19] Salah and colleagues reported an UCVA of 20/40 or better in 92.8% of patients in the low myopia group (-2.00 to -6.00 D).[15] As has been reported[12], a higher percentage of LASIK patients have good uncorrected visual acuity at 1 month. Efficient visual outcomes and the speed at which they are obtained are real advantages for patients undergoing LASIK as compared to PRK.

The inclusion of data from both eyes from some patients may have introduced a statistical bias in some of our results. Data from two eyes from one individual will be correlated to a greater degree than data from two eyes from two separate individuals. This potential bias, which can also occur in other studies that employ similar methodologies, should be considered when interpreting results.

LASIK maintained its stability throughout the 12-month period whereas PRK showed an initial

Table 4
Intraoperative and Postoperative Flap Complications in 314 LASIK-treated Eyes

	Complications n	(%)	Loss of 2 or More BSCVA Snellen Lines n	(%)
Intraoperative				
Loss of suction/ incomplete flap	6	(2.0)	0	
Thin flap	2	(0.6)	0	
Postoperative				
Epithelial ingrowth	7	(2.0)	1	(0.3)
Diffuse interface keratitis	2	(0.6)	0	
Slipped flap	1	(0.3)	1	(0.3)
Total	19	(6.0)	2	(0.6)

hyperopic correction at 1 month. A previous study had a predictability for LASIK of 92.5% for ±1.00 D of emmetropia, which is comparable to our group (Ruiz L, Slade SG, Upedegraf S, et al. A single centre study to evaluate the efficacy, safety, and stability of laser in situ keratomileusis for low, moderate and high myopia with and without astigmatism. 1998; unpublished data). Undercorrection was the most frequent complication in studies for higher amounts of myopia[20], but this was not seen in our study of low myopia. Retreatment was required in 1.6% of the LASIK eyes and is much less than the reported range of 9.3% to 17%[21-23] for higher amounts of myopia. In our study, it is similar to the rate for PRK (3.6%), which itself is dependent on preoperative spherical equivalent refraction.[16]

A reduction in BSCVA is seen consistently in a small percentage of eyes after LASIK.[22] No loss of two or more lines of BSCVA occurred in the low myopia PRK or LASIK groups. In the moderately myopic group, loss of two or more lines of BSCVA occurred in 2.0% of the LASIK and 1.8% of the PRK eyes. Most of this loss of BSCVA was due to complications that occurred intraoperatively. Flap complications occurred in 6% of the LASIK cohort and in two patients (0.6%) resulted in significant visual loss. This incidence of flap complications is in accordance with recently published data.[24] At the start of this study, the study surgeons had collectively performed 50 LASIK procedures with a previous laser and collectively were still near the beginning of a learning curve; other groups[21,25] have commented on the higher incidence of flap complications during this period. Nonetheless, the possibility of flap complications is a serious drawback to an unequivocal recommendation for LASIK as the treatment of choice for low myopia and careful counseling of the patient is mandatory preoperatively.

In this study, there was a high non-attendance rate for patients after both procedures, but in particular after LASIK. This "lost to follow-up" issue has not been addressed in previous studies in terms of visual outcome. However, Higa and colleagues[26] made the observation that individuals with low myopia were more likely to miss their 12-month follow-up examination. Only 19.4% of the original LASIK cohort compared to 53.3% in the PRK group attended their final examination at 12 months. It could be that those with very good vision are so happy they do not bother to come back, or that those with poor vision are so unhappy that they had already sought a second opinion. To explore this further, we looked at the characteristics of those who did attend versus those who did not attend their next scheduled examination. The primary outcome of interest after refractive surgery is undoubtedly UCVA. Our data suggest that patients are not basing their decision to attend or miss their next appointment on the basis of poor UCVA. Other studies have shown that it is professionals in their middle 30s who seek refractive surgery.[9] One can understand that given good early results following LASIK, there might be a progressive drop off in attendance to follow-up examinations.

Our study showed that in comparison to PRK, LASIK was an efficient, predictable, and stable method for the treatment of low or moderate myopia. One may now consider lowering the previous recommendation of -6.00 D as the lower limit for which to treat myopia by this technique. Patients appear to have a high level of satisfaction with LASIK as a result of the rapid rate of visual recovery. This would appear to be supported by the relatively higher rates of non-attendance to follow-up examinations observed among LASIK patients with good visual outcomes.

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