ARTICLES

Eleven-year follow-up of laser in situ keratomileusis

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PURPOSE: To report the long-term (11-year) outcomes (stability and complications) of laser in situ keratomileusis (LASIK) in patients with high myopia.

SETTING: University refractive surgery center.

METHODS: Seven patients (4 with bilateral treatment and 3 with unilateral treatment) who had myopic LASIK and completed 11 years of follow-up were included in the study.

RESULTS: The mean age of the 2 men and 5 women was 41.7 years ± 6.5 (SD) (range 34 to 50 years). The mean follow-up was 140.18 ± 6.70 months (range 132 to 150 months). At 11 years, the spherical equivalent error was statistically significantly reduced, from a mean of −12.96 ± 3.17 diopters (D) (range −19.00 to −10.00 D) before LASIK to a mean of −1.14 ± 1.67 D (range −4.25 to 1.00 D) after ($P<.001$). Predictability of postoperative refraction 6 months and 11 years after LASIK showed that 6 eyes (55%) were within ±1.00 D of intended correction. No late postoperative complications occurred. Five patients (8 eyes, 73%) were satisfied with the final outcome.

CONCLUSIONS: Laser in situ keratomileusis was moderately predictable in the correction of high degrees of myopia. After the sixth postoperative month, refractive and topographic stability were obtained. No long-term sight-threatening complications occurred during the follow-up period.

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As the number of refractive operations increases every year, refractive surgery continues to gain worldwide acceptance for its safety. An important factor in the general acceptance of refractive surgery by patients and physicians was the introduction of laser in situ keratomileusis (LASIK).[1–5] The use of LASIK for the surgical correction of myopia is rapidly gaining worldwide acceptance. Quick visual rehabilitation, minimum postoperative discomfort, and the ability to correct high degrees of refractive errors with little postoperative corneal haze are a few reasons for the popularity of LASIK over other surgical options for vision correction.

With accumulated experience and the application of more sophisticated techniques, the safety and efficacy of refractive surgery have increased considerably in recent years. In addition, patients' satisfaction and complaints, together with the physicians' clinical suggestions, are being investigated over the long term to determine the maximum efficacy of refractive surgery.

Despite the number of studies that support the efficacy of LASIK, there is great concern about the long-term possible complications of such an invasive technique.[6–10] After LASIK, the cornea is permanently structurally altered, not only by the laser central stromal ablation (depending on the attempted correction), but also by the creation of the flap itself. The possibility of chronic stromal remodeling, unstable corneal biomechanics, and late regression remains.

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To make conclusions about the safety of any invasive surgical procedure, it is important to study the long-term possible postoperative alterations and complications, especially in these permanently tectonically changed corneas. To investigate further long-term refractive and mechanical stability and late sequelae in post-LASIK corneas, we conducted a study in which all eyes had a minimum follow-up of 11 years.

PATIENTS AND METHODS

Eleven eyes of 7 patients (4 with bilateral treatment, 3 with unilateral treatment) who had myopic LASIK and had completed 11 years of follow-up were enrolled in this study. The 11 eyes (52%) were from a group of 21 eyes that had initially participated in a clinical trial for the safety and efficacy of LASIK; however, 10 did not complete the 11-year follow-up.

All patients signed an informed consent explaining the novel nature of the procedure. Patients were excluded if any of the following criteria applied after the preoperative examination: previous intraocular or corneal surgery, history of herpes keratitis, or diagnosed autoimmune disease. Inclusion criteria were 20 years old or older, stable myopia for the past 2 years, no contact lens wear for at least 2 weeks before preoperative evaluation and surgery, no active or residual corneal disease (eg, scarring, dry eye, blepharitis, lagophthalmos), astigmatism less than 1.50 diopters (D), and corneal optical thickness at least 480 µm. Patients with diabetes or systemic collagen disease likely to affect wound healing were excluded.

The preoperative examination included slitlamp microscopy, uncorrected visual acuity (UCVA), Snellen best corrected visual acuity, manifest and cycloplegic refractions, intraocular pressure (IOP), corneal topography (Corneal Analysis System, version 2.104, EyeSys Laboratories Inc.), and optical pachymetry of the central cornea (Haag-Streit).

Before surgery, the eye was anesthetized with topical oxybuprocaine hydrochloride eyedrops 4 mg/mL (Novesin 0.4%), 1 drop every 5 minutes for a total of 3 drops. Peribulbar anesthesia was then administered using 2 to 4 cc of lidocaine hydrochloride 20 mg/mL (Xylocaine 2%). A Barraquer eyelid speculum was placed, and the eye was cleaned with normal saline. A nasally based, 150 µm thick corneal flap was made with a Draeger lamellar rotor keratome (Storz Instruments) using the 0.15 mm spacer. This semiautomatic rotor keratome operates with a rotational mode of the blade.

The corneal bed was ablated with a 193 nm excimer laser (Aesculap Meditec MEL 60); beam fluence at the cornea was 220 mJ/cm^2; the firing rate, 20 Hz; and the ablation zone 5-0 mm. The photorefractive keratectomy algorithm for which the machine was programmed was used. In patients with more than 12.00 D of attempted correction, the module was programmed for a second consecutive treatment. (The maximum attempted correction per treatment was 12.00 D.) The automated, 4.9 mm diameter, computer-controlled contracting iris diaphragm of the unit with its incorporated suction ring was placed on the corneal bed, and the intended correction was entered into the module. Before the ablation, beam quality was checked on photographic paper.

Patients were examined every 24 hours for the next 3 to 5 days. All eyes received antibiotic–steroid combination eyedrops 4 times per day for 4 weeks. Follow-up was scheduled at 1 day, 2 weeks, 1, 3, and 6 months, and 1 year. At each visit, a full refraction and slitlamp and topographic examinations were performed. During the first postoperative year, examinations were performed with the Corneal Analysis System. At the last follow-up examination, the Technomed C-Scan (Technomed GmbH) was used.

No included eye had any other ocular surgery during the follow-up period. At the last follow-up, pachymetry was measured by ultrasound (DGH 5100 Technology).

Questionnaire

A questionnaire was designed to assess patients' overall satisfaction at the last postoperative visit. In each case, an analog scale from 1 to 5 was used (1 = dissatisfied; 5 = extremely satisfied).

Statistical Analysis

Results are presented as mean ± SD. Group differences in continuous variables were evaluated using the paired *t* test. The change in manifest refraction spherical equivalent (SE) was plotted over time to determine long-term stability, and the difference as a function of time was analyzed using paired 2-tailed *t* tests (at 1 to 3 months, 3 to 6 months, 6 to 12 months, and 12 months to 11 years). A *P* value less than 0.05 was considered statistically significant.

RESULTS

The mean age of the 2 men and 5 women was 41.7 ± 6.5 years (range 34 to 50 years). The mean follow-up was 140.18 ± 6.70 months (range 132 to 150 months).

Refractive Outcomes, Stability, Predictability

The mean preoperative SE was −12.96 ± 3.17 D (range −19.00 to −10.00 D), and the mean attempted spherical correction was −12.59 ± 2.96 D (range −18.00 to −10.00 D). At 11 years, the mean SE error was statistically significantly reduced to −1.14 ± 1.67 D (range −4.25 to 1.00 D) ($P<.001$). At 6 months, refractive stability and topographic stability were obtained and remained stable during the follow-up period, with no significant changes between that time and 11 years (mean −0.96 ± 1.88 versus −1.14 ± 1.67) ($P = .36$) (Figures 1 to 3). Predictability of postoperative refraction 6 months and 11 years after LASIK showed that 6 eyes (55%) were within ±1.00 D of the intended correction (Figure 4). No significant changes in achieved corrections were observed between 6 months and 11 years after LASIK (mean 11.52 ± 2.07 D versus 11.36 ± 2.20 D) ($P = .38$).

Uncorrected and Best Spectacle-Corrected Visual Acuity

The pre-LASIK UCVA was poor (counting fingers) in all eyes. During the first postoperative year and at the last follow-up examination, 5 (46%) of 11 eyes had a UCVA of 20/40 or better. The mean difference between

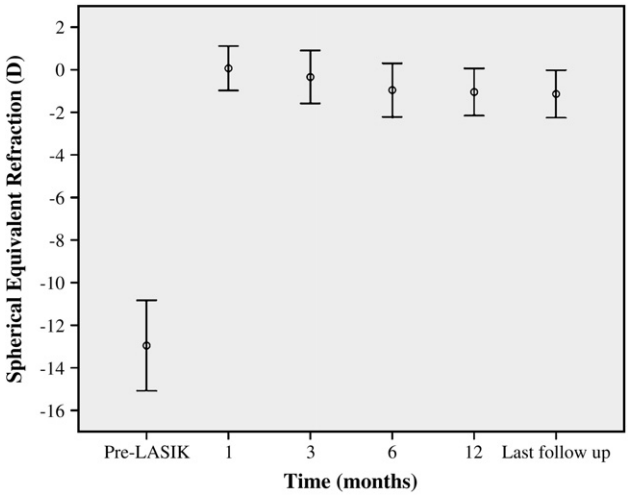


Figure 1. Mean spherical equivalent refraction (D) change after myopic LASIK over an 11-year follow-up shows refractive stability was at 6 months (with refractive regression between the first and the sixth post-LASIK month). There was no significant change in refractive stability between the 6 months and 11 years. The error bars represent 95% confidence intervals.

preoperative and postoperative UCVA was a gain of 4 lines (range +1 to +10 lines) (Figure 5, *A*). Four eyes gained only 1 line of UCVA, 2 because of residual myopia and 2 because of amblyopia.

Preoperatively, the best spectacle-corrected visual acuity (BSCVA) ranged from 20/100 to 20/20. Three eyes (27%) maintained the pre-LASIK BSCVA. Five eyes (46%) had a gain of 1 to 4 lines, and 3 eyes (27%) lost 2 to 3 lines as a result of keratome-related complications (buttonholed flap and half cut, resulting in irregular astigmatism) and laser (decentration) complications. The mean difference between preoperative and postoperative BSCVA was a gain of 0.6 lines (range −3 to +4 lines) (Figure 5, *B*).

Questionnaire

Five patients (8 eyes, 73% of all eyes) reported being happy with the results (score 5). The other 2 patients (3 eyes) reported being unhappy because of residual refractive error, loss of BSCVA, and significant subjective visual problems (eg, glare, halos, ghost images).

Pachymetry

The mean preoperative corneal optical pachymetry was 531.46 ± 29.46 µm (range 480 to 570 µm). The mean at the last follow-up was 436.00 ± 47.07 (range 343 to 480 µm) in 8 eyes.

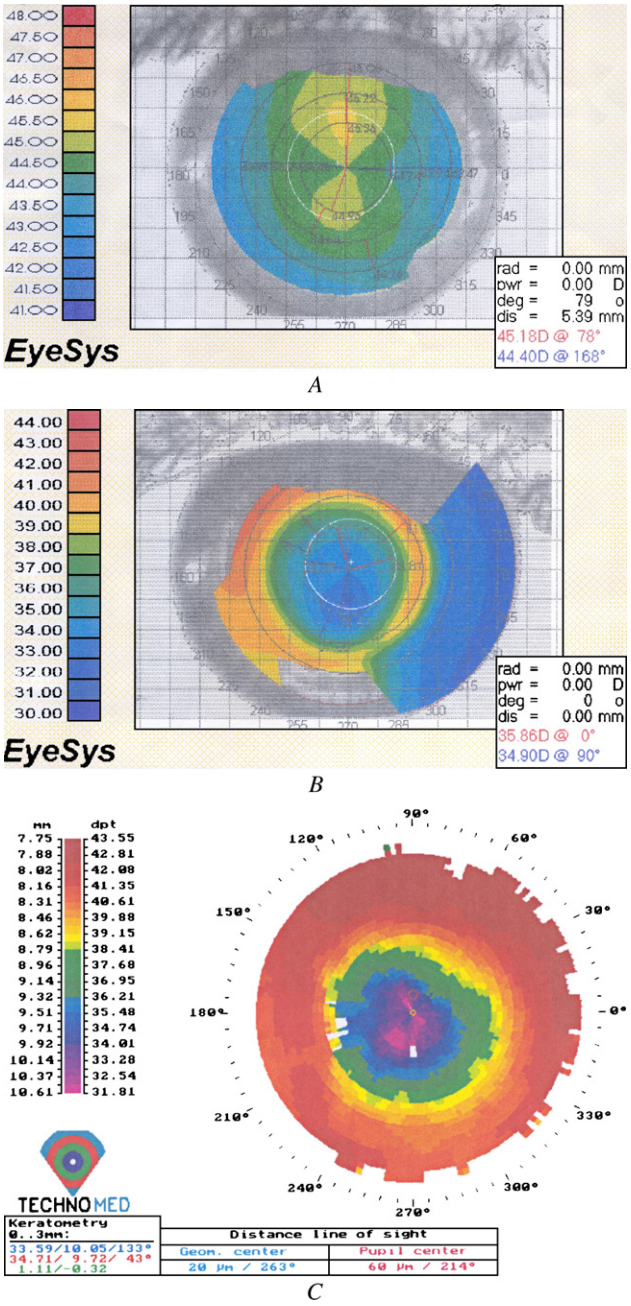
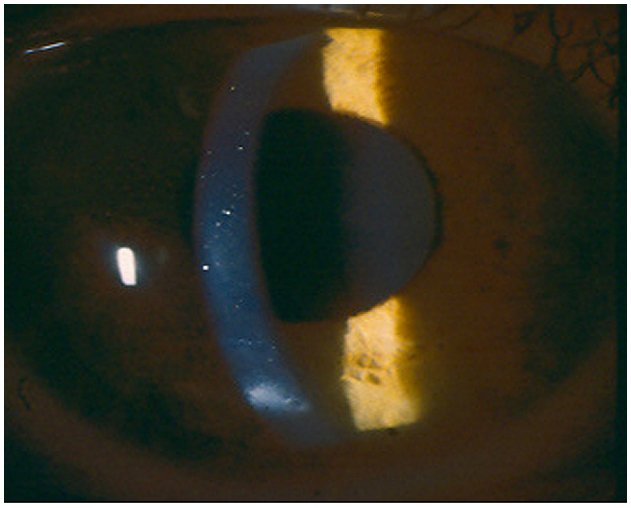


Figure 2. Preoperative topography (*A*) and topography at 6 months after LASIK (*B*) and 11 years after LASIK (*C*).

Adverse Effects and Postoperative Complications

Three eyes had postoperative complications, 2 related to flap creation (irregular astigmatism resulting from buttonhole and half cut) and 1 to laser ablation (1.3 mm decentration) that caused significant postoperative astigmatism and loss of BSCVA. Most eyes (3/11; 82%) had night-vision



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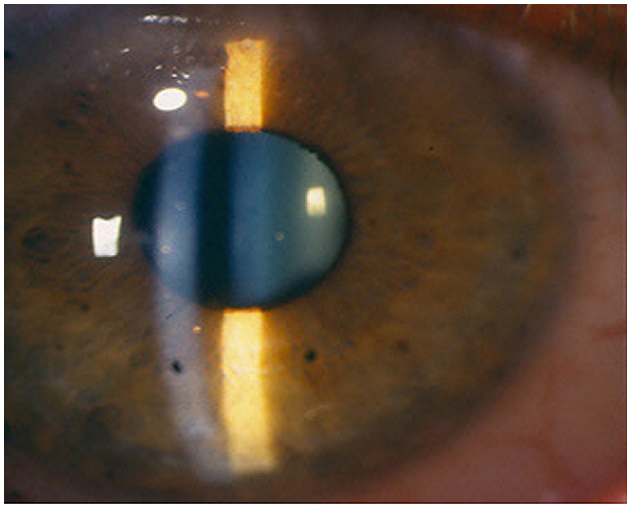

B

Figure 3. Slitlamp examination of an eye 10 months (*A*) and 11 years (*B*) after LASIK shows improvement in haze at the inferior part of flap's edge.

problems (eg, halos). No late postoperative complications occurred in this series of patients, and there was no evidence of cataract formation.

DISCUSSION

Refractive surgery, a subspecialty of ophthalmology, is rapidly gaining worldwide acceptance. The introduction of laser in situ keratomileusis (LASIK) in the field of refractive surgery, with the impressive final outcomes (eg, quick visual rehabilitation, minimum postoperative discomfort, and the ability to correct high degrees of myopia without postoperative corneal haze) compared with previously used techniques, contributed to further

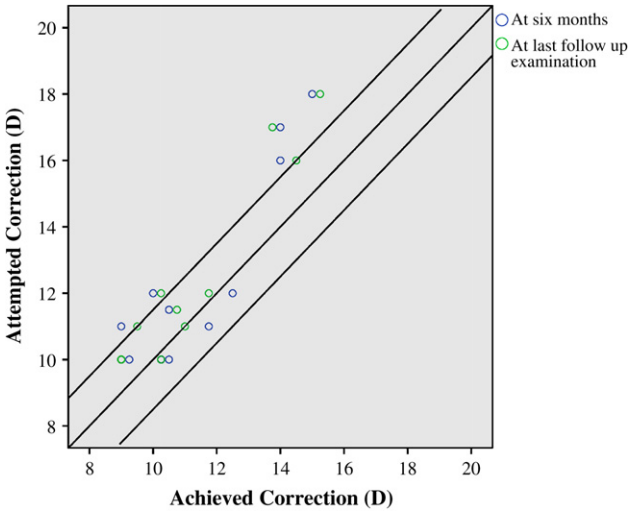

Figure 4. Predictability of the refractive outcome at 6 months and at last follow-up examination after LASIK.

acceptance of refractive surgery among patients and physicians.

Despite this, the technique of LASIK is relatively new. It has been only 15 years since the first published case series of blind human eyes after LASIK.[1] To our knowledge, the longest studies of LASIK have a 6-year follow-up.[6] During these years, great improvements in microkeratome and excimer laser technology have led to a significant decrease in intraoperative and early postoperative complications. Nevertheless, the question of long-term postoperative complications remains, with the major issue being the possible long-term effects on ocular structures of such an invasive technique. The appearance of late-onset complications distinctive to LASIK (eg, alterations in IOP measurements and intraocular lens calculations, late-onset diffuse lamellar keratitis and ectasia) has led ophthalmologists to adopt a more conservative approach regarding the long-term results of such a relatively new technique.[11–13]

In the present study, no long-term complications were observed. Refractive and topographic stability were achieved after the sixth post-LASIK month. This observed delay in refraction and topographic stability could be mainly because of the increased amount of attempted corrections in the study. It is known that after high attempted myopic corrections, it takes longer for refraction to stabilize than after smaller corrections.[9]

Another important finding was the absence of post-LASIK corneal ectasia despite the increased attempted corrections. A simple explanation is the small optical zone used in this study (5.0 mm), which reduced the amount of ablated cornea (according to the law of Munnerlyn et al.[14]). As a counterbalance, there was an increased incidence of

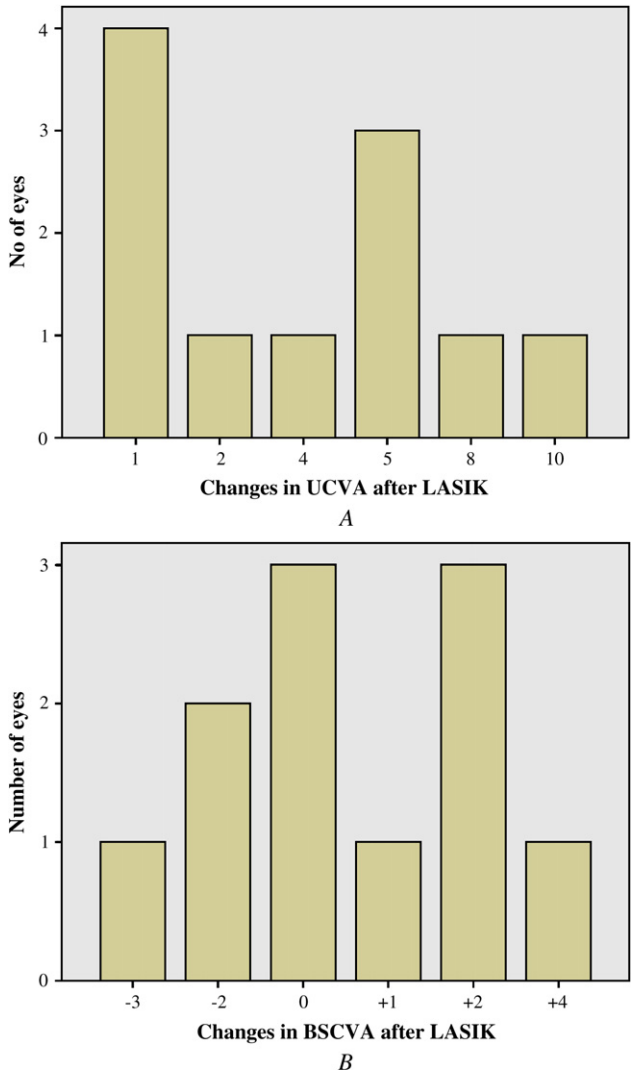

Figure 5. Change in UCVA (*A*) and BSCVA (*B*) between preoperative and the last postoperative follow-up.

night-vision problems in these patients. The improvement in excimer lasers, larger optical zones (up to 9.0 mm), a more conservative approach to attempted corrections (leaving more than 250 to 300 μm of residual bed thickness), and appropriate patient selection (exclusion of patients with subclinical keratoconus or thin corneas) have led to the increase in the safety and efficacy of LASIK in recent years. Furthermore, improvement in microkeratome technology that reduces the incidence of flap-related complications (which had an increased rate in the current study) further improves the outcomes of LASIK.

Unexpectedly, 5 patients, representing 73% of eyes, reported being satisfied with the final outcomes despite the increased incidence (82%) of night-vision problems and the moderate predictability. It seems that patients with high degrees of ametropia, such as the patients in the current study, are more receptive to such problems.

Results similar to ours have been reported in published long-term follow-up studies of LASIK. Six years after LASIK, Sekundo et al.[6] reported an increase in patients' satisfaction score (75%) despite the high incidence of cut failures (15%) and night-vision problems (75%) and the low predictability of attempted corrections. (At the end of the study, only 45% of eyes were within ±1.00 D of attempted correction.) Similarly, 5 years after LASIK, O'Doherty et al.[7] reported high levels of patient satisfaction with increased predictability of attempted correction (comparison with that in Sekundo et al.'s and our study) in patients with moderate myopia; the mean preoperative SE was lower than that in the other 2 studies (−4.85 D and −12.96 D, respectively).

This study has several potential limitations. These include the small number of eyes, absence of data during the interval between 6 months and 11 years, low rate of patients completing follow-up (52%), possible age-induced refraction, topographic alterations during the long-term follow-up (chronic stromal remodeling), lack of comparison with a control group, and the retrospective nature of the study.

In summary, to our knowledge, this is the first long-term (11-year) follow-up LASIK study. No late postoperative complications related to the technique were observed, while refractive stability was observed after the sixth postoperative month. Most patients were satisfied with the final outcomes. Further studies, including more patients and longer follow-up using modern generation and closer to the current existing instruments, are needed to draw final conclusions.

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