

Laser Subepithelial Keratomileusis for the Correction of High Myopia With the Schwind ESIRIS Scanning Spot Laser

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ABSTRACT

PURPOSE: To investigate the efficacy of laser subepithelial keratomileusis (LASEK) for the correction of high myopia with the Schwind ESIRIS scanning spot laser (Schwind eye-tech-solutions GmbH & Co, Kleinostheim, Germany).

METHODS: Fifty-one patients (76 eyes) were treated with a mean preoperative spherical equivalent refraction of -7.55 diopters (D) (range: -6.0 to -10.75 D). All eyes received a LASEK technique using 15% alcohol with a 20-second application.

RESULTS: An intact epithelial flap was obtained in 73 (96%) eyes. At 1 week, uncorrected visual acuity (UCVA) was $\geq 20/30$ in 53 (70%) eyes and $\geq 20/60$ in all eyes. At 6 months ($n=76$), the mean SE was $+0.08$ D (range: -1.00 to $+1.875$ D) with 73 (96%) eyes within ± 1.0 D of the intended correction and 60 (79%) eyes within ± 0.5 D. At 12 months ($n=46$), the mean SE was -0.07 D (range: -1.375 to $+2.0$ D) with 44 (96%) eyes within ± 1.0 D of the intended correction and 37 (80%) eyes within ± 0.5 D. Myopic cylindrical corrections were attempted in 68 eyes (range: -0.25 to -4.25 D) with vector analysis demonstrating a mean 85% correction. At last follow-up, UCVA was $\geq 20/20$ in 47 (62%) eyes, $\geq 20/25$ in 63 (83%) eyes, and $\geq 20/40$ in 75 (99%) eyes. Three (4%) eyes gained two lines of Snellen decimal equivalent best spectacle-corrected visual acuity compared to preoperative levels, 68 (89%) eyes showed no change or gained one line, and 5 (7%) eyes lost one line. None lost more than one line. Only 2 (3%) eyes at 6 to 12 months had more than $+1$ axial corneal haze and 50 (66%) showed no evidence of haze on slit-lamp examination.

CONCLUSIONS: Laser subepithelial keratomileusis for myopia up to -11.00 D with the Schwind ESIRIS laser provides good refractive and visual outcomes, with acceptable visual recovery and minimal complications. [*J Refract Surg.* 2006;22:253-262.]

Over the past two decades, numerous studies have demonstrated the efficacy of excimer laser photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) for the correction of low degrees of hyperopia and low, moderate, and even high degrees of myopia and astigmatism.¹⁻¹⁰ Comparative studies of PRK and LASIK have demonstrated minimal differences in terms of predictability and visual outcome.⁷⁻¹⁰ However, perceived advantages in terms of rapid postoperative recovery have made LASIK the procedure of choice for most refractive surgeons.¹¹ Although outcomes after LASIK are generally satisfactory, site-threatening intralamellar complications can occur, albeit rarely, and may be visually devastating.¹²⁻¹⁵ In addition, although long-term data for PRK suggest good refractive and biomechanical corneal stability,¹⁶⁻¹⁸ there is a paucity of data concerning LASIK and the data available appear to suggest uncertain refractive stability for high hyperopic and myopic corrections.¹⁹⁻²²

Such concerns have led to renewed interest in surface ablation techniques such as PRK and more recently laser subepithelial keratomileusis (LASEK).²³ It has been postulated that LASEK may offer some advantages. As a surface ablation technique, LASEK avoids the rare intralamellar complications associated with LASIK, whereas the creation of an intact epithelial sheet to cover the ablated area might induce less haze and regression, which occasionally limits the efficacy of PRK, as well as provide a faster visual recovery.²³ Published research over the past few years has indicated favorable outcomes with LASEK with refractive and visual outcomes comparable to those with PRK and LASIK.²⁴⁻²⁶ This has led to many refractive surgeons adopting LASEK techniques,

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The authors have no proprietary or financial interests in the materials presented herein.

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Received: March 1, 2005

Accepted: June 6, 2005

although LASIK still remains the favored procedure, with LASEK often being reserved for eyes with thin corneas, where the risk of postoperative ectasia is an issue, or in those whose lifestyle makes them susceptible to LASIK-flap displacement.¹⁵

Whatever the technique, the treatment of high order refractive errors remains problematic. All studies, whether performed by PRK, LASIK, or LASEK, indicate reduced efficacy in terms of refractive and visual outcomes with the treatment of refractive errors above +4.00 diopters (D) of hyperopia and -6.00 D of myopia. Opinions are still divided as to which excimer laser technique (if any) offers the best outcomes both in the short- and long-term for high order corrections. Although issues of tissue conservation and long-term biomechanical and refractive stability are a concern for many in relation to LASIK, other surgeons will not advocate the use of PRK and LASEK techniques because of concerns regarding the development of iatrogenic haze, which can be associated with increasing depths of stromal ablation with surface techniques.^{1-3,7,8,27}

To address some of these issues, we conducted a prospective pilot study to examine the efficacy of LASEK techniques for correction of high order myopic errors. Fifty-one consecutive patients (76 eyes) with spherical equivalent refractive errors between -6.0 and -10.75 D were treated with the Schwind ESIRIS scanning spot excimer laser (Schwind eye-tech-solutions GmbH & Co, Kleinostheim, Germany). All eyes were followed for 6 to 12 months, and refractive and visual outcomes were carefully analyzed.

PATIENTS AND METHODS

PATIENT ASSESSMENT

Fifty-one consecutive patients (34 women and 17 men) (76 eyes) were treated between October 2002 and May 2004. Mean patient age was 37 years (range: 24 to 52 years). Patients with pre-existing ocular pathology, previous anterior segment surgery, and connective tissue disorders were excluded. The mean preoperative manifest distance spherical equivalent refractive error was -7.55 D (range: -6.00 to -10.75 D). The mean preoperative cylindrical refractive error was -1.21 D (range: 0 to -4.25 D). The mean follow-up was 9.6 months (range: 6 to 12 months, median 12 months).

Preoperatively, patients were counseled regarding the precise nature of the procedure and its perceived risks and benefits. A full ophthalmic examination was performed, which included Snellen decimal equivalent visual acuity assessment (measured in standardized mesopic conditions of 2 lux), refraction, auto-refraction, keratometry, corneal topography with wavefront

analysis using the Keraton Scout Corneal Analyzer (Optikon 2000, Rome, Italy), slit-lamp microscopy, tonometry, mesopic pupil diameter measurement, and mydriatic funduscopy. During subjective refraction, reliance was placed on fogging techniques, in particular the +1.00 D blur test, to ensure that an accurate end point was reached consistently. This test assumes that when a further, unnecessary +1.00 D is added, the patient will be "fogged" to approximately 20/40. If, with this extra +1.00 D, Snellen acuity is significantly better than 20/40, then too much minus has been prescribed and the spherical component can be revised accordingly.

LASER

A Schwind ESIRIS excimer laser with an emission wavelength of 193 nm was used. This laser uses a 0.8-mm flying-spot with a Gaussian beam with a repetition rate of 250 Hz and a 250-Hz infrared eye tracker, which monitors the pupil margin and centers the ablation on the entrance pupil center.

OPERATIVE PROCEDURE

Patients underwent unilateral treatments; the more myopic or non-dominant eye was almost invariably the first to be treated. The second eye was usually treated 4 to 6 weeks later. Patients who were contact lens intolerant and would therefore have considerable problems with aniseikonia with postoperative spectacle correction or who had a strong preference for bilateral treatments underwent simultaneous surgery only after careful counseling concerning the elective nature of the procedure.

Following informed consent, treatments were performed by a single surgeon (D.O.). All eyes received an identical LASEK technique. Preoperatively, three drops each of topical amethocaine 1%, chloramphenicol 0.5%, and dexamethasone 0.1% were instilled over a 15-minute period. It is the authors' clinical experience that the use of amethocaine 1%, rather than other types of topical anesthetic drops, augments epithelial detachment in LASEK. The laser was programmed for the desired correction and the infrared tracker activated. Patients received treatments with programmed optical zones of 6.5 mm (n=45), 7.0 mm (n=19), or 7.5 mm (n=12), depending on the measured size of the preoperative mesopic pupil diameter. All treatments were based on Munnerlyn algorithms²⁸ with attempted correction of only lower order aberrations. The mean attempted spherical equivalent refractive correction was -7.58 D (range: -6.00 to -10.75 D). The patient was aligned beneath the laser aperture and practiced fixating on a target light. To ensure that the selected

optical zone was always as large (if not larger) than the mesopic/scotopic pupil size, the room lights and laser fixation targets were temporarily switched off and the selected optical zone was assessed in relation to the pupil diameter measured on the laser monitor by the infrared tracker (at a luminance measured at 0 lux). Following insertion of a lid speculum, 15% alcohol was applied to the central corneal epithelium for 20 seconds using a 9.0-mm LASEK well (J2900; Janach, Como, Italy). The alcohol was then drained from the well using a LASIK eye spear (BD Ophthalmic Systems, Sarasota, Fla) and the surface irrigated with balanced salt solution (BSS) (Aqsia; Baush & Lomb, Waterford, Ireland). An epithelial micro-hoe (J2915A, Janach) was then used to separate and peel back an intact epithelial flap approximately 8.0 mm in diameter with a large 6.0- to 8.0-mm superior hinge. Following formation of the flap, laser treatment was applied to the exposed anterior stromal surface. Once the laser ablation was completed, the surface was irrigated with chilled BSS and the epithelial flap replaced with an olive-tipped epithelial spatula (J2920A, Janach). A plano bandage contact lens (Focus, Night & Day; Ciba Vision, Duluth, Ga) with a diameter of 13.8 mm and base curve of 8.6 mm was then inserted and the eye inspected at the slit-lamp to ensure good replacement of the epithelial flap.

POSTOPERATIVE TREATMENT AND ASSESSMENT

Topical chloramphenicol 0.5% and dexamethasone 0.1% were administered immediately after the procedure. Oral analgesics were prescribed and two minimis vials only of guttae benoxinate 0.4% were given, with instructions to only be administered if the postoperative pain was severe and with a maximum dosage of 1 drop every 2 hours. Chloramphenicol 0.5% and fluorometholone (FML) 0.1% were administered 4 times a day for 1 week. The bandage contact lens was removed at 3 days. After the first week, FML 0.1% drops were administered on a tapering dosage for an additional 4 weeks postoperatively.

Postoperative examinations were carried out at 3 days, 1 week, and 1, 3, 6, and 12 months. At each visit, full refraction and slit-lamp microscopy were performed. Patients were asked to report any symptoms of dryness, pain on opening their eyes on waking, and the presence of halos around light sources at night that significantly impaired visual performance. Following subjective refraction and in standardized mesopic conditions of 2 lux, patients were asked to comment on the presence of halo phenomena around the Snellen chart. To assess disturbances in central corneal transparency, a subjective grading of stromal haze was made at each

visit. This was based on the following criteria: 0 = no haze; 0.5 = trace/just perceptible; 1 = easily seen with slit-lamp; 2 = moderate haze; 3 = pronounced haze, iris details visible; and 4 = scarring, iris details obscured.

VECTOR ANALYSIS

To investigate vectoral astigmatic change in the manifest refraction, vector analysis was performed in all eyes according to the system described by Retzlaff et al.²⁹

RESULTS

PERIOPERATIVE DATA AND EARLY POSTOPERATIVE RECOVERY

Using the methodology described above, an intact epithelial flap was successfully obtained in 73 (96%) eyes. Adherent flaps occurred in 3 (4%) eyes, although in all of these cases, it was still possible to obtain and replace a partial epithelial flap.

Most patients reported some ocular pain during the first 12 to 24 hours following surgery, which typically settled over the next 12 to 24 hours. Although all patients were carefully counseled preoperatively concerning alternative treatment modalities such as LASIK, with particular reference to improved postoperative discomfort, no patient declined LASEK treatment of the second eye because of pain experienced after the first eye.

The bandage contact lens was removed at 3 days. On slit-lamp examination, epithelial closure appeared to have occurred in all eyes, although epithelial irregularities were common. At 1 week uncorrected visual acuity (UCVA) was $\geq 20/30$ in 53 (70%) eyes, $\geq 20/40$ in 68 (89%) eyes, and $\geq 20/60$ in all eyes. Best spectacle-corrected visual acuity (BSCVA) was $\geq 20/30$ in 64 (84%) eyes, $\geq 20/40$ in 71 (93%) eyes, and $\geq 20/50$ in all eyes. A 1 month, BSCVA was $\geq 20/30$ in all eyes, and in 72 (95%) eyes, BSCVA was either unchanged or within ± 1 line compared to preoperative levels.

REFRACTIVE OUTCOME AND STABILITY

Spherical Equivalent. The mean spherical equivalent changes in refraction with time are shown Figure 1. Refractive stability generally occurred within a few weeks, with only a minimal overcorrection at 1 week, which settled to emmetropia at 1 month and remained stable thereafter throughout the follow-up period. All eyes reached 6- to 12-month follow-up. The mean spherical equivalent refractive error at 6 months (n=76) was +0.08 D (range: -1.00 to +1.875 D) with a standard deviation of ± 0.53 D. At 12 months (n=46), the mean spherical equivalent refractive error was -0.07 D (range: -1.375 to +2.00 D) with a standard deviation of ± 0.55 D. At 6 months (n=76),

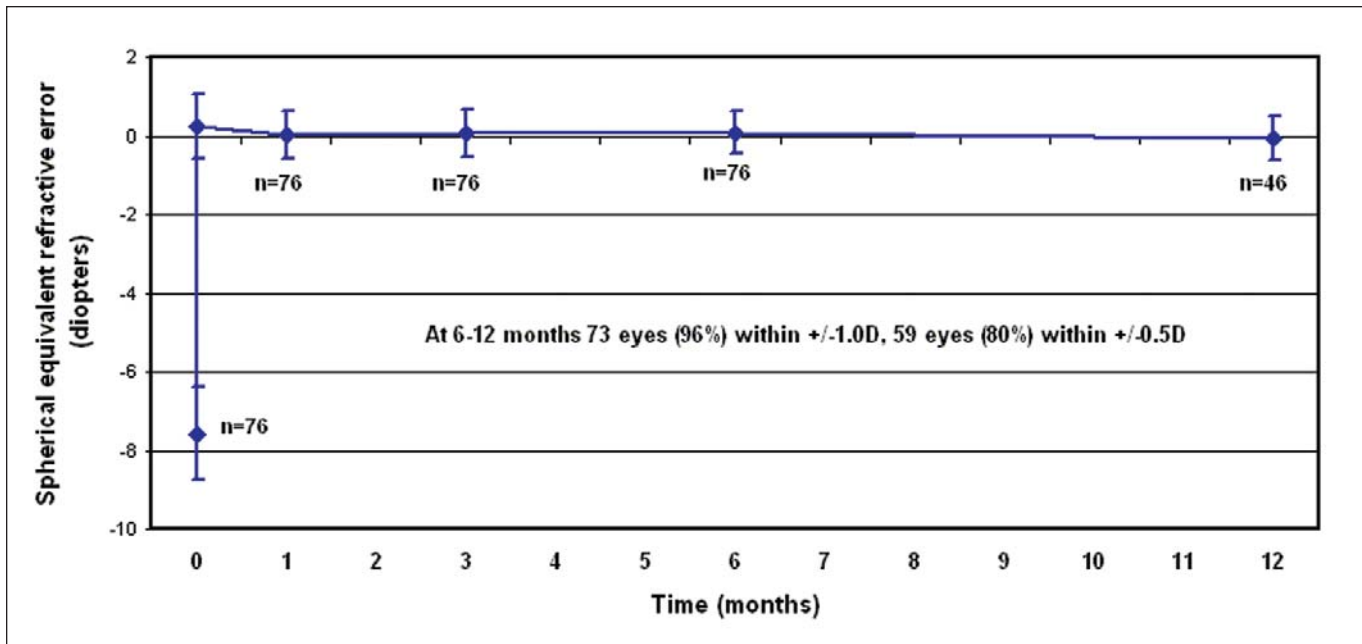


Figure 1. Refractive outcome with time.

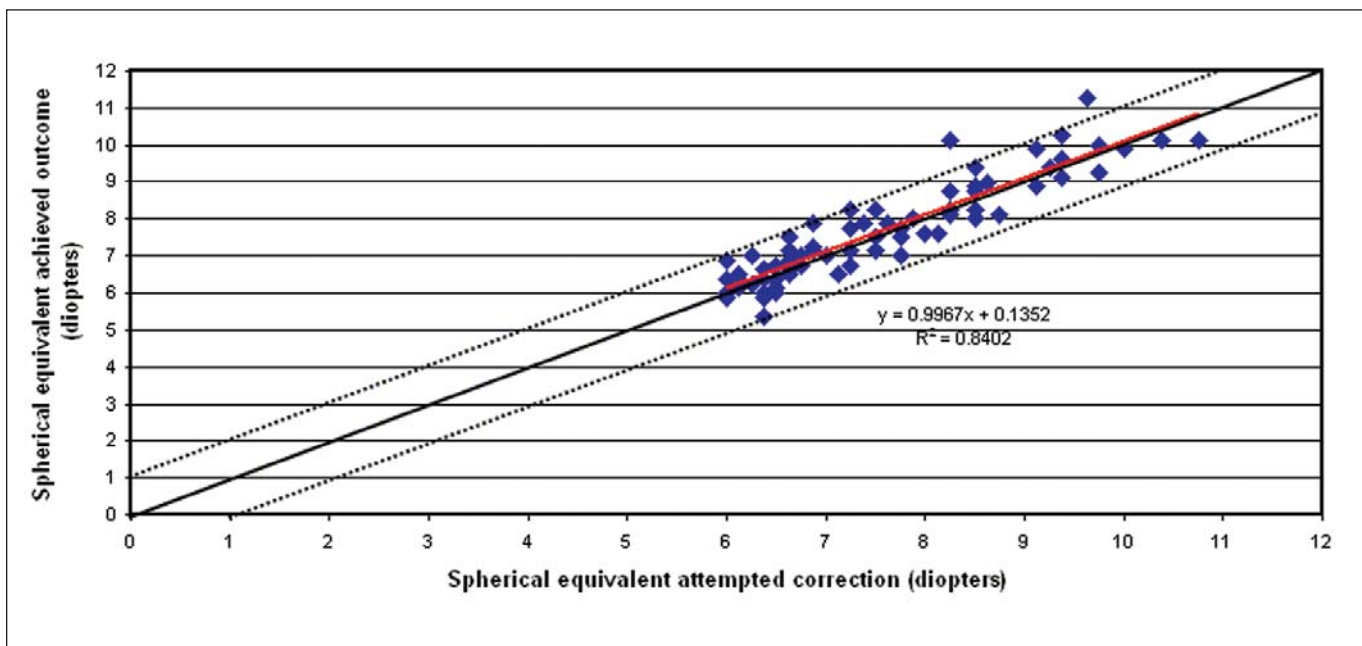


Figure 2. Scattergram of achieved versus attempted outcomes at 6 months (n=76).

73 (96%) eyes were within ± 1.00 D of the intended correction and 60 (79%) eyes were within ± 0.50 D. At 12 months (n=46), 44 (96%) eyes were within ± 1.00 D of the intended correction and 37 (80%) eyes were within ± 0.50 D. Scattergrams of the achieved versus attempted corrections at 6 and 12 months are shown in Figures 2 and 3.

Of our cohort of 76 eyes, 50 eyes received corrections between -6.00 and -8.00 D. At 6 to 12 months,

50 (100%) eyes were within ± 1.00 D of the intended correction and 43 (86%) eyes were within ± 0.50 D. Twenty-six eyes received correction between -8.00 and -10.75 D. At 6 to 12 months, 23 (88%) eyes were within ± 1.00 D of the intended correction and 20 (77%) eyes were within ± 0.50 D.

Sub-analysis of the refractive data revealed no significant differences in outcomes in terms of patient age or selected optical zone treatment size.

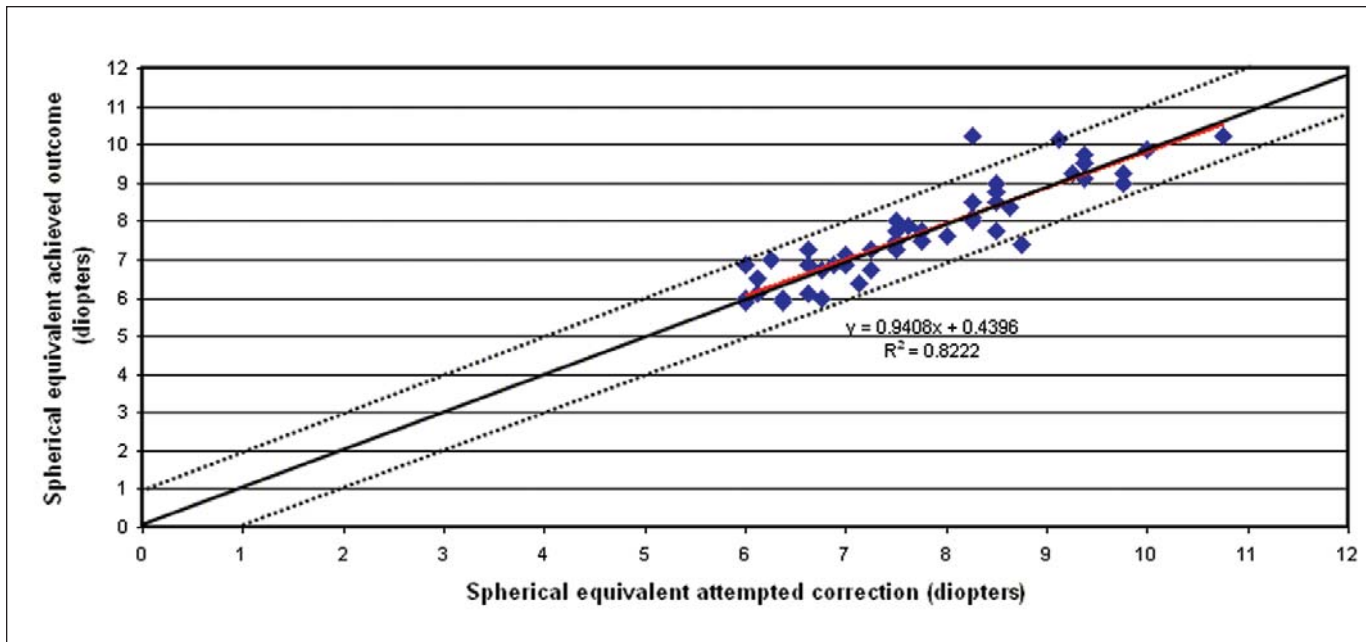


Figure 3. Scattergram of achieved versus attempted outcomes at 12 months (n=46).

Cylindrical Correction. Myopic cylindrical corrections were attempted in 68 of the 76 eyes treated. In these 68 eyes, the mean preoperative cylindrical refractive error was -1.375 D at 94° (range: -0.25 to -4.25 D). At 6 to 12 months, the mean postoperative cylindrical refractive error was -0.59 D at 70° (range: 0 to -2.50 D). Vector analysis demonstrated a mean 85% cylindrical correction. Preoperatively, 30 (44%) of 68 eyes had cylindrical refractive errors >-1.00 D and 18 (26%) eyes had errors of ≥ -2.00 D. At 6 to 12 months postoperatively, 7 (10%) eyes had cylindrical errors ≥ -1.00 D and only 1 (1.5%) eye had cylindrical errors >-2.00 D.

Eighteen of 68 eyes received myopic cylindrical correction ≥ -2.00 D. The mean preoperative cylindrical refractive error in these eyes was -2.60 D at 80° (range: -2.00 to -4.25 D). At 6 to 12 months, the mean postoperative cylindrical error was -0.86 D at 43° (range: 0 to -2.50 D). Vector analysis demonstrated a mean 81% cylindrical correction for these high order astigmatic corrections. This compares to the 50 eyes that received corrections ≤ -1.75 D, where the mean preoperative cylindrical refractive error was -0.90 D at 99° , with a mean postoperative cylindrical refractive error of -0.48 D at 80° at 6 to 12 months, with vector analysis demonstrating a mean 90% cylindrical correction.

Eight eyes of our cohort had no measured cylindrical error preoperatively and underwent spherical corrections only. At 6 to 12 months postoperatively, in 6 of 8 eyes, the mean measured cylindrical refractive error was -0.625 D (range: 0 to -1.25 D), which was with the rule in every case (axis range: 170° to 30°).

All of these eyes achieved satisfactory visual (no loss of lines of BSCVA) and refractive outcomes (all within ± 0.50 D of the intended correction) with only a trace of haze in one of these eyes at last follow-up.

VISUAL PERFORMANCE

Unaided Visual Acuity. At 6 to 12 months (n=76), UCVA was $\geq 20/20$ in 47 (62%) eyes, $\geq 20/25$ in 63 (83%) eyes, $\geq 20/30$ in 70 (92%) eyes, $\geq 20/40$ in 75 (99%) eyes, and $\geq 20/60$ in all eyes (Fig 4). Preoperatively, 9 eyes had BSCVA $\leq 20/25$, 4 eyes had BSCVA $\leq 20/30$, and 2 eyes had a BSCVA of only 20/40.

Best Spectacle-corrected Visual Acuity. At 6 to 12 months (n=76), 3 (4%) eyes gained 2 lines of Snellen decimal equivalent BSCVA, measured in mesopic conditions, compared to preoperative levels. Twelve (16%) eyes gained 1 line, 56 (74%) eyes showed no change, and 5 (7%) eyes lost 1 line. No eyes lost more than 1 line (Fig 5).

CORNEAL HAZE

Average corneal haze scores with time are shown in Figure 6. Haze, if it occurred, generally appeared at 1 month, was maximal at 3 months, and declined thereafter. At 6 to 12 months postoperatively (n=76), 50 (66%) eyes showed no evidence of any corneal haze on slit-lamp examination. Eighteen (24%) eyes had only the merest trace of haze (grade 0.5). Six (8%) eyes showed grade 1 haze at 6- to 12-month follow-up. Two (3%) eyes had grade 2 haze at 6 to 12 months with BSCVA being unchanged in one of these eyes and improved by 1 line in the other.

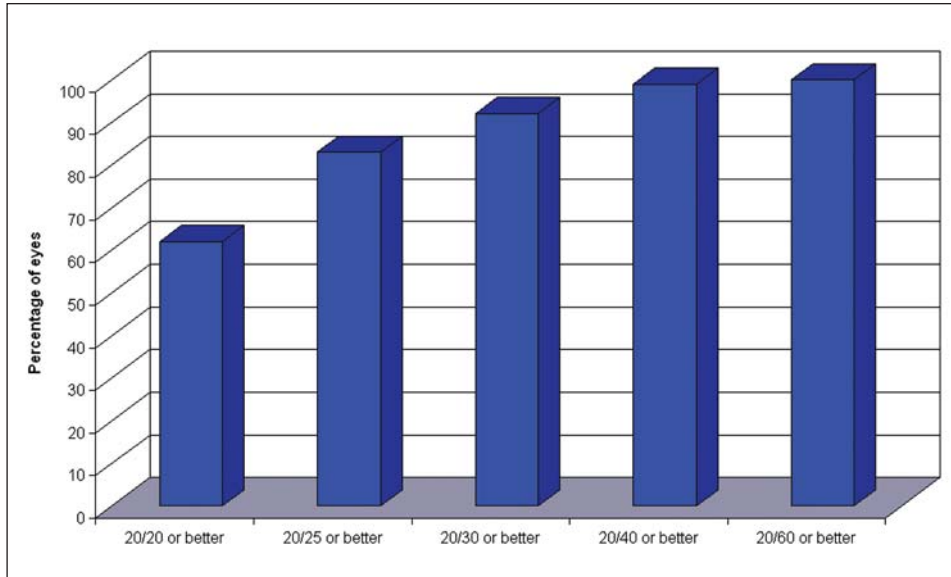


Figure 4. UCVA at 6 to 12 months (n=76).

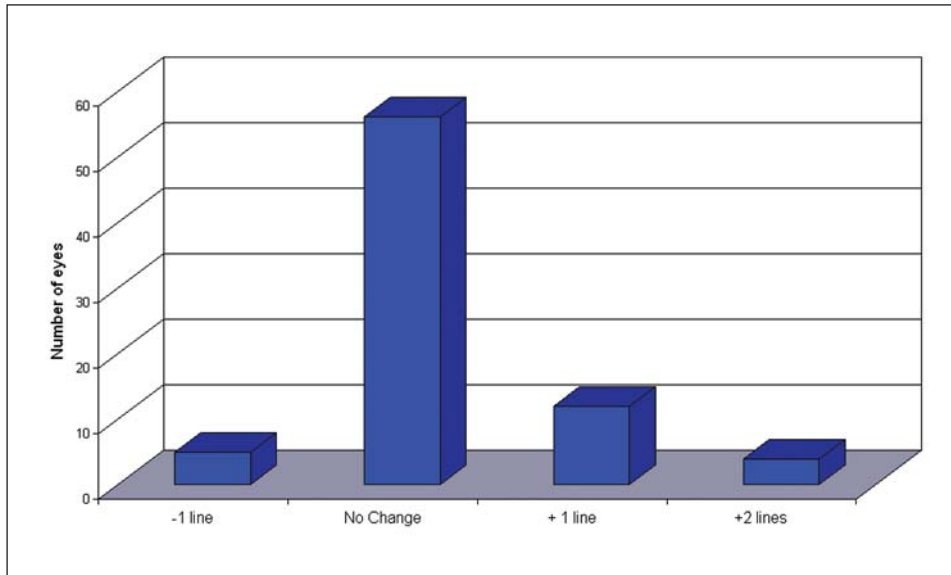


Figure 5. Change in BSCVA at 6 to 12 months compared to preoperative level (n=76).

COMPLICATIONS

Complications were few. No eyes were found to have sight-threatening complications. On direct questioning concerning halos around light sources at night, there were no reports of significant perturbations. Patients did not report symptoms of persistent dryness or recurrent corneal erosions.

DISCUSSION

The use of 15% alcohol applied for 20 seconds with the preoperative administration of amethocaine 1% eye drops allowed the trouble-free creation of an intact epithelial flap in the majority of cases in our cohort (97%). Gabler et al³⁰ demonstrated viability of the majority of the epithelial cells within the flap when concentrations of alcohol solution of 20% were admin-

istered for a maximum of 20 to 30 seconds. When longer application times were used, all of the cells died.³⁰ The importance, in terms of clinical recovery and outcome, in maintaining viable epithelial cells within the LASEK flap remains undetermined and requires further investigation. However, the ability in our study to obtain intact LASEK flaps with low alcohol concentrations (15%) and short application times (20 seconds) helps maintain epithelial cell viability and limits adjacent tissue damage from alcohol administration.

Although comparative studies of PRK and LASIK have demonstrated little difference in terms of predictability and visual outcome,⁷⁻¹⁰ perceived advantages in terms of the fast postoperative recovery have made LASIK the procedure of choice for most refractive surgeons.¹¹ In LASEK, it has been postulated that the

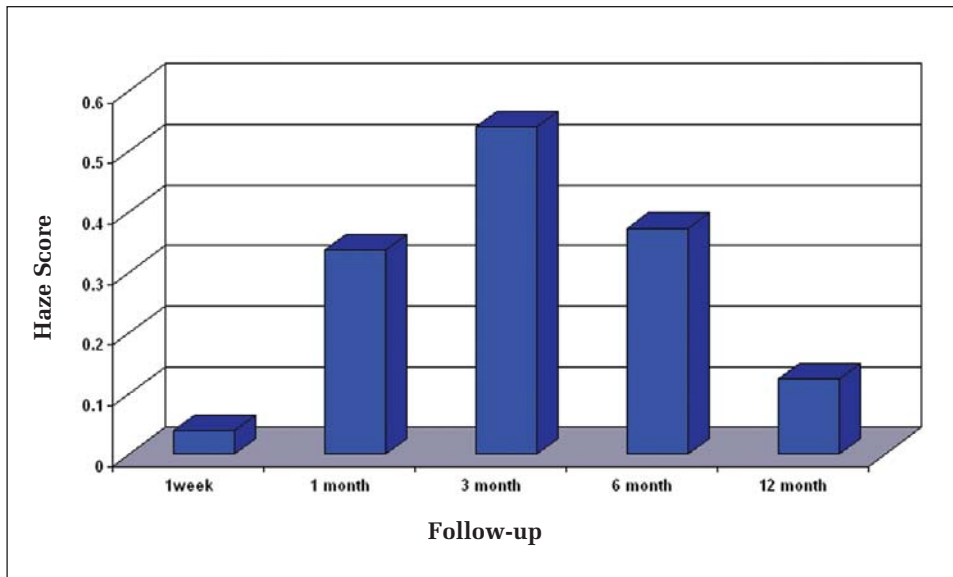


Figure 6. Mean haze scores with time after LASEK for high myopia.

creation of an intact epithelial sheet to cover the ablated area might provide a faster visual recovery than that seen after PRK.²³ Comparative studies of PRK and LASEK have demonstrated conflicting results in terms of early postoperative recovery. Although Leccisotti³¹ demonstrated no differences in terms of pain, epithelial healing, or visual recovery between PRK and LASEK, Atrata and Rehurek²⁶ and Lee et al³² in prospective bilateral studies found less postoperative pain and faster visual recovery after LASEK. In contrast, Litwak et al³³ found more pain and slower epithelial healing after LASEK, although in their study the epithelium was exposed to 20% alcohol for 45 seconds. According to the work of Gabler et al,³⁰ this would result in the death of virtually all epithelial cells in the flap, and therefore it might not be surprising that epithelial healing was slower.

Postoperative recovery after excimer laser procedures is generally slower and can be more problematic with high order compared to low order myopic corrections.^{1-3,5-10} In the present study, recovery after LASEK for high myopia was generally uneventful and reasonably rapid. Although a number of patients reported ocular pain during the first 12 to 24 hours after surgery, none declined LASEK treatment of the second eye. Epithelial closure was achieved in all eyes at 3 days, and patients typically had functional visual acuity at 1 week with a mean spherical equivalent refractive error of +0.19 D (range: -1.25 to +2.00 D) and UCVA \geq 20/60 in all eyes with almost 90% \geq 20/40. By 1 month, considering the degree of preoperative myopia, visual performance was excellent, with a mean spherical equivalent refractive error of -0.003 D (range: -1.625 to +1.25 D) and BSCVA \geq 20/30 in all eyes. Although in comparative studies LASIK undoubtedly

offers more rapid postoperative recovery,³⁴⁻³⁶ visual recovery after LASEK even with the correction of high degrees of myopia is not excessive, with most patients obtaining reasonable refractive and visual outcomes by 1 week and excellent results at 1 month.

Whatever the technique, the treatment of high order refractive errors remains problematic, with poorer reported predictability, stability, and visual outcomes compared to low order corrections. In the present study, refractive outcomes and predictability were satisfactory for high myopic corrections (-6.00 to -11.00 D), with 96% of eyes within \pm 1.00 D of the intended correction and 80% within \pm 0.50 D. These results compare favorably with other studies^{24-26,36-38} and indicate that LASEK can offer acceptable refractive outcomes for the correction of high myopic errors. As might be expected, predictability was less for corrections between -8.00 and -11.00 D compared to those between -6.00 and -8.00 D. However, with 88% of eyes within \pm 1.00 D and 77% within \pm 0.50 D of the intended correction for treatments between -8.00 and -11.00 D, results are still satisfactory and clinically acceptable considering the degree of postoperative myopia.

Although LASIK clearly offers advantages over surface ablation techniques in terms of quick early postoperative recovery, published randomized, prospective, and bilateral studies comparing PRK and LASIK show little differences in medium and long-term outcomes for corrections between -6.00 and -12.00 D.⁷⁻¹⁰ Similarly, comparative studies of PRK and LASEK indicate equivalent refractive and visual results.^{31,32} Published studies comparing LASEK and LASIK are few. In two randomized investigations for low myopic corrections,^{34,35} outcome measures indicated few differences, albeit with better contrast sensitivity after LASEK.

Kim et al,³⁶ however, in a retrospective analysis of high myopic corrections, found that both techniques were safe and effective, although LASIK appeared to provide superior results in terms of visual predictability and corneal transparency. Further studies, especially randomized controlled investigations of high myopia, are required, but considering the results of the present study and the published literature, it is likely that LASEK for myopia up to -12.0 D is as effective in terms of medium- and long-term refractive outcomes as either LASIK or PRK.

Refractive stability in our study over the follow-up period appeared to be good (see Figs 1-3). With the exception of a minimal overcorrection 1 week after surgery, refractive outcome during follow-up remained stable. Further follow-up is required, but in light of the recent publication of long-term studies of up to 12 years with surface ablation (PRK), it is likely that stability of the induced refractive correction will continue at least over the next 10 to 15 years and probably longer.¹⁶⁻¹⁸ For LASIK, long-term published data are somewhat limited and the refractive and biomechanical stability of high order corrections remain uncertain.¹⁹⁻²² By its very nature LASIK must be regarded as more invasive in terms of corneal biomechanical stability than surface ablation procedures. The LASIK flap once cut may contribute little to the mechanical stability of the cornea and probably never completely adheres to the underlying stromal bed, with late traumatic flap displacement being reported as an infrequent complication.¹⁵ Certainly, tissue conservation in high myopic LASIK corrections is an important concern and studies of corneal ectasia limit the depth of tissue ablation with reference to the residual stromal bed thickness.¹³ Such anxieties regarding tissue conservation and long-term biomechanical and refractive stability are not such an issue in LASEK.

The correction of astigmatism with excimer laser ablations remains a challenge. Residual postoperative astigmatism probably occurs because of axis misalignment. The Schwind ESIRIS laser has an effective infrared tracker, which centers the ablation on the entrance pupil and not on the refractive center (visual axis) of the eye. It also has no system as of yet for accurate registration to account for cyclotorsion effects that commonly occur when vision is obscured and when the patient assumes a prone position. However, despite these limitations, achieved outcomes in eyes where myopic cylindrical corrections were attempted were generally acceptable with vector analysis demonstrating a mean 85% cylindrical correction, with only 10% of treated eyes with cylindrical errors >-1.00 D postoperatively compared to 45% preoperatively. As might

be expected, predictability was less for high order myopic cylindrical corrections (≥ -2.00 D) compared to lower order treatments (≤ -1.75 D).

Considering the degree of attempted myopic correction, visual outcome was acceptable. At 6 to 12 months, UCVA was $\geq 20/20$ in 62% of eyes and $\geq 20/40$ in 99% (see Fig 4). Similarly, BSCVA at 6 to 12 months was unchanged or improved in 93% of eyes and no eyes lost more than 1 line of decimal equivalent Snellen acuity (see Fig 5). Such results compare favorably to other published studies of high myopic corrections either with LASEK, LASIK, or PRK.^{5,7-10,19,20,24-26,31,32,36-38} Concerning BSCVA, our results have to be interpreted with regard to expected improvements in terms of better retinal magnification when correction is located at the corneal rather than the spectacle plane. However, our results indicated that good visual outcomes may be achieved with high myopic LASEK corrections.

Excimer laser refractive surgery is undertaken on healthy eyes, hence any deterioration in postoperative corneal transparency is of great concern. In myopic PRK, subepithelial haze develops over the central cornea by the fourth week postoperatively with maximal disturbances at 3 to 6 months and is associated with increasing depths of stromal ablation.^{1-3,7,8,27} In LASEK, it has been postulated that the creation of an intact epithelial sheet to cover the ablated area might reduce epithelial-stromal cross-talk during the early phases of postoperative wound healing and induce less haze, which can occasionally limit the efficacy of PRK, especially for high myopic corrections.²³ Prospective bilateral comparative studies of PRK and LASEK have produced conflicting results. Whereas Hashemi et al³⁹ could find no differences, Atrata and Rehurek²⁶ and Lee et al³² demonstrated less haze in LASEK-treated eyes. In the present study, subepithelial corneal haze, if it occurred, was maximal at 3 months and declined thereafter (see Fig 6). Significant haze was an unusual event, with 89% of eyes being completely clear or showing only the merest trace of haze at last follow-up. This is encouraging given the degree of myopic correction and the use of large optical zone treatments (6.5 to 7.5 mm), with calculated ablation depths typically >100 μm , with an average of approximately 130 μm . Indeed, in only two eyes was haze greater than +1 and both of these eyes had good visual performance in terms of UCVA and BSCVA assessed in mesopic conditions. However, such results must be interpreted with regard to modern flying-spot excimer laser technology, which provides wide diameter ablations with exquisitely smooth surfaces. Such factors are known to play an important role in the propensity to haze development after surface ablation procedures.⁴⁰

Many surgeons advocate the use of topical mitomycin-C (MMC) when performing surface ablations such as PRK for high myopia. Carones et al,⁴¹ in a randomized, controlled study of PRK for high myopia, showed better results with MMC in terms of postoperative haze and refractive and visual outcomes. Camellin,⁴² in a non-randomized study of LASEK for myopia, found that although MMC reduced postoperative haze, refractive outcome was less predictable and higher order aberrations increased after LASEK with MMC. In the current study, MMC was not used and refractive and visual outcomes were satisfactory. At present little is known concerning the long-term effects of MMC use in refractive surgery. Although it is a useful agent in reducing subepithelial haze in problematic cases,⁴³ reports of occasional scleral melting associated with MMC use in pterygium surgery⁴⁴ suggest that some caution should be adopted. This study shows that good results can be obtained with LASEK for high myopia without MMC use, and until more research in this area has been performed and published, it is the authors' current practice to only use MMC in retreatments and complex cases (eg, excimer refractive surgery for postkeratoplasty astigmatism).

Few complications occurred in the present study. No eye lost more than 1 line of decimal equivalent Snellen BSCVA assessed in mesopic conditions, and as discussed above, only 2 eyes developed grade 2 subepithelial haze, which did not appear to affect postoperative visual performance.

Although we did not perform objective measurements of mesopic/scotopic visual performance or use a standardized questionnaire, which may have revealed more subtle changes, on direct questioning, no patient complained of significant perturbations of night vision. Although the induction of fourth order spherical aberration with spherical myopic ablation profiles is an important factor in the development of night vision disturbances after excimer laser myopic ablations, the relationship between pupil size and the diameter of the optical zone is also significant. The selection of large optical zone treatments and the use of the infrared tracker to ensure that the selected optical zone was always at least as large, if not larger, than the measured mesopic/scotopic pupil diameter were important in minimizing night vision disturbances postoperatively in our cohort.

Interestingly, no patient in our series of high myopic LASEK treatments reported persistent symptoms of dry eye (although Schirmer tests and tear break up times were not routinely performed) or recurrent corneal erosion syndrome. It is the authors' experience that symptoms of "dryness" or difficulty opening the

eyes on waking are fairly common in the early postoperative period after LASEK/PRK and in a few patients can be persistent, even necessitating peripheral anterior stromal puncture procedures if problems persist beyond 12 months. However, perhaps because of the increased depths of stromal ablation required for high order corrections, postoperative epithelial adhesion problems did not occur.

LASEK for high myopia up to -11.00 D with the Schwind ESIRIS laser provides good refractive and visual outcomes with few complications. Visual recovery was acceptable with most patients achieving reasonable functional unaided acuity by 1 week postoperatively. Refractive stability was maintained over 12 months, and despite significant depths of stromal ablation, sight-threatening corneal haze did not occur.

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