
Six-year follow-up of laser in situ keratomileusis for moderate and extreme myopia using a first-generation excimer laser and microkeratome

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Purpose: To evaluate objectively and subjectively the long-term outcome of laser in situ keratomileusis (LASIK) in patients with high and very high myopia.

Setting: Department of Ophthalmology, Philipps University, Marburg, Germany.

Methods: Thirty-three eyes of 19 patients were followed for a mean of 76 months (range 50 to 84 months) after primary LASIK using the Keratom I excimer laser (Schwind) and the ALK microkeratome (Chiron). Refraction, glare, pachymetry, corneal topography, and tear-film secretion and stability were measured. At the last examination, patients also answered a 14-item questionnaire.

Results: Preoperatively, the mean spherical equivalent was -13.65 diopters (D). At 1 year, it was -0.25 D and after 6 years, -0.88 D. Fifteen percent of eyes lost ≥ 2 lines of best spectacle-corrected visual acuity (BSCVA), and 9% gained ≥ 2 Snellen lines. At the end of the study, 46% of eyes were within ± 1.0 D of the attempted corrected and 88% were within ± 3.0 D. There were 5 microkeratome-associated complications; 3 resulted in loss of BSCVA. The latest pachymetry showed a mean corneal thickness of $498.5 \mu\text{m}$ (range 396 to $552 \mu\text{m}$). There were no cases of keratectasia. Seventy-five percent of patients noted an increase in their quality of life. Seventy-one percent were satisfied with their postoperative visual acuity; however, 75% noticed glare and halos at night.

Conclusions: Laser in situ keratomileusis correction of very high myopia did not cause keratectasia in the long term provided the corneal thickness was respected. A flap thickness setting of $130 \mu\text{m}$ with a first-generation microkeratome resulted in a high number of cut failures. Most patients were happy with the results despite a modest level of accuracy and glare.

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A combination of lamellar keratotomy and 193 nm excimer laser ablation of the cornea was independently described by Burrato and by Pallikaris and coauthors¹ between 1989 and 1990. This new procedure, named laser in situ keratomileusis (LASIK), appeared to have major advantages over the popular photorefractive keratectomy (PRK) because of a modest healing response and the consequent lack of scar tissue.^{2,3} However, over time, problems associated with this new

technique have been recognized. Thus, the upper refractive limits are now considered to be less than -10.0 diopters (D), in rare instances up to -12.0 D, when a 6.0 mm optical zone is used. The main reasons for this limitation are a widespread belief that the remaining posterior stroma should have a minimal thickness of $250 \mu\text{m}$, as suggested by Seiler and coauthors,⁴ and awareness of the poor quality of vision and the low predictability of correction.⁵ However, the long-term stability of the postsurgical cornea is of paramount importance since keratectasia can be considered a major mid- to long-term complication leading to corneal transplantation.^{6,7} Despite a steady rise in the number of LASIK procedures worldwide, no structured long-term

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studies as for PRK⁸ are available. This study looked at the long-term anatomical and refractive stability of post-LASIK corneas. Other objective and subjective parameters were evaluated.

Patients and Methods

Twenty-five patients who had LASIK surgery between September 1993 and July 1995 were enrolled in this study, which was approved by the university ethics committee. All patients signed an informed consent explaining the novel nature of the procedure. A minimal follow-up protocol included visits at 1 day, 1 week, 1 and 3 months, and 1, 3, and 5 years. Eyes with any ocular disease but myopia were excluded from the study; amblyopic eyes with a best spectacle-corrected visual acuity (BSCVA) better than 0.1 were included. Study patients had to be older than 20 years and have at least 2 years of stable refraction.

Thirty-three eyes of 19 patients were available at the end of the study. The mean age of the 19 patients was 39.9 years (range 28 to 59 years). In 8 patients, a unilateral treatment was performed, in 7 because of unilateral high myopia and anisometropia and in 1 because of complications during the first-eye surgery.

All surgery was performed by the same surgeon (W.W.) under retrobulbar anesthesia with a pupil constricted by pilocarpine 1% eyedrops. The flaps were cut using the Chiron ALK microkeratome (predecessor of the Automated Corneal Shaper® [Bausch & Lomb Surgical]). This microkeratome enables the creation of flaps with a maximum diameter of 7.2 mm. In 3 cases, a 160 µm plate was used and in the remaining eyes, a 130 µm plate. In the first 4 eyes operated on in 1993, a complete nonrefractive cut was performed and a cup secured with a running 10-0 nylon suture at the end of the procedure. Starting in 1994, a nasal hinge technique without suturing was used. Laser ablation was done with a 193 nm argon-fluoride excimer laser, the Keratom I (Schwind). It was a first-generation wide-beam excimer laser with an iris-diaphragm system. The ablation rate per 1.0 D of correction at a 6.0 mm zone was 11.1 µm and at a 5.5 mm zone, 9.4 µm.

Preexisting astigmatism greater than 1.0 D cylinder was also corrected. The treatment refraction was derived by converting the spherical equivalent (SE) refraction at the spectacle plane to the corresponding value at the corneal plane. No preoperative scotopic pupil measurements were done. The laser ablation diameter was chosen according to the preoperative pachymetry and the presumed depth of ablation. As a rule of thumb, the sum of the nonrefractive and the refractive cuts had to be at least one half the preoperative stromal thickness.

Objective and subjective refraction and slitlamp biomicroscopy were done routinely. Intraocular pressure, dilated indirect ophthalmoscopy, and Placido-disk-based corneal topography (EyeSys Inc.) were performed at all visits after 1 month. Glare (Nykto-meter [Rodenstock]), ultrasound pachymetry, sensation (Bonnet anesthesiometer), and tear-film secretion (Schirmer II test) and stability (breakup time [BUT]) were measured at the last follow-up. Binocular function before and 6 years after surgery was assessed by the cover and Bagolini tests and stereopsis (Lang test). Patients also answered a 14-item questionnaire at the last visit. Refractive data analysis was done using Datagraph med 2.8 d software (Pieger GmbH).

Results

The mean follow-up in the 33 eyes at the last examination was 76 months (range 50 to 84 months). The preoperative uncorrected visual acuity (UCVA) and BSCVA along with the safety and efficacy indices are summarized in Table 1.

Predictability

The predictability of the refractive change is shown in Figure 1. The attempted mean spherical correction at the corneal plane was -10.90 D (range -5.25 to -17.50 D) and the mean cylindrical correction, -1.00 D cyl (range -0.50 to -5.00 D cyl), giving an SE of -11.40 D. The mean preoperative SE at the spectacle plane was -13.65 D. Figure 2 shows the re-

Table 1. Summary of the mean preoperative and postoperative visual acuity data along with the respective safety and efficacy indices.

Visual Acuity/Index	Preoperative	Postoperative	
		1 Year	6 Years
BSCVA, mean (range)	0.61 (0.1-1.2)	0.54 (0.2-1.0)	0.56 (0.05-1.0)
Safety index		0.88	0.92
UCVA, mean (range)	CF*-0.08	0.38 (0.05-1.0)	0.35 (0.05-1.0)
Efficacy index		0.62	0.57

BSCVA = best spectacle-corrected visual acuity; UCVA = uncorrected visual acuity

*27 eyes

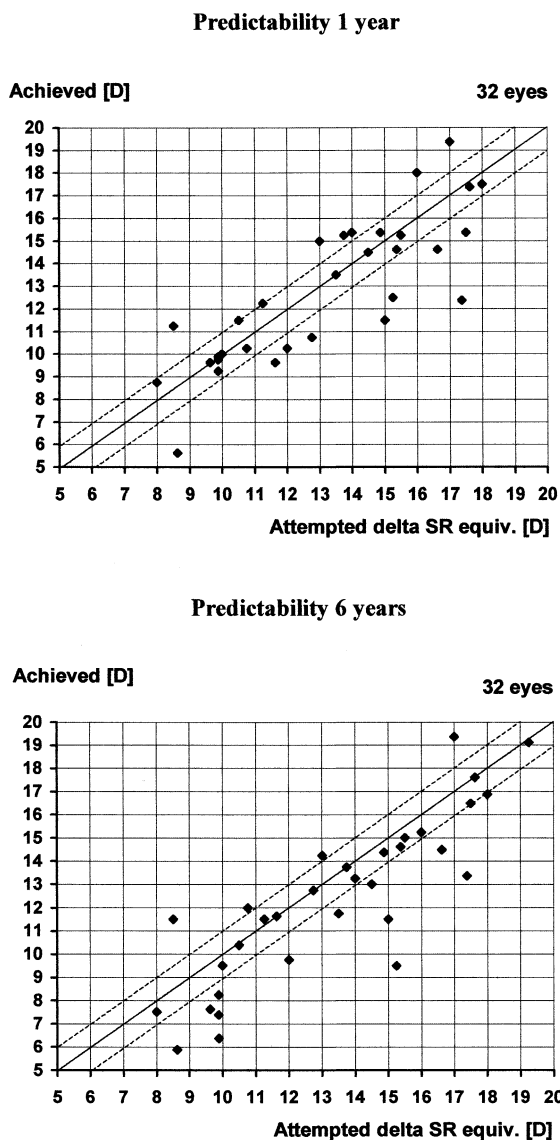


Figure 1. (Sekundo) Predictability of the refractive change 1 year (*top*) and 6 years (*bottom*) after surgery. One eye is missing because of a preoperative refraction greater than -20.0 D.

fractive outcome plotted against the attempted refraction. Fifty-two percent and 46% of eyes were within ± 1.0 D of the attempted correction, 76% and 67% were within ± 2.0 D, and 94% and 88% were within ± 3.0 D at 1 year and at the conclusion of the study, respectively. Primary overcorrection of up to 2.0 D was seen in 5 eyes and primary undercorrection, in 3 eyes; a gross regression of 3.0 D occurred in 3 eyes.

Efficacy

The preoperative UCVA was counting fingers at 1 m in 27 eyes and 0.01 to 0.08 in the other 6 eyes. At 76

months, a mean UCVA of 0.34 was achieved (range 0.05 to 1.0). Thirty-three percent of eyes had a UCVA ≥ 0.5 at the last visit. Figure 3 includes all eyes including those with primary undercorrection. The efficacy index (postoperative UCVA divided by preoperative BSCVA) was 0.62 after 1 year and 0.57 after 6 years (Table 1).

Safety

The mean preoperative BSCVA was 0.61. After 76 months, it was 0.56. One eye gained 3 lines of BSCVA at the last visit, 2 eyes gained 2 lines, and 3 eyes gained 1 line. At 6 years, 2 eyes lost 4 lines of BSCVA (failed cut, central island), 2 lost 3 lines (myopic macular degeneration), 1 lost 2 lines, and 6 lost 1 line. All eyes that lost more than 2 lines of BSCVA had preoperative myopia greater than -10.0 D. The BSCVA remained unchanged in 16 eyes in the long term. Figure 4 summarizes the findings in percentage values.

Stability

The mean SE was -0.25 D at 1 year and -0.88 D at 6 years. Figure 5 shows the achieved change in refraction over time along with the standard deviation.

Pachymetry and Ablation Depth

The mean central corneal pachymetry was 572.0 μm (range 482 to 625 μm) preoperatively and 498.5 μm (range 396 to 552 μm) at the end of the study. The mean ablation depth calculated by the excimer laser's computer was 109 μm (range 65 to 148 μm).

Flap Complications

There were 5 flap complications: 1 buttonhole, 1 partial externalization of the microkeratome pass, 1 ultrathin flap with wrinkles in Bowman's layer, and 2 cases of significant peripheral epithelial ingrowths in both eyes of the same patient. All complications occurred in the 130 μm plate group. In 3 cases, the flap failure led to a loss of BSCVA.

Tear Film and Corneal Sensation

Although 35% of eyes had Schirmer II values over 10.0 mm and BUT ≥ 11 seconds, 2 eyes of the same patient developed symptomatic, severe dry-eye syndrome. This patient also developed bilateral peripheral epithelial ingrowths. The same 2 eyes were among 3 eyes with reduced corneal sensation. (The third eye had a scarred flap.) All other eyes had normal

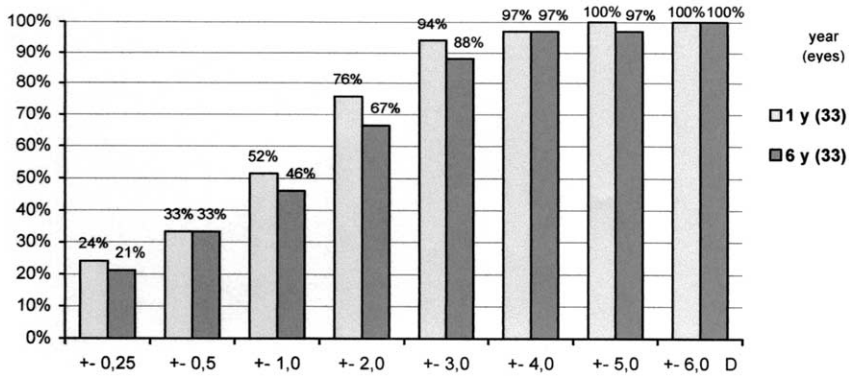


Figure 2. (Sekundo) Refractive outcome: Percentage of eyes within attempted correction.

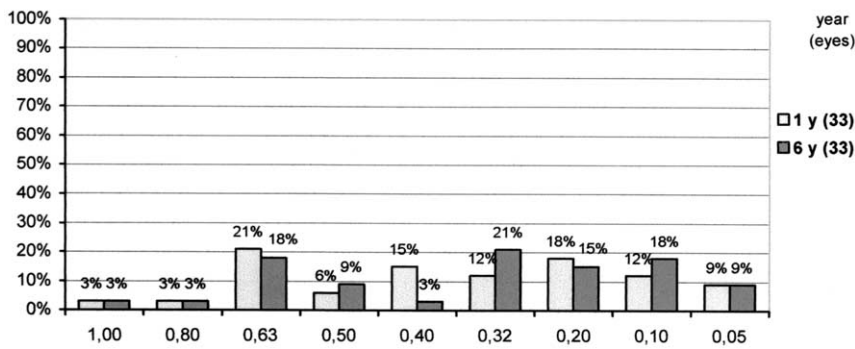


Figure 3. (Sekundo) Efficacy: Percentage of eyes with each UCVA. Amblyopic eyes and eyes with primary undercorrection were included.

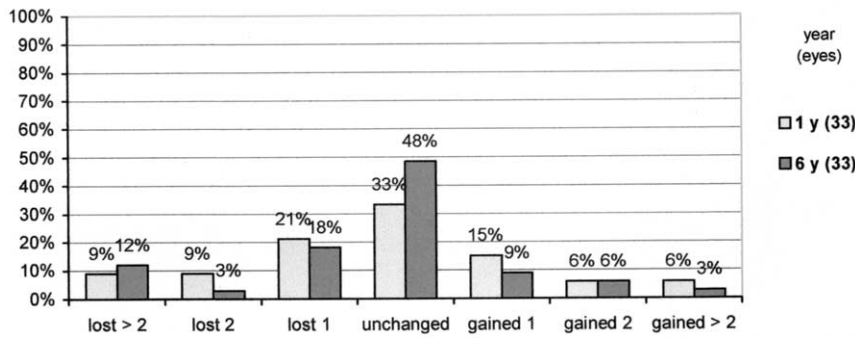


Figure 4. (Sekundo) Safety: Change in BSCVA 1 year and 6 years after LASIK (percentage of eyes).

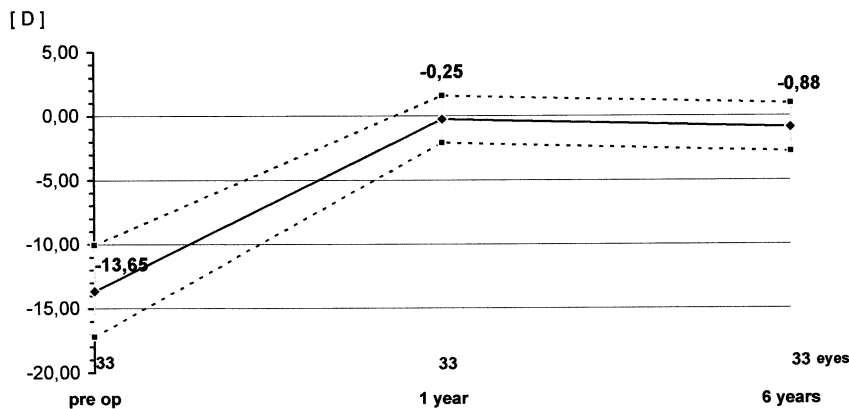


Figure 5. (Sekundo) Stability: Achieved change in refraction over time (means ± standard deviations).

corneal sensation of 0.96 g/mm^2 measured with a Bonnet device.

Glare

Ninety percent of patients were unable to distinguish any marks when night vision under glare conditions was measured. The other 10% could see the first 2 marks. The preoperative glare measurement had been performed with a different device so no direct comparison was possible.

Topography

Comparison of the preoperative and postoperative corneal topography using the same Placido-based system showed no evidence of keratectasia. Centration was calculated using the tangential map, showing deviation from the vertex in 2 meridians. In 5 eyes, the decentration was 0.7 to 2.0 mm and in 10 eyes, 0.1 to 0.5 mm. Seventeen eyes had well-centered postablation topography (within 0.1 mm). The mean simulated postoperative K-reading was 36.40 D (range 32.05 to 41.36 D).

There was no difference between the preoperative and postoperative binocular functions.

Questionnaire

On a scale of 0 to 10 for current satisfaction with one's visual acuity, the mean score was 5.7. Scores from 0 to 4 were considered "being unhappy"; 29% of patients were not happy with their UCVA. This percentage was smaller than that immediately after surgery, 35%. Eighty-one percent noticed an improvement in their UCVA after surgery as opposed to the time before LASIK. Twenty-eight percent of patients described their BSCVA as "worse than before surgery" and 72%, as better or unchanged. The preoperative refraction of patients who were dissatisfied with their BSCVA was -12.0 D .

There were no microkeratome-associated complications in this group; however, 2 eyes of the same patient developed severe dry-eye disease and peripheral epithelial ingrowths and 2 eyes had decentrations of 1.5 mm and 2.0 mm. After almost 7 years, 75% continued to complain of ghosting images and/or halos. Patients who graded their halos between 8 and 10 also felt a decline in their BSCVA (see above) and had irregular flaps due to cut failures or a preoperative refraction greater than

-15.0 D . However, 81% of all patients questioned said they would recommend the surgery to friends and would have the surgery again.

Discussion

In the early 1990s, at the beginning of the LASIK era, there was a widespread belief that this procedure had a much higher range of correction than PRK.^{2,3} In 1999, Knorz et al.⁹ suggested limiting the myopic correction range to a maximum of -10.0 D because of poor quality of vision and fairly low predictability of correction in eyes with high myopia. However, these suggestions were based on results obtained after 2 years of follow-up. Even recent studies do not exceed 1 or 2 years of follow-up.¹⁰⁻¹² Most refractive candidates inquire about the long-term effects of LASIK. The present study is important because there are no long-term follow-up studies such as those done for PRK.⁸ Results obtained for PRK cannot be extrapolated to LASIK.

In a recent experimental study, Müller and coauthors¹³ show that dermatan sulfate containing 100 to 120 μm of anterior corneal stroma provides a higher degree of rigidity and mechanical stability than posterior lamellae containing keratan sulfate. While in PRK and laser-assisted subepithelial keratectomy, Bowman's layer and the anterior stroma are removed according to the ablation diameter,¹⁴ a microkeratome cut weakens the anterior 130 to 180 μm of cornea over a diameter of up to 9.5 to 10.0 mm. Thereafter, a weaker posterior stromal part is ablated. In this regard, thinner flaps might be desirable. However, our study showed a high flap complication rate with the 130 μm plate when a first-generation microkeratome was used. This finding supports the observations of Jacobs and Taravella,¹⁵ who found a complication rate of 6.40% with the Automated Corneal Shaper compared to 0.16% with a second-generation microkeratome (Hansatome). The ALK microkeratome used in our study is actually a predecessor of the Automated Corneal Shaper, the only difference being the flap diameter.

The maximum diameter obtained with the ALK was 7.2 mm compared to 8.5 mm with the Automated Corneal Shaper. In contrast to other studies,^{6,11,12} we did not encounter cases of corneal ectasia even after 76 months despite a comparable treatment range. The mean central corneal pachymetry was $572.0 \mu\text{m}$ before

surgery and 498.5 μm at the conclusion of the study. A 130 μm plate was used in most eyes ($n = 30$). Using theoretical values, one can assume that the thinnest residual bed was 266 μm . Several additional explanations can be offered: (1) We performed no retreatments. (2) A smaller flap diameter might exert a less destabilizing effect on the cornea. (3) The older wide-beam lasers removed less tissue per diopter of correction than the new flying-spot lasers. There was also no transition zone, contributing to scotopic and mesopic visual disturbances.

Our study highlights the problems of quality of vision. Often, Snellen acuity, particularly after enhancements, is given as a measure of success.^{11,12} Nevertheless, 75% of our patients have glare at night, with the worst symptoms in patients who had decentrations, cut problems, or treatments over -15.0 D with subsequent flat corneas down to 32.5 D in 1 extreme case. Our decentration rate of >0.5 mm was 15%. This relatively high number can be the result of using retrobulbar anesthesia and pilocarpine in contrast to patient self-fixation supported by the eye-tracker technology of modern lasers. Objectively, virtually all patients in this study had poor mesopic vision. Moreover, our study leaves no doubts that this problem continues to persist in the long term and possibly forever.

As mentioned, a careful approach was chosen at the beginning of the study, enabling a well-timed adjustment of the initial PRK nomograms. In this way, we could avoid postoperative hyperopia and achieve a favorable mean postoperative outcome of -0.25 D after the first year. Our study showed a modest increase in myopia of 0.6 D between 12 and 76 months. This is an encouraging finding, suggesting long-term stability of the ablated cornea within the surgical setting of this study. However, we caution against extrapolating our conclusions to modern microkeratomes and lasers because of different flap sizes and ablation profiles. In contrast, perfect long-term transparency of the cornea in cases with no flap failures can be assumed to apply generally to flap-based procedures as the only finding we saw in these eyes was an occasional iron line.

A question still to be answered is why 81% of patients appeared to be quite happy with the overall results when all of them had poor night vision. Unlike in low myopia, patients with high myopia experience and are prepared to have some halos at night for the benefit of

better UCVA. Many patients were familiar with this problem and described a similar degree of glare with contact lenses before surgery. A mean preoperative BSCVA of 0.6 is related not only to minimization of the image by spectacles but also to a considerable number of amblyopic eyes. It is conceivable that these patients never experienced better quality of vision. However, one has to remember that these treatments were performed in the early 1990s with early technology. Considering the significant improvement in lens refractive surgery in the past decade, one would approach an identical refractive challenge with other means today. Moreover, we believe that further improvement in lens design may lower the indication for corrective corneal laser surgery to -8.0 D, as indicated by Pallikaris and coauthors.⁶

In summary, to our knowledge, this is the first LASIK study with a follow-up of 76 months. It shows that LASIK correction of very high myopia does not cause keratectasia in the long term provided corneal thickness is respected. A flap thickness setting of 130 μm with a first-generation microkeratome resulted in a high number of cut failures. Most patients were happy with the results achieved despite a modest level of accuracy and glare.

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