Laser In Situ Keratomileusis for Moderate and High Myopia and Myopic Astigmatism

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Objective: This study evaluated the predictability, stability, and safety of laser in situ keratomileusis (LASIK) in myopia and myopic astigmatism.

Design: The study design was a prospective, unmasked, nonrandomized clinical trial.

Participants: Participating were 25 patients with myopia (37 eyes) with astigmatism of less than 1.00 diopter (D), divided into 3 subgroups (−5.00 to −9.90 D, 8 eyes; −10.00 to −14.90 D, 10 eyes; −15.00 to −29.00 D, 19 eyes), and 37 patients with myopia (56 eyes) with corneal astigmatism of 1.00 to 4.50 D, divided into 3 subgroups (−5.00 to −9.90 D, 12 eyes; −10.00 to −14.90 D, 24 eyes; −15.00 to −29.00 D, 20 eyes).

Intervention: LASIK was performed using the Automatic Corneal Shaper and the Keracor 116 excimer laser.

Main Outcome Measures: Visual acuity, manifest refraction, central corneal islands, ablation decentration, and patient satisfaction were measured.

Results: At 12 months, predictability, regression between 1 and 12 months, uncorrected visual acuity (UCVA), loss of two or more lines of corrected visual acuity, and patient satisfaction of the spherical (toric) groups are reported. *Subgroups −5.00 to −9.90 D:* 100% (75%) ±1.00 D; regression less than or equal to 1.00 D in 100% (91.7%); UCVA greater than or equal to 20/40 in 87.5% (70%); none lost two or more lines; 100% (84%) highly satisfied. *Subgroups −10.00 to −14.90 D:* 60% (78.3%) ±1.00 D; regression less than or equal to 1.00 D in 100% (87%); UCVA greater than or equal to 20/40 in 77.8% (86.4%); 10% (4.3%) lost two lines; 90% (91%) highly satisfied. *Subgroups −15.00 to −29.00 D:* 38.9% (21.4%) ±1.00 D; regression less than or equal to 1.00 D in 72.2% (64.3%); UCVA greater than or equal to 20/40 in 33.3% (40%); 5.6% (7.1%) lost two lines; 78% (50%) highly satisfied. Differences of predictability and change of manifest refraction between subgroups of −5.00 to −9.90 D and −15.00 to −29.00 D were statistically significant. Central islands (decentrations) were observed in 17% (5.6%) of eyes of the spherical and in 16% (4.1%) of the toric group. Overall, the corneal interface was visible in 8.2%.

Conclusions: The LASIK method used in this study showed stability of manifest refraction and adequate uncorrected central visual acuity in a large percentage of patients with myopia up to −15.00 D. Corneal stability was not as uniform. Central corneal islands were observed in a sizable minority of patients despite pretreatment. For myopia greater than 15.00 D, accuracy and patient satisfaction were sufficiently poor to advise against using the authors' treatment technique in these groups. Visually significant microkeratome and laser-related problems were noted in a smaller percentage of patients. Patients with astigmatism correction were less pleased with results than were patients who received spherical corrections. *Ophthalmology 1998;105:932–940*

Information to date suggests that patients with more than −6.00 diopter (D) of myopia are at high risk of developing refractive instability, corneal scarring, night aberration, and loss of Snellen visual acuity after wide area ablation photorefractive keratectomy (PRK).[1–3] Can laser in situ keratomileusis (LASIK) do better? If so, will we have to accept a new set of problems? The reader finds a dearth of information about LASIK in the scientific literature. The fact that LASIK needs further refinement is shown by the decentration results reported by Pallikaris at the Association for Research in Vision and Ophthalmology annual meeting in 1996 and by the wide range of results obtained by individual surgeons, even when using similar protocols.[4–6] Refractive predictability is poorly studied as are questions of refractive stability, decentration, variability in optical quality, ectasia, and the relative advantages of multipass versus single-pass treatments. LASIK is highly promoted and surgical volume is increasing, but doubts will remain about its overall efficacy until the literature contains more information about refractive predictability, refractive stability, the incidence of microkeratome-related complications, and the incidence of decentered ablations and other issues of importance to the scientific community.

In an initial study, we tested different keratomes and different ablation profiles.[4] We encountered a high incidence of intraoperative complications related to the surgical technique, the keratome, and our learning curve. In

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addition, we observed a significant number of central islands. We used the data obtained to standardize our surgical technique and the ablation pattern. In the current study, we used the standardized technique to evaluate refractive predictability and stability, corneal topography, corneal interface scarring and thickness, and patient satisfaction.

Patients and Methods

Surgical Technique

Surgery was performed using topical anesthesia (oxybuprocaine 0.4%). The Automatic Corneal Shaper (Chiron Vision, Inc, Claremont, CA), equipped with a mechanical stop and the LASIK suction ring, was used to cut an 8.5-mm hinged flap. The preset flap thickness was 160 μm in all eyes, but actual thickness was not measured to avoid possible contamination of the surgical field. After the cut, suction was released, the suction ring was removed, and the corneal flap was carefully displaced nasally using a blunt spatula (Bangerter iris spatula; Storz Co., Heidelberg, Germany). The patient then was asked to fixate the coaxial helium-neon laser of the Keracor 116 (Chiron Technolas Co., Munich, Germany), and the laser was centered over the middle of the entrance pupil.[7] The oblique lights were dimmed slightly during the ablation to make fixation easier and to maintain a pupil size of approximately 3 to 4 mm to facilitate fixation control by the surgeon. If fixation by the patient was not possible, the ablation was subjectively centered over the middle of the entrance pupil by the surgeon using the suction ring (without suction). The stromal bed was neither irrigated nor dried to avoid changes in hydration. Fluid accumulating at the hinge during the ablation was removed with a Merocel sponge (Merocel Co., Mystic, CT). After the ablation, the back of the flap and the stromal bed were irrigated and the flap replaced. We then irrigated the interface to float the flap and remove debris. The flap then was painted into position with a wet and soft Merocel sponge. Once the flap was aligned, we waited for 2 minutes to ensure proper adhesion. No air was used to dry the flap. After surgery, gentamicin eyedrops (3 mg/ml) were administered, and the eye was covered with a hard shield for the first night. Topical treatment with gentamicin eyedrops (one drop three times daily) was continued for 5 days and then discontinued. No corticosteroids were used throughout the follow-up period.

Ablation Parameters

Ablation was performed using the Keracor 116 excimer laser (Chiron Technolas Co.). We used software version 2.2, which is a software distributed by the laser manufacturer for PRK. No adjustments were made for LASIK. This software suggests a multizone ablation, but the number of zones and their diameter can be modified by the surgeon. Based on our initial pilot study,[4] we used a single-zone and single-pass ablation for the spherical correction. The diameter of the ablation varied depending on the amount of myopia to be corrected. In addition, a pretreatment was used to prevent central islands. The pretreatment consisted of an additional laser ablation of a certain percentage of the spherical correction, which was delivered within a 3-mm zone. The treatment parameters used in our study are listed in Table 1. They are based on the results of our pilot study.[4] In group 2, an additional astigmatism correction was performed. The Keracor 116 performs astigmatic ablations by scanning the laser beam in the axis of the minus-cylinder. The maximum beam excursion is 13.5 mm along this axis. During the scanning process, the beam gradually enlarges to a maximum diameter of 4.5 mm. Corneal curvature is therefore flattened in a meridian 90° away from the scanning axis, and astigmatism will be corrected within a 4.5-mm zone. During the ablation, the hinge and the corneal limbus were protected with a Merocel sponge to avoid ablation in the scanning axis. The treatment sequence was as follows: group 1, pretreatment, single-pass spherical ablation; group 2, astigmatism, pretreatment, single-pass spherical ablation.

A central thickness of the remaining stromal bed of at least 200 μm was used to prevent ectasia. We measured corneal thickness before surgery and subtracted 360 μm (160-μm—flap thickness plus 200-μm thickness of stromal bed). The remaining value was the maximum we removed during the ablation. If the calculated ablation should exceed this value, the zone size of the spherical correction would be reduced by 0.5 mm. An active eye-tracking device was used to compensate any movements of the eye.[4] The eye tracker, developed by Chiron Technolas, Munich, Germany, uses an infrared video camera to capture the image of the undilated pupil and automatically follows the movements of the eye.

Patient Population

We operated on 93 consecutive eyes (55 patients) between December 1994 and February 1996. All patients had to be contact lens intolerant, defined as the patient's subjective inability to tolerate hard or soft contact lenses. Exclusion criteria were age younger than 18 years and chronic eye diseases such as cataract, glaucoma, uveitis, keratoconus, diabetes, and autoimmune diseases. Corneal topography was used to screen for keratoconus, and all eyes exhibiting asymmetric astigmatism in excess of 2 D were excluded. The study was approved by our ethical review board. All patients were fully informed on the experimental nature of our study, and written consent was obtained.

Patients were divided into two groups. Group 1 consisted of 37 eyes (25 patients) with myopia of −5.00 to −29.00 D and corneal astigmatism of less than 1.00 D. The average age in group 1 was 38 ± 12.6 years (range, 18–60 years). Group 1 was subdivided into three subgroups to analyze outcome in reference to the preoperative spherical equivalent (−5.00 to −9.90 D, 8 eyes, all of them saw 20/40 or better; −10.00 to −14.90 D, 10 eyes, 9 of them saw 20/40 or better; and −15.00 to −29.00 D, 19 eyes, 3 of them saw 20/40 or better). Group 2 included 56 eyes (37 patients) with myopia of −5.00 to −25.00 D and corneal astigmatism of 1.00 to 4.50 D. The average age in group 2 was 36 ± 11.4 years (range, 18–60 years). Group 2 also was subdivided into three subgroups (−5.00 to −9.90 D, 12 eyes, 10 of them saw 20/40 or better; −10.00 to −14.90 D, 24 eyes, 22 of them saw 20/40 or better; and −15.00 to −29.00 D, 20 eyes, 7 of them saw 20/40 or better).

In 12 patients of group 1 and in 19 patients of group 2, both eyes were treated. The time interval between treatments was 1 week in most cases (range, 1–10 weeks). In none of the eyes was an adjustment of the treatment of the second eye based on the results of the first eye made. In 27 eyes of group 1 and 52 eyes of group 2, we aimed for emmetropia. Some patients (10 eyes of group 1 and 4 eyes of group 2), however, requested residual myopia between −1.00 and −3.00 D for reading and were treated accordingly.

Table 1. Treatment Parameters

Spherical Correction at Vertex (D)	Ablation Zone (mm) for Vertex Correction	Pretreatment* (% of vertex correction)	Ablation Zone (mm) for pretreatment
−6 to −10	6	100	3
−10.25 to −15	5.5	75	3
−15.25 to −20	5	50	3
> −20	4.5	25	3

* Pretreatment is used to prevent central islands.

Manifest Refraction and Visual Loss

All patients were examined before surgery, 1 day, 1 week (range, 5–10 days), 1 month (range, 4–8 weeks), 6 months (range, 4–6 months), and 12 months (range, 12–14 months) after surgery. We measured subjective spectacle refraction. In addition, cycloplegic refraction was performed before surgery. All refractions given are spectacle refractions. To evaluate the stability of the manifest refraction, myopic regression of the spherical equivalent between 1 and 6 months, 6 and 12 months, and 1 and 12 months was calculated. The Wilcoxon *U* test was used for statistical comparison. Uncorrected and spectacle-corrected visual acuity were tested using projection charts (Rodenstock Rodamat, Rodenstock Co., Munich, Germany). On day 1, uncorrected visual acuity (UCVA) was tested only. Visual loss was calculated as the difference in line number on a logarithmic scale (e.g., a drop from 20/20–20/40 or from 20/100–20/200 both represent a 3-line loss). Contact lenses were discontinued at least 2 weeks (hard lenses) or 1 week (soft lenses) before examination.

Visual Acuity

Visual acuity was tested as described above. To determine the efficacy of LASIK, the postoperative visual acuity of eyes that saw 20/40 or better before surgery was evaluated.

Corneal Topography

Corneal topography was measured at each follow-up visit (TMS-1; Computed Anatomy, Inc, New York, NY) in all eyes at all visits. At least two maps were obtained for each eye at each visit, and the qualitatively better one was used for evaluation. Corneal topography was always the first measurement performed to avoid any changes due to tear film instability. For evaluation, preoperative and postoperative color maps of every eye were printed using an adjustable color scale. The scale was the same for each follow-up of each eye to allow for comparison. A step size of 1.00 D was used in all maps. All color maps were rated by one observer (BW). We evaluated the incidence of central islands or keyhole patterns, defined as an increase of refractive power of at least 2.00 D within an area of at least 2 mm in diameter, and decentrations, defined as decentration of the ablation zone in reference to the center of the entrance pupil of at least 1.0 mm. To evaluate stability of corneal power, we also evaluated the change between the topographic maps taken at 1 and 6 months, 6 and 12 months, and 1 and 12 months by comparing the two maps, evaluating the color change and the change in zone size or regularity. We evaluated color changes within the central ablation zone and measured the diameter of this zone at the inner border of the anular transition zone. In cylindrical ablations, we measured the smaller diameter, which is the one in the steeper meridian of the cornea as we flattened the steeper meridian in our approach. We used the following categories: (1) no or minimal regression, defined as a maximum change of refraction of 1.00 D between the two maps and a maximum change of the inner diameter of the ablation zone of 1 mm; (2) moderate symmetric regression, defined as a change of the refractive power of the ablation zone of more than 1.00 D and up to 3.00 D, and/or a change of the inner diameter of the ablation zone of more than 1 mm; (3) severe symmetric regression, defined as a change of the refractive power of the ablation zone of more than 3.00 D, regardless of the diameter; (4) asymmetric regression, defined as asymmetric changes of at least 2.00 D; (5) keratectasia, defined as localized increases of refractive power of at least 4.00 D; and (6) other changes.

Interface Scarring and Pachymetry

Slit-lamp microscopy was performed at each visit under high magnification (×16), and the corneal interface was rated subjectively by one observer as "invisible," "barely visible," "clearly visible," or "scar." Compared to the haze scoring system published by Fantes et al,[8] barely visible was rated equivalent to 0.5, and clearly visible equivalent to 1, whereas scar was used to describe any opacities even slightly interfering with the visibility of iris structures. Binocular ophthalmoscopy and pachymetry (System Corneo-Gage II, Sonogage Co., Cleveland, OH) were performed before surgery and at 6 months.

Endothelial Cell Counts

In a subgroup of 44 eyes of 29 consecutive patients, endothelial cell counts were performed before surgery and 6 months after surgery. Cell morphology was not evaluated. We evaluated results in three groups (attempted correction −5.00 to −9.90 D, 11 eyes; −10.00 to −14.90 D, 14 eyes; and −15.00 to −29.00 D, 20 eyes). Statistical analysis was performed using the *t* test for paired data. Slides of the central endothelium were taken with a noncontact specular microscope mounted on a photographic slit lamp (model 40 SL/P; Zeiss Co., Oberkochen, Germany). A grid was superposed, and cells were counted by one observer (BW). In this technique, the effect of magnification, which has to be considered after corneal ablations in contact techniques, is too small to influence the results.[9]

Patient Satisfaction

A short questionnaire was completed before surgery and at 12 months after surgery by all patients. Patients were asked to rate their satisfaction with the result of the surgery (high, moderate, not satisfied) and whether they would have the surgery again.

Table 2. Data of the Eyes that Did Not Complete 12 Months Follow-up

Initials/Eye	SE Preoperative (D)	SCVA Preoperative	Follow-up (mos)	SE Postoperative	SCVA Postoperative	Remarks
Group 1						
S.G., OD	−29.00	20/100	1	−1.00	20/100	Happy
Group 2						
R.K., OD	−11.50	20/50	1	−1.00	20/30	Happy
R.K., OS	−15.75	20/50	1	−0	20/50	Happy
S.H., OD	−15.00	20/40	1	−1.25	20/50	Unhappy
N.K., OD	−30.50	20/50	4	−6.50	20/60	Happy
N.K., OS	−31.50	20/50	4	−5.50	20/50	Happy
H.S., OD	−19.50	20/100	6	−11.25	20/60	Unhappy
H S., OS	−18.50	20/40	6	−7.00	20/40	Unhappy

SE = spherical equivalent; SCVA = spectacle-corrected visual acuity.

Results

Dropout Analysis

Eight of the 93 eyes (5 patients) were lost to follow-up because the patients lived too far away. Their results are given in Table 2. The remaining 85 eyes (50 patients) were available for each follow-up visit.

Manifest Refraction and Visual Loss

The refractive outcome of both groups and their subgroups is given in Table 3. The percentage of eyes within 0.50 and 1.00 D, respectively, was higher in the subgroups that received a lower correction, and differences between corrections of −5.00 to −9.90 D and −15.00 to −29.00 D were statistically significant. In addition, predictability was slightly lower in the toric group, but only one of the differences was statistically significant (percentage of eyes within ±0.50 D at 12 months; range of correction, −5.00 to −9.90 D; $P = 0.003$). Refractive stability of both groups is given in Table 4. Refractive stability was greater in lower corrections in both groups, but differences were not significant in group 1. In group 2, however, stability was significantly greater for corrections of −5.00 to −9.90 D than for corrections of −15.00 to −29.00 D. For corrections of −5.00 to −9.90 D, none of the eyes lost two or more lines. For corrections of −10.00 to −14.90 D, one eye (10%) of the spherical group and one eye (4.3%) of the toric group lost two lines, and for corrections of −15.00 D and higher, one eye (5.6%) of the spherical group and one eye (7.1%) of the toric group lost two or more lines of spectacle-corrected visual acuity as well. Overall, 4 (4.3%) of the 93 eyes had lost 2 lines of spectacle-corrected visual acuity at the last follow-up. In one patient, visual loss was caused by a central island, which was reoperated on unsuccessfully. In two patients, visual loss was caused by a keyhole pattern in corneal topography, and in one patient, the ablation zone was smaller than the entrance pupil.

Visual Acuity

The visual acuity of eyes that saw 20/40 or more before surgery is given in Table 5. Results were similar in both groups. Comparing the percentage of eyes that saw 20/40 or better without correction, it was higher for corrections of −5.00 to −9.90 D than for corrections of −10.00 to −14.90 D on day 1 but similar on day 5, which may indicate that visual recovery is slower the higher the amount of correction performed. Statistical analysis within each group

Table 3. Predictability of Correction after LASIK in Spherical (S) and Toric (T) Myopia: Percentage of Eyes within the Respective Range of the Attempted Correction

Range of Correction (D)	Follow-up (mos)	No. of Eyes		±0.50 D		±1.00 D		±2.00 D		Undercorrected >2.00 D		Overcorrected >2.00 D	
		S	T	S	T	S	T	S	T	S	T	S	T
−5 00 to −9 90	1	8	12	50	58.3	75	75	100	91 7	0	8.3	0	0
	6	8	12	50	50	87 5*	66 7*	100	91 7	0*	8.3	0	0
	12	8	12	87 5*	25†	100*†	75*	100*	100*	0*	8 3*	0	0
−10.00 to −14 90	1	10	23	40	56 5	70	73 9	90	87	10	8 7	0	4 3
	6	10	23	40	60 9*	60	73.9*	100*	87	0*	8.7*	0	4 3
	12	10	23	50	60 9*	60	78.3*	100*	91 3*	0*	8 7*	0	0
−15 00 to −29.00	1	18	14	44.4	28 6	72 2	50	83 3	71.4	16 7	28 6	0	0
	6	18	14	27.8	28.6	50	35.7	72 2	64 3	27.8	35 7	0	0
	12	18	14	22 2	14 3	38 9	21.4	55 6	57 1	44 4	42 9	0	0

* Significant difference versus corrections of −15.00 to −29.00 D.
† Significant difference versus corrections of −10.00 to −14.90 D.

Table 4. Stability of Correction after LASIK in Spherical (S) and Toric (T) Myopia (Change of Manifest Spectacle Refraction and Change of Corneal Topography; Percentage of Eyes that Showed Regression of Manifest Refraction or Corneal Topography, Respectively, within the Respective Range and within the Respective Follow-up Interval)

Range of Correction (D)	Interval (mos)	No. of Eyes		Change of Spectacle Refraction								Change of Corneal Topography							
				±0.50 D		±1.00 D		±2.00 D		Change >2.00 D		±1.00 D		>1.00 D, <3.00D		Asymmetric Change		Other	
		S	T	S	T	S	T	S	T	S	T	S	T	S	T	S	T	S	T
−5.00 to −9.90	1 to 6	8	12	87.5	91.7	100	91.7	100	100	0	0	100	100	0	0	0	0	0	0
	6 to 12	8	12	100	91.7	100	91.7*	100	100*	0	0*	100	100	0	0	0	0	0	0
	1 to 12	8	12	75	75*	100	91.7	100	100*	0	0*	100	100	0	0	0	0	0	0
−10.00 to −14.90	1 to 6	10	23	90	91.3	100	100	100	100	0	0	80	95.7	10	0	0	0	10	4.3
	6 to 12	10	23	90	78.3	100	87	100	100	0	0	100	100	0	0	0	0	0	0
	1 to 12	10	23	80	69.6	100	87*	100	95.7	0	4.3	90	100	10	0	0	0	0	0
−15.00 to −29.00	1 to 6	18	14	72.2	78.6	83.3	85.7	94.4	92.9	5.6	7.1	88.8	85.7	5.6	14.3	0	0	5.6	0
	6 to 12	18	14	72.2	50	83.3	64.3	88.9	78.8	11.1	21.2	88.8	100	0	0	5.6	0	5.6	0
	1 to 12	18	14	61.1	50	72.2	64.3	77.8	71.4	22.2	28.6	88.8	85.7	0	14.3	5.6	0	5.6	0

* Significant difference versus corrections of −15.00 to −29.00 D.

was not performed because the number of eyes in the subgroup that received the highest corrections was too small.

We also evaluated the number of patients in each subgroup who saw 20/40 or better before surgery and had lost two or more lines in at least one eye at 12 months. For corrections of −5.00 to −9.90 D, none of the seven patients in the spherical group and none of the eight patients in the toric group lost two or more lines. For corrections of −10.00 to −14.90 D, 1 (14.3%) of the 7 patients in the spherical group and 1 (7.1%) of the 14 patients in the toric group lost 2 or more lines. For corrections of −15.00 to −29.00 D, one (33.3%) of the three patients in the spherical group and none of the four patients in the toric group lost two or more lines.

Corneal Topography

Central islands, defined as an increase of refractive power of at least 2.00 D within an area of at least 2 mm in diameter, were the most frequent complication observed. In group 1, they occurred in 25% at 1 week and 17% at 12 months. In group 2, they occurred in 37% at 1 week and 16% at 12 months. At 12 months, decentrations were observed in 5.6% of group 1 and 4.1% of group 2. The evaluation of corneal topography stability is included in Table 4. Keratectasia and regression of more than 3.00 D were not observed in our study and therefore not included. We observed a high stability of corneal refraction, which indicates very stable corrections, even in patients with high myopia. A regression occurred in

Table 5. Visual Acuity after LASIK for Spherical (S) and Toric (T) Myopia in Eyes that Had a Preoperative SCVA of 20/40 or Better (percentage of eyes given)

Range of Correction (D)	Follow-up	No. of Eyes		UCVA ≥ 20/40		SCVA ≥ 20/40		SCVA ≥ 20/25		SCVA ≥ 20/20	
		S	T	S	T	S	T	S	T	S	T
−5.00 to −9.90	Preop	8	10	0	0	100	100	100	50	62.5	40
	1 day	8	10	50	30	NA	NA	NA	NA	NA	NA
	5 days	8	10	75	80	100	80	37.5	20	0	10
	1 mos	8	10	87.5	80	100	100	87.5	70	12.5	20
	6 mos	8	10	87.5	80	100	100	100	70	50	50
	12 mos	8	10	87.5	70	100	90	100	60	37.5	30
−10.00 to −14.90	Preop	9	22	0	0	100	100	55.6	45.5	11.1	27.3
	1 day	9	22	22.2	22.7	NA	NA	NA	NA	NA	NA
	5 days	9	22	66.7	50	88.9	54.5	22.2	13.6	0	4.5
	1 mo	9	22	77.8	72.7	88.9	95.5	33.3	40.9	22.2	13.6
	6 mos	9	22	66.7	77.3	88.9	100	55.6	50	11.1	27.3
	12 mos	9	22	77.8	86.4	88.9	100	55.6	54.5	11.1	27.3
−15.00 to −29.00	Preop	3	5	0	0	100	0	0	0	0	0
	1 day	3	5	0	0	NA	NA	NA	NA	NA	NA
	5 days	3	5	0	40	0	60	0	0	0	0
	1 mo	3	5	33.3	20	33.3	80	0	0	0	0
	6 mos	3	5	33.3	40	33.3	100	0	0	0	0
	12 mos	3	5	33.3	40	66.7	100	33.3	0	33.3	0

SCVA = spectacle-corrected visual acuity; UCVA = uncorrected visual acuity; Preop = preoperative; NA = not tested.

corrections of more than −15.00 D only and was limited to 14.3% of eyes in this group. Conversely, the decreasing incidence of central islands indicates that small localized changes of corneal shape take place.

Interface Scarring and Pachymetry

At 12 months, the corneal interface was invisible in 25 eyes (29.4%), barely visible in 53 eyes (62.4%), and clearly visible in 7 eyes (8.2%). No scars were observed. There was no correlation between interface visibility and the attempted correction.

Average central corneal thickness was 575 ± 39 μm (range, 475–669 μm) before surgery and 451 ± 46 μm (range, 362–604 μm) at 6 months. Average ablation calculated by the laser software was 136 ± 32 μm (range, 58–185 μm). The average actual ablation as defined by the difference in central thickness before surgery and 6 months after LASIK was 124 ± 42 μm (range, 36–203 μm). Thus, the actual central thickness of the stromal bed, defined as the central thickness at 6 months minus the flap thickness (160 μm), was 291 ± 46 μm (range, 202–444 μm).

Endothelial Cell Counts

For attempted corrections of −5.00 to −9.90 D, the mean cell density was 2457 ± 299 cells/mm^2 (range, 1694–2783 cells/mm^2) before surgery and 2457 ± 320 cells/mm^2 (range, 1734–2862 cells/mm^2) 6 months after LASIK. The mean cell loss of 0.1 ± 172 cells/mm^2 (range, −363 to +322 cells/mm^2) was not statistically significant ($P = 0.49$). For attempted corrections of −10.00 to −14.90 D, the mean cell density was 2821 ± 222 cells/mm^2 (range, 2541–3207 cells/mm^2) before surgery and 2741 ± 201 cells/mm^2 (range, 2450–3206 cells/mm^2) 6 months after LASIK. The mean cell loss of 81 (2.6%) ± 180 cells/mm^2 (range, −605 to +182 cells/mm^2) was not statistically significant ($P = 0.07$). For attempted corrections of −15.00 to −29.00 D, the mean cell density was 2547 ± 308 cells/mm^2 (range, 1936–3025 cells/mm^2) before surgery and 2482 ± 442 cells/mm^2 (range, 1573–3388 cells/mm^2) 6 months after LASIK. The mean cell loss of 65 (2.9%) ± 253 cells/mm^2 (range, −605 to +363 cells/mm^2) was not statistically significant ($P = 0.14$).

Patient Satisfaction

The results of the questionnaire are given in Table 6. Satisfaction was highest in spherical corrections, with all patients highly satisfied in corrections of −5.00 to −9.90 D. In corrections of −10.00 to −14.90 D, 90% were highly satisfied, but one patient (10%) was not satisfied. For corrections of more than −15.00 D, 22% were not or just moderately satisfied. After toric corrections, 16% were not or just moderately satisfied, even in corrections of −5.00 to −9.90 D. After corrections of more than −15.00 D, 50% of the patients were not or just moderately satisfied.

Complications and Reoperations

An intraoperative complication occurred in one eye (1.1%). A thin flap was cut, and two lines of spectacle-corrected visual acuity were lost at 12 months in this case. Flap thickness was estimated to be less than 100 μm by the surgeon, but actual thickness was not measured to avoid damage to the flap. It was not possible to determine the cause of this complication, but most likely a partial loss of suction occurred during the keratome path. Two eyes (2.1%) were reoperated on because of complications due to the lamellar keratotomy. In one eye, epithelial ingrowth developed and was treated successfully.[4] This eye lost one line of spectacle-corrected visual acuity. In another eye, partial dislocation of the flap was observed on the first day, and the flap was repositioned. However, folds persisted and a one-line loss of spectacle-corrected visual acuity occurred. Another four eyes (4.2%) required reoperation because of complications related to the laser ablation. In one eye, an irregular central island was treated, but this eye lost two lines of spectacle-corrected visual acuity. In the other three cases, reablation was performed because of undercorrections. No loss of visual acuity occurred in these eyes. Undercorrections of more than 20% of the attempted correction were considered significant enough to offer a second procedure to the patient in case the patient was not satisfied.

Discussion

Predictability

For mild-to-moderate spherical myopia (range, −1.00 to −7.50 D), approximately 79%[10] to 90%[11,12] of eyes were within 1.00 D after PRK. For higher spherical corrections (range, −5.00 to −10.00), a predictability of 44%[12] to 66%[1] was reported for PRK. After LASIK, 100% were within 1.00 (Table 3). For spherical corrections of −10.00 to −14.90 D, predictability was 38%[1] to 58%[13] after PRK, whereas it was 60% after LASIK (Table 3). For corrections of more than −15.00 D, the predictability after LASIK dropped significantly, with just 38.9% within 1.00 D of target refraction (Table 3). These findings are in good agreement with those of others using LASIK to correct a wide range of myopia.[5,6,14] Predictability usually was less than 50% within 1.00 D in corrections higher than −12.00 to −15.00 D.[5,6,14] Comparing spherical and toric ablations, we observed a slightly higher predictability after spherical ablations, but one of the differences was significant only (Table 3). After other lamellar refractive procedures, such as myopic keratomileusis[15] or automated lamellar keratoplasty,[16,17] a predictability of 26%[15] to 38%[16,17] within 1.00 D was reported treating a wide range of myopia (−4.00 to −28.00 D). Only one other study reported a predictability of 76% after automated lamellar keratoplasty, but low myopia as well as a retreatment rate of 77% was included, and only 16.4% (21 of 128 eyes) were within 1.00 D after the initial procedure.[18] The lower predictability of automated lamellar keratoplasty is explained by studies on human cadaveric eyes that showed a considerable range of deviation from predicted thickness in all microkeratomes tested,[19] which also was confirmed clinically.[16]

Refractive Stability

For low spherical myopia, a regression of more than 1.00 D of myopia was observed in 9%[12] to 11%[11] after PRK. For moderate myopia (range, −5.00 to −9.90 D), regression of more than 1.00 D occurred in 5%[1] to 20%[12] after

Table 6. Patient Questionnaire 12 Months after LASIK

	Correction		
	−5.00 to −9.90 D	*−10 00 to −14.90 D*	*−15.00 to −29.00 D*
Spherical myopia			
No. of eyes	8	10	18
LASIK again? (%)			
Yes	100 (n = 8)	90 (n = 9)	94 (n = 17)
No	0	10 (n = 1)	6 (n = 1)
Satisfaction (%)			
High	100 (n = 8)	90 (n = 9)	78 (n = 14)
Moderate	0	0	17 (n = 3)
No	0	10 (n = 1)	5 (n = 1)
Need for glasses (distance correction) (%)			
Never	76 (n = 6)	70 (n = 7)	55 (n = 10)
Occasionally	12 (n = 1)	20 (n = 2)	17 (n = 3)
Most of the time	12 (n = 1)	10 (n = 1)	28 (n = 5)
Toric myopia			
No. of eyes	12	23	14
LASIK again? (%)			
Yes	100 (n = 12)	100 (n = 23)	86 (n = 12)
No	0	0	14 (n = 2)
Satisfaction (%)			
High	84 (n = 10)	91 (n = 21)	50 (n = 7)
Moderate	8 (n = 1)	9 (n = 2)	36 (n = 5)
No	8 (n = 1)	0	14 (n = 2)
Need for glasses (distance correction) (%)			
Never	50 (n = 6)	56 (n = 13)	36 (n = 5)
Occasionally	42 (n = 5)	35 (n = 8)	7 (n = 1)
Most of the time	8 (n = 1)	9 (n = 2)	57 (n = 8)

PRK. After LASIK, we found a stable refraction with no regression of more than 1.00 D. For spherical corrections of −10.00 to −15.00 D, regression averaged −1.56 D[13] and was more than 1.00 D in 14%[1] to as many as 100%[2] after PRK. After LASIK, there was much less regression, with none of the eyes of the spherical group and 8% of the toric group regressing more than 1.00 D (Table 4). Higher corrections (≥−15.00 D) were less stable, and 28% regressed by more than 1.00 D, 22% even more than 2.00 D (Table 4). Comparing spherical and toric ablations, there was slightly less regression after spherical ablations, but differences were not significant. Comparing LASIK to automated lamellar keratoplasty and myopic keratomileusis, regression was much higher after myopic keratomileusis and automated lamellar keratoplasty, with 44%[16,17] to 60%[15] of eyes regressing more than 1.00 D.

Visual Acuity

For spherical corrections of −5.00 to −9.90 D, UCVA was 20/40 or better in 53%[12] to 67%[1] after PRK compared to 71%[6] and 88% (Table 5) after LASIK. For spherical corrections of −10.00 to −14.90 D, UCVA was 20/40 or better in 38%[1] to 60%[13] after PRK compared to 45%[6] and 78% (Table 5) after LASIK. For higher corrections, only 33% saw 20/40 or better UCVA after LASIK. Efficacy of spherical and toric corrections was similar (Table 5). It frequently is stated that visual recovery is more rapid after LASIK than after PRK. In both groups, 80% to 100% had a spectacle-corrected visual acuity of 20/40 or better on day 5 (range of correction, −5.00 to −14.90 D), which seems to confirm this assumption (Table 5). Spectacle-corrected visual acuity was not tested on day 1, but 20% to 50% saw 20/40 or better UCVA. However, looking at higher levels of visual acuity, recovery seems to be slower (Table 5). Because the number of eyes that saw 20/40 or better before surgery is small, theses findings need further study.

Regarding visual loss, the U.S. Food and Drug Administration panel on excimer laser PRK stated that loss of best-corrected visual acuity should be limited to 5% of eyes losing two or more lines.[20] Overall, 4 (4.3%) of the 93 eyes in our study had lost 2 or more lines of spectacle-corrected visual acuity at 12 months, the results of which compare to 4% reported by a retrospective study on LASIK.[14] However, we observed no loss in corrections up to −10.00 D, whereas for corrections of −10.00 to −14.90 D, 10% of the spherical group and 4.3% of the toric group lost two or more lines. For corrections of more than −15.00 D, 5.6% of the spherical group and 7.1% of the toric group lost two or more lines. One year after PRK for low myopia, a loss of two lines of spectacle-corrected visual acuity was reported in 1.2%[2] and 4% to 7%.[10] After PRK in high myopia (range, −8.00 to −15.25 D), 13% to 15% of eyes lost two lines of spectacle-corrected visual acuity.[1,13] After myopic keratomileusis or automated lamellar keratoplasty, a loss of two or more lines occurred in up to 17%.[15] These data suggest that visual loss occurs more frequently after PRK, myopic keratomileusis, and automated lamellar keratoplasty than after LASIK in corrections of −5.00 to −14.90 D.

When interpreting visual loss, one must consider spec-

tacle magnification as we measured spectacle-corrected visual acuity in all eyes. In corrections of more than −10.00 D, a gain of at least one line should be expected because of higher magnification. However, we observed a loss of two or more lines in four eyes that received corrections of more than −10.00 D. In addition, the number of just moderately or not satisfied patients was highest in corrections of −15.00 to −29.00 D (Table 6). This indicates that the reshaping of the cornea causes significant optical aberrations that pose an upper limit to the amount of correction that can be performed safely. The upper limit depends on the diameter of the optical zone, which is, in turn, related to the amount of correction and the corneal thickness. Assuming a 15° field of view and a 3-mm pupil diameter, the diameter of the ablation zone must be 4.46 mm. Assuming a 5-mm pupil diameter, which is quite common even in daylight, the required diameter of the ablation zone increases to 6.28 mm.[21] Thus, correcting high myopia by reshaping the cornea will cause significant aberrations in correction of −15.00 D or more as the diameter of the ablation zone becomes 5 mm or less (Table 1). We will have to look for other options to correct these patients with high myopia, such as phakic intraocular lenses[22,23] or clear lens exchange.[24] Based on our data, the upper limit seems to be approximately −15.00 D, which is in agreement with other studies,[5] but this may change as we learn more about the long-term results of phakic intraocular lenses. In addition, the above considerations assume perfectly centered ablations. Decentrations were observed in 4.1% to 5.6% in our study. Others reported an incidence of 9.1%,[25] 4%,[26] and 2.9%,[27] respectively, based on corneal topography. Decentrations will increase the likelihood of optical aberrations and therefore reduce the range of safe corrections even further.

Corneal Topography

The theoretical assumption was that LASIK causes no or a very limited healing response only. We already showed that there is no histologically visible wound-healing response in the early postoperative phase.[4] Animal studies support these findings.[28] Our data also show that topographically visible changes of corneal refraction occur in 14.3% only and are limited to large amounts of correction (Table 4) compared to 41% after PRK.[29] The very limited healing response solves the problem of regression, which occurs after PRK for high myopia. Conversely, a limited healing response is much less forgiving. In PRK, the strong healing response causes leveling of irregularities, and central islands gradually disappear.[10,30,31] LASIK seems to be less forgiving, and central islands resolved only partially in our study. Conversely, we observed a change of corneal refraction in some cases, and some central islands resolved, which proves that some healing response or corneal remodeling takes place after LASIK as well. The reason for the remodeling still is unclear. One possible explanation is a thickening of the corneal epithelium, which tends to smooth small and circumscribed irregularities of the cornea. Some preliminary data suggest that, indeed, epithelial thickening is responsible for the regression observed in patients with high myopia after LASIK (R. Zaldivar, personal communication, 1997).

Interface Scarring and Pachymetry

An advantage of LASIK, compared to PRK, is a considerably lower incidence of haze or scarring. In 91.8%, the corneal interface was not or just barely visible, which is equivalent to a haze score of less than 1. In 8.2%, the interface was clearly visible, which could be compared to a haze score of 1. No higher haze scores and no scarring were observed. These results compare to a haze score of 2 in 8.7%[13] and 15%[1] after PRK for high myopia. Scars were observed in 17.3% after PRK for myopia greater than −6.10 D.[2]

We also performed endothelial cell counts. At 6 months, we found no loss in corrections of −5.00 to −9.90 D and a loss of 2.6% and 2.9% in corrections of −10.00 to −14.90 D and −15.00 to −29.00 D, respectively. Findings were not statistically significant. Others reported a loss of 0.3% to 0.4% at 6 months[6] and 8.67% at 1 year[3] after LASIK. After PRK, a loss of 1.5% at 1 to 3 years was observed,[32] whereas others reported a loss of 0.8% after 7 months.[9] Experimentally, no significant changes were observed, even in 400-μm keratectomies.[33]

Complications

During our learning curve, which included all of the first 36 consecutive eyes operated on by the authors, a number of intraoperative complications occurred.[4] Using a standardized technique, only one minor complication was encountered. Four eyes (4.3%) were reoperated on because of problems related to the laser ablation (undercorrection, three eyes; central islands, one eye). However, in two eyes (2.2%), reoperations were required because of complications related to the lamellar procedure (epithelial ingrowth, one eye; flap dislocation with persistent folds, one eye). Seiler et al[2] reported an overall reoperation rate of 14% after PRK (27 of 193 eyes) for myopia. The rate was 6.5% in eyes with baseline refractions between −3.10 to −6.00 D and 40% in eyes with baseline refractions of more than −6.00 D.[2] Others reported a reoperation rate of up to 60% 1 year after PRK for myopia of more than −10.00 D.[34] After automated lamellar keratoplasty, rates of up to 77% were reported.[18] Overcorrections of more than 2.00 D were observed in one eye of the toric group at 1 and 6 months but returned to less than 2.00 D at 12 months (Table 3). Undercorrections of more than 2.00 D occurred in both groups and were more pronounced in toric ablations. Both in spherical and toric ablations, undercorrections were significantly more frequent in corrections of more than −15.00 D (Table 3).

We are aware of a number of limitations to our study. The number of patients is small, and in many cases, both eyes were included, which biases statistical evaluation. We also must consider that our results were compared with those of historic data on PRK and lamellar refractive

procedures reported in the literature, which may mislead our conclusions. Another problem that was already addressed is the use of spectacle-corrected visual acuity instead of contact lens–corrected visual acuity, which results in an underestimation of the visual loss observed. Finally, follow-up still is too short to evaluate possible late complications such as keratectasia.

Despite these limitations, our results indicate that LASIK provides stability of manifest refraction and adequate UCVA as well as a high degree of patient satisfaction without significant visual loss in patients with myopia up to −10.00 D. Results still may be acceptable in patients with myopia up to −15.00 D, but the rate of visual loss is higher, and patient satisfaction is lower. For myopia greater than 15.00 D, accuracy and patient satisfaction were sufficiently poor to advise against the use of LASIK. In addition, patients with astigmatism correction were less pleased with results than were patients who received spherical corrections.

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