Long-term results of superficial laser in situ keratomileusis after ultrathin flap creation

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PURPOSE: To study the long-term efficacy, safety, and stability of laser in situ keratomileusis (LASIK) after unintentional ultrathin flap creation less than 80 μm.

SETTING: University refractive surgery center.

METHODS: This retrospective case series comprised 25 patients (33 eyes) who had LASIK after flap creation less than 80 μm with the Moria M2 disposable microkeratome (head 90 μm). Flap thickness was measured with intraoperative ultrasound pachymetry. Manifest refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity, predictability, stability, complications, patient satisfaction, and confocal microscopy images were studied.

RESULTS: The mean follow-up was 14.58 months ± 3.73 (SD) (range 12 to 25 months). The mean flap thickness was 72.1 ± 5.9 μm (range 58 to 80 μm), and the mean preoperative spherical equivalent (SE) refraction was –5.59 ± 2.01 diopters (D) (range −10.25 to −3.25 D). On the first postoperative day, the UCVA was 20/25 or better. The SE manifest refraction was 1.00 D or less in all patients. The mean SE manifest refraction was −0.75 ± 0.55 D (range −1.00 to +0.75 D) (P<.01). At the last follow-up, changes in visual acuity and manifest refraction were not statistically significant; no late postoperative complications were observed. All patients were satisfied with the final outcome. Qualitative analysis of confocal microscopy images revealed interface particles and activated keratocytes.

CONCLUSIONS: Despite the small sample and retrospective nature of the study, superficial LASIK seemed to be a safe and predictable technique for myopic refractive corrections. Patients were satisfied with the results and had rapid visual recovery with no intraoperative or early or late postoperative complications. If the safety and efficacy of an ultrathin flap are confirmed by additional studies, superficial LASIK could represent a new approach that combines the advantages of surface and lamellar procedures.

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Laser in situ keratomileusis (LASIK) is a safe and popular refractive surgical procedure to correct myopia, hyperopia, and astigmatism. The procedure's rapid, painless recovery of vision and lack of subepithelial haze are mainly the result of the creation of a corneal flap with a microkeratome.[1–3]

The ideal flap thickness has been 130 μm and greater. This limit is considered necessary for easier intraoperative manipulations, better flap-to-bed fitting, fewer striae, and fewer intraoperative complications (buttonhole, half cuts, steps).[4–6] Surgeons have begun to reconsider the ideal flap thickness[7,8] because of the possibility of post-LASIK corneal ectasia and the limited residual corneal bed after flap creation and ablation,[9] the trend toward bigger ablation zones, supplementary topography and wavefront-guided ablations,[10] and flap-induced aberrations.[11]

Theoretically, a thinner flap could ease these concerns because it permits larger ablation zones and attempted corrections and wavefront and topoguided supplementary ablations may be possible without the fear of postoperative corneal ectasia. It also preserves the overall biomechanical integrity of the cornea, has better functional results than conventional flaps (because a thinner flap can be better adjusted to the ablated residual corneal bed as a result of less stromal tissue in its composition), and induces fewer aberrations than a conventional thicker flap. In other words, a thinner than conventional flap could combine the advantages of lamellar and surface approaches.

Recently published articles regarding thin-flap LASIK report encouraging results with this "new" approach.[12–15] Faster visual recovery and better contrast sensitivity results

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than with thicker flaps are a few of the advantages of thin flaps. Despite these, issues regarding the long-term safety, efficacy, and results of the procedure (refractive stability, regression, complications such as flap melting and increasing incidence of epithelial ingrowth) remain unanswered because the current studies are limited by short-term follow-up. The purpose of this study was to evaluate the long-term refractive and visual outcomes of LASIK after unintentional creation of flaps less than 80 μm.

PATIENTS AND METHODS

This retrospective case series was of 33 eyes of 25 patients who had LASIK after unintentional ultrathin flap creation (58 to 80 μm) using the Moria M2 disposable microkeratome (head 90 μm, superior-hinged corneal flap) and completed follow-up examinations at least 1 year after surgery (Table 1). All patients received informed consent before their participation in the study and gave written informed consent in accordance with institutional guidelines and the Declaration of Helsinki.

Clinical Examination

A complete ophthalmic examination was performed preoperatively to exclude ocular disease. Exclusion criteria were active anterior segment disease; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery; history of herpes keratitis; diagnosed autoimmune disease; systemic connective tissue disease or atopic syndrome; and corneal topographic findings suspicious for keratoconus.

Surgical Technique

The LASIK procedures were performed in a standardized manner. A drop of proparacaine hydrochloride 0.5% (Alcaine) was instilled in each eye 5 minutes and just before the procedure. This was followed by povidone–iodine (Betadine) preparation of the lids. Eyelashes were isolated by a drape, and a speculum with suction was placed in the operative eye. The cornea was marked with a corneal marker using gentian violet staining. The microkeratome settings were chosen according to the manufacturer's nomogram. The 90 μm disposable head was used in all cases to create a superior hinge. After the microkeratome pass, the flap was lifted and central ultrasound pachymetry (DGH 5100 Technology, Inc.) of the residual stromal bed was performed. Three measurements were taken, and the minimum value was subtracted from the preoperative corneal thickness. This difference was considered the flap thickness (subtraction pachymetry). The flap was floated back into position after the ablation, and the stromal bed was irrigated with a balanced salt solution. Flap alignment was checked using gentian violet preoperative corneal markings, and a striae test was performed to ensure proper flap adherence.

All patients were examined 60 minutes postoperatively to check flap adherence. They were given flurbiprofen sodium 0.03% drops (Ocuflur) 4 times daily for 2 days, dexamethasone 0.1%–tobramycin 0.3% drops (TobraDex) 4 times daily for 2 weeks, and sodium hyaluronate 0.18% drops (Vismed) hourly for 1 month.

Table 1. Patients' demographic and refractive data.

Parameter	Value
Number of patients	25
Eyes	33
Sex (male/female)	9/16
Age (y)	
Mean ± SD	30.44 ± 7.18
Range	21 to 51
Preop corneal pachymetry (μm)	
Mean ± SD	539.09 ± 22.27
Range	499 to 583
Follow-up (mo)	
Mean ± SD	14.58 ± 3.73
Range	12 to 25
Preoperative SE refraction (D)	
Mean ± SD	−5.59 ± 2.01
Range	−10.25 to −3.25
Post-LASIK SE refraction (D)	
Mean ± SD	−0.75 ± 0.55D
Range	−1.00 to +0.75 D*

LASIK = laser in situ keratomileusis; SE = spherical equivalent
*($P < .001$)

Follow-up Examinations

Preoperative and postoperative follow-up included uncorrected visual acuity (UCVA) (Snellen), best spectacle-corrected visual acuity (BSCVA) (Snellen), manifest refraction, complications, confocal microscopy analysis, and subjective symptoms.

Confocal microscopy was performed with a modified confocal scanning laser ophthalmoscope (HRT II, Heidelberg Engineering). The addition of the Rostock Cornea Module converted the HRT II into a confocal corneal microscope that allowed the acquisition of 2-dimensional images of various corneal layers by sequentially scanning a 670 nm laser beam. After a local anesthetic agent (1 drop of proparacaine hydrochloride [Alcaine] and high-viscosity gel (carbomer 3.0 mg/g [Thilogel]) were instilled, the patients were asked to fixate on an external fixation target. The instrument objective was brought into optical contact with the cornea tissue by a disposable sterile poly(methyl methacrylate) (PMMA) cup and Thilogel. Depth scans across the entire cornea were performed manually while an external electronic unit kept track of the focal plane. The external interface of the PMMA cup was taken as the reference point for thickness measurements.

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Images of the various corneal layers were acquired at the optical center of the cornea. The acquired images consisted of 384 pixels × 384 pixels over a 300 μm × 300 μm field of view with a transversal resolution of about 2 μm and a longitudinal resolution of approximately 4 μm. Qualitative evaluation of the images was performed with a special interest at the flap interface, the anterior and posterior layers of the flap, and the deeper stromal layers.

Visits were scheduled on the postoperative days 1, 3, 15, and 30 and then every 3 months.

Statistical Analysis

Group differences for continuous variables were tested using the unpaired and paired Student *t* tests and 1-way analysis of variance for normally distributed data. Differences in categorical variables were tested using the chi-square or Fisher exact test for independence. Results are presented as mean ± standard deviation. A *P* value less than 0.05 was regarded as statistically significant.

RESULTS

The mean age of the 9 men and 16 women was 30.44 ± 7.18 years (range 21 to 50 years). Mean follow-up was 14.58 ± 3.73 months (range 12 to 25 months). The mean preoperative spherical equivalent (SE) refraction was −5.59 ± 2.01 D (range −10.25 to −3.25 D). The pre-LASIK UCVA was uniformly poor at counting fingers (CF). The BSCVA was 20/25 or better in all eyes; it was 20/20 preoperatively in 25 eyes.

All eyes had primary LASIK (8 patients bilaterally and 17 (14 with left second eye) unilateral superficial LASIK) using the Allegretto Wave excimer laser (Wavelight Technologie) at the same treatment zone (6.50 mm). Mean preoperative cornea pachymetry was 539.09 ± 22.27 μm (range 499 to 583 μm).

Refractive Outcome: Predictability

On the first postoperative day, all eyes were within ±1.00 D of emmetropia (mean SE post-LASIK −0.75 ± 0.55 D; range −1.00 to +0.75 D) ($P<.001$) (Table 1). Refractive stability was obtained on the first postoperative day and remained stable during the follow-up period with no significant changes between any interval ($P>.05$) (Figure 1).

The predictability on the first postoperative day is shown in Figure 2.

Visual Outcomes

The mean UCVA significantly improved from CF to 20/25 or better in all eyes; 22 eyes (67%) had UCVA of 20/20 at the first postoperative day. No significant changes between any follow-up intervals were observed. The BSCVA remained unchanged or improved in all eyes. Specifically, 30 eyes (91%) remained unchanged and 3 eyes gained 1 line of BSCVA.

Other Findings

On the first postoperative day and during the follow-up period, no flap irregularities (eg, edema, striae) were observed at the slitlamp examination. Flap edges could not be detected in 27 of 33 eyes.

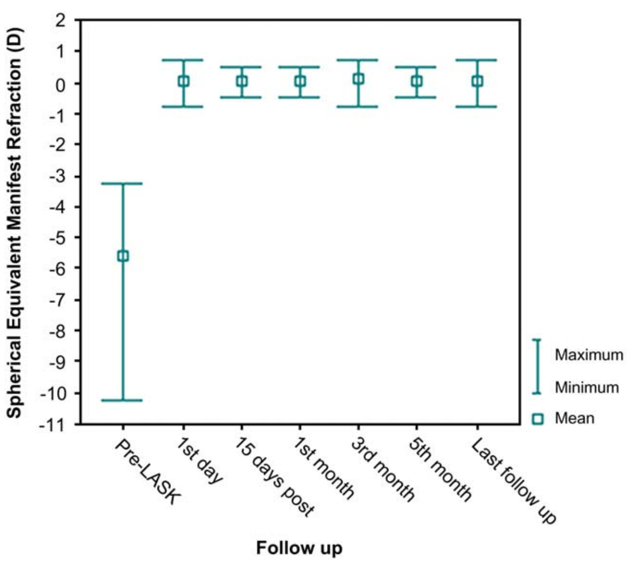

Figure 1. Refractive stability during the follow-up period with no significant changes between intervals ($P>.05$).

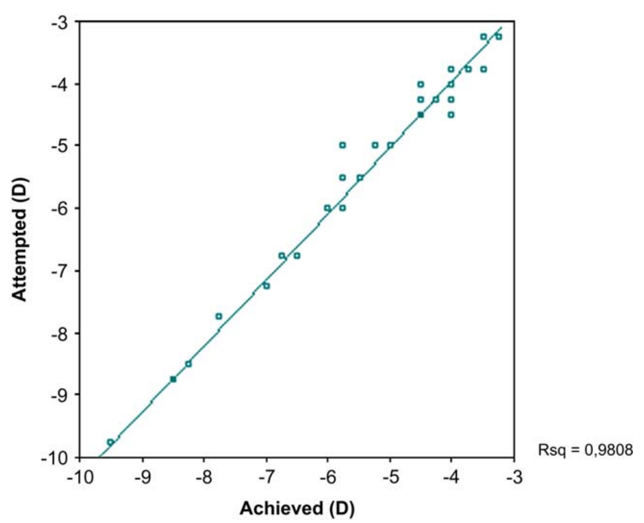

Figure 2. Predictability on the first postoperative day.

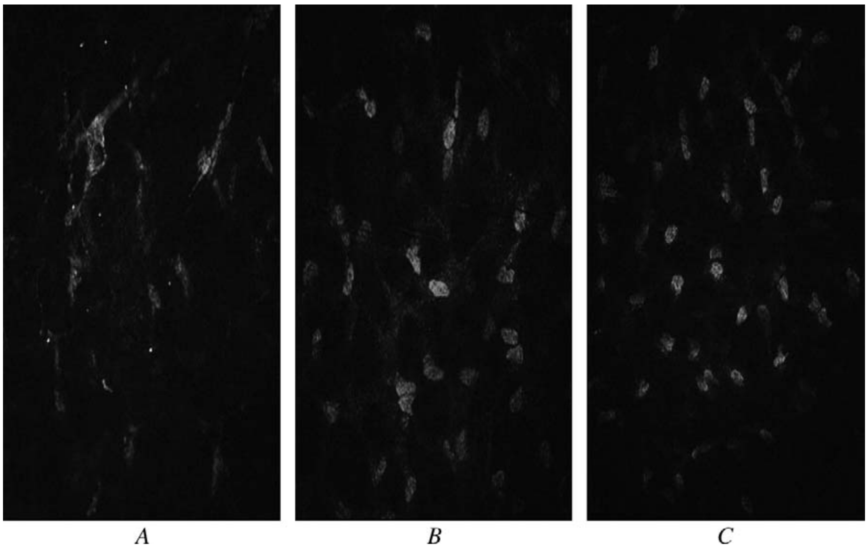

Figure 3. *A*: Confocal microscopy image of flap interface (74 μm) with increased scattering and small particles. *B*: Confocal microscopy image of stroma immediately posterior to flap interface (130 μm) with activated keratocytes. *C*: Confocal microscopy image of deep stromal layers (328 μm) with normal keratocytes.

Confocal microscopy analysis revealed regular epithelial and subepithelial layers with indications of regenerated subepithelial nerves even 1 month after surgery (Figure 3). No occurrences of subepithelial striae and/or microfolds were observed. Flap interface thicknesses were less than 80 μm as indicated by the pachymetry measurements of the confocal microscope, while small particles were observed at the flap interface in all eyes. Increased scattering caused by keratocyte activation was detected immediately posterior to the flap interface; the keratocytes exhibited an abnormal spindle-like formation at this layer. Deeper layers of the stroma indicated normal, oval-like formation of keratocytes with minimum scattering of the nuclei.

Questionnaire

On a scale of 1 to 5 for current overall satisfaction, all patients reported being happy with the results (score 5) on the first postoperative day.

Adverse Effects and Postoperative Complications

No eye had intraoperative or early or late postoperative complications.

DISCUSSION

Flap thickness in LASIK is an important parameter of the surgery. When Pallikaris et al.[3] described the LASIK technique, the best flap thickness was considered to be 130 to 160 μm. Thinner flaps are considered intraoperative problems for surgeons, especially inexperienced surgeons, because thin flaps are difficult to manage, which increases the risk for flap striae and irregular astigmatism.[4–6] Improvements in microkeratomes and laser technology have lead to new views of the ideal thickness of the flap.

We reconsidered the ideal flap thickness for several reasons: the increasing incidence of post-LASIK corneal ectasia, even in cases with residual corneal thickness more than 250 μm[9]; growing demand to correct large ametropia; and the development of more sophisticated laser devices that could increase the ablation treatment zones up to 9.0 mm; wavefront- and topography-guided customized ablations, both of which can increase how much corneal stroma can be removed[10]; and the aberrations induced by flap creation itself.[11]

These reasons have encouraged surgeons to perform more superficial ablations and have escalated interest in advanced surface ablations. Despite the recent improvements in surface ablations, such as the application of mitomycin-C and the development of Epi-LASIK, there is still an increasing concern regarding the postoperative pain, low rate of visual recovery, and need for prolonged use of corticosteroids.

We found that superficial LASIK after ultrathin flap creation led to rapid visual rehabilitation with good predictability and stability over a long-term follow-up. The faster visual rehabilitation with ultrathin flaps could be seen on the first postoperative day and may be related to a thinner corneal flap. The thinner flap can result in less postoperative stromal edema and a better fit over the ablated corneal bed. Other studies[7,13] found similar results, reporting that flaps thinner than 100 μm had better functional results than thicker flaps with increased safety and efficacy. Yeo and Song[14] report that thin corneal flaps led to no significant postoperative complications compared with thicker flaps. However, Vesaluoma et al.[15] found that thin flaps increased interface reflectivity early postoperatively and that there were more particles in the flap interface. Similarly, we observed small particles in the interface in all patients; however, the particles seemed smaller than those in the flap interfaces with standard thickness flaps. Unlike the findings of Vesaluoma et al.,[15] we did not observe subepithelial microfolds or striae.

Deeper stromal layers showed normal keratocytes, which is indicative of a less pronounced wound-healing response. Part of these differences could be related to the thinner flaps in our study and the longer postoperative follow-up. In addition to these studies, we found that the advantages offered by the ultrathin flaps (predictability, stability, and postoperative complication) become numerous over a long period (up to 2 years) without any late postoperative complications.

This retrospective study had a small sample and thus may lack the power to derive meaningful results. Another issue is the lack of comparison with patients with thicker flaps. Such a prospective comparative study would require the development of new microkeratomes with target flap thickness less than 80 μm. The eyes in this study had unintended thin flaps. Possible predisposing factors that could also affect our results are preoperative corneal thickness, keratometric values, and the second cut in bilateral procedures.

It will be difficult to develop a microkeratome that creates ultrathin flaps because current technology relies on specific standard deviations.

Superficial LASIK was stable and predictable and gave rapid visual recovery. There were no progressive sight-threatening complications during the 2-year follow-up. Future prospective comparative randomized studies with new microkeratomes that create ultrathin flaps are needed.

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