ORIGINAL ARTICLE

Thin LASIK Flap Creation Using the SCHWIND Carriazo-Pendular Microkeratome

George D. Kymionis, MD, PhD; Dimitra M. Portaliou, MD; Nikolaos S. Tsiklis, MD, MSc; Sophia I. Panagopoulou, PhD; Ioannis G. Pallikaris, MD, PhD

ABSTRACT

PURPOSE: To study the outcomes of LASIK after intended ultra-thin flap creation using the SCHWIND Carriazo-Pendular microkeratome with the 90-μm head.

METHODS: Forty-seven eyes of 26 patients (mean age 28.78±6.98 years) underwent LASIK with a superior hinge flap using the 90-μm head of the SCHWIND Carriazo-Pendular microkeratome. Evaluation included flap parameters (thickness, diameter, hinge size), complications, and visual outcome.

RESULTS: No intraoperative or early postoperative complications were observed. The mean flap thickness was 79.88±6.94 μm (range: 70 to 93 μm). Mean flap diameter was 9.25±0.45 mm (range: 8.5 to 11 mm) whereas mean hinge size was 4.63±0.66 mm (range: 3 to 6.5 mm). No eye lost lines of best spectacle-corrected visual acuity, and all eyes were emmetropic within one diopter postoperatively.

CONCLUSIONS: The SCHWIND Carriazo-Pendular microkeratome with the 90-μm head seems to have increased accuracy in intended creation of ultra-thin flaps. [*J Refract Surg*. 2009;25:xxx-xxx.]

Laser in situ keratomileusis (LASIK) is a well known refractive surgical procedure for the correction of myopia, hyperopia, and astigmatism.[1-3] The procedure's advantages (fast, painless recovery of vision and lack of subepithelial haze) are mainly due to the creation of a corneal flap.[4,5]

Until recently, the ideal flap thickness has been ⩾130 µm to guarantee easier intraoperative manipulations, better flap-to-bed fitting, fewer striae, and fewer intraoperative complications such as buttonhole or irregular flaps.[6-8] Nevertheless, the possibility of corneal ectasia after LASIK due to limited residual corneal bed after flap creation and ablation,[9] the trend for bigger ablation zones, supplementary topography- or wavefront-guided treatments,[10] and flap-induced aberrations[11] have created a shift towards thinner flaps.

Laser in situ keratomileusis with ultra-thin flaps seems to have several advantages over conventional flaps.[12-17] Ultra-thin flaps preserve more untreated corneal tissue and therefore may be able to maintain the overall biomechanical integrity of the cornea.

The purpose of this study is to evaluate the results of LASIK after ultra-thin flap (<100 µm) creation with the SCHWIND Carriazo-Pendular microkeratome (90-µm head) (SCHWIND, Kleinostheim, Germany).

PATIENTS AND METHODS

The current prospective study included 26 myopic patients (14 men and 12 women, 47 eyes) with a mean age of 28.78±6.98 years (range: 20 to 54 years) who underwent

From Institute of Vision and Optics University of Crete, Greece (Kymionis, Portaliou, Tsiklis, Panagopoulou, Pallikaris); and Bascom Palmer Eye Institute, University of Miami, Miami, Fla (Kymionis).

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

Correspondence: Nikolaos S. Tsiklis, MD, MSc, Vardinoyannion Eye Institute of Crete, University of Crete, Medical School, Dept of Ophthalmology, 71110 Heraklion, Crete, Greece. Tel: 30 2810 371800; Fax: 30 2810 394653; E-mail: ntsiklis@hotmail.com

Received: September 3, 2007

Accepted: February 12, 2008

TABLE

Demographic and Preoperative Refractive Data of 47 Eyes That Underwent LASIK With the SCHWIND Carriazo-Pendular Microkeratome

Demographic	Mean±Standard Deviation (Range)
No. of eyes/patients	47/26
Sex (male/female)	14/12
Age (y)	28.78±6.98 (20 to 54)
Corneal pachymetry (μm)	565.63±27.10 (501 to 616)
Steepest K (D)	43.46±1.56 (39.93 to 46.44)
Sphere (D)	−4.57±2.66 (−8.75 to −2.25)
Cylinder (D)	−1.36±1.19 (−4.75 to −0.25)

LASIK with the SCHWIND Carriazo-Pendular microkeratome using a 90-μm head. Based on the keratometric measurements, rings 9 or 10 were used in 10 and 16 patients, respectively. According to the manufacturer's nomogram, in patients with keratometric values >42.00 diopters (D), ring 9 was used, and for values <42.00 D, ring 10 was used. The Table demonstrates patient refractive and demographic data. A written informed consent in accordance with the institutional guidelines and the Declaration of Helsinki was obtained by all participants.

Preoperative Measurements

Preoperative examination included uncorrected visual acuity (UCVA) (decimal scale), best spectacle-corrected visual acuity (BSCVA) (decimal scale), cycloplegic refraction, slit-lamp examination with fundus evaluation, and corneal topography (C-Scan; Technomed, Baesweiler, Germany).

Exclusion criteria were active anterior segment disease; residual, recurrent, or active ocular disease; and previous intraocular or corneal surgery, history of herpetic eye disease, corneal scarring, glaucoma, severe dry eye, and topographic evidence of keratoconus.

Surgical Technique

Laser in situ keratomileusis procedures were performed in a standardized manner by the same surgeon (G.D.K.) using the ALLEGRETTO WAVE excimer laser (WaveLight Technologies, Erlangen, Germany).

A drop of proparacaine hydrochloride 0.5% (Alcaine; Alcon Laboratories Inc, Ft Worth, Tex) was instilled in each eye 5 minutes before and in the beginning of the procedure, followed by a povidone-iodine (Betadine; Lavipharm, Peania, Greece) 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 SCHWIND Carriazo-Pendular microkeratome with the 90-μm head was used in all cases to create a superior hinge. A new blade was used for each eye.

Flap thickness was measured by performing intraoperative ultrasound pachymetry (DGH 5100; DGH Technology Inc, Exton, Pa) using the subtraction technique (central corneal thickness minus stromal bed thickness). All measurements were performed after inserting the speculum and drying the conjunctival fornices. Three measurements were obtained and averaged (all measurements had to be within 10 μm of one another; otherwise, a fourth measurement was obtained and the three measurements within 10 μm were included for mean measurement calculation). After flap creation, any fluid present in the bed was wiped with a dry sponge prior to measuring stromal bed thickness. Three measurements were taken and averaged for the final recorded measurement. If they varied by more than 10 μm, a fourth measurement was taken (as the pre-keratectomy measurements). The difference between these two mean measurement sets was recorded as the flap thickness. 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. The flap was then allowed to dry for 2 minutes. A soft contact lens was applied in all eyes as a bandage and was removed on the first postoperative day.

All patients were examined 60 minutes postoperatively to check flap adherence. They were given flurbiprofen sodium 0.03% drops (Ocuflur; Allergan, Irvine, Calif) four times daily for 2 days, dexamethasone 0.1%–tobramycin 0.3% drops (TobraDex, Alcon Laboratories Inc) four times daily for 2 weeks, and sodium hyaluronate 0.18% drops (Vismed; TRB Chemedica, Newcastle under Lyme, United Kingdom) hourly for 1 month.

Postoperative Follow-up

Patients were instructed to wear protective eye shields at night and to return the following day, on postoperative day 3, and 1 month after the procedure.

RESULTS

Visual Outcomes

All eyes were emmetropic within 1.00 D at the 1-month postoperative examination (mean spherical equivalent refraction −0.25±0.48 D [range: −0.75 to

0.50 D]). Mean UCVA significantly improved from counting fingers to 0.80±0.21 (range: 0.2 to 1.275) on the first postoperative day and 0.95±0.21 (range: 0.3 to 1.27) on the third postoperative day. The mean UCVA at 1 month was 0.99±0.22 (range: 0.425 to 1.27) whereas mean BSCVA was 1.00±0.16 (range: 0.7 to 1.27). No eye lost lines of BSCVA.

Flap Characteristics

The mean flap thickness was 79.88±6.94 µm (range: 70 to 93 µm). Mean flap diameter was 9.25±0.45 mm (range: 8.5 to 11 mm), and mean hinge size was 4.63±0.66 mm (range: 3 to 6.5 mm).

Complications and Adverse Effects

No intraoperative complications occurred in this series. Few interface particles were observed on postoperative slit-lamp examination in four eyes whereas two eyes presented with microstriae. No surgical intervention was performed in these eyes as the flap microstriae were out of the visual axis and did not affect UCVA or BSCVA or induced irregular astigmatism. No dislocations or corneal haze occurred. On the first postoperative day, one eye presented with diffuse lamellar keratitis stage I and was treated successfully with corticosteroids.

DISCUSSION

Laser in situ keratomileusis alters the organization of the collagen fibrils and the long-term structural integrity of the cornea. Normally, 300 to 500 lamella run from limbus to limbus with angular offsets; this orientation becomes increasingly dense in the anterior stroma where significantly more oblique branching and interweaving are noted.[18,19] Cutting the corneal lamellae during flap creation leads to biomechanical alterations that may predispose to cornea ectasia.

Flap thickness is one of the most important parameters in LASIK surgery. Barraquer first proposed in 1950 that 250 µm of residual corneal tissue is a safe limit for the long-term biomechanical stability of the cornea.[20] Since then, corneal ectasia after LASIK in patients with even >300 µm of untreated corneal tissue has been reported.[21,22] The need for higher attempted corrections with less risk of ectasia has led surgeons to prefer flaps thinner than 100 µm even though they are difficult to manage and therefore might increase the risk of flap striae and irregular astigmatism.[6-8]

The purpose of this study was to evaluate the results of ultra-thin flap LASIK with the SCHWIND Carriazo-Pendular microkeratome 90-µm head. A new sterilized head and blade were used for every eye, minimizing the probability of contamination by microbial pathogens and a possible thinner second cut or a buttonhole flap.[9] No intraoperative or early postoperative complications (needing additional surgical intervention) occurred. Sekundo et al[23] reported that placement of a bandage soft contact lens after LASIK does not exert any positive effect on microstriae and macrostriae incidence and worsens the first-day UCVA insignificantly. This study did not include patients with ultra-thin flaps. Due to previous flap dislocations after ultra-thin flap LASIK, a bandage contact lens was applied to all patients in this series during the first 24 hours. No flap dislocation was observed. Despite the complications (irregular astigmatism and striae) reported by other authors,[6-8] we did not observe such complications in this series (two eyes presented with microstriae that were out of the visual axis and did not affect UCVA or BSCVA or induced irregular astigmatism). The application of a bandage contact lens seems to decrease the incidence of such complications after ultra-thin flap LASIK.

An issue with thin flap creation is the long-term decrease of corneal thickness, which is estimated at approximately 11 µm per year, which may lead to flap deterioration.[24] On the contrary, long-term studies after LASIK[3] demonstrated absence of late postoperative complications with stable visual performance. The deeper corneal stromal layers showed normal keratocytes, which indicated decreased wound healing response probably due to thin flap creation.

A few potential limitations are apparent in this study such as the small sample size of treated eyes, limited follow-up, lack of a comparative group (other mechanical microkeratome or femtosecond group), and absence of multiple peripheral corneal thickness measurements with anterior segment optical coherence tomography (OCT).[25] Future studies should include evaluation of anterior segment OCT to characterize the uniformity and shape of the flaps, in addition to biomechanical studies to assess the viscoelasticity of the cornea after ultra-thin microkeratome flaps.

REFERENCES

1. Pallikaris IG, Papatzanaki ME, Stathi EZ, Frenschock O, Georgiadis A. Laser in situ keratomileusis. *Lasers Surg Med*. 1990;10:463-468.
2. Pallikaris IG, Papatzanaki ME, Siganos DS, Tsilimbaris MK. A corneal flap technique for laser in situ keratomileusis. Human studies. *Arch Ophthalmol*. 1991;109:1699-1702.
3. Kymionis GD, Tsiklis NS, Astyrakakis N, Pallikaris AI, Panagopoulou SI, Pallikaris IG. Eleven-year follow-up of laser in situ keratomileusis. *J Cataract Refract Surg*. 2007;33:191-196.
4. Tahzib NG, Bootsma SJ, Eggink FA, Nabar VA, Nuijts RM. Functional outcomes and patient satisfaction after laser in situ keratomileusis for correction of myopia. *J Cataract Refract Surg*. 2005;31:1943-1951.

5. Solomon KD, Fernández de Castro LE, Sandoval HP, Bartholomew LR, Vroman DT. Refractive surgery survey 2003. *J Cataract Refract Surg.* 2004;30:1556-1569.
6. Jacobs JM, Taravella MJ. Incidence of intraoperative flap complications in laser in situ keratomileusis. *J Cataract Refract Surg.* 2002;28:23-28.
7. Tham VM, Maloney RK. Microkeratome complications of laser in situ keratomileusis. *Ophthalmology.* 2000;107:920-924.
8. Lin RT, Maloney RK. Flap complications associated with lamellar refractive surgery. *Am J Ophthalmol.* 1999;127:129-136.
9. Pallikaris IG, Kymionis GD, Astyrakakis N. Corneal ectasia induced by laser in situ keratomileusis. *J Cataract Refract Surg.* 2001;27:1796-1802.
10. Kymionis GD, Panagopoulou SI, Aslanides IM, Plainis S, Astyrakakis N, Pallikaris IG. Topographically supported customized ablation for the management of decentered laser in situ keratomileusis. *Am J Ophthalmol.* 2004;137:806-811.
11. Pallikaris IG, Kymionis GD, Panagopoulou SI, Siganos CS, Theodorakis MA, Pallikaris AI. Induced optical aberrations following the formation of a laser in situ keratomileusis flap. *J Cataract Refract Surg.* 2002;28:1737-1741.
12. Lin RT, Lu S, Wang LL, Kim ES, Bradley J. Safety of laser in situ keratomileusis performed under ultra-thin corneal flaps. *J Refract Surg.* 2003;19:S231-S236.
13. Cobo-Soriano R, Calvo MA, Beltrán J, Llovet FL, Baviera J. Thin flap laser in situ keratomileusis: analysis of contrast sensitivity, visual, and refractive outcomes. *J Cataract Refract Surg.* 2005;31:1357-1365.
14. Yeo HE, Song BJ. Clinical feature of unintended thin corneal flap in LASIK: 1-year follow-up. *Korean J Ophthalmol.* 2002;16:63-69.
15. Vesaluoma M, Pérez-Santonja J, Petroll WM, Linna T, Alió J, Tervo T. Corneal stromal changes induced by myopic LASIK. *Invest Ophthalmol Vis Sci.* 2000;41:369-376.
16. Aslanides IM, Tsiklis NS, Astyrakakis NI, Pallikaris IG, Jankov MR. LASIK flap characteristics using the Moria M2 microkeratome with the 90-micron single use head. *J Refract Surg.* 2007;23:45-49.
17. Kymionis GD, Tsiklis N, Pallikaris AI, Diakonis V, Hatzithanasis G, Kavroulaki D, Jankov M, Pallikaris IG. Long-term results of superficial laser in situ keratomileusis after ultrathin flap creation. *J Cataract Refract Surg.* 2006;32:1276-1280.
18. Komai Y, Ushiki T. The three-dimensional organization of collagen fibrils in the human cornea and sclera. *Invest Ophthalmol Vis Sci.* 1991;32:2244-2258.
19. Radner W, Zehetmayer M, Aufreiter R, Mallinger R. Interlacing and cross-angle distribution of collagen lamellae in the human cornea. *Cornea.* 1998;17:537-543.
20. Barraquer JI. *Queratomileusis y Queratofaquia.* Bogota, Columbia: Instituto Barraquer de America; 1980:340-342, 405-406.
21. Rabinowitz YS. Ectasia after laser in situ keratomileusis. *Curr Opin Ophthalmol.* 2006;17:421-426.
22. Seiler T, Koufala K, Richter G. Iatrogenic keratectasia after laser in situ keratomileusis. *J Refract Surg.* 1998;14:312-317.
23. Sekundo W, Dick HB, Meyer CH. Benefits and side effects of bandage soft contact lens application after LASIK: a prospective randomized study. *Ophthalmology.* 2005;112:2180-2183.
24. Patel SV, Erie JC, McLaren JW, Bourne WM. Confocal microscopy changes in epithelial and stromal thickness up to 7 years after LASIK and photorefractive keratectomy for myopia. *J Refract Surg.* 2007;23:385-392.
25. Stahl JE, Durrie DS, Schwendeman FJ, Boghossian AJ. Anterior OCT analysis of thin IntraLase femtosecond flaps. *J Refract Surg.* 2007;23:555-558.

AUTHOR QUERIES

The title was changed per Dr Waring. Okay as edited?

Page 2, left column: Which ring was used in patients with a keratometric value of exactly 42.00 D (ie, ...>42 ring 9,...<42 ring 10)?

Does the following statement pertain to the authors' personal experience? If not, please provide a reference.

Due to previous flap dislocations after ultra-thin flap LASIK, a bandage contact lens was applied to all patients in this series during the first 24 hours.