Published in final edited form as:

J Cataract Refract Surg. 2010 May ; 36(5): 810–813. doi:10.1016/j.jcrs.2009.12.025.

Influence of flap thickness on visual and refractive outcomes after laser in situ keratomileusis performed with a mechanical keratome

Alok S. Bansal, MD, Terrence Doherty, MD, J. Bradley Randleman, MD, and R. Doyle Stulting, MD, PhD

Emory Eye Center and Emory Vision, Atlanta, Georgia, USA.

Abstract

PURPOSE—To study the effect of flap thickness on visual acuity and refractive outcomes after laser in situ keratomileusis (LASIK) using 2 blade types with a mechanical microkeratome.

SETTING—Emory Vision, Atlanta, Georgia, USA.

METHODS—This retrospective analysis was of LASIK cases performed between January 2005 and June 2006 using an Amadeus I microkeratome and an ML7090 CLB blade (blade A) or a Surepass blade (blade B). Outcomes analyzed included flap thickness, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction spherical equivalent (MRSE), the enhancement rate, and surgical complications 3 months postoperatively.

RESULTS—Two hundred sixty-three eyes of 153 patients were analyzed; blade A was used in 158 eyes and blade B, in 105 eyes. The mean flap thickness was significantly thinner with blade A than with blade B ($107 \mu\text{m} \pm 12 [\text{SD}]$ versus $130 \pm 20 \mu\text{m}$) ($P < .0001$). There was no overall correlation with either blade between flap thickness and UDVA, CDVA, or MRSE (all $r < 0.2$). At 3 months, there was no statistically significant difference in UDVA, CDVA, or MRSE between the 2 blade groups at 3 months (all $P > .10$), and there was no difference in the complication rates.

CONCLUSION—Flap thickness did not affect visual or refractive outcomes with a mechanical micro-keratome with either blade type.

FINANCIAL DISCLAIMER—No author has a financial or proprietary interest in any material or method mentioned.

There is ongoing debate regarding the optimum flap thickness for laser in situ keratomileusis (LASIK).^{1,2} The terms *thick-flap LASIK* and *thin-flap LASIK* have arisen to describe traditional microkeratome flaps (mean thickness approximately $150 \mu\text{m}^3$) and those created with newer microkeratomes or a femtosecond laser (mean thickness approximately $100 \mu\text{m}^{1,2,4-6}$), respectively.

Thick flaps have been associated with biomechanical weakening of the cornea and an increased risk for postoperative corneal ectasia.⁷ Thin flaps maximize residual stromal bed thickness (RSB), reducing the risk for corneal ectasia,^{8,9} and allow correction of larger refractive errors.¹⁰ However, there are theoretical disadvantages of thinner flaps, including higher rates of intraoperative complications (eg, buttonhole flaps, flap dislocation),¹¹ poorer

long-term stability, and the potential for inferior visual outcomes due to irregular astigmatism.¹²

The purpose of this study was to evaluate the influence of flap thickness on visual acuity and refractive outcomes after LASIK using 2 different blades with a mechanical microkeratome. A previous study¹³ found that flap thickness with this mechanical micro-keratome varied depending on the blade used.

PATIENTS AND METHODS

This retrospective chart review included patients who had LASIK for myopia at Emory Vision, Atlanta, Georgia, USA, by the same surgeon (R.D.S.) from January 2005 to June 2006. This population represents a subset analysis of data used in a previous publication.¹³ The study was approved by the Emory University Institutional Review Board. Patients were excluded from analysis if they had previous ocular surgery.

All procedures were performed using an Allegretto Wave excimer laser (WaveLight AG) and the same Amadeus I mechanical microkeratome. In all cases, a 140 μm microkeratome head was used with a blade oscillation rate of 8000 rpm and a translation speed of 2.5 mm/second. An 8.5 mm, 9.0 mm, or 9.5 mm suction ring was used depending on corneal diameter. The same blade was used in both eyes in bilateral cases.

Two types of microkeratome blades were used during the study. Before June 2005, Surepass blades (Advanced Medical Optics) were used. After that date, the refractive surgery center switched to the ML7090 CLB blade (Med-Logics, Inc.) for comparative evaluation. A previous study¹³ found that flaps created with the Amadeus I microkeratome were thinner and had less variance when an ML7090 CLB blade (blade A) was used than when a Surepass blade (blade B) was used.

Preoperative parameters included patient age, sex, corrected distance visual acuity (CDVA), manifest refraction spherical equivalent (MRSE), and central corneal thickness (CCT). Central corneal thickness and RSB thickness were measured intraoperatively using a Pachette II ultrasonic pachymeter (DGH Technology, Inc.). Flap thickness was calculated by subtracting the lower of 2 central bed thickness measurements before laser ablation from the lower of 2 preoperative CCT measurements.

Postoperative parameters measured included uncorrected distance visual acuity (UDVA), CDVA, and MRSE 3 months postoperatively as well as intraoperative and postoperative complications.

The Student *t* test was used to evaluate differences between groups. The correlation between flap thickness and UDVA, CDVA, and MRSE was assessed using the Pearson coefficient (*r*).

RESULTS

The study evaluated 263 eyes of 153 patients; 95 eyes (36%) were of male patients and 168 eyes (64%), of female patients. Blade A was used in 158 eyes (60%) and blade B, in 105 eyes (40%). The mean age of the patients was 40 years $\pm$ 10 (SD) (range 20 to 66 years) for the blade A group and 41 $\pm$ 11 years (range 21 to 64 years) for the blade B group, respectively (*P* = .5).

Overall, the mean preoperative CDVA was -0.023 ± 0.070 logMAR ($\sim$ 20/20 Snellen equivalent), the mean MRSE was -3.21 ± 2.84 diopters (D), and the mean CCT was 550 $\pm$

30 μm . Table 1 shows the preoperative data by blade group. There were no significant differences between the 2 blade groups in any preoperative parameter.

At the 3-month follow-up visit, the overall mean postoperative UDVA was 0.009 ± 0.107 logMAR ($\sim 20/20$ Snellen equivalent), the mean CDVA was -0.039 ± 0.073 logMAR ($\sim 20/20$ Snellen equivalent), and the mean MRSE was 0.09 ± 0.39 D. Table 2 shows the 3-month postoperative data by blade group. The mean flap thickness was statistically significantly thinner in the blade A group ($P < .0001$). There were no statistically significant differences between the 2 blade groups in postoperative UDVA, CDVA, or MRSE.

At 3 months, flap thickness was not correlated with postoperative UDVA ($r = -0.08$) (Figure 1), CDVA ($r = -0.04$) (Figure 2), or MRSE ($r = -0.15$) (Figure 3). Stratification of the data by blade type also showed no correlation between flap thickness and postoperative UDVA, CDVA, or MRSE in either blade group ($r < 0.20$ for each) (Table 3). There were no statistically significant differences in the intraoperative or postoperative complication rate between the blade groups (Table 4).

DISCUSSION

The microkeratome used in this study can produce both thick and thin LASIK flaps depending on the blade used. Our results suggest that flap thickness and microkeratome blade type do not affect postoperative visual acuity, refractive outcomes, or complication rates.

Several other studies^{1,2,4-6} found comparable visual and refractive outcomes with thick-flap and thin-flap LASIK using other microkeratomes or a femtosecond laser for flap creation. Azar et al.¹ found no difference in visual outcomes between 33 eyes having sub-Bowman keratomileusis with an IntraLase femtosecond laser (Abbott Medical Optics) and 62 eyes having thick-flap LASIK with a Hansatome microkeratome (Bausch & Lomb). Our institution does not routinely measure contrast sensitivity in all patients; however, Cobo-Soriano et al.⁴ found better contrast sensitivity in eyes having thin-flap LASIK with an LSK-One microkeratome (Moria). In addition, Cheng et al.¹⁴ found no difference in higher-order wavefront aberrations between thin flaps and thick flaps in LASIK (mean flap thickness 112 ± 11 μm versus 155 ± 13 μm) using an M2 microkeratome (Moria).

In contrast, Prandi et al.¹⁵ found that thinner flaps created with a Model One microkeratome (Moria) were correlated with better UDVA and MRSE at 1 month and 6 months (mean flap thickness 117 ± 25 μm , range not given). Using the same microkeratome, Eleftheriadis et al.¹⁶ found that thinner flaps were correlated with better UDVA at 1 week and 1 month but not at 6 months (mean flap thickness 118 ± 23 μm ; range 70 to 184 μm). The authors speculate that thinner flaps allow faster visual recovery due to resolution of flap edema and better molding of the flap to the underlying stromal bed.¹⁶

The differences between our results and those in the earlier studies may be because the previous studies had varying results at multiple time points over the first 6 months. We measured outcomes at 1 time point (ie, 3 months postoperatively), which we believe is the first point of maximum visual and refractive stability in our clinical practice. Nevertheless, we believe the differences in outcomes over the first few months are clinically insignificant.

Because thin-flap LASIK (also called sub-Bowman keratomileusis) maintains the integrity of the deeper corneal stroma, which is inherently weaker than anterior stroma,^{7,17,18} thin-flap LASIK should be more biomechanically stable than traditional flap LASIK and may approximate surface ablation biomechanically. However, further research is warranted, especially studies that focus on the effect of both flap thickness and flap morphology on

corneal biomechanics. Although surface ablation can produce excellent visual outcomes, thin-flap LASIK has the advantage of more rapid visual recovery.^{19,20}

Potential intraoperative complications of thin-flap LASIK include higher rates of buttonhole flaps or flap dislocation.¹¹ There were no serious intraoperative complications in our study, and there was only 1 early flap dislocation; these results are similar to those reported by Azar et al.¹ and Slade et al.²⁰

Most current literature on thin-flap LASIK reports outcomes of flaps created with a femtosecond laser^{1,2,20}; however, thin, reproducible LASIK flaps can also be created with a variety of mechanical microkeratomes.^{13,21,22} There may be a limit to how thin one should create a femtosecond flap because increased corneal haze has been reported with ultrathin flaps created with a femtosecond laser.²³

This study has the inherent limitations of a retrospective analysis; however, because the populations were similar preoperatively, we do not believe the study design induced significant bias into the results. In an attempt to reduce selection bias, our cohort included all consecutive patients having LASIK in a given time period. Our sample size, although small, is similar to that of other studies that evaluated similar outcomes. Larger studies with a longer follow-up might detect small differences based on flap thickness, although based on the lack of such correlations in our study population, we do not believe the differences would be clinically significant.

Based on the current literature and the results of our study, which found that flap thickness was not related to postoperative visual acuity or refractive error, thinner and more reproducible flaps seem to be more advantageous for most patients in terms of maintaining the benefits of LASIK while reducing the risk for postoperative corneal ectasia.

Acknowledgments

Supported in part by Research to Prevent Blindness, Inc., New York, New York, and the National Institutes of Health Core Grant P30 EYO6360, Bethesda, Maryland, USA.

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Figure 1. Relationship of overall flap thickness to UDVA (logMAR) (UDVA = uncorrected distance visual acuity).

Figure 2.

Relationship of overall flap thickness to CDVA (logMAR) (CDVA = corrected distance visual acuity).

Figure 3. Relationship of overall flap thickness to MRSE (MRSE = mean refraction spherical equivalent).

Table 1

Preoperative data.

Parameter	Mean $\pm$ SD		P Value
	Blade A	Blade B	
CDVA (logMAR)	-0.027 ± 0.065	-0.017 ± 0.078	.274
MRSE (D)	-3.06 ± 2.98	-3.45 ± 2.62	.267
CCT (μm)	550 ± 30	549 ± 32	.858

CCT=central corneal thickness; CDVA=corrected distance visual acuity; MRSE = manifest refraction spherical equivalent

Table 2

Three-month postoperative data.

Parameter	Blade A	Blade B	P Value
Flap thickness (μm)			
Mean $\pm$ SD	107 $\pm$ 12	130 $\pm$ 20	<.0001
Range	69–149	86–181	
Mean UDVA (logMAR) $\pm$ SD	0.002 $\pm$ 0.103	0.020 $\pm$ 0.113	.188
Mean CDVA (logMAR) $\pm$ SD	−0.044 $\pm$ 0.073	−0.32 $\pm$ 0.074	.189
Mean MRSE (D) $\pm$ SD	0.10 $\pm$ 0.33	0.06 $\pm$ 0.38	.374

CDVA = corrected distance visual acuity; MRSE = manifest refraction spherical equivalent; UDVA = uncorrected distance visual acuity

Table 3

Correlation of flap thickness to visual and refractive outcomes.

Parameter	<i>r</i> Value*	
	Blade A	Blade B
UDVA	−0.09	−0.23
CDVA	−0.03	−0.18
MRSE	−0.13	−0.16

CDVA = corrected distance visual acuity; MRSE = manifest refraction spherical equivalent; UDVA = uncorrected distance visual acuity

* Pearson correlation coefficient

Table 4

Postoperative complications.

Complication	Eyes, n (%)	
	Blade A (n = 158)	Blade B (n=105)
Epithelial defect	2 (1.3)	1 (1.0)
Diffuse lamellar keratitis	1 (0.6)	0
Flap dislocation	1 (0.6)	0