Blade source effect on laser in situ keratomileusis flap thickness with the Amadeus I microkeratome

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PURPOSE: To determine the effect of different blades on laser in situ keratomileusis (LASIK) flap thickness created with the Amadeus I microkeratome (Ziemer Ophthalmic Systems).

SETTING: Emory University Department of Opthalmology and Emory Vision, Atlanta, Georgia, USA.

METHODS: This retrospective nonrandomized comparative case study from January 2005 through June 2006 compared LASIK flap thickness created with blades from 2 manufacturers: the Surepass from Surgical Instrument Systems and distributed by AMO and the ML7090 CLB distributed by Med-Logics, Inc. Sex, preoperative corneal thickness, surgical-eye sequence, flap thickness and variance, and residual stromal bed were evaluated in each group.

RESULTS: This study evaluated 424 eyes of 226 patients. Surepass blades were used in 238 eyes and ML7090 CLB blades in 186 eyes. There were no significant differences between the 2 blade groups in preoperative corneal thickness, sex, or cases with corneal thickness greater than 550 μm. Mean flap thickness and variance were significantly lower in the ML7090 CLB group than in the Surepass group (P<.0001). There were no significant differences in flap thickness in either group based on sex; however, in both groups, flap thickness was significantly lower in second eyes and in eyes with a preoperative thickness less than 550 μm (P<.001).

CONCLUSIONS: The Amadeus I microkeratome created thinner, more consistent LASIK flaps with the ML7090 CLB blade than with the Surepass blade. Preoperative corneal thickness and eye sequence affected flap thickness, while sex did not.

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Laser in situ keratomileusis (LASIK) anterior lamellar flaps can be created with several types of mechanical microkeratomes or femtosecond lasers, and there can be significant variability in flap thicknesses with any device.[1–5] Different microkeratomes use a variety of suction platforms, motorized mechanisms, and oscillating blades that can affect overall flap thickness and reproducibility.[3–7] Specific blade characteristics, including vault and edge design, can also affect flap thickness.

Low residual stromal bed (RSB) thickness is a significant risk factor for postoperative corneal ectasia,[8,9] which may occur when the flap thickness is greater than intended.[10,11] The ability to create reproducibly thin LASIK flaps may not only reduce the risk for ectasia, it may also improve postoperative visual outcomes.[12–14]

The purpose of this study was to evaluate the accuracy and precision of LASIK flap thickness produced by the Amadeus I microkeratome (Ziemer Ophthalmic Systems) using Surepass blades (Surgical Instrument Systems) and ML7090 CLB blades (Med-Logics, Inc.)

PATIENTS AND METHODS

This retrospective chart review was of patients who had LASIK at Emory Vision, Atlanta, Georgia, by the same surgeon (R.D.S.) from January 4, 2005, to June 6, 2006. Patients

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were excluded from analysis if they had previous ocular surgery. The study was approved by the Emory University Institutional Review Board.

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

Two microkeratome blades were used during the study period. Before June 2005, Surepass blades were used and after that date, ML7090 CLB blades.

Central corneal thickness and residual stromal bed (RSB) thickness were measured intraoperatively with a Pachette II ultrasonic pachymeter (DGH Technologies, Inc.). Flap thickness was calculated by subtracting the lower of 2 RSB measurements from the lower of 2 preoperative corneal thickness measurements. Eye sequence was coded as right eye first and left eye second except when only 1 eye had LASIK, in which case that eye was coded as the first eye.

Preoperative corneal thickness, flap thickness, and RSB thickness measurements (mean thickness and variance) were analyzed by patient sex, sequence in which the eyes had surgery, preoperative corneal thickness, and type of microkeratome blade used.

Mean, standard deviations, and 95% confidence intervals (CIs) were calculated; *t* tests and chi-square analyses were used to compare group means and variances. To compensate for approximately 30 separate comparisons, *P* values less than 0.001 were considered significant; the Bonferroni method was used to adjust for multiple comparisons. Cohen *d* was calculated as a standardized measure of effect size.

RESULTS

Of the 226 patients, 127 (57%) were women and 98 (43%) were men; in 1 case, no sex was recorded. Surepass blades were used in 186 eyes (43.9%) and ML7090 CLB blades, in 238 eyes (56.1%). There were no significant differences between the Surepass group and the ML7090 CLB group in preoperative corneal thickness (mean 549.9 ± 32.3 μm versus 551.1 ± 29.4 μm; $P = .684$), sex (39.5% versus 47.5% male eyes; $P = .1$), or percentage of eyes with a corneal thickness greater than 550 μm (45.7% versus 49.1%; $P = .5$).

The mean flap thickness produced by the Surepass blades was significantly greater than that produced by the ML7090 CLB blades (130.8 μm versus 107.3 μm) ($P < .0001$) (Figure 1). The variance in flap thickness produced by the Surepass blades (SD 20.23 μm; 95% CI, 18.11-22.88 μm) was also significantly greater than that produced by the ML7090 CLB blades (SD 12.82 μm; 95% CI, 11.62-14.29 μm ($P < .0001$). There were no significant differences in either group in the mean or variance in flap thickness based on sex or ring diameter and no differences in flap thickness variance based on eye sequence or preoperative corneal thickness (Table 1). In both groups, the mean flap thickness was significantly thinner in second eyes and in eyes with a preoperative corneal thickness less than 550 μm. However, in both groups, the correlation between preoperative corneal thickness and flap thickness was poor ($r = 0.2$, both groups) (Figure 2).

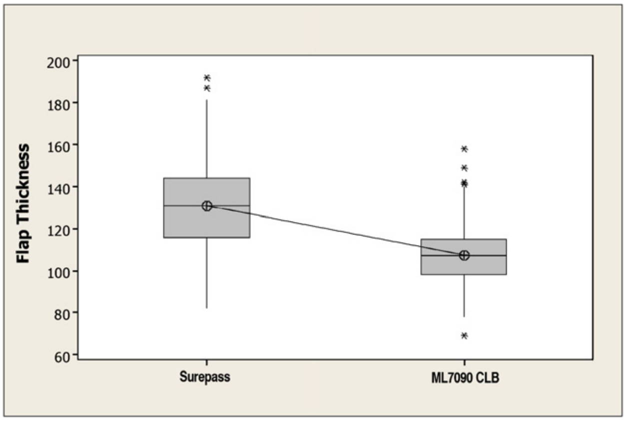

Figure 1. Box plot diagram of LASIK flap thicknesses (μm) produced by 2 microkeratome blades.

DISCUSSION

This study confirmed that specific microkeratome blades affect LASIK flap thickness and predictability with the Amadeus I microkeratome. The ML7090 CLB blades produced thinner flaps with less variation in thickness than those produced by the Surepass blades.

Previous studies[1,3–5] found significant variation in flap thickness created by various types of mechanical microkeratomes. Solomon et al.[5] compared 6 types of microkeratomes and found the Amadeus 140 μm and the MK2000 145 (Nidek) produced the most consistent LASIK flap thicknesses. Shemesh et al.[7] found that the Hansatome (Bausch & Lomb Surgical) created thicker flaps than ACS (Chiron) or MK (Nidek) microkeratomes. Flanagan and Binder[1] also found significant differences between the ACS microkeratome and Summit Krumeich Barraquer microkeratome (Alcon Surgical).

Previous studies of flap thickness using the Amadeus I microkeratome have found significantly thicker flaps than what we observed using the ML7090 CLB blades.[4,5] Solomon et al.[5] report a mean Amadeus I flap thickness of 134 ± 15 μm. Jackson et al.[4] found the Amadeus I 140 μm produced a mean thickness of 153 ± 18 μm in the first eye treated and 134 ± 25 μm in the second eye treated. These values are consistent with our observation of a mean thickness of 131 μm with the Surepass blades, which were originally recommended by the microkeratome distributor.

Previous studies[1,3–5,7] showed that the flap in the second eye treated with the same microkeratome

Table 1. Effect of sex, surgical sequence, and preoperative pachymetry on flap thickness.

	Surepass Blade (n = 186)		ML7090 CLB Blade (n = 238)	
		Variance (μm)		Variance (μm)
Characteristic	Mean (μm)	SD (95% CI)	Mean (μm)	SD (95% CI)
Sex				
Female	127.8	20.8 (18.0-24.5)	109.4	13.6 (11.9-15.8)
Male	133.9	17.9 (14.9-22.2)	105.0	11.5 (10.0-13.6)
P value	.04	.2	0.01	.3
Sequence				
First eye	133.4	22.5 (19.2-27.2)	109.2	12.6 (11.0-14.9)
Second eye	126.8	16.9 (14.4-20.5)	104.4	12.3 (10.7-14.5)
P value	.001	.03	.001	.7
Preop CT (μm)				
≤550	126.2	20.8 (17.9-24.7)	104.0	12.6 (10.9-14.7)
>550	136.4	18.1 (15.4-21.9)	110.8	12.2 (10.6-14.3)
P value	<.0001	.1	<.0001	.7

CI = confidence interval; CT = corneal thickness

blade is usually significantly thinner than that produced in the first eye. We confirmed this observation; however, the magnitude of difference between first eye and second eye with the ML7090 CLB and Surepass blades was only 5 to 7 μm; therefore, the difference appears to be statistically, but likely not clinically, significant with the Amadeus I microkeratome.

Previous studies[1,4,5,7] also found a positive correlation between preoperative corneal thickness and flap thickness. Although we found thicker flaps in eyes with a preoperative corneal thickness greater than 550 μm, in both groups there was poor correlation between preoperative corneal thickness as a continuous variable and flap thickness.

When the performance of microkeratome blades is evaluated, one must consider not only the mean flap thickness and variance but also the likelihood that an excessively thick flap will be produced, because especially thick flaps, even when produced only occasionally, could lead to the development of postoperative corneal ectasia if they happen to occur in eyes with relatively thin corneas and relatively high refractive errors. We observed a maximum thickness of 192 μm with the Surepass blades and 158 μm with the ML7090 CLB blades; 58 (31.2%) of 186 flaps created with the Surepass blades were thicker than 140 μm, while only 3 (1.3%) of 238 flaps created with the ML7090 CLB blades were thicker than 140 μm.

Flap thickness and variability with the Amadeus I mechanical microkeratome and ML7090 CLB blade combination reported in this study and those previously reported with the Moria LSK-One manual microkeratome[6] are similar to those reported with the IntraLase femtosecond laser (IntraLase Corp.).[15,16] Thus, it appears that one can achieve the potential advantages of thin-flap LASIK[12–14,17,18] with mechanical microkeratomes or femtosecond lasers.

In summary, the Amadeus I microkeratome created thinner, more consistent LASIK flaps with the ML7090 CLB blade than with the Surepass blade. Preoperative corneal thickness and eye sequence minimally affected flap thickness, while sex does not.

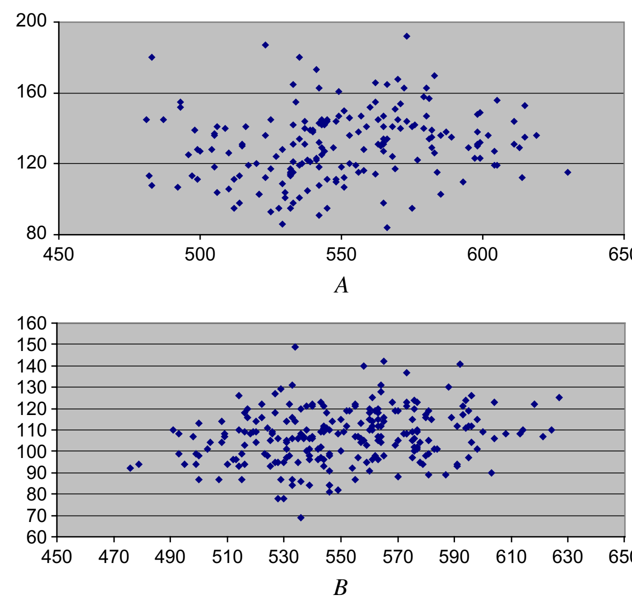

Figure 2. Laser in situ keratomileusis flap thickness (μm) (*y*-axis) based on preoperative corneal thickness (μm) (*x*-axis). *A*: Surpass blades. *B*: ML7090 CLB blades.

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