

Reproducibility of Flap Thickness With IntraLase FS and Moria LSK-1 and M2 Microkeratomes

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ABSTRACT

PURPOSE: To compare flap thickness reproducibility of the femtosecond laser and two mechanical microkeratomes.

METHODS: Flap thickness for all eyes was measured as the difference between the preoperative (day of surgery) full corneal thickness and post-flap creation central stromal bed thickness using ultrasonic pachymetry. Flap thickness values produced by three different microkeratome systems were compared for accuracy and reproducibility.

RESULTS: For 99 flaps created using the IntraLase FS laser with an intended thickness of 110 μm , the mean achieved thickness was $119 \pm 12 \mu\text{m}$ (range: 82 to 149 μm). In 100 eyes treated with the Moria LSK-1 microkeratome with an intended flap thickness of 160 μm , the mean achieved thickness was $130 \pm 19 \mu\text{m}$ (range: 71 to 186 μm). In 135 eyes treated with the Moria M2 microkeratome with an intended flap thickness of 130 μm , mean thickness was $142 \pm 24 \mu\text{m}$ (range: 84 to 203 μm). The standard deviation and range of corneal flap thickness created with the IntraLase FS laser was significantly smaller than either mechanical microkeratome ($P < .0001$).

CONCLUSIONS: When compared to two commonly used mechanical microkeratomes, mean achieved flap thickness was more reproducible with the IntraLase FS laser, reducing the comparative risk of overly thick flaps. [*J Refract Surg.* 2006;22:556-561.]

Predictable flap thickness is of paramount importance in LASIK to avoid complications such as buttonhole defects in thin flaps or corneal ectasia in thick flaps.¹ Either scenario carries a significant risk for loss of best corrected visual acuity. The thickness of the LASIK flap may also affect subsequent excimer laser photoablation, as stromal anatomy,² ultraviolet absorbance,³ and hydration may vary with corneal depth.

Mechanical microkeratome systems produce flap thicknesses with a standard deviation of approximately 20 to 40 μm ⁴⁻⁶ and flap diameters with a standard deviation of $\pm 0.3 \text{ mm}$. More variable results can be seen in eyes with extremes of corneal curvature, thickness, diameter, and/or small deep-set orbits.^{7,8}

The ideal microkeratome system would allow the surgeon precise control over flap dimensions, be insensitive to corneal thickness, and accommodate a wide variety of orbital and corneal anatomy. The femtosecond laser keratome (IntraLase Corporation, Irvine, Calif) is purported to address many of the limitations encountered with current microkeratome systems with flap thickness theoretically predictable to within $\pm 10 \mu\text{m}$.⁹

The femtosecond laser operates via low energy photodisruption, without producing significant thermal or shockwave damage, or removal of appreciable amounts of corneal tissue.^{10,11} Current clinical techniques are described in detail elsewhere.¹² In clinical studies, the IntraLase FS laser has produced excellent refractive results.^{9,12,13}

The purpose of the current study is to report flap thickness measurements in a series of one author's (J.H.T.) initial cases using the IntraLase FS laser as compared to two mechanical microkeratome systems used routinely by the same surgeon over the past 2 to 5 years.

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PATIENTS AND METHODS

This retrospective, consecutive, non-randomized, case series included patients undergoing LASIK. Patients received and signed a written informed consent prior to undergoing surgery. As the measurement of flap thickness is routinely measured by the authors for all LASIK cases as part of patient care and data comparisons were not contemplated until after initial experience with the IntraLase device, no IRB approval was obtained. The data were collected from consecutive cases using each device. No methodology was used to assign patients to a treatment cohort, as patients treated with the mechanical microkeratomers underwent surgery prior to the acquisition of the IntraLase FS. Because very few mechanical microkeratome cases were performed after that time, a prospective comparison of flap thickness amongst devices was not possible.

All surgeries were performed by the same surgeon (J.H.T.) in an outpatient private practice setting. Indications for surgery were the same for both microkeratome and IntraLase procedures, and included eyes with central corneal thickness readings $>490 \mu\text{m}$ with refractive errors and corneal topographic findings acceptable for correction with LASIK. To demonstrate refractive stability, all eyes underwent a minimum of two manifest refractions 1 to 2 weeks apart prior to surgery. The preoperative examination included measurement of uncorrected and best corrected distance and near visual acuity, manifest and cycloplegic refraction, slit-lamp examination, pupillometry to assess mesopic pupil diameter (Colvard; Oasis Medical, Glendora, Calif), corneal topography (Humphrey Systems, Irvine, Calif; and Orbscan II, Bausch & Lomb, Rochester, NY), wavefront aberrometry (Wavescan, VISX Inc, Santa Clara, Calif), central ultrasonic pachymetry (Pachette II; DGH, Exton, Pa), applanation tonometry, and dilated fundus examination. The excimer laser ablation was performed with a VISX S3 or S4 system (VISX Inc).

SURGICAL PROCEDURE

After instillation of topical anesthetic and a sterile preparation of the lids and periorbita, each patient was brought into the operating suite and placed in a supine position on a reclining chair located between the VISX and IntraLase FS laser systems and attached to the VISX system. After asking the patient to blink twice gently, central corneal thickness was measured ultrasonically with a hand-held probe (Pachette II). The thinnest of three sequential measurements served as the preoperative corneal thickness reading.

MECHANICAL LASIK

For mechanical microkeratome-assisted LASIK, the

eye was prepared as described above, and the patient positioned under the excimer laser microscope. The patient was asked to blink twice gently and to look straight ahead, whereupon three consecutive central pachymetry measurements were obtained while the surgeon gently held the lids apart with sterile, gloved fingers. Following this, the eye was draped in a sterile fashion and a rigid lid speculum was inserted. A second drop of proparacaine HCL 0.5% was instilled, followed promptly by application of a suction ring, irrigation with 2 to 3 drops of 0.9% normal saline solution, and passage of either the Moria LSK-1 (manual) or automated M2 microkeratome (Moria, Antony, France). The standard nomogram incorporating keratometry pachymetry values recommended by the manufacturer was used for both mechanical microkeratomers to select ring diameter size and stop settings. Only the blades produced and recommended by the manufacturer were used, and a fresh blade was used for each eye of bilateral cases. A Merocel sponge was used to absorb fluid, ensuring the absence of excess fluid on the cornea or within the conjunctival fornices, and the flap was reflected back upon its hinge using a dry technique onto a protective Merocel drain (Chayet Sponge; Katena, Denville, NJ). Pachymetry was then performed upon the stromal bed, and the thinnest of three sequential readings was recorded as the residual stromal bed thickness.

FEMTOSECOND LASER FLAP CREATION

For eyes treated with femtosecond laser-assisted LASIK, the technique described below is fairly standard and comparable to that described by others in the literature.¹² Pachymetry measurements were obtained as described above, and a second drop of proparacaine HCL 0.5% was instilled, followed promptly by application of a disposable suction fixation ring without the use of a speculum, centering the cornea within the ring. The VISX bed was rotated to the left to position the patient under the IntraLase FS laser and locked in position.

The computer was pre-programmed for each procedure with a superior hinged flap, diameter of 9.0 mm, intended flap thickness of $110 \mu\text{m}$, a hinge angle of 50° , side cut angle of 45° , raster pattern energy of $2.7 \mu\text{J}$, pulse separation of $11 \times 11 \mu\text{m}$, and a side cut energy of 4.7 to $4.9 \mu\text{J}$. No hyperopic treatments were performed in this series.

Without further lubrication, the cornea was applanated with a disposable glass contact lens cone attached to the IntraLase FS laser and the laser was lowered into position over the eye. The surgeon observed the alignment of the applanation through the IntraLase

TABLE
Comparison of Mechanical and IntraLase FS Flap Thickness

	No. Eyes	Intended Flap Thickness (μm)	Mean Flap Thickness (μm)	Standard Deviation (μm)	Range (μm)
IntraLase FS	99	110	119	12	82 to 149
Moria LSK-1 (mechanical "1")	100	160	130	19	71 to 186
Moria M2 (mechanical "2")	135	130	142	24	84 to 203

P < .0001 (Bartlett's χ^2 test) used to identify differences amongst all three groups. *F* tests used to compare standard deviations between LSK-1 and IntraLase (*P* < .0001) and standard deviations between M2 and IntraLase (*P* < .0001).

microscope until the cornea was appanated outside the desired cap diameter and no fluid meniscus was evident through the operating microscope. The appanated cornea was further aligned via software to center the planned flap diameter on the pupil, and the laser treatment delivered. After completing the IntraLase treatment, no attempt was made to lift the flap for 5 to 10 minutes to allow for dissipation of gas bubbles created by photodisruption that might affect the accuracy of pachymetry measurements obtained from the stromal bed.

FLAP ELEVATION

After IntraLase treatment was completed, the eye was draped in a sterile fashion and a rigid lid speculum inserted. The corneal flap was mobilized using a blunt-tipped Slade spatula (Katena Instruments) using no additional lubrication to the ocular surface as described elsewhere.¹² The spatula tip was slightly moistened to facilitate dissection of residual adhesions and then used to enter the laser wound in the superior quadrant near the hinge and break the microadhesions within the stromal interface. Immediately following reflection of the flap, central pachymetry was recorded through the pupil entrance, without using any eye drops, in the manner described above. The difference between the preoperative reading and this reading was recorded as the flap thickness.¹³

STATISTICAL ANALYSIS

The collected data were exported to Microsoft Excel. An *F* test was used to determine the significance of standard deviations and two-sample *t* tests were used to determine the significance of the mean achieved flap thickness for each group. Regression analysis was used to evaluate the effect of preoperative corneal thickness on the achieved flap thickness. Two-sample *z*-tests were used to compare the pair-wise difference in the effect of preoperative corneal thickness on the achieved flap thickness (ie, the slope of the regression

model) for the three keratomes. To examine the likelihood of a flap thickness >170 μm, the Fisher exact test was used to compare the three data sets, and the Clopper-Pearson exact method was used to determine the 95% confidence intervals for this event in each group.

RESULTS

MEAN ACHIEVED VS PREDICTED FLAP THICKNESS

The Table summarizes the results obtained with each of the three microkeratomes. For the LSK-1 (n=100), the 160-μm head produced an average flap thickness of 130±19 μm (range: 71 to 186 μm). The M2 (n=135), with a predicted thickness of 130 μm, achieved an average flap thickness of 142±24 μm (range: 84 to 203 μm). The IntraLase FS (n=99), with a software input of 110 μm, achieved an average flap thickness of 119±12 μm (range: 82 to 149 μm).

The mean difference between the achieved versus attempted flap thickness was similar with the IntraLase and M2 keratomes. IntraLase flaps were on average 9±10.5 μm thicker than intended whereas flaps with the Moria M2 were on average 12±19.8 μm thicker than intended. This difference was not statistically significant (two-sample *t* test; *P* = .17). Flaps with the LSK-1 were on average 30±14.1 μm thinner than intended. This was significantly different compared to the other devices (two-sample *t* test, *P* < .0001).

COMPARISON OF ACHIEVED FLAP THICKNESS

These data are summarized in the Table. Standard error values were 0.24 for IntraLase, 0.24 for LSK-1, and 0.21 for M2. The standard deviation of mean achieved flap thickness was significantly less with the IntraLase than the Moria M2 or LSK-1 keratomes.

CORRELATION OF FLAP THICKNESS WITH TOTAL CORNEAL THICKNESS

Scatterplots comparing total corneal thickness measurements with achieved flap thickness measurements

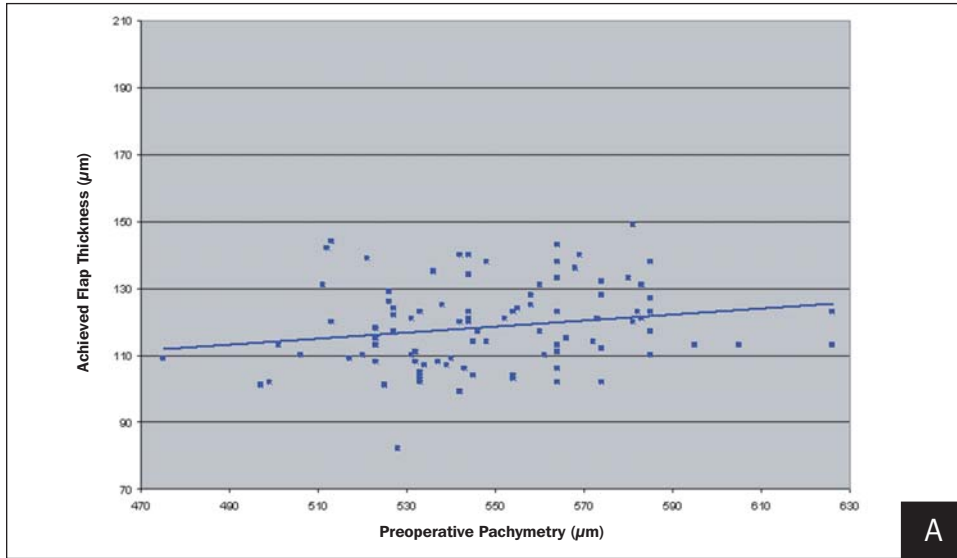
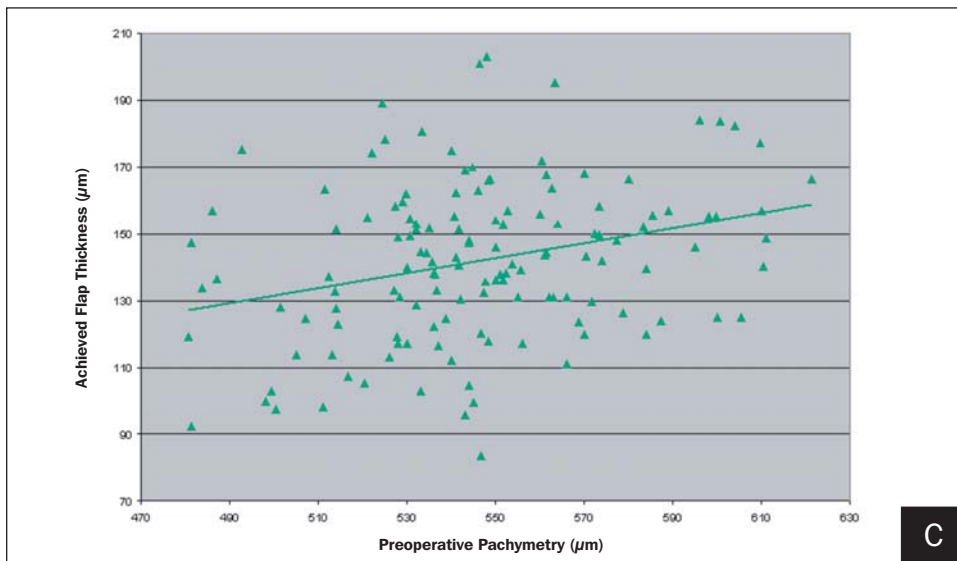
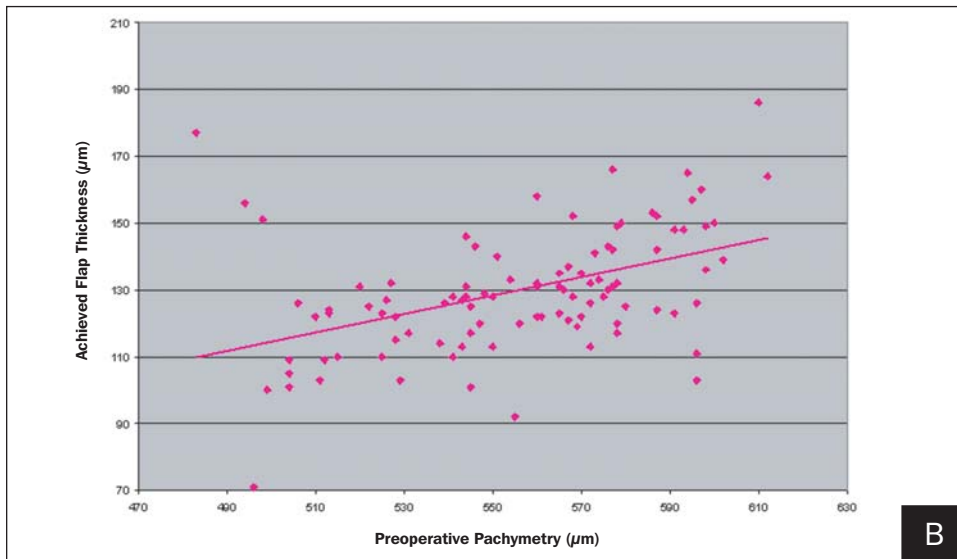


Figure. Preoperative pachymetry versus achieved flap thickness using the **A**) IntraLase (intended flap thickness 110 μm) ($y=0.0904x+69.004$, $R^2=0.0386$, standard error=12.3), **B**) Moria LSK-1 (intended flap thickness 160 μm) ($y=0.276x-23.525$, $R^2=0.2084$, standard error=16.8), and **C**) Moria M2 intended flap thickness 130 μm) ($y=0.233x+19.924$, $R^2=0.0831$, standard error=22.7).



are depicted in the Figure. The LSK-1 showed a weak positive correlation between these two variables with regression analysis ($R^2=0.21$), whereas no correlation for the M2 or IntraLase FS was noted ($R^2=0.08$ and 0.04 , respectively). The coefficients of determination for the regression models are all <0.3 . This indicates that, although corneal thickness may affect achieved flap thickness using the Moria LSK-1, other factors play a role in determining this value.

FLAP THICKNESS DISTRIBUTION

The skew and kurtosis of each treatment group were calculated to gauge whether the data distribution could be considered symmetric or normal. Skew values were $+0.203$ for IntraLase, $+0.218$ for LSK-1, and $+0.056$ for M2. These slightly positive values indicate a mild degree of asymmetry in the distribution of data, with a tail biased towards more positive values. Kurtosis values were -0.1329 for IntraLase, $+0.769$ for LSK-1, and -0.130 for M2. The kurtosis values indicate LSK-1 has a slightly peaked distribution whereas IntraLase and M2 are slightly flat.

INCIDENCE OF THICK FLAPS

The incidence of thick flaps ≥ 170 μm was as follows: IntraLase: 0/99 (0%); LSK-1: 2/100 (2%); and M2: 14/135 (10.4%). In the two LSK-1 flaps ≥ 170 μm , preoperative corneal thicknesses were 483 and 610 μm . In the 14 M2 flaps ≥ 170 μm , mean corneal thickness values were not significantly different than the total population (554 versus 561 μm , $P=.37$) with a wide range of values (492 to 610 μm). The Fisher exact test was used to compare these three proportions and found the probability of achieving a thick flap ≥ 170 μm is statistically significant ($P<.0002$) amongst these three keratome groups. Ignoring the slight skew in the data and using symmetric data modeling with the Clopper-Pearson exact method, the 95% confidence interval for the percentage of flaps ≥ 170 μm for IntraLase is 0.0% to 3.7%, for LSK-1 is 0.2% to 7.0%, and for M2 is 5.8% to 16.8%. As such, a trend towards a greater likelihood of flaps thicker than 170 μm with the LSK-1 and M2 is demonstrable from the available data.

COMPLICATIONS

No serious complications were encountered with any of the three microkeratomes during the course of this study, and no eyes experienced delayed visual recovery or visual loss. Loose epithelium in the periphery of the flap without sloughing was encountered in one eye with the LSK-1, whereas no abnormalities of this type were noted with the other instruments.

Suction loss was encountered during two treatments

with the IntraLase FS. Both suction loss events occurred during the mid-phase of the raster pattern phase of flap construction. In one case, the same suction ring was re-applied and the case completed approximately 5 minutes later using the same appplanation cone. In the other instance, the treatment was repeated 4 days later without incident using the same cone and depth settings. Neither case revealed free tissue fragments or multiple tissue planes during flap dissection or manipulation.

DISCUSSION

Previous studies have shown that flap creation with the femtosecond laser offers surgeons significantly more predictable flap thickness and other dimensional parameters compared to current mechanical microkeratomes.¹³ The narrower range of achieved flap thickness and smaller standard deviation of flap thickness is superior to published results of current microkeratomes.^{4-6,14,15}

In our study, the IntraLase FS laser with an intended flap thickness setting of 110 μm yielded statistically more reproducible flap thickness than two commercially available commonly used mechanical microkeratomes. As summarized in the Table, our data show that: 1) based on comparisons of standard deviation, IntraLase flap thickness is more reproducible than either microkeratome; 2) the LSK-1 was less accurate than either the IntraLase FS or the M2; and 3) the range of values achieved with the IntraLase FS is smaller than for the LSK-1 or M2. The level of reproducibility in this study using the IntraLase FS is consistent with that reported by Binder,¹² who found a standard deviation of 12 μm and a mean thickness of 125 μm when a flap thickness of 110 μm was attempted. Kezirian and Stonecipher¹⁶ also reported similar improvements in flap thickness reproducibility results in a study comparing IntraLase flap creation with the Bausch & Lomb Hansatome and Moria Carriazo-Barraquer microkeratomes. Although the accuracy of ultrasonic pachymetry is widely acknowledged to be $\leq \pm 10$ μm for measurements of corneal thickness, the majority of studies of this type have used this method (including those cited above), and this technology is the only practical method to measure intraoperative corneal thickness in a clinical setting at this time.

Combined with the overall thinner mean achieved flap thickness, the smaller standard deviation value of the IntraLase flaps led to a statistically significant reduction in the risk of an excessively thick flap (>170 μm). Assuming a normal distribution of data, a particular microkeratome's standard deviation and mean achieved flap thickness can be used to estimate the number of

eyes likely to experience excessively thin or thick flaps with each keratome. For a population of 10,000 procedures performed, the 110- μm setting of the IntraLase FS (achieved mean flap thickness of $119 \pm 12 \mu\text{m}$) would be expected to produce <3 flaps with a thickness >170 μm . In contrast, due to the higher mean thickness and standard deviations, the LSK-1 (achieved mean flap thickness of $130 \pm 19 \mu\text{m}$) would be anticipated to have approximately 250 flaps thicker than 170 μm , a nearly 100-fold increase. Owing to its even higher mean thickness and standard deviation, the M2 would be expected to have >600 flaps thicker than 170 μm , a more than 200-fold increase. Further analyses using larger data samples would be useful to help confirm or refute the trends observed in this study.

It is important to note that all devices used to create corneal flaps have less than perfect precision. In the IntraLase FS series, one flap was 30 μm thicker than the mean, whereas in the LSK-1 and M2, the thickest flaps were 56 and 61 μm thicker than their respective means. To determine whether sufficient stromal tissue is available for the excimer ablation, surgeons can perform intraoperative pachymetry prior to excimer treatment. To reduce the potential of finding an inadequate stromal bed, surgeons can avoid performing LASIK surgery in eyes with borderline estimated residual corneal bed thickness. The data from this series suggest a maximal flap thickness estimate that is 2.5 standard deviations above the mean achieved with a particular keratome might be used for such estimates (in our clinical practice, this value would be approximately 150 μm for the IntraLase FS 110- μm setting, 180 μm for the LSK-1, and 200 μm for the M2). The maximal flap thickness estimate for the IntraLase FS could be further reduced by choosing a 100- μm setting. By using a more sophisticated predictive nomogram for flap thickness based on individual eye preoperative keratometry and pachymetry, the maximal flap thickness estimate for mechanical keratomes might also be reduced in these eyes.

The two procedure interruptions experienced with the laser keratome (compared to none with the mechanical instruments) may be partly the result of the early experience that this data represents. Although still more time consuming than mechanical keratectomy, the recent increase in laser repetition rate to 30 kHz has shortened procedure times, and along with greater surgeon experience, may reduce the incidence of suction loss in the future. Lastly, loss of suction during femtosecond photodisruption appears to be less serious than a similar occurrence during mechanical keratectomy. In contrast to recommended delays of 2 to 6 months,¹⁷ femtosecond laser procedures can be completed either

immediately or with minimal delays of hours to days rather than months of waiting time required for mechanical keratectomy.

Further confirmation of the promising clinical results obtained with the IntraLase FS in this and other studies^{12,16} is warranted.

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