Factors predictive of LASIK flap thickness with the Hansatome zero compression microkeratome

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Factors Predictive of LASIK Flap Thickness With the Hansatome Zero Compression Microkeratome

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ABSTRACT

PURPOSE: To determine the explanatory power of preoperative variables and corneal flap thickness in laser in situ keratomileusis (LASIK) using the Hansatome zero compression microkeratome (Bausch & Lomb, Rochester, NY).

METHODS: A prospective, nonrandomized, comparative interventional case study was performed on 250 eyes of 129 consecutive patients who underwent LASIK surgery using the Hansatome zero compression microkeratome. A 160-μm or 180-μm microkeratome head and an 8.5- or 9.5-mm suction ring were used in the procedures. Preoperative measurements included refraction, spherical equivalent, keratometry, intraocular pressure, corneal white-to-white, anterior chamber depth, and corneal eccentricity. Corneal thickness was measured intraoperatively using ultrasonic pachymetry before and after flap creation, and the difference was taken as flap thickness. Flap diameter was measured with a corneal gauge. Data were analyzed using simple, multiple, stepwise linear and non-linear regression analyses and two-tailed *t* tests.

RESULTS: The mean flap thickness was 124±17 μm with the nominal 160-μm head and 142±20 μm with the nominal 180-μm head. One third (33%) of the total variation in flap thickness could be accounted for by three preoperative variables: average corneal thickness, spherical equivalent refraction, and choice of 160- or 180-μm microkeratome head. A simple correlation of 0.114 was noted between corneal eccentricity and flap thickness, but this variable did not add significant explanatory power on multiple regression analysis. Linear regression analysis allowed determination of a flap thickness nomogram with a standard error of the estimate of 16.9 μm and a 95% confidence interval of ±33.1.

CONCLUSIONS: Corneal thickness is the most systematic predictor of corneal flap thickness using the Hansatome microkeratome. Because three preoperative variables account for only 33% of the range in flap thickness, future studies should focus on variations in blade extension and corneal biomechanical factors, which may also play an important role in determining flap thickness. [*J Refract Surg*. 2005;21:253-259.]

Laser in situ keratomileusis (LASIK) has become the most frequently performed procedure for the correction of mild to moderate myopia. In LASIK, a hinged corneal flap is created using a microkeratome and the stromal bed is ablated by an excimer laser.[1-4] Consistency and predictability of corneal flap thickness are crucial in both surgical planning and producing successful LASIK outcomes. Complications associated with thin flaps include flap slippage, striae, irregular astigmatism, buttonholes, and free caps. Flaps so thin that they dissect Bowman's membrane may result in corneal haze. Thicker flaps cause decreased stromal bed thickness, increasing the risk for biomechanical corneal changes and iatrogenic corneal ectasia.[5-8] In thicker flaps, the resulting thinner stromal bed may also lessen the possibility of enhancement surgery if later needed.

Several recent studies have shown that the manufacturer-assigned predicted flap thickness of currently available microkeratomes varies significantly from intraoperative flap thickness measurements, often producing thinner flaps than intended.[9-18] In this study, simple, multiple, and stepwise linear and nonlinear regression analyses were performed to evaluate the explanatory power of preoperative variables and flap thickness in eyes undergoing LASIK using either a 160- or 180-μm Hansatome microkeratome zero compression head.

PATIENTS AND METHODS

PATIENTS

This prospective, nonrandomized, comparative interventional case study included 250 eyes of 129 consecutive pa-

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tients (50 men and 79 women) who underwent LASIK by a single surgeon (J.S.P.). Mean patient age was 40.4±9.3 years. Informed consent was obtained from all patients. Inclusion criteria comprised myopia ranging between −1 and −12 diopters (D), astigmatism <5 D, with adequate corneal thickness to allow a 250-µm bed assuming a flap thickness of 160 or 180 µm, depending on the labeling of the microkeratome head. Clinical factors precluded randomization of microkeratome head or ring, because of concerns about leaving adequate residual corneal thickness to potentially allow enhancement surgery and full treatment and adequate flap diameter to encompass the laser ablation and transition zone. Instead, a decision tree was used, where corneas with the flattest preoperative keratometry of <43.5 were assigned the 9.5-mm ring and steeper corneas the 8.5-mm ring. Similarly, assignment to the 160- or 180-µm-labeled head was determined based on preoperative pachymetry in relation to predicted ablation depth, so that thinner corneas or corneas with high refractive error were more likely assigned the 160-µm footplate.

Preoperative Examination

The preoperative examination and measurements included visual acuity on an ETDRS chart, slit-lamp biomicroscopy, refraction, infrared pupillometry (Colvard pupillometer; Oasis, Glendora, Calif), slit-scanning videokeratography (Orbscan II; Bausch & Lomb, Salt Lake City, Utah), and complete dilated funduscopic examination.

Surgical Technique and Intraoperative Measurements

All patients were prepared and draped in the usual fashion. One drop each of proparacaine (Alcaine; Alcon, Ft Worth, Tex), ketolorac (Acular; Allergan, Irvine, Calif), loteprednol (Lotemax; Bausch & Lomb, Rochester, NY), and ciprofloxacin (Ciloxan, Alcon) were administered to each eye. A Liebermann lid speculum was placed. Three measurements of the central cornea were obtained using a 50-mHz Corneo-Gage Plus ultrasonic pachymeter (Sonogage, Cleveland, Ohio). The probe tip was centered perpendicularly over the undilated entrance pupil, after the patient focused on the flashing red target light. An 8.5- or 9.5-mm suction ring was centered over the entrance pupil and the intraocular pressure was verified with a Barraquer applanation tonometer. The 8.5-mm ring was used if the flattest keratometry value on Orbscan simulated K was ⩾43; otherwise the 9.5-mm ring was used. A superiorly hinged, lamellar corneal flap was formed with either a 160- or 180-µm Hansatome zero compression microkeratome head, based on surgeon discretion. Two to three drops of balanced salt solution were applied to the corneal surface prior to the passage of the microkeratome head. The total time between the initiation and release of suction was recorded using a stopwatch. The flap was lifted and the bed dried with a sponge. Three ultrasonic measurements of the stromal bed thickness were obtained, holding the probe tip perpendicularly over the center of the undilated entrance pupil. Laser ablation was performed under standard techniques using a Technolas 217 (Bausch & Lomb) or VISX Star 3 (VISX, Santa Clara, Calif) laser system. The depth of laser ablation was adjusted via choice of optical zone, to allow a minimum of a 250-µm stromal bed, as determined by subtracting the ablation depth provided on the laser screen from the residual pachymetry determined after the flap lift.[19] The horizontal flap diameter was recorded (Corneal Gauge; American Surgical Instruments, Westmont, Ill).

The flap thickness was determined by subtracting the mean bed pachymetry from the mean pre-flap pachymetry. For 198 eyes, a new Accuglide blade (Bausch & Lomb) was used. For 52 eyes, the same blade was used on the second eye of the same patient. The preoperative variables analyzed in this study included age, gender, spherical equivalent refraction, intraocular pressure, average simulated keratometry derived from Orbscan videokeratography, ultrasonic central pachymetry, Orbscan-derived corneal diameter (white-to-white), anterior chamber depth, and corneal eccentricity. Intraoperative variables analyzed included ring diameter (8.5/9.5 mm) and footplate (160/180 µm), and new blade versus same blade on second eye of the same patient.

Statistical Analyses

Simple, multiple, and stepwise linear and nonlinear regression analyses were performed to evaluate the explanatory power of preoperative variables and flap thickness. Data were analyzed using Shazam version 3.1 (K. White, Vancouver, British Columbia). Statistical significance was defined as $P<.05$ on two-tailed t tests.

RESULTS

Preoperative Findings

Mean spherical equivalent refraction and mean keratometric values were −4.5±2.3 D and 44.3±1.3 D, respectively. Mean values for all preoperative measures by cohort (160- or 180-µm) are presented in Table 1. Of these variables, a statistically significant difference at the $P<.05$ level was noted for mean sphere, mean spherical equivalent refraction, and mean central corneal pachymetry between the two groups.

TABLE 1

Mean Preoperative Measurements for the Hansatome Zero Compression 160- and 180-μm Microkeratome Cohorts

Parameter	160-μm	180-μm
Sphere (D)*	−4.43±2.36	−3.30±1.94
Spherical equivalent refraction (D)*	−4.88±2.38	−3.96±1.99
Steepest keratometry (D)	44.51±1.40	44.70±1.58
Flattest keratometry (D)	44.12±1.25	44.09±1.60
Central corneal pachymetry (μm)*	545.95±31.57	564.17±37
Mean age (y)	40.04±9.75	41.06±8.9
Male:female ratio	0.36	0.43

Statistically significant difference at $P<.05$ noted between the groups.

TABLE 2

Mean (Range) Central Corneal, Stromal Bed, and Corneal Flap Thickness (μm) Using the 160-μm and 180-μm Microkeratome

Thickness	160-μm Microkeratome (n=138 eyes)	180-μm Microkeratome (n=112 eyes)
Central corneal	546.0±31.6 (486 to 639)	564.1±37.0 (490 to 665)
Stromal bed	421.9±32.0 (358 to 502)	421.8±37.5 (347 to 531)
Corneal flap	124.1±17.4 (71 to 171)	142.3±19.6 (115 to 191)

INTRAOPERATIVE FINDINGS

The mean corneal thickness, stromal bed thickness, and calculated flap thickness, standard deviations, and ranges are shown in Table 2 for the 160- and 180-μm microkeratome groups. The 160-μm-labeled microkeratome head cuts on average 124±17 μm. The 180-μm-labeled microkeratome head cuts on average 142±20 μm. The 180-μm footplate produced flaps that averaged 18 μm thicker than the 160-μm head.

One third (33%) of the total variation in flap thickness in this group was explained by the following three preoperative variables: the average corneal thickness ($P<.0001$), spherical equivalent refraction ($P<.0001$), and choice of 160- or 180-μm head ($P<.0001$). The Orbscan gives a metric called corneal eccentricity, which is a quantitative measure of corneal asphericity. This shape metric is not linearly dependent on keratometry. Corneal eccentricity and flap thickness had a simple correlation of 0.114 ($P=.075$); similarly, corneal eccentricity had a simple correlation of 0.14 with the ratio of corneal flap thickness to total corneal pachymetry ($P<.03$). However, corneal eccentricity showed no statistically significant addition to explaining flap thickness variation in multiple regression analysis. No statistically significant correlation was found with flap thickness and age, gender, average keratometry, corneal diameter, anterior chamber depth, or flap diameter.

The simple correlation between flap thickness and intraocular pressure was 0.18 ($P=.004$). However, in confirmation of the Rotterdam study,[20] the simple correlation between preoperative pachymetry and intraoperative pressure was 0.27, with statistical significance of $P<.01$. (For every 1 μm increase in corneal pachymetry, the intraocular pressure increased on average 0.021 mmHg by linear regression analysis. This closely parallels the larger Rotterdam study, which showed an average increase of 0.019 mmHg for every 1 μm increase in pachymetry, further validating our data set.) However, once we control for pachymetry using standard regression techniques, the statistical significance of intraocular pressure as an explanatory variable for variation in flap thickness diminishes to statistical insignificance ($P>.10$).

The mean time of elevated intraocular pressure from the initiation to release of suction averaged 13.5±0.4 seconds. No apparent association was noted between suction time and flap thickness, but there was little case-to-case variation in suction time in this study.

Preoperative corneal thickness was found to be the most systematic predictor of flap thickness, as shown in the Figure. Linear regression analysis showed the following mathematical relationship:

Expected Flap Thickness (μm) = 44.48 + 0.1968 (mean corneal thickness) + 2.6682 (spherical equivalent refraction) + 12.712 (microkeratome head; where 0 for 160-μm head and 1 for 180-μm head).

This flap thickness nomogram has a standard error of the estimate of 16.9 μm. The resulting 95% confidence interval is ±33.1 μm and the 99% confidence interval is ±43.8 μm.

Does using a new blade on each eye affect flap thickness? In examining the second eyes of 121 patients, where 69 had a new blade used on the second eye, the mean flap thickness of the second eye of the new blade group was 135.13±1.06 μm (range: 103 to 191 μm) compared to a mean flap thickness of 131.87±21.57 μm (range: 74 to 184 μm) in the second eye of the used blade group. We found that, holding preoperative corneal thickness constant, the flap thickness was 6.32 μm

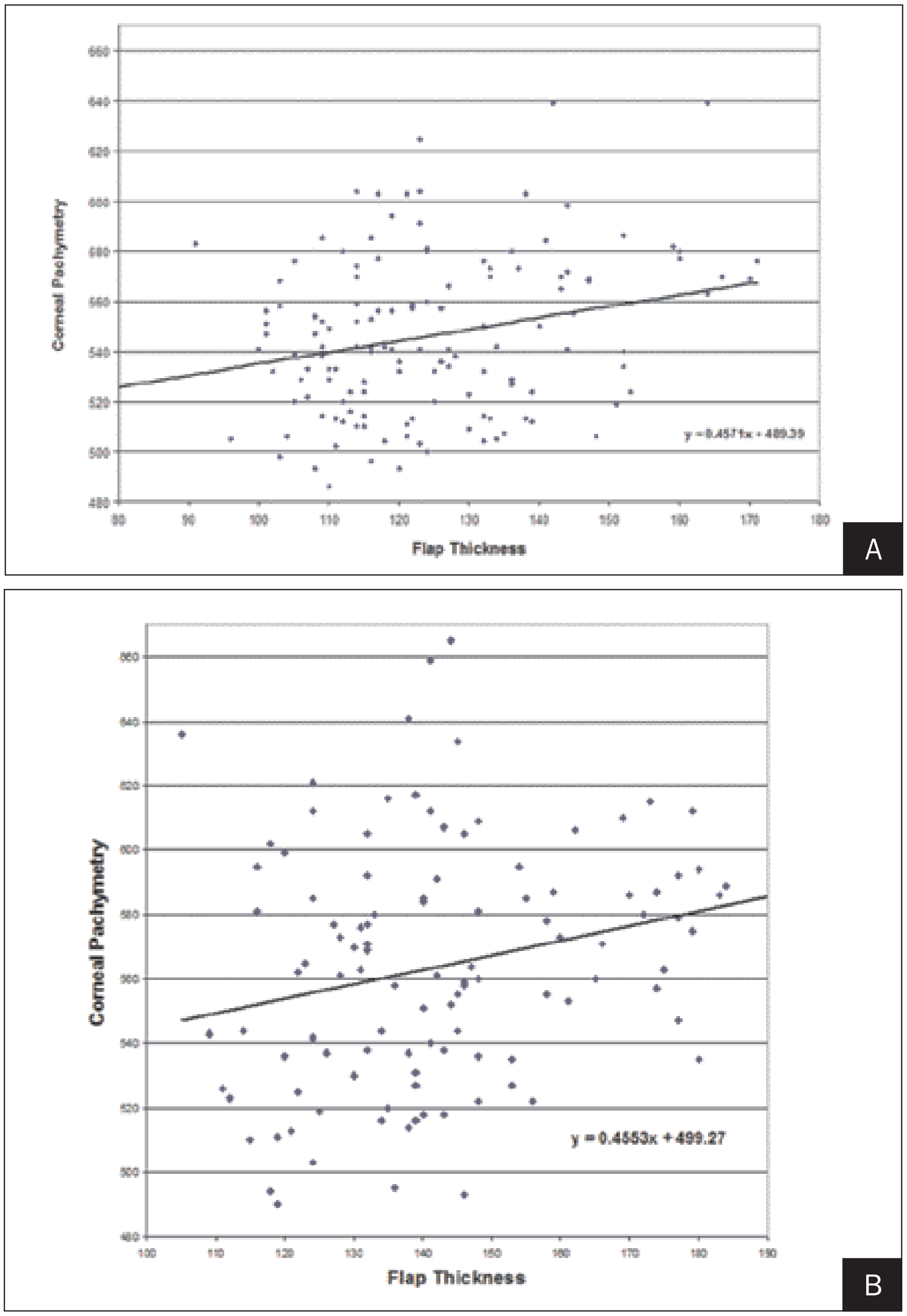

Figure. Central corneal thickness is positively correlated with corneal flap thickness for the **A)** 160-μm and **B)** 180-μm microkeratome groups.

thicker with a new blade than with the same blade used on the second eye (*P*=.10).

In this nonrandomized study, the 8.5-mm ring was used in LASIK on 201 eyes and the 9.5-mm ring in 49 eyes. A statistically significant correlation was found between horizontal flap diameter and ring diameter (*P*=.0001). On average, the 9.5-mm ring produced flaps 0.45 mm larger than the 8.5-mm ring.

DISCUSSION

Several recent studies have shown that the currently available microkeratomes produce flaps of variable thickness, often creating flaps thinner than intended.[9-18] Using intraoperative ultrasonic pachymetry, Yildirim et al[9] found that the Hansatome (with the standard head) does not always produce a corneal flap of intended thickness, with a mean flap thickness of 120.8 µm using a 180-µm microkeratome plate, as did Miranda et al[21] (131±28 µm with the 180-µm head), Giledi et al[22] (116±19.8 µm with the 160-µm head and 117±18 µm with the 180-µm head), Solomon et al[23] (129±21 µm with the 160-µm head and 136±25 µm with the 180-µm head), and Erie et al[24] by confocal microscopy (160±28 µm with the 180-µm head). In our study of the Hansatome zero compression head, we found a mean flap thickness of 124 µm and 142 µm using the 160- and 180-µm depth plates, respectively, closely paralleling the findings of Maldonado et al[25] using laser reflectometry and Solomon et al[23] using subtraction pachymetry in their prospective multicenter study.

As the average flap thickness indicates, in the majority of cases, the flaps were thinner than the nominal labeling of the microkeratome heads. However, in a few cases, the flap was the same or slightly thicker than the heads were labeled, which has been reported by other investigators using more than one method of flap measurement.[11,18,22,23,26,27] This suggests that intraoperative pachymetry may be a useful and important adjunct in LASIK surgery to help ensure adequate stromal bed to safely perform the laser ablation according to preoperative planning.[18,23,27,28]

To date, few studies have attempted to find a correlation between preoperative variables and the corneal flap thickness with the Hansatome microkeratome,[9,11,13,16,23,29] and this is the first report with the zero compression head (designed to lessen flap compression, which is associated with a higher incidence of intraoperative epithelial defects[30]). Yildirim et al[9] found a low correlation with preoperative corneal thickness and no correlation with preoperative keratometry when using a Hansatome microkeratome. Miranda et al[21] found no correlation between flap thickness and corneal thickness, age, or keratometry. Gailitis et al[16] reported a positive correlation with preoperative corneal thickness and no correlation with the preoperative keratometric values using the Hansatome microkeratome with a standard head. Giledi et al[22] reported a correlation between preoperative spherical equivalent refraction and flap thickness (thinner flaps in higher myopia), and a paradoxical finding of thinner flaps in patients with thicker corneas using a standard Hansatome head. In our study of the Hansatome with the zero compression head, we found a statistically significant, positive correlation between the preoperative corneal thickness and flap thickness. This is in direct contrast to the findings of Giledi et al[22] of thicker flaps in thinner corneas with the standard Hansatome head, but in concurrence with their observation of a trend toward thinner flaps in patients with higher myopia (holding corneal pachymetry constant).

Animal studies by Seo et al[31] demonstrated that an increase in the duration of suction time resulted in a thicker flap and greater incision angle. There was little case-to-case variation in suction duration in our study, so this variable was relatively controlled.

We did not find statistically significant correlation with flap thickness and age, gender, intraocular pressure, average keratometry, corneal eccentricity, white-to-white, anterior chamber depth, and flap diameter. In contrast to other reports,[21] we did not find a statistically greater flap thickness variation in females versus males. One third of the variation in flap thickness was explained by the average corneal thickness, spherical equivalent refraction, and the choice of 160- or 180-µm head. No correlation was noted between spherical equivalent refraction and preoperative corneal pachymetry, demonstrating that this preoperative variable was not simply serving as a surrogate marker for pachymetry in this relationship.

Other considerations to account for the remaining two thirds of the variation in flap thickness could be variation in the extension of the blade from the footplate, due to current tolerance in manufacturing specifications.[32] This is a potential area for improvement that may be addressed in future iterations of the Hansatome microkeratome. Other factors that might explain variation in corneal flap thickness could reflect the complex biomechanical process underlying lamellar keratectomy,[33] which might be influenced by variables such as suction duration, incision angle,[31] oscillation rate and speed of head advancement,[34] and corneal resistance to deformation (as reflected by corneal hysteresis). This viscoelastic characteristic of the cornea defined by corneal hysteresis may be an aggregate of the effects of thickness, rigidity,[35] hydration, curvature, and possibly other biomechanical factors.

Whereas the results of our study of flap thickness showed a standard error of the mean of between 17.4 and 19.6 µm, which is in the range of most reported studies, a goal for future microkeratome designs (both mechanical and laser) is to reduce this variation to <10 µm. Linear regression analysis allowed us to derive a nomogram to help predict flap thickness using the aforementioned three preoperative variables (ie, corneal pachymetry, spherical equivalent refraction, and microkeratome head). However, the 95% confidence interval of this estimate is ±33 µm, emphasizing the need for intraoperative measurement.

We found that holding corneal thickness constant, a flap was on average 6.32 µm thicker with the new blade than with the same blade on the second eye, although the sample size was limited and statistical significance was not reached (P=.10). Similarly, Gailitis et al,[16] using the Hansatome microkeratome, found a 14.1 µm difference that was statistically significant between the first versus the second operated eye ($P<.001$). Shemesh et al[18] also found a statistically significant difference of 20.21 µm ($P<.001$) in the corneal flap thickness between the first and second operated eyes. Miranda et al[21] found a mean 8.9 µm difference ($P<.0005$), and Solomon et al[23] reported that the second flap was on average 11 µm thinner with the Hansatome 180-µm head and 3 µm thinner with the 160-µm head. This has important clinical implications: switching to a new blade may be advisable before performing LASIK on the second eye if intraoperative flap thickness is low in the first to avoid thin flaps and dissection of Bowman's membrane.

Our study has some limitations regarding design and methods. We relied on the indirect measurement of the corneal flap thickness using ultrasonic pachymetry and a subtraction technique. The epithelial and stromal bed surface were exposed to some moisture or fluids prior to performing pachymetry measurements. Pachymetry performed on a dry stromal bed has been shown to be 20 to 30 µm thinner than when a damp surgical sponge is used to barely moisten the stromal bed surface.[36] By calculating the flap thickness using a subtraction technique, any apparent increase or decrease in stromal bed thickness can cause an under- or overestimation of flap thickness, respectively. Further investigations need to be done by performing direct measurement of the flap by high frequency ultrasonic pachymetry,[36,37] optical coherence tomography,[28] and confocal microscopy,[24] which may be theoretically more accurate than current ultrasonic pachymetry subtraction techniques. In addition, we did not prospectively randomize the eyes for suction ring size, footplate depth, or the sequence of eyes in bilateral cases (ie, the right eye was always operated on first).

In summary, we found that the Hansatome, in the hands of a single surgeon, on average produces thinner flaps than nominally labeled regardless of plate size or suction ring used. A positive correlation was noted between thicker preoperative pachymetry and thicker flaps. When using the same blade for bilateral cases, the flaps made on the second eye were thinner than the first eye. The average corneal thickness, spherical equivalent refraction, and the choice of 160- or 180-µm head were three variables that explain approximately one third of the variation in flap thickness. Further randomized studies are required to evaluate factors affecting flap thickness using different microkeratomes, ring sizes, blade designs, suction times, and vacuum settings.

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