

Laser in situ keratomileusis flap thickness using the Hansatome microkeratome with zero compression heads

Suphi Taneri, MD

PURPOSE: To evaluate predictability and possible factors affecting flap thickness in laser in situ keratomileusis (LASIK) using the Hansatome microkeratome (Bausch & Lomb Surgical) with zero compression heads.

SETTING: Zentrum für Refraktive Chirurgie Münster, Münster, Germany.

METHODS: A prospective nonrandomized comparative (self-controlled) trial analyzing flap thickness in 153 consecutive patients having LASIK using the Hansatome microkeratome with zero compression was conducted. Two hundred thirty-eight eyes that had uncomplicated primary LASIK ($n = 237$) or secondary LASIK ($n = 1$) by the same surgeon and same technique using 4 different microkeratomes of the same model were evaluated. Each keratome cut was performed with a new Accuglide (Bausch & Lomb) blade in a 160 μm ($n = 89$), 180 μm ($n = 128$), or 200 μm ($n = 21$) Hansatome zero compression head coupled to a 8.5 mm ($n = 106$) or 9.5 mm ($n = 131$) suction ring. Only Hansatome elements with the same serial numbers were combined. Ultrasound subtraction pachymetry was routinely used to determine intraoperative flap thickness. Flap thickness was correlated with microkeratome head dimension, suction ring size, preoperative keratometry obtained by Orbscan IIz (Bausch & Lomb), preoperative corneal thickness as obtained by ultrasound pachymetry, refractive error, and age.

RESULTS: Measured intraoperative flap thickness was significantly different ($P < .01$) from predicted flap thickness. The mean flap thickness was $97 \mu\text{m} \pm 18$ (SD) (range 65 to 163 μm), $111 \pm 20 \mu\text{m}$ (range 61 to 177 μm), and $131 \pm 20 \mu\text{m}$ (range 89 to 162 μm) for the 160 μm , the 180 μm , and 200 μm heads, respectively. There was a good correlation between microkeratome head and corneal flap thickness. However, there was a variability between devices. There was a low correlation between baseline ultrasound pachymetry at the time of surgery and corneal flap thickness ($r = .26$) and a small effect of ring size. There was no correlation with keratometry, refractive error, or age.

CONCLUSIONS: There was a remarkable difference in the flap thickness of microkeratomes of the same make and model. This emphasizes the need to measure intraoperative flap thickness and to evaluate every microkeratome separately. Factors affecting flap thickness seem to be more device dependent than patient related; obtaining flap thickness in the first eye did not enable predictions of the flap thickness in the fellow eye.

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Laser in situ keratomileusis (LASIK) has been the method of choice for the correction of myopia, hyperopia, and astigmatism in most patients for several years. Quick visual recovery without pain is made possible by the presence of a superficial corneal flap and has gained this procedure widespread popularity.¹ Enthusiasm for this procedure has been tempered by the potential for serious complications that are mostly related to the creation of the flap,² in contrast to surface ablation procedures.^{3,4} Reproducible flap thickness is crucial in ensuring a favorable

outcome. Currently, the Hansatome is the most popular microkeratome.

We report the LASIK flap thickness obtained during a prospective study of LASIK using the Hansatome microkeratome with zero compression heads by a single surgeon. The Hansatome heads were redesigned to better preserve epithelial integrity. Epithelial defects after LASIK have been associated with patient discomfort, photophobia, delayed visual recovery, epithelial ingrowth, diffuse lamellar keratitis, and increased retreatment rates.^{5–7}

PATIENTS AND METHODS

The study comprised 153 consecutive patients having LASIK by the same surgeon and same technique using the Hansatome microkeratome with zero compression heads. Subtraction pachymetry was routinely used to calculate flap and residual bed thickness. Only flaps created by a specific Hansatome head/ring combination that was used more than 10 times were included. Two hundred thirty-seven primary and 1 secondary microkeratome cuts could be evaluated; eccentric or irregular flaps were excluded.

Exclusion criteria for this study in addition to other contraindications for LASIK included history or slitlamp signs of ocular trauma or ocular surgery and systemic use of corticosteroids, anti-metabolites, or immunosuppressants. Patients with a history of recurrent basement membrane dystrophy or recurrent erosion syndrome were not included. Soft contact lenses were discontinued at least 1 week and rigid contact lenses at least 2 weeks before the initial examination and the procedure, respectively.

The initial clinical examination at least 24 hours before surgery included visual acuity, slitlamp biomicroscopy, tear-film breakup time, applanation tonometry (Goldmann), automated refraction with and without cycloplegia and pupil dilation, Orbscan IIz (Bausch & Lomb) evaluation, aberrometer testing (Zywave), dilated funduscopic examination, infrared pupillometry (Colvard), and stereoscopic depth perception (Stereo Test). Additionally, an ultrasound pachymeter (DGH model 500) was used by the surgeon to determine central corneal thickness on the day of initial examination and on the operating table just before and after the microkeratome pass. The pachymeter was checked at regular intervals according to the manufacturer's recommendations. The disinfected pachymeter probe was placed lightly on the center of the cornea after the cornea was anesthetized with proparacain eyedrops. Three measurements were taken each time to compare the reproducibility and consistency of the readings.

Eyes were excluded from this analysis if a complete set of measurements was not obtained. The same operator used the same pachymeter for all measurements in the office and in the laser suite to rule out interobserver variations and differences between devices. Informed consent was obtained from every patient before surgery.

Keratome Assignment

Microkeratome cuts using 4 keratomes of the same model were evaluated: Hansatome number 2385 ($n = 25$), number 5171 ($n = 34$), number 6057 ($n = 89$), and number 6071 ($n = 90$). Hansatome assignment was random and based on operating-room logistics, alternating between cases. Each keratome

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From the Augenabteilung am St. Franziskus-Hospital, Münster, Germany.

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Reprint requests to Suphi Taneri, MD, Zentrum für Refraktive Chirurgie Münster, Hohenzollernring 57, 48145 Münster, Germany. E-mail: taneri@refraktives-zentrum.de.

cut was performed with a new flawless AccuGlide disposable blade in a 160 μm , 180 μm , or 200 μm Hansatome zero compression head coupled to a 8.5 mm or 9.5 mm suction ring. Only Hansatome elements (ie, motors, heads, and suction rings) with the same serial numbers were combined. Other Hansatomes were used during the study period. However, to yield more reliable data, specific keratome/head/ring combinations were included in this analysis only if they were used at least 10 times.

The 160 μm , 180 μm , and 200 μm Hansatome zero compression heads were used 89, 128, and 21 times, respectively. They were coupled to a 8.5 mm suction ring in 106 cases and to a 9.5 mm suction ring in 132 cuts.

Primary Surgical Technique

All LASIK procedures were performed by the same surgeon in a standardized manner. In same-day bilateral cases, the right eye was always treated first. Approximately 30 minutes before surgery, 1 drop of ofloxacin was instilled in the eye. The eyelids were disinfected with iodine and draped in a sterile fashion. Topical anesthesia was achieved with several drops of proparacaine or oxybuprocaine and then a speculum with suction was placed in the operative eye and central corneal thickness was recorded 3 times using the same ultrasound probe as that used in office. The cornea was marked with different corneal markers using gentian violet staining. Excessive dye was removed with Ringer's solution. The Hansatome suction ring was centered over the entrance pupil and depressed for a few seconds before 25.6 mm Hg suction was applied. Pupil dilation indicating rise in intraocular pressure was observed. As soon as stable suction was achieved according to the Hansatome central unit's display, intraocular pressure was digitally checked and the patient was asked whether vision had deteriorated. The cornea and the suction ring were moisturized using Ringer's solution. The keratome was placed on the suction ring, and the keratome pass was performed. Suction was released, the microkeratome was removed, and the cut was evaluated, including epithelial defects.

A Chayet ring was applied, and the flap was reflected onto the Chayet ring using a LASIK spatula. The pachymeter was again used to determine corneal bed thickness before ablation. The eye tracker was focused and centered on the center of the entrance pupil. Standard or wavefront-guided ablation was performed using the Technolas 217z laser (Technolas/Bausch & Lomb Surgical) with PlanoScan or Zyoptix version 3.14 software and no nomogram change during the study period. Visible fluid including blood from transected corneal vessels, if present, was removed from the stromal bed with a Merocel sponge (Medtronic Ophthalmics) before and during laser ablation. The flap hinge and under-surface were protected by a Merocel sponge during ablation. The flap was repositioned with an irrigation cannula and the interface was irrigated. Proper alignment was ensured by gently wiping over the flap with a wet Merocel sponge or the irrigation cannula. The Chayet ring was removed. The flap was allowed to dry in position for 2 to 3 minutes. Ofloxacin and cortisone eyedrops were instilled before the speculum and drape were removed. The flap position was verified by slitlamp microscopy approximately 30 minutes after surgery, and the patient was discharged with protective glasses.

Postoperative Management

Postoperative examinations were performed routinely at 24 hours, 4 to 8 days, 4 to 6 weeks, 3 months, 6 months, and

12 months. Ofloxacin and cortisone eyedrops 4 times daily for 5 to 8 days were given. Unpreserved hyaluronic acid was administered for dry-eye symptoms as needed.

Main Outcome Measures

Primary outcome measures were the flap thickness as obtained by intraoperative ultrasound subtraction pachymetry and the incidence of intraoperative epithelial defects.

RESULTS

Two hundred thirty-eight eyes with 237 primary and 1 secondary microkeratome cuts were included in the study. The eyes had LASIK for the surgical reduction of myopia ranging from 0 to -15.00 diopters (D) or hyperopia ranging from 0.25 to 5.75 D and astigmatism up to -4.50 D. Mean ultrasound pachymetry just before the keratome pass was 550 ± 30 µm (range 486 to 661 µm). Mean simulated keratometry in the flat axis as obtained by Orbscan IIz measurements was 43.0 ± 1.4 D (range 37.4 to 46.1 D); mean simulated keratometry in the steep axis was 44.2 ± 1.6 D (range 37.9 to 47.8 D). The mean age of the participants was 39 years (range 19 to 68 years).

Only 1 eye had an epithelial abrasion from the keratome pass. Measured intraoperative flap thickness was significantly different (*P* < .01) from the predicted flap thickness. The mean flap thickness was 97 ± 18 µm (range 65 to 163 µm), 111 ± 20 µm (range 61 to 177 µm), and 131 ± 20 µm (range 89 to 162 µm) for the 160 µm, 180 µm, and 200 µm heads, respectively (ie, significantly lower than labeled flap thicknesses). There was a good correlation with microkeratome head size; however, the range was wide (Table 1).

The variability in the mean flap thickness and the standard deviation between microkeratome devices was high (Table 2).

On average, 7 µm thinner flaps were obtained with the 8.5 mm rings compared with the 9.5 mm rings (Table 3).

There was a low correlation between baseline ultrasound pachymetry at the time of surgery and corneal flap thickness (*r* = .26). Flap thickness increased with increasing central corneal pachymetry (Figure 1). There was a lower correlation between pachymetry at the initial examination and flap thickness by ultrasound and Orbscan

Table 1. Flap thickness versus head size.

| Head (µm) | Flap Thickness (µm) | |
|-----------|---------------------|--------|
| | Mean ± SD | Range |
| 160 | 97 ± 18 | 65-163 |
| 180 | 111 ± 20 | 61-177 |
| 200 | 131 ± 20 | 89-162 |

Table 2. Flap thickness versus microkeratome.

| Head (µm) | Microkeratome | |
|-----------|---------------|-----------|
| | Serial No. | Mean ± SD |
| 160 | 2385 | 105 ± 24 |
| | 5171 | 99 ± 21 |
| | 6057 | 103 ± 15 |
| | 6071 | 91 ± 15 |
| 180 | 2385 | 108 ± 15 |
| | 5171 | 107 ± 27 |
| | 6057 | 117 ± 21 |
| | 6071 | 105 ± 18 |
| 200 | 2385 | — |
| | 5171 | 109 ± 8 |
| | 6057 | 130 ± 20 |
| | 6071 | 144 ± 13 |

measurements. There was no correlation with refractive error (Figure 2). Examining minimal, maximal, and average keratometry yielded no significant influence (Figure 3). The patient's age showed no influence on the measured flap thickness (Figure 4).

To evaluate the effect of keratome-related versus patient-dependent factors, the difference in thickness of each flap and the mean thickness that was obtained using the identical keratome head and ring combination was calculated. The mean difference was 0 ± 18 µm (range -44 to 60 µm). The absolute difference between fellow eyes from the mean of the specific head/ring combination was 19 ± 15 µm (range 0 to 61 µm).

DISCUSSION

There have been other reports of the complications of LASIK indicating that the microkeratome cut is the most sensitive part of this refractive procedure. Even minor intraoperative complications such as epithelial defects have been shown to have the potential to decrease the final outcome because of their association with diffuse lamellar

Table 3. Flap thickness versus ring size.

| Ring Size (mm) | Mean ± SD | Range |
|-----------------------------|-----------|---------|
| 8.5 | | |
| Preop CCT (µm) | 546 ± 31 | 486-661 |
| Stromal bed thickness (µm) | 442 ± 33 | 372-539 |
| Corneal flap thickness (µm) | 104 ± 22 | 65-165 |
| 9.5 | | |
| Preop CCT (µm) | 554 ± 30 | 491-632 |
| Stromal bed thickness (µm) | 444 ± 31 | 355-524 |
| Corneal flap thickness (µm) | 111 ± 21 | 61-177 |

CCT = central corneal thickness

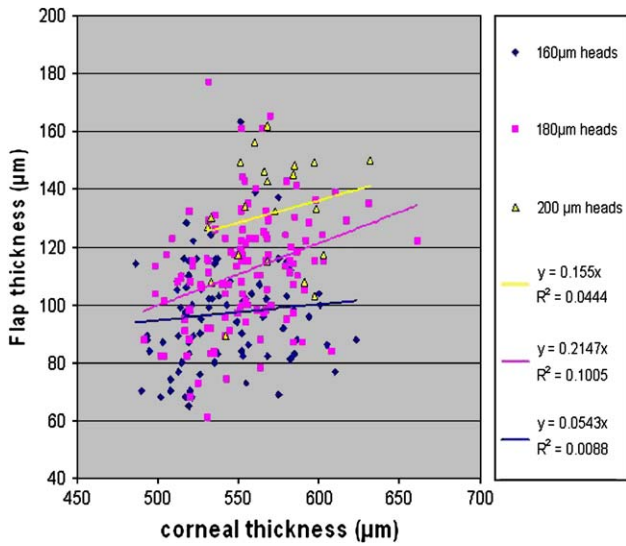


Figure 1. Flap thickness with all 160 µm, 180 µm, and 200 µm Hansatome heads correlated with central corneal thickness immediately before the keratome passage.

keratitis, flap slippage, and keratocyte apoptosis in the underlying stroma.^{5,7-14} Risk factors for epithelial defects include epithelial basement membrane dystrophy, age, and corneal thickness.^{5,15,16} Tangential forces during the microkeratome pass are thought to be the main reason for epithelial defects.^{5,16} With the old Hansatome design, Solomon et al.¹⁷ found an incidence of 8.8% for epithelial defects that was comparable to the incidence obtained by other mechanical microkeratomes in their study. Recently, the Hansatome microkeratome has been equipped with

zero compression heads designed to reduce the incidence of epithelial defects by lowering compression of the flap and shearing forces on the epithelium. We attempted to study the incidence of epithelial defects with the use of this popular microkeratome.

The incidence of epithelial defects was low (0.4%) and the extension of the abrasion observed was small using the new zero compression heads. This supports recent observations by Kohnen et al.¹⁸ who found a significant reduction compared with standard Hansatome heads in an intraindividual trial.

A major drawback of current mechanical microkeratomes is the lack of predictability of actual flap thickness despite the innovative advances in microkeratome design and the growing number of models. For example, a recent report evaluating the Moria M2 microkeratome found a flap thickness standard deviation of 24 µm.¹⁹ Solomon et al.¹⁷ found standard deviations of 15 to 35 µm examining 6 different microkeratome models. The Hansatome microkeratome is based on the oscillating blade principle. To our knowledge, this is the first study to address predictability of flap thickness and to evaluate affecting factors with the newly designed zero compression heads.

We chose to measure central corneal thickness by ultrasound pachymetry, which uses the Doppler effect, as this is a proven and easy-to-perform method. It has been shown to be as consistent as partial coherence interferometry.^{20,21} In the presence of corneal haze, ultrasound pachymetry seems to be more reliable than scanning light systems such as the Orbscan II.²²⁻²⁴ However, the coefficient of variation in pachymetry of a normal cornea increases from $\pm 5\%$ to $\pm 20\%$ ²⁵ when 2 readings are needed to calculate flap thickness.²⁵ Considering these limitations, an SD of

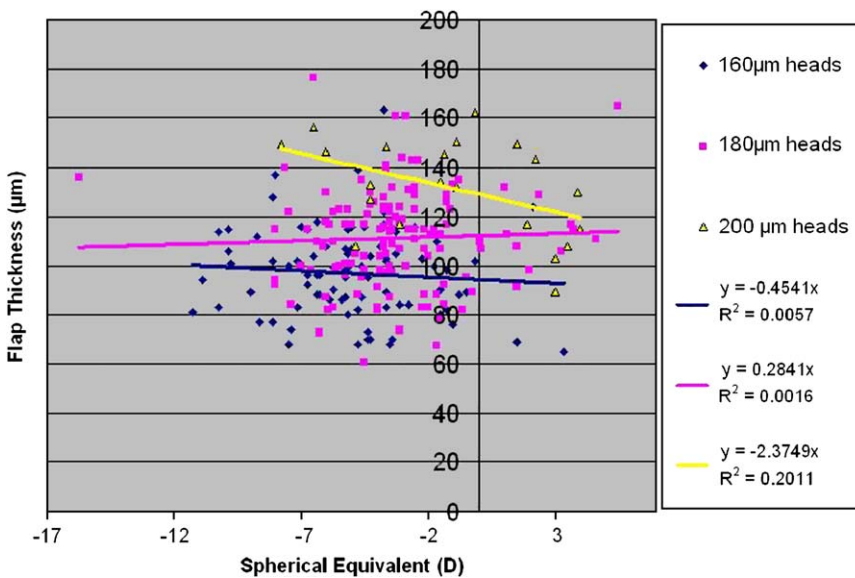


Figure 2. Flap thickness with all 160 µm, 180 µm, and 200 µm Hansatome heads correlated with the baseline spherical equivalent.

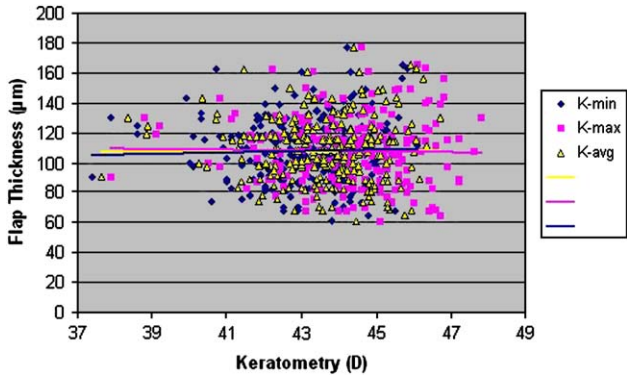


Figure 3. Flap thickness correlated with minimum, maximum, and average keratometry.

$\pm 8 \mu\text{m}$ seems to be the theoretical minimum using ultrasound subtraction pachymetry.

Despite its refined design, the Hansatome with zero compression heads created corneal flaps of variable thicknesses. As expected from previous reports with the old Hansatome head design, we found significantly thinner than labeled flaps on average.^{17,26–29} There was no difference between right and left eyes.

The mean standard deviations of all 4 tested microkeratomers were 18 μm , 20 μm , and 20 μm for the 160 μm , the 180 μm , and the 200 μm heads, respectively. Using a femto-second laser, Binder³⁰ reports a standard deviation of only 12 μm when attempting to create 110 μm flaps. The standard deviations in our study are comparable to those reported with other mechanical microkeratomers. However, we observed a remarkable difference between the 4 Hansatome devices: For a specific head/ring combination, the standard deviation varied between 13 μm and 27 μm . This device dependency is not detected if only 1 device of different models is evaluated in comparative studies.

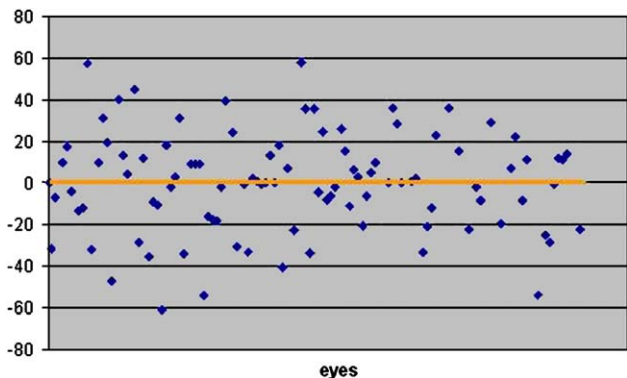


Figure 4. Difference of an individual flap thickness from the mean flap thickness obtained with identical microkeratome parameters (ie, a specific microkeratome head and ring combination with the same serial number).

Of greater concern to safety than a high standard deviation is a wide range of flap thicknesses. Flaps that are too superficial may result in buttonholes and flaps that are too thick may weaken corneal tectonic stability. Our results of 65 to 163 μm for the 160 μm heads, 61 to 177 μm for the 180 μm heads, and 89 to 162 μm for the 200 μm heads indicate that it may be unwise to rely on consistently thinner than labeled average values, as some propagate. Narrowing this wide range should be the highest priority for all microkeratome manufacturers.

Examining factors affecting flap thickness with mechanical microkeratomers, one finds contradictory reports. The most tested variables include head and ring size, corneal thickness, keratometry, refractive error, and age. Strong positive and negative correlations of these factors are described. However, we found a strong positive correlation only with head size, not with the other variables. One may speculate that other influences must play a role. Maybe blade sharpness, suction duration, pressure on the ring, and other variables should be taken into account. For example, longer suction duration resulted in thicker flaps and greater incision angles in porcine eyes with the old Hansatome design.³¹ Unfortunately, no clinical trials on this subject are reported.

Looking at the difference between the individual flap thickness and the mean flap thickness cut with the same Hansatome head and ring combination, we found a range from -44 to $60 \mu\text{m}$ (SD 18 μm) (ie, an actual flap was up to 44 μm thinner or up to 60 μm thicker than the mean flap cut with the same parameters). Unlike most other studies, we did not use the same keratome and the same blade in both eyes of a patient and could not directly compare both flaps in a patient. However, we could calculate the absolute difference between fellow eyes from the individual mean for the specific microkeratome head and ring combination. We found a mean difference in fellow eyes of $19 \pm 15 \mu\text{m}$ ranging up to 61 μm . In other words, even obtaining intraoperative flap thickness in 1 eye did not enable precise predictions for the fellow eye because variations with seemingly identical parameters were too high.

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