Flap Measurements With the Hansatome Microkeratome

Leopoldo Spadea, MD; Loredana Cerrone, MD; Stefano Necozione, MD; Emilio Balestrazzi, MD

ABSTRACT

PURPOSE: To evaluate flap thickness, flap diameter, and hinge length during laser in situ keratomileusis (LASIK) and to correlate these measurements with preoperative keratometric power, central corneal thickness, and patient refraction, gender, and age.

METHODS: In this prospective study of 50 eyes of 28 patients (mean age 31 ± 6.6 yr; range, 24 to 43 yr) results of LASIK for myopia were analyzed (mean spherical equivalent refraction of -7.16 ± 1.69 D; range, -2.75 to -13.50 D). Corneal flaps were created using the Hansatome microkeratome (Bausch & Lomb Surgical) with a 160-μm plate and a 9.5-mm suction ring. Corneal thickness was evaluated using an ultrasonic 50-MHz pachymeter (Sonogage Corneo Gage Plus) and the mean keratometric power was measured with a Corneal Analysis System videokeratographic unit (EyeSys). Data were analyzed using t-test, Pearson product moment correlation coefficient, and Spearman's rho non-parametric correlation coefficients.

RESULTS: Mean corneal flap thickness was 142.6 ± 20.8 μm (range, 107 to 177 μm), mean flap diameter was 9.9 ± 0.3 mm (range, 9.2 to 10.5 mm), and mean hinge length was 6.2 ± 0.4 mm (range, 5.2 to 7 mm). Statistically significant correlations (P<0.05) were found between mean keratometric power and flap hinge length, mean keratometric power and flap diameter, preoperative spherical equivalent refraction and flap diameter, corneal thickness and flap hinge length, as well as patient age and corneal thickness.

CONCLUSIONS: The Hansatome microkeratome was an effective and safe instrument in the creation of corneal flaps for LASIK. Consideration of preoperative keratometric power and corneal thickness may help to reduce or avoid complications. [J Refract Surg 2002;18:149-154]

In 1961, Barraquer described keratomileusis based on stromal subtraction at the corneal vertex.1 In 1986, Ruiz described in situ keratomileusis, reinforcing the idea of preserving the central Bowman's layer; the microkeratome was used to resect a central corneal disk to induce the required flattening. In 1983, Trokel and colleagues described the use of the excimer laser in refractive surgery.2 This lead to the technique of keratomileusis, which combines cutting of the plano anterior disc with the microkeratome and refractive photoablation in the stromal bed performed by the excimer laser (LASIK).3 LASIK offers many advantages over photorefractive keratectomy (PRK), but the creation of the corneal flap has been associated with a number of intraoperative (buttonhole, free cap, etc) and postoperative (flap striae, epithelial ingrowth, keratectasia, etc.) complications.4,5 The use of the microkeratome to create the flap is a critical component of LASIK. We evaluated LASIK flap measurements in a series of patients with myopia who had LASIK using an automated microkeratome.

PATIENTS AND METHODS

This prospective study included patients who had LASIK for myopia at the S. Salvatore Hospital of L'Aquila between November 1999 and March 2000. Exclusion criteria included active or recurrent corneal disease, corneal opacities, keratoconus, unstable myopia, glaucoma or intraocular pressure greater than 18 mmHg, retinal disorders, connective disorders, pregnancy, age less than 20 years, dry eye syndrome, macular disease, deep ambiopipia, or diabetes.

All patients underwent a complete ophthalmological examination, including cycloplegic refraction, videokeratography, and corneal pachymetry. Corneal topography was performed using the
Corneal Analysis System, (EyeSys Lab, Houston, TX). The best of four keratoscopic images obtained from each eye was chosen. We considered mean keratometric power of the 3-mm central cornea (effective refractive power, displayed in the EyeSys Holladay Diagnostic Summary), indicating the spherical equivalent power of the cornea within the 3-mm pupil zone. Corneal thickness was determined as the mean of five measurements obtained from the center of the cornea by means of a Corneo-GAGE Plus pachymeter (Sonogage Inc, Cleveland, OH). This 50-MHz ultrasound pachymeter has a repeatability of ±3 μm and an accuracy of ±0.4 μm, with a transducer tip diameter of 1.50 mm.

After obtaining informed consent, patients had LASIK. All patients discontinued contact lens use for at least 1 month preoperatively. All LASIK procedures were performed by one surgeon (LS). After application of topical anesthesia (Lidocaine 4%) and centration over the entrance pupil, the 9.5-mm suction ring of the Hansatome microkeratome (Bausch & Lomb Surgical, serial number 2594, model number HT 230) was applied on the sclerocorneal limbus. The suction ring induced an ocular pressure over 65 mmHg, verified with the Barraquer applation tonometer. Always utilizing a single-use new blade and the 160-μm plate, a superior hinged lamellar flap was created. The suction ring was removed and the corneal flap was retracted, exposing the underlying corneal stroma. The ultrasonic measurements were performed before microkeratome application and after the corneal flap was lifted, on a dry surface. The difference between the two measurements was considered the flap thickness. The maximum horizontal diameter of the bed and the length of the flap hinge were measured using a surgical caliper (Moria Surgical, Antony, France). As soon as the stromal excimer laser ablation was completed, the stromal bed was washed with balanced salt solution (BSS, Alcon Lab., Fort Worth, TX). The flap was folded back in its original position by using a spatula, and after verifying that the flap had adhered to the stromal bed, without any suture, the speculum was withdrawn. Eye protection with a hard shield was advised for the day after surgery and all patients were instructed not to rub their eye. Patients received for the first 15 days butyrate clobetasone 0.1% drops, ofloxacin 0.3% drops, and sodium diclofenac 0.1% drops three times a day, then tapered and titrated.

Statistical Analysis

Mean values and standard deviations of corneal thickness, flap thickness, flap horizontal diameter, and hinge length of 50 eyes of 28 patients were calculated, related to patient refraction, gender, and age. The Pearson product moment correlation coefficient was used to determine the relationship between two numerical variables. A t-test for correlation coefficient was used to estimate the statistical significance of correlation coefficients. Since the value of the correlation is markedly influenced by extreme values, it does not provide a good description of the relationship between the two variables when the distribution of the variables is skewed or it contains outlying values. Thus, the data were converted into ranks and also Spearman’s rho non-parametric correlation coefficients were calculated. All statistical analyses were performed using SAS/Statistic software (Statistical Analysis System Institute, Rel. 6.12, Cary, NC: SAS Institute, 1997).

RESULTS

Fifty eyes of 28 patients (20 females and 8 males) were enrolled in the study. Mean patient age was 31 ± 6.6 years (range, 24 to 43 yr). Preoperative refraction was between -2.75 and -13.50 D (mean spherical equivalent refraction of -7.20 ± 1.7 D). Mean corneal thickness preoperatively was 536.6 ± 27.8 mm (range 499 to 612 mm) and mean keratometric power was 43.80 ± 1.40 D (40.40 to 45.90 D).

A mean flap thickness of 142.6 ± 20.8 μm (range, 107 to 177 μm) resulted, instead of 160 μm of the microkeratome plate (Figs 1 to 3). Thus, mean flap thickness was about 17.4 μm thinner than labeled. Mean flap horizontal diameter was 9.9 ± 0.3 mm (range, 9.5 to 10.5 mm), instead of 9.5 mm of the suction ring (Figs 4 to 6). Mean hinge length was 6.2 ± 0.4 mm (range, 5.2 to 7 mm) (Figs 7 to 9). Statistically significant correlations (P<.05) were found between mean keratometric power and flap hinge length, mean keratometric power and flap

![Figure 1. Correlation between corneal flap thickness (μm) and preoperative mean keratometric power (D). (Spearman Correlation Analysis r=0.216, P=.132; Pearson Correlation Analysis r=0.235, P=.100).](image)
diameter, preoperative spherical equivalent refraction and flap diameter, corneal thickness and flap hinge length, as well as patient age and corneal thickness (Tables 1 and 2; Figs 4, 6 to 8).

We observed no cases of free cap, buttonhole, flap displacement, wrinkles, dot remnants in the interface due to epithelial or tear film debris, or to foreign particles.

**DISCUSSION**

Refractive correction of myopia is still controversial and represents a difficult clinical problem. High myopia spectacles induce optical aberrations, limitations in the visual field, and poor cosmesis. Contact lenses offer better visual results than spectacles, but many patients cannot tolerate them. Excimer laser PRK offers good results in low to
moderate myopia, but poor predictability, regression of effect, and corneal haze occur in cases of high myopia.

LASIK to correct high myopia has generated high expectations among refractive surgeons. The excimer laser has been used to remove tissue from the disk, as a traditional keratomileusis, and from the underlying stromal bed, as in LASIK.

LASIK offers many advantages over PRK, but it presents risks related to the use of the microkeratome. Some of the intraoperative risks of LASIK concern corneal flap size (free cap, small cap, large cap, incomplete cap), corneal flap depth (buttonhole, epithelial tear, thin flap, full thickness anterior chamber penetration), corneal flap form (wrinkled, edematous, irregular, shrunken), flap location (flap displacement) or the corneal hinge (short, large, absent, burns). Tham and Maloney found an overall rate of microkeratome complication of 0.68% (1 in 150); 1.3% (1 in 77) in the surgeon’s first 1000 eyes, decreasing to 0.4% (1 in 250) in the last 1000 eyes. There is a significant learning curve in the use of the microkeratome.

It is probable that the choice of a different type of microkeratome affects the percentage of risks and intraoperative complications. Different microkeratomes create different morphologic features as they excise corneal tissue. Differences in instrument design, mechanics of tissue excision and blade oscillation, and instrument traverse combined with surgical skill influence the configuration of lamellar keratotomy (Table 3). The quality of the cutting edge may be influenced by the relationship between the speed of the pass and the rate of blade oscillation/rotation. Therefore, it seems that a lower feed during oscillation/rotation results in a smoother pattern of the cutting edge. A clinical study compared the Hansatome and the Automated Corneal Shaper (ACS) microkeratome; the percentage of intraoperative flap complications and difficult
placements was significantly lower with the Hansatome. An experimental study reported a progressive thinning/thickening of the flap in the direction toward the hinge. Behrens reported better satisfactory cut quality and reproducibility after single use of stainless steel blades in the ACS microkeratome; cut quality degraded dramatically by repeated use of blades.

Progressive corneal ectasia is a particularly insidious postoperative complication of LASIK, and it can occur a few to several months after surgery. The etiology of iatrogenic keratectasia is still unknown, but it seems to be related to residual corneal bed thickness. One cause may be error in measuring the overall corneal thickness by means of pachymetry, another by underestimating the excimer laser ablation depth, and the last by underestimation of flap thickness. According to other authors, in LASIK one should leave almost 250 μm of residual corneal bed. We reported a case of iatrogenic keratectasia that occurred after LASIK for myopia performed with a manually guided microkeratome. After penetrating keratoplasty, histologic button examination showed a central flap thickness of 282 μm, instead of 120 μm of estimated thickness, and a residual stromal bed of less than 100 μm (personal communication, ASCRS, Boston, MA, May 2000).

The greatest care must be taken in making flap measurements (thickness, diameter, and hinge length), and in surgical planning, to reduce risks and complications. In our study, the true dimensions of the flap made by the Hansatome microkeratome using the 160-μm plate and 9.5-mm suction ring were a mean 142.6-μm thickness and 9.9-mm diameter. Therefore, a flap 17 μm thinner than expected leaves more residual corneal bed, reducing the postoperative risk of keratectasia. One must remember that this number is a mean value; indeed the true flap thickness ranged from 107 to 177 μm. Maldonado, using optical coherence tomography (OCT) after LASIK for high myopia with the Hansatome microkeratome with 160-μm plate, measured a mean corneal cap thickness of 124.8 ± 18.5 μm, 1 day postoperatively. Yildirim, using the Hansatome microkeratome with a 180-μm plate, with ultrasonic examination found a mean corneal flap thickness of 120.8 ± 26.3 mm.

A diameter of 9.9 mm instead of 9.5 mm allows a larger ablation and reduces the interference risk of the photoablation with the hinge, but it increases the risk of intraoperative bleeding in cases of vascularization of the peripheral cornea, as in chronic contact lenses users.

The hinge size is a critical factor in flap-related complications of LASIK. A larger hinge prevents the formation of an unhinged flap, a lamellar corneal disk (free cap). This study demonstrated some positive correlations between preoperative mean keratometric power and flap hinge length, mean keratometric power and flap diameter, preoperative spherical equivalent refraction and flap diameter, corneal thickness and flap hinge length. Therefore, a low preoperative keratometric power (less than 41.00 D) and a thin cornea are correlated to a smaller flap and to a shorter hinge.

In this series of patients we noted no case of flap with a central hole (buttonhole). This complication occurs when the central area of the cornea is steeper, as in a keratoconic cornea. For this reason it is important to have an accurate evaluation of videokeratographic maps. Moreover, microkeratome malfunction may cause a buttonhole during LASIK in eyes that do not have significant corneal steepening.

In accordance with other authors who used the Hansatome microkeratome, we found no correlation between flap thickness and corneal steepening or corneal thickness. If we examine more eyes, we may obtain some statistically significant

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**Table 3**

Comparison of Microkeratomes

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>No. Eyes</th>
<th>Microkeratome</th>
<th>Plate (μm)</th>
<th>Mean ± SD Evaluated Flap Thickness (μm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pérez-Santonja</td>
<td>1997</td>
<td>100</td>
<td>ACS</td>
<td>130</td>
<td>86.6 ± 12</td>
</tr>
<tr>
<td>Pérez-Santonja</td>
<td>1997</td>
<td>43</td>
<td>ACS</td>
<td>160</td>
<td>114.1 ± 17</td>
</tr>
<tr>
<td>Behrens</td>
<td>2000</td>
<td>90</td>
<td>ACS</td>
<td>180</td>
<td>125 ± 32</td>
</tr>
<tr>
<td>Spadae</td>
<td>2001</td>
<td>50</td>
<td>Hansatome</td>
<td>160</td>
<td>142.6 ± 20.8</td>
</tr>
<tr>
<td>Maldonado</td>
<td>2000</td>
<td>83</td>
<td>Hansatome</td>
<td>180</td>
<td>124.8 ± 18.5</td>
</tr>
<tr>
<td>Behrens</td>
<td>2000</td>
<td>50</td>
<td>Hansatome</td>
<td>180</td>
<td>151 ± 18</td>
</tr>
<tr>
<td>Yildirim</td>
<td>2000</td>
<td>140</td>
<td>Hansatome</td>
<td>180</td>
<td>120.8 ± 26.3</td>
</tr>
<tr>
<td>Behrens</td>
<td>2000</td>
<td>50</td>
<td>Supratome</td>
<td>160</td>
<td>192 ± 32</td>
</tr>
<tr>
<td>Yi</td>
<td>1999</td>
<td>69</td>
<td>Moria SCMD</td>
<td>160</td>
<td>137.2 ± 33.7</td>
</tr>
</tbody>
</table>
correlations. On the other hand, Yi and colleagues, using the Moria SCMD microkeratome, noted in 69 eyes no correlation between flap thickness, amount of myopia, steepening of cornea, or time taken to complete the flap, but did note a statistically significant positive correlation between flap thickness and overall corneal thickness ($P=.001$, $r = 0.833$).\(^2\)

The Hansatome microkeratome is an effective and safe instrument to create a corneal flap, but this study stresses the importance of considering preoperative data (mean keratometric power, corneal thickness) in order to reduce or avoid complications.

REFERENCES