WaveLight FS200 vs Hansatome LASIK: Intraoperative Determination of Flap Characteristics and Predictability by Hand-held Bioptigen Spectral Domain Ophthalmic Imaging System

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ABSTRACT

PURPOSE: To intraoperatively determine and compare the characteristics and predictability of LASIK flaps made by the WaveLight FS200 femtosecond laser (Alcon Laboratories Inc) and Hansatome (Bausch & Lomb) microkeratome using a hand-held spectral domain ophthalmic imaging system (Bioptigen Inc).

METHODS: Sixty eyes from 30 patients undergoing bilateral LASIK were prospectively evaluated. Patients were divided into two equal groups to undergo flap creation with either 100-μm femtosecond laser flaps (FS flap group) or 120-μm microkeratome flaps (MK flap group). Flap thickness was measured intraoperatively after creation of the flap but prior to lifting using the hand-held probe of the spectral domain imaging system. Geometry of the flap edge and smoothness of the stromal bed after lifting the flap was also evaluated in all cases.

RESULTS: Mean difference between planned and achieved flap thickness in the paracentral region was 2.84±3.16 mm for the FS flap group and 11.33±10.27 mm for the MK flap group, whereas in the periphery, it was 5.72±3.26 mm in the FS flap group and 24.67±10.35 mm in the MK flap group. The differences between groups were statistically significant ($P<0.001$, Kruskal-Wallis test). The edges of the flaps were vertical in the FS flap group and the stromal bed was smoother, whereas in the MK flap group, the edges were more sloping and the stromal bed more irregular.

CONCLUSIONS: The WaveLight FS200 femtosecond laser is able to produce planar flaps with a high degree of predictability between the desired and achieved flap thickness. The ability to study the flap characteristics intraoperatively (when flap edema and stromal bed hydration changes have not yet occurred) with the hand-held probe of the Bioptigen imaging system ensures greater accuracy than measurements done postoperatively using other anterior segment optical coherence tomography prototypes. [*J Refract Surg*. 2012;28(11 Suppl):S815-S820.]

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Laser in situ keratomileusis (LASIK) is one of the most popular and frequently performed refractive corneal surgeries today. The flaps in LASIK may be created by the use of a microkeratome or femtosecond laser. The mechanical microkeratome uses shear force through the use of an oscillating blade, traveling across the cornea whereas the femtosecond laser creates a corneal resection by delivering laser pulses at a predetermined depth. These pulses create microphotodisruption or an expanding bubble of gas (CO_2) and water that in turn cleave the tissue and create a plane of separation.[1] Whatever the method of flap creation the critical components remain the same: safety, efficiency, predictability, and biomechanical wound healing.[2]

One of the important determinants of the successful and safe outcome of LASIK is the thickness and uniformity of the flap created. Thicker flaps may result in less flap wrinkling and therefore less irregular astigmatism.[3,4] On the other hand, thin flaps may provide more stroma potentially available for deeper ablations.[3] Femtosecond laser–created flaps have been shown to have a more uniform and predictable thickness than most microkeratome flaps,[5-8] although some microkeratomes have been shown to produce thin, relatively planar flaps.[9,10] Previous studies have reported flap characteristics of lower frequency, ie, 30 or 60 kHz, femtosecond lasers.[6,8,11] However, it has also been documented that faster femtosecond lasers may have better predictability compared to older models.[12] The WaveLight FS200 femtosecond laser (Alcon Laboratories Inc, Ft Worth, Texas) uses a 200-kHz repetition rate and 1030-nm wavelength. It makes a flap in approximately 6 seconds.

Spectral domain optical coherence tomography (SDOCT) has revolutionized anterior and posterior segment imaging by providing axial resolutions that are twice as high (5 to 7 µm) as time-domain OCT (approximately 10 µm)[13] and acquiring

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scans 45 to 130 times faster than time-domain OCT.[14] Spectral domain OCT also reduces speckle noise, thereby improving the resolution of boundaries between various ocular tissue layers and visualization of small pathologic changes.[15] The Bioptigen Spectral Domain Ophthalmic Imaging System (Bioptigen Inc, Durham, North Carolina) is a recently introduced anterior and posterior segment OCT that allows high-resolution imaging of weakly back scattering biological tissues in vivo.[16] The Bioptigen system has customizable high-speed image acquisition, allows for variability of scanning depths from the cornea to the inner retina, and is unique in the fact that it is hand-held and hence images can be taken with the patient in the supine position making it possible to take intraoperative measurements. This makes it suitable for both the clinic and operating suite. Images acquired on this 840-nm ophthalmic SDOCT have a depth-independent axial resolution of 4.5 µm and transverse resolution of 3 µm.

Although anterior segment OCT has been used to measure the flap thickness at various intervals postoperatively,[17-21] intraoperative assessment of flap characteristics by OCT has not been reported to our knowledge. In this study, we intraoperatively evaluated the flap characteristics including predictability and uniformity of thickness achieved, regularity of the stromal bed, and geometry of flap edge in patients undergoing LASIK flap creation by the WaveLight FS200 femtosecond laser or by a microkeratome (Hansatome; Bausch & Lomb Inc, Rochester, New York) using the hand-held Bioptigen SDOCT.

PATIENTS AND METHODS

In this prospective, comparative case series conducted at a tertiary care ophthalmic hospital, patients who underwent LASIK for simple myopia or myopic astigmatism were evaluated. All patients gave written informed consent and the study was approved by the ethics committee of the institute. The study was performed under the tenets of the Declaration of Helsinki.

Preoperative Evaluation

All patients underwent a complete preoperative ophthalmic examination including uncorrected visual acuity for distance and near, manifest refraction, cycloplegic refraction, slit-lamp examination, Goldmann applanation tonometry, dilated funduscopy, and tear film assessment using the Schirmer strip and tear film break up time. Corneal topographic analysis was performed using the Pentacam (Oculus Inc, Lynnwood, Washington).

Inclusion criteria were age of at least 21 years, documented stable refraction for 1 year, and manifest refraction spherical equivalent >-1.50 diopters (D) with or without astigmatism. Exclusion criteria included central corneal thickness <500 µm measured by Pentacam, previous refractive or ocular surgery, keratoconus, dry eye, uveitis, and any ocular or systemic disease likely to affect corneal wound healing.

Patients meeting the inclusion criteria were divided into two groups to undergo flap creation by the WaveLight FS200 laser of 100 µm (FS flap group) or by the microkeratome of 120 µm (MK flap group). Stromal ablation was performed with the WaveLight EX500 excimer laser (Alcon Laboratories Inc) in all patients.

Surgical Procedure

Femtosecond Laser Flap. The WaveLight FS200 femtosecond laser, which has a frequency of 200 kHz and 1030-nm wavelength, was used by a single surgeon (R.S.) to create the flap in all patients. The default flap diameter was kept as 8.5 mm. Other standardized parameters included canal width of 1.3 mm, side-cut angle of 85°, a superior hinge with a hinge angle of 60°, length of 4.5 mm, and width of 0.6 mm.

Microkeratome Flap. A Hansatome microkeratome was used to make corneal flaps with a superior hinge and diameter of 8.5 mm. A 120-µm blade was used in all cases.

Spectral Domain OCT

The Bioptigen was used for image acquisition. Preoperatively, the hand-held probe including a part of the connection cable was covered with a sterile plastic drape. The drape was tightened around the optical bore with sterile tape. An opening was made in the drape at the anterior end of the optical bore to enable measurements. These measures enabled the OCT scan to be performed in a sterile environment without any contact to the surgical site.

The scan protocol included centered radial volume scans of 8-mm diameter. Outcome measures studied were flap thickness determined paracentrally, ie, 1 to 1.5 mm on either side of the center (Figs 1 and 2), and peripherally near the edge of the flap (3.5 to 4 mm from the center); stromal bed architecture; and flap edge. The flap was distinguished from the stromal bed by its increased internal reflectivity. Measurement at the center of the flap was avoided as the contrast is poor near the corneal vertex because the interface reflections are overwhelming and both flap and bed internal reflectivities are high.[21] To measure the flap thickness, imaging was done after creation of the flap by the femtosecond laser or microkeratome but prior to lifting the flap for excimer laser ablation. For evaluation of the side-cut angle and stromal bed, the flap was lifted and images taken. Three images were taken and the images

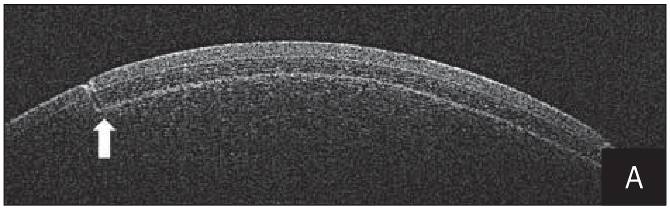
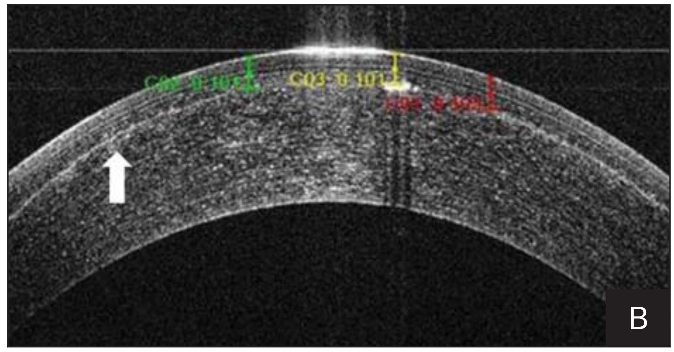


Figure 1. Intraoperative measurement of femtosecond flap thickness using spectral domain optical coherence tomography showing the thickness at the paracentral region. **A)** Arrow shows a vertical edge characteristic of a femtosecond laser–created flap. **B)** Arrow shows the planar stromal bed with calipers marking the flap thickness at various positions.



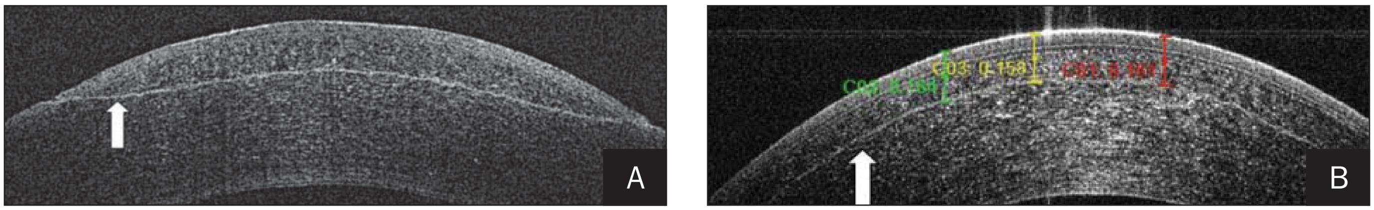


Figure 2. Intraoperative measurement of microkeratome flap thickness using spectral domain optical coherence tomography showing the thickness at the paracentral region. **A)** Arrow shows the sloping edge of a microkeratome flap. **B)** Arrow shows the flap approximated to the stromal bed and variation in flap thickness as noted by the calipers marked.

TABLE

LASIK Flap Thickness

Group	Achieved Flap Thickness (Mean±SD [Range] [μm]) Paracentrally	Peripherally
FS flap	102.84±3.16 (99 to 105)	105.72±3.26 (102 to 108)
MK flap	131.33±10.27 (110 to 141)	144.67±10.35 (124 to 155)

SD = standard deviation, FS = femtosecond laser, MK = microkeratome

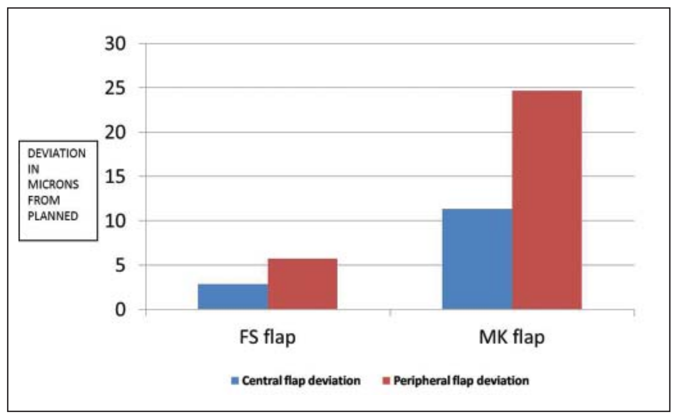


Figure 3. Planned versus achieved thickness at the paracentral region and periphery between femtosecond (FS) laser and microkeratome (MK) flaps.

were averaged to remove the distortion resulting from light refraction at the air–corneal interface and transition in the tissue.

Measurements for each image were made by a single experienced examiner (C.M.) who was masked to the method of flap creation. The calipers tool of the Bioptigen SDOCT was used to measure the flap thickness. All measurements were made perpendicular to the anterior corneal surface.

Data entry was done using SPSS for Windows (version 15.0; SPSS Inc, Chicago, Illinois). Significance was set at $P<.05$. Data were compared using the parametric or non-parametric tests depending on normality of the data.

RESULTS

Sixty eyes (30 patients [17 women (57%) and 13 men (43%)]) undergoing LASIK were included in the study. Mean patient age was 30.6±6.8 years (range: 21 to 47 years). Each group comprised 30 eyes. Steep keratometry in the FS flap group was 44.18±2.16 D and 44.27±2.03 D in the MK flap group ($P=.48$).

Flap thickness data in each of the groups are summarized in the Table. The mean of the difference between the planned and achieved flap thickness in the paracentral region was 2.84±3.16 mm for the FS flap group and 11.33±10.27 mm in the MK flap group. The flap thickness near the edge of the flap (3.5 to 4 mm from the center) was 5.72±3.26 mm in the FS flap group and 24.67±10.35 mm in the MK flap group (Fig 3). The differences between the groups were statistically significant ($P<.001$, Kruskal-Wallis test).

The edges of the flaps were vertical in femtosecond laser–created flaps and the stromal bed was smoother (Fig 4) whereas in the MK flap group, the

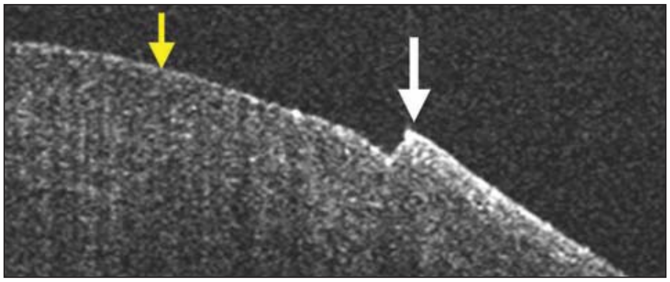


Figure 4. Intraoperative spectral domain optical coherence tomography of a femtosecond laser flap bed showing regular stromal bed (yellow arrow) and vertical edges (white arrow).

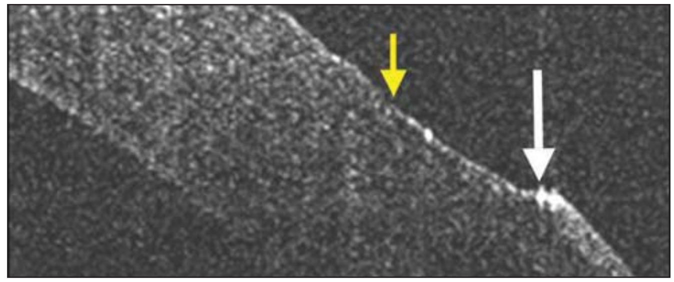


Figure 5. Intraoperative spectral domain optical coherence tomography of a microkeratome flap bed showing irregular stromal bed (yellow arrow) and sloping edges (white arrow).

edges were more sloping and the stromal bed more irregular (Fig 5).

DISCUSSION

In the present study, we were able to determine quantitative (flap thickness, planarity) as well as qualitative (geometry of flap edge, architecture of stromal bed) characteristics of the flaps created by the Wavelight FS200 femtosecond laser and compare them with those of the Hansatome microkeratome intraoperatively. Planarity implies that the flap is of relatively uniform thickness from the center to the periphery, whereas predictability would be determined by the difference between the intended and achieved thickness at different points of the flaps

The Wavelight FS200 flaps in this study were highly predictable, being within 3 and 6 µm of the intended thickness at the center and periphery, respectively, whereas the microkeratome flaps deviated by nearly 11 and 24 µm from the intended thickness at the center and periphery, respectively. The results of this study have been corroborated in some studies,[22-24] which show a standard deviation of the microkeratome flap as high as 26 µm, but in certain studies the microkeratome flaps have been shown to be much more predictable with a low standard deviation ranging from 2 to 9 µm.[9,25,26] With the microkeratome, multiple factors determine the flap thickness profile, such as the quality of the blade's cutting edge, speed of the microkeratome pass, speed of blade oscillation, ease of pass on the cornea, and advancement of the microkeratome along the track of the suction ring.

This wide variation of flap thickness with mechanical microkeratomes may be of significant concern with regards to iatrogenic corneal ectasia after LASIK, which has been reported to have an incidence of 0.66%.[27] As the flap does not contribute to the mechanical strength of the cornea, it has been proposed that a residual stromal bed of at least 250 µm should be preserved after flap creation and stromal ablation to avoid postoperative keratectasia.[3,28] This makes flap thickness and hence its predictability a critical factor for LASIK safety, especially in patients having relatively thinner corneas. In contrast to the microkeratome flaps, the thickness of the femtosecond-created flaps using the WaveLight FS200 laser in the present study was close to the desired thickness. Increased use of a femtosecond laser to create flaps in the future, thus may contribute significantly to decreasing the risk of postoperative LASIK ectasia, especially in patients with borderline corneal thickness.

A nearly four-fold difference in planarity of the flaps was noticed between the FS and MK flap groups in the current study. For 110-µm flaps created by the WaveLight FS200 laser, the difference in flap thickness between the center and periphery was <3 µm, whereas the microkeratome flaps were meniscus-shaped being nearly 13 µm thinner at the center than peripherally. Variable thickness over the extent of microkeratome flaps, being thinner in the center and thicker in the periphery, has also been reported previously.[29] Newer mechanical microkeratomes can produce thin flaps of approximately 100-µm thickness, comparable to femtosecond laser–created flaps.[30] The anterior one-third of the stroma and the peripheral cornea are biomechanically stronger than the posterior two-thirds and the central cornea.[31,32] Thus, a microkeratome-created, meniscus-shaped flap even if of the same thickness as a femtosecond laser–created planar flap centrally, cuts deeper in the periphery and may damage more of the strong peripheral fibers.

Intraoperative imaging of the flap edge with the Bioptigen SDOCT demonstrated the vertical edges of the flaps created by the femtosecond laser, whereas the microkeratome flaps had sloping edges. Vertical edges created by the femtosecond laser contribute to stronger healing of the flap edges and make them less prone to displacement than microkeratome-created flaps.

In our study, we assessed flap thickness with the Bioptigen SDOCT intraoperatively, ie, after creation of the flap but prior to lifting for ablation of the stromal bed. Studies reported in the literature have assessed intraoperative predictability of flap thickness created with the femtosecond laser using ultrasound subtraction pachymetry,[33] where the flap thickness is indirectly derived from the difference in corneal thickness measured prior to creation of the flap and after lifting the flap. However, this method has its limitations as time-dependant hydration changes can occur in the corneal stroma. Anterior segment OCT has also been used to determine the flap thickness at various time intervals (1 day to 6 months) after surgery for both microkeratome- and femtosecond laser–created flaps.[6,21] Scans on anterior segment OCT have to be taken in a seated position and hence intraoperative measurement is not possible. Postoperative edema of the flap as well as the stromal bed may make the subsequent measurements less accurate. Systematic changes in flap thickness up to 1 week and bed thickness up to 3 months have also been reported.[21] The hand-held Bioptigen SDOCT thus offers a distinct advantage for accurate assessment of flap thickness as the measurements are done immediately after creation of the flap, so that flap or stromal bed changes have not yet occurred. Accurate intraoperative measurement of flap thickness (created either by femtosecond laser or microkeratome) could serve as an invaluable guide to the surgeon who can alter the stromal bed ablation parameters if significant deviation in the flap thickness is noted. This would be especially useful in cases with relatively thinner corneas where excess ablation, with an inadequate stromal bed thickness, could increase the risk of postoperative LASIK ectasia.

A limitation of the study was that as the images were acquired intraoperatively, multiple measures were not possible. Also being a relatively new machine, the caliper tools of the Bioptigen need to be validated further in future studies.

The Bioptigen hand-held SDOCT can serve as a useful armamentarium in the hands of the refractive surgeon for the intraoperative assessment of flap characteristics and immediate modification of treatment parameters if required. The WaveLight FS200 femtosecond laser is able to produce flaps with a high degree of predictability between the desired and achieved flap thickness. Accurate intraoperative measurement of flap thickness (created by either femtosecond laser or microkeratome) can be an invaluable guide to the surgeon who can alter the stromal bed ablation if significant deviation in the flap thickness is noted. This will in turn translate into better LASIK outcomes and improved safety of the procedure.

AUTHOR CONTRIBUTIONS

Study concept and design (R.S., C.M., S.D.); data collection (C.M., S.D., K.W.); analysis and interpretation of data (R.S., C.M., S.D.); drafting of the manuscript (R.S., C.M., S.D.); critical revision of the manuscript (K.W.); statistical expertise (C.M., S.D.); administrative, technical, or material support (R.S., K.W.); supervision (R.S.)

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