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Cornea and cataract surgery

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ORIGINAL RESEARCH

Digital analysis of flap parameter accuracy and objective assessment of opaque bubble layer in femtosecond laser-assisted LASIK: a novel technique

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Video abstract

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Background: The purpose of this study was to determine flap parameter accuracy, extent of the opaque bubble layer, and incidence of skip lines in femtosecond laser-assisted stromal in situ keratomileusis (LASIK) using the WaveLight® FS200 laser and optoelectronic clinical measurements.

Methods: Images from 101 flaps were automatically recorded during consecutive routine LASIK procedures performed using the WaveLight FS200 femtosecond laser and the EX500 excimer laser. Digital processing of these images was used to evaluate objectively the diameter of FS200-created flaps, by comparing planned versus achieved procedures and to evaluate the incidence and extent (area) of the opaque bubble layer.

Results: The intended flap diameters were between 8.00 mm and 9.50 mm. The achieved flap diameters showed extremely high precision, and were on average –0.16 ± 0.04 mm smaller for a 8.00 mm intended flap diameter, –0.12 ± 0.03 mm smaller for a 8.50 mm flap, and up +0.06 ± 0.06 mm wider for a 9.50 mm flap. With an average flap area of 72.4 mm², the mean area of the opaque bubble layer (4.1 ± 4.3 [range 0–14.34] mm²) corresponded to a 6% opaque bubble layer-to-flap area. Specifically, 80% of the femtosecond-created flaps had an essentially zero opaque bubble layer (<2.7% of the flap area).

Conclusion: In our clinical experience, flaps created using FS200 and this novel highly objective assessment technique demonstrate both precision and reproducibility. The incidence of opaque bubble layer was minimal.

Keywords: femtosecond laser precision, bladeless laser-assisted stromal in situ keratomileusis, corneal flap diameter, opaque bubble layer, skip lines, WaveLight FS200

Introduction

There has been almost a decade of continuous improvement since the introduction of the near-infrared Nd:glass ultrashort pulse (100×10^{-15} second) laser, known as the femtosecond, as a tool for creating flaps for the laser-assisted stromal in situ keratomileusis (LASIK) procedure.[1] The laser light, due to its near-infrared wavelength (1.053 µm), has little interaction with the corneal surface (unlike the ultraviolet wavelength of excimer lasers), and thus can propagate through the corneal tissue. However, the concentrated energy per pulse when properly focused inside the corneal stroma can generate local ablation and a small amount of microplasma, which results in microscopic cavitation and gas bubbles; proper arrangement in a raster form of a large number of tightly spaced (eg, less than 8 µm apart) consecutive bubbles is the principle of femtosecond laser flap creation.[2,3]

Novel methodology for calculation of flap parameters

Initially, an image was captured with a calibrated millimeter scale and a dedicated disposable applanation cone. Based on the scale established by a 10 mm reference, the cone diameter was calculated as 13.414 mm, which corresponds to the data for diameter provided by the manufacturer. To account for variation in size of the disposable applanation cone, 20 random cones were selected and measured using a mechanical micrometer-precision caliper. Measured mechanically, the average cone diameter was 13.415 ± 0.01 µm, confirming the accuracy of the internal camera imaging application.

Flap dimensions and area determination

The pixel to mm conversion scale was established to be 0.0453 mm/pixel for the horizontal meridian, on the horizontal plane, along the nasal-temporal line (0–180 degrees, Figure 1). For the vertical meridian, on the coronal plane, along the superior–inferior line (90–270 degrees) the conversion scale was established to be 0.047 mm/pixel. This difference is attributed to a consistent compression ratio difference of the internal camera imaging optics. For the vertical meridian measurements, a virtual extension of the radial shape was assumed, ignoring deviation from the circular shape due to the canal.

The designated flap parameters were imported from the patient's image file, as shown in Figure 2. The images were uploaded in Adobe Photoshop CS5 version 12.04 (Adobe Systems Inc, San Jose, CA, USA). Pixel dimensions were determined using the "elliptical marquee tool" option set to "fixed size". For example, a 296 × 285 elliptical marquee can be used to fit fully with the border of a 13.41 × 13.41 mm cone.

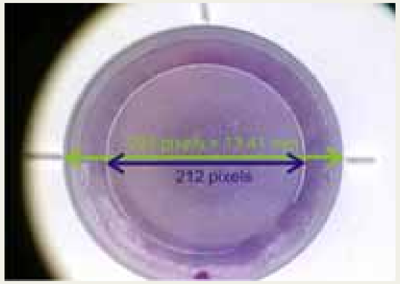

Figure 1 Image showing calibrated cone and flap.
Notes: Green arrow corresponds to applanation cone 13.41 mm across, as calculated previously. Blue arrow corresponds to flap diameter. Based on the scale established, the flap diameter was calculated to be 9.56 mm. This flap has no opaque bubble layer and no skip line.

Flap size was determined by selecting the elliptical marquee to match the size of the virtual circle that defines each slide, which is typically circular (see Figure 2, in which the flap was designed to be elliptical, ie, two different diameters, 8.50 mm and 8.00 mm). Conversely, using the established pixel to mm conversion scale, the pixel size of each flap dimension was converted to mm units. The pixel size for width was used to measure the horizontal dimension, and the pixel size for height was used to measure the vertical flap dimension (assuming an uninterrupted circular shape). Likewise, the "histogram tool" report was read to establish the flap area (assuming an uninterrupted circular shape) in pixels, which is subsequently converted to metric units (mm²).

Determination of OBL dimensions and area

The OBL area was measured using the Magic Wand tool, whereby the area within the flap with "white" more than 50% was selected (Figure 3). Likewise, the pixel area was determined by the histogram tool, with conversion in mm². The percentage of the OBL to total flap area, as determined in the previous step, was then computed.

Determination of skip line incidence

Determination of the presence of a skip line was made when at least five consecutive "comb" lines were determined to be present in the flap area.

Statistical analysis

Linear regression analysis was used to seek possible correlations between intended and achieved flap dimensions. Descriptive statistics (average, minimum, maximum, standard deviation, and range), comparative statistics, and linear regression were performed in Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA, USA) and OriginLab version 8 (OriginLab Corp, Northampton, MA, USA). Analysis of variance between groups was performed using the Origin Lab statistics tool.

Results

Of the 101 flaps examined, the majority (n = 63) were intended to 8.50 mm in diameter, one 8.70 mm, and one 9.00 mm (Table 1).The intended versus achieved flap dimensions according to intended size is summarized in Table 4. As stated earlier, separate measurements were undertaken for the horizontal meridian (0–180 degrees) and for the vertical meridian (90–270 degrees). The overall correlation between intended versus achieved horizontal size is shown in Figure 4 ($P < 0.0001$), while the correlation between the

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Figure 2 Patient documentation file showing a rare example of an elliptic flap intended for correction of astigmatic myopia.
Notes: There are two diameters, namely 8.5 mm horizontal meridian (0–180 degrees) and 8.00 mm for the vertical meridian (90–270 degrees). This flap has no opaque bubble layer or skip line, and in this respect represents the majority of cases in our study.

intended versus achieved vertical size is shown in Figure 5 ($P < 0.0001$).

Because of the nature of the measurements involved, ie, a grouped set of data, difference plots were drawn to demonstrate specific bias between the intended versus achieved size. A Bland-Altman plot for the intended versus achieved horizontal size is shown in Figure 6, and the intended versus achieved vertical size is shown in Figure 7. A study of measured bias (difference of achieved vs intended diameter) is presented in Figure 8.

The incidence of OBL (Table 2), was measured to have a mean area of 5.8% (minimum 0%, maximum 20.3%). No significant variation was found between OD and OS eyes (Table 3). Of the 101 flaps examined, 31 showed no OBL.

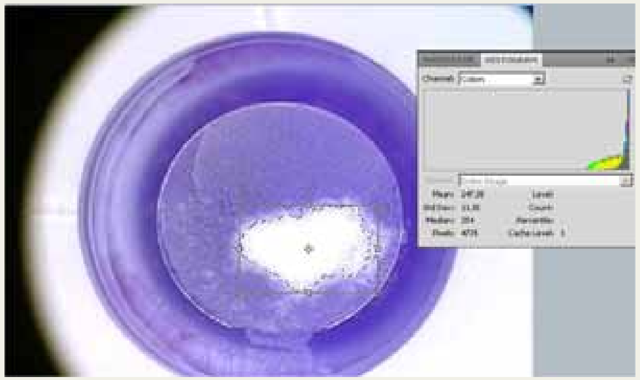

Figure 3 Methodology for measurement of opaque bubble layer area.
Notes: The area within the flap with white more than 50% is selected with the Magic Wand tool. The pixel area is determined by the histogram tool, and subsequently converted to metric units. This is the maximal opaque bubble layer encountered in our study in a minority of cases, not exceeding 20% of the flap surface.

Table 1 Intended diameters of the flaps studied

Flap intended diameter (mm)	n
7.5	0
8.0	19
8.5	63
9.0	2
9.5	17

A histogram for incidence of OBL is shown in Figure 9. Of the 101 flaps examined, nine (8.91%) showed a noticeable skip line.

Discussion

Accuracy and precision of flap size

Despite an excellent overall correlation between intended and achieved flap size (Pearson's $r^2 = 0.96$; $P < 0.001$ for the horizontal and $r^2 = 0.997$; $P < 0.001$ for the vertical meridian), there was a very small bias between intended and achieved flap size, independent of the meridian (vertical or horizontal) but related to the indented flap diameter. Specifically, for the small flap size (diameter 8.00 mm), the mean achieved flap diameter was minimally smaller, ie, for the horizontal diameter 7.85 ± 0.04 (range 7.93 max–7.80 min) mm and for the vertical diameter 7.83 ± 0.03 (range 7.87 max–7.80 min) mm. Therefore, precision as indicated by the standard deviation was found to be between ±0.04 and ±0.03 mm. Accuracy, as determined by the bias related to the intended flap size was also impressive at –0.15 and –0.17 mm, respectively, for the horizontal and vertical diameters. No variation was noted between OD and OS eyes, which further confirms the accuracy of these findings (Table 3). As shown in Figure 8, accuracy and precision was similar for the 8.50 mm flap diameter. Specifically, the bias was –0.12 mm (mean 8.38 ± 0.03 [range 8.43 max–8.34 min] mm for the horizontal diameter and 8.39 ± 0.02 [range 8.41 max–8.34 min] mm for the vertical diameter), and was also insignificant for the 8.70 mm and 9.00 mm flaps, although there were just two cases with these intended numbers. In regard to the largest flap size (9.50 mm), this small bias became positive. Specifically, the average achieved diameter was 9.56 ± 0.00 mm for the horizontal diameter and 9.53 ± 0.03 mm for the vertical diameter.

However, it is noted that in a similar study[12] involving porcine cadaver eyes and the prototype 200 kHz femtosecond laser UltraFlap (WaveLight GmbH, Erlangen, Germany), the successor of which is the FS200 femtosecond laser (Alcon, Fort Worth, Texas), a positive bias of approximately +0.03 to +0.06 mm was found for all flap diameters, and the flap diameter precision was found to correspond to a larger standard deviation (±0.10 to ±0.15 mm). This wider uncertainty may be attributed to the fact that the study was conducted using mechanical measurements (sliding caliper). Thus, we introduce this novel technique as a new benchmark for evaluating flap dimensions in LASIK. In another recently published study that examined the predictability of dimensions for flaps

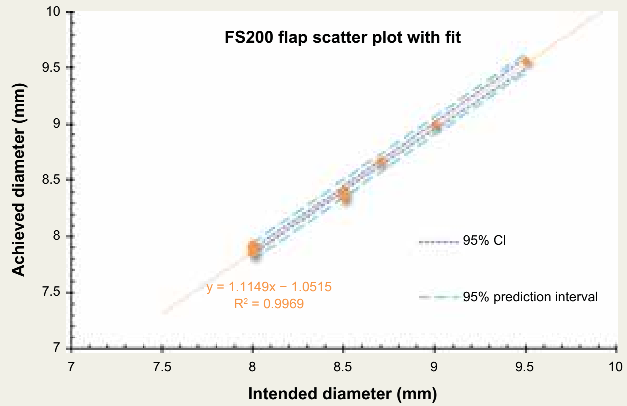

Figure 4 Overall correlation between intended versus achieved horizontal flap size.
Notes: The linear fit regression line and coefficient of linearity determination (R^2) are shown. The 95% CI and 95% prediction interval lines are also plotted.
Abbreviation: CI, confidence interval.

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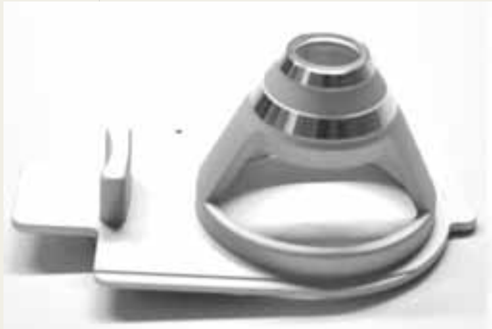
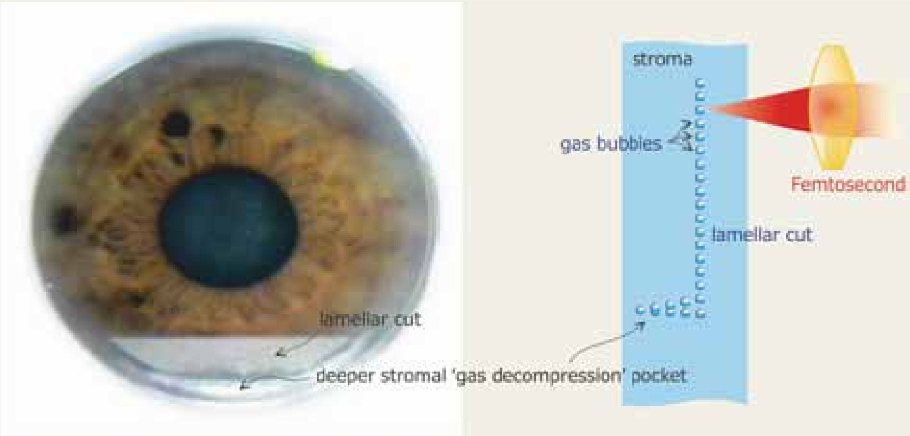
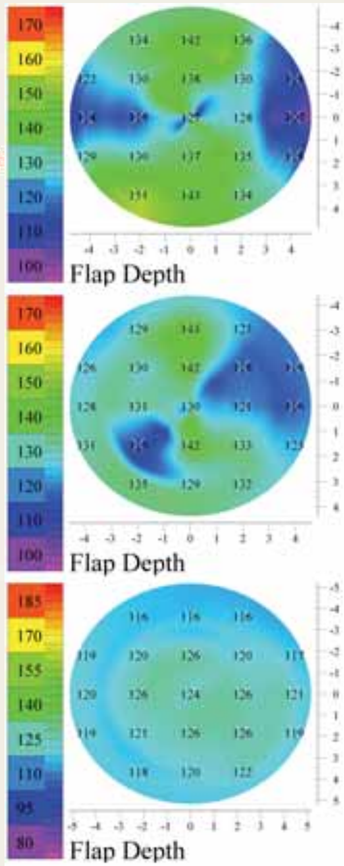
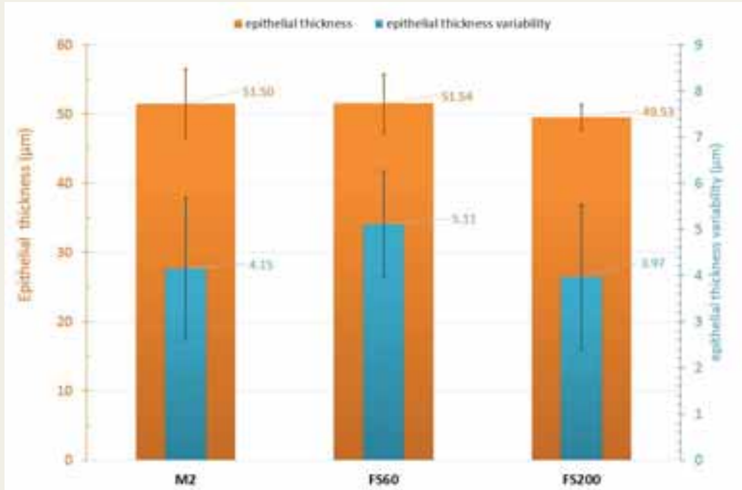
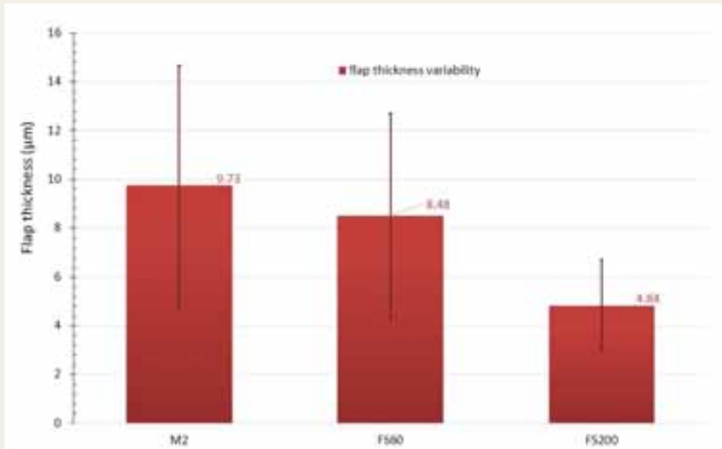


High Frequency Ultrasound comparison of topographic central, paracentral and peripheral LASIK flap thickness variability, in flaps created by a mechanical microkeratome (M2) and two different femtosecond lasers (FS60 and FS200).









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Conclusions:

1-cataract
2-DSAEK
3-PK
4-DALK
5-AK
6-refractive surgery-LASIK