Novel model of digitized clinical validation of femtosecond LASIK flap parameters and Opaque Bubble Layer (OBL) occurrence

ASCRS, San Francisco 2013

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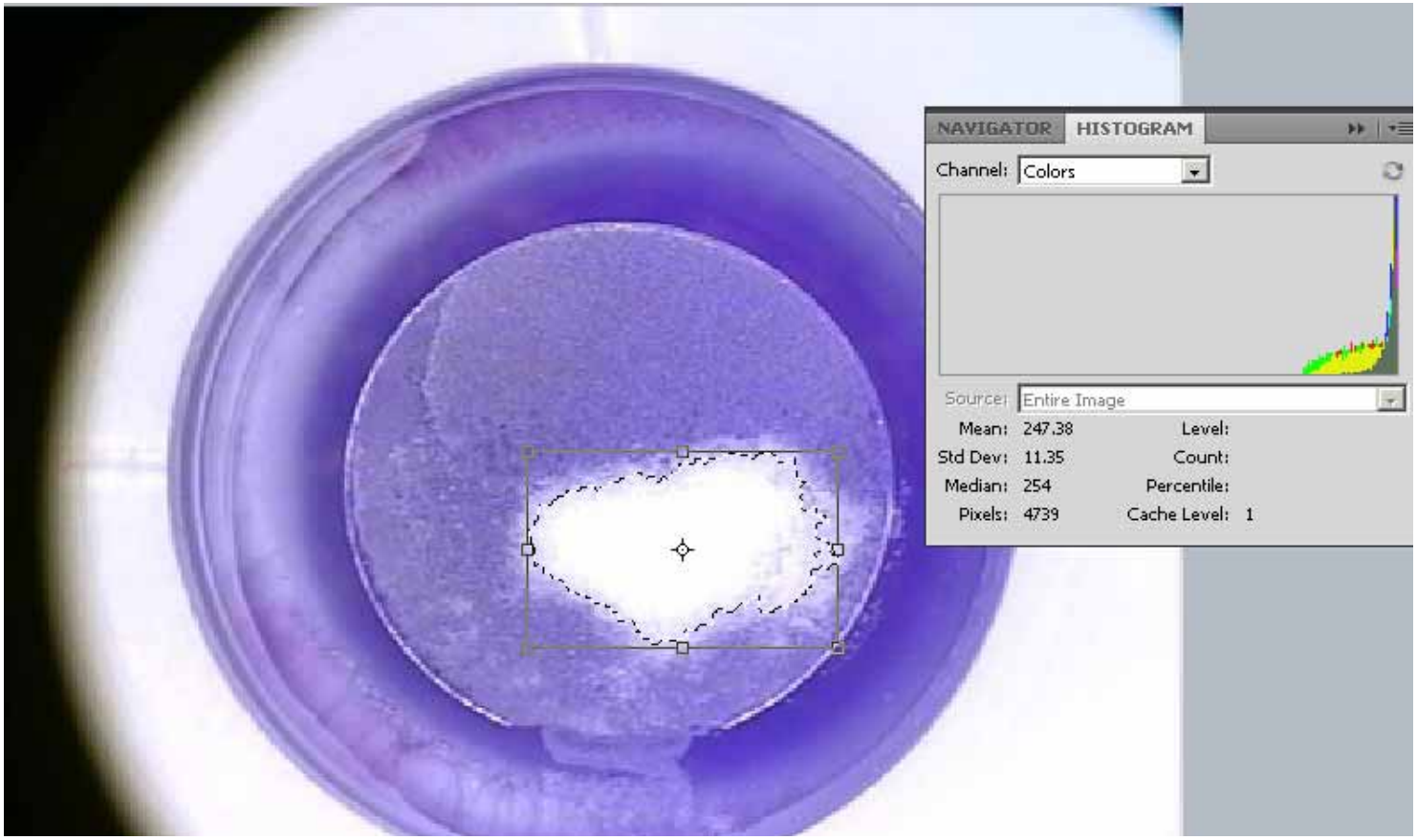
Financial Interests: I. Kontari: None
A. J. K: Consultant for Alcon, Avedro

Objective:

- To digitally, objectively, and investigator-bias free measure achieved flap diameter and opaque bubble layer extent
- Only the jpeg report provided b the FS200 at the end of the procedure will be proccessed seamlessly through this software for objective flap parameter and OBL measurement
- This project is based on our previous published work on setting a new flap measurement benchmark for femtosecond-assisted LASIK


Results:

- For the 206 myopic flaps intended diameter was 8mm and achieved 7.95 mm (+/-012); For the 52 hyperopic flaps, intended diameter was 9.5mm, and achieved 9.52mm (+/-0.08). 60% had no OBL, 35% had under 2% surface area OBL and 5% had up to 20% of surface OBL.



Initial flap image-imported to the software

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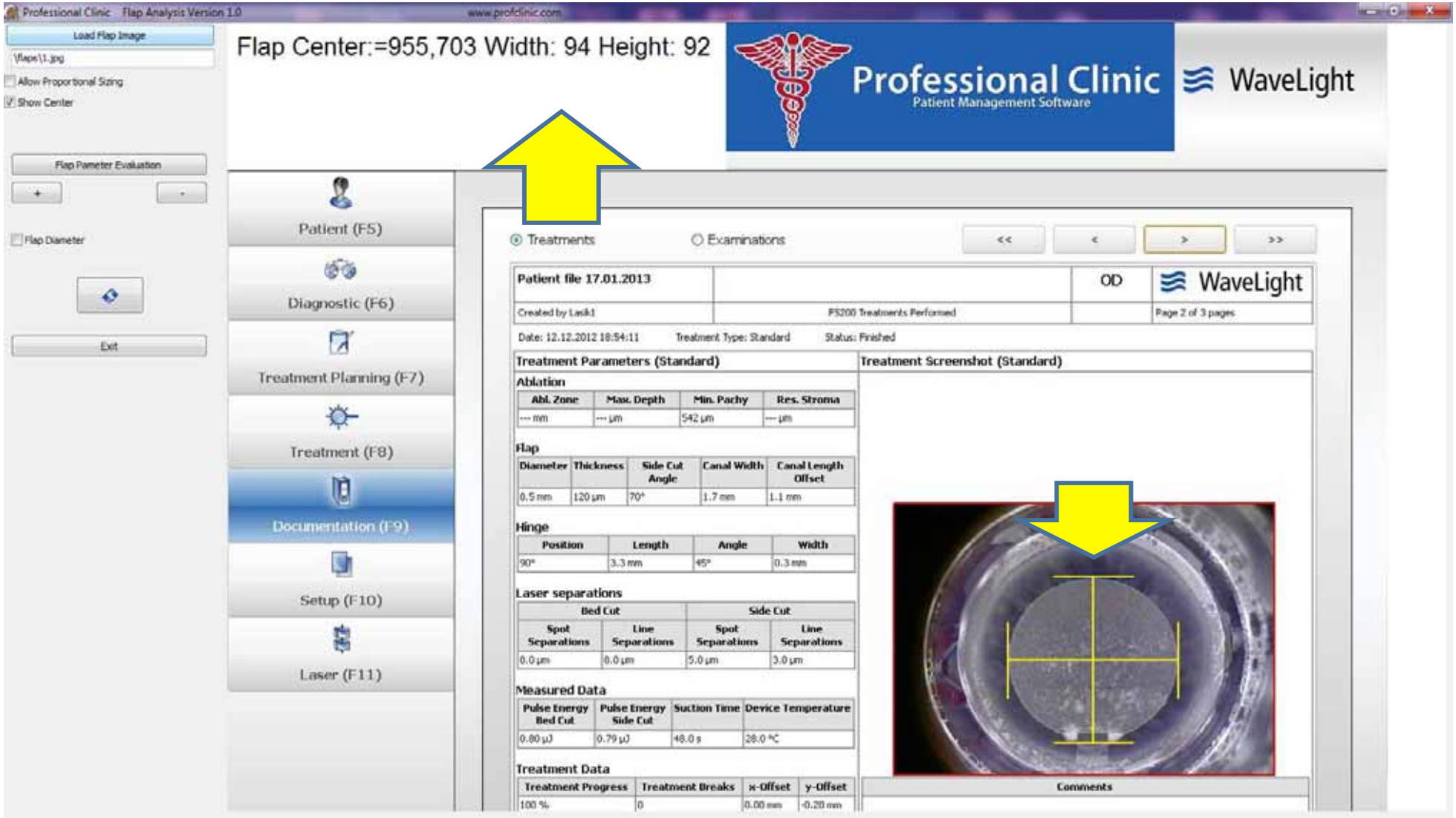
Step-1: Flap diameter objective determination
free from inter-examiner and intra-examiner potential bias
there is no examiner handling of patient privacy-sensitive data



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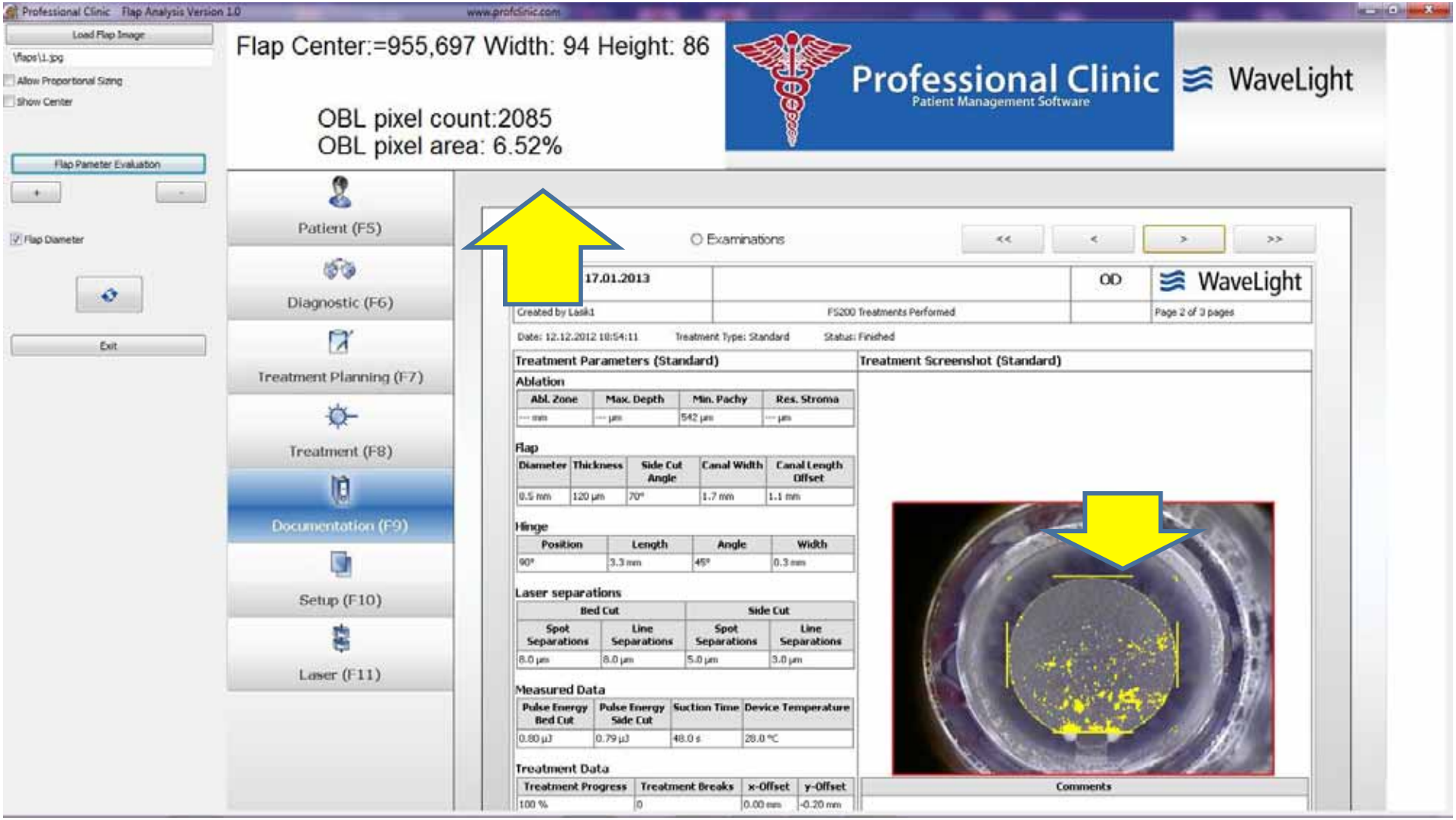
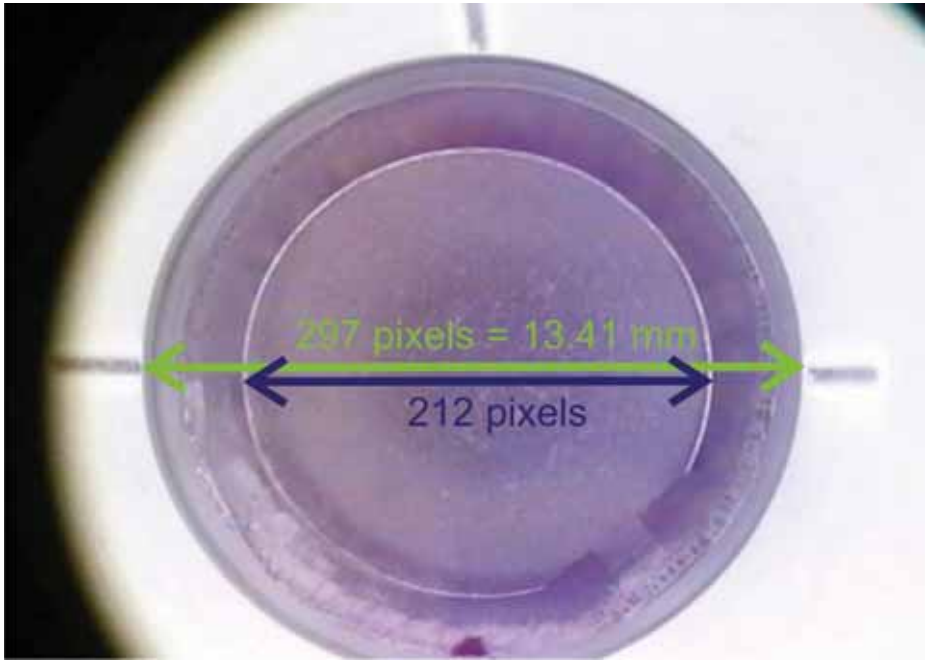
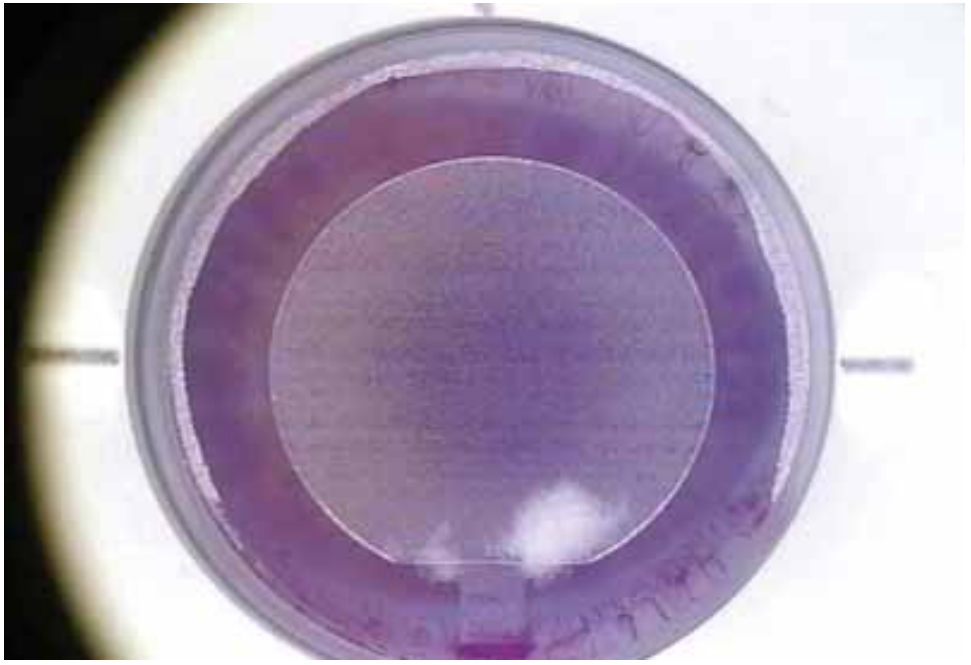
Step 2: OBL extent determination in relation to the actual flap surface achieved calculated in step 1



Introduction:

The evaluation of the safety and accuracy of flap parameters and OBL occurrence in femtosecond LASIK



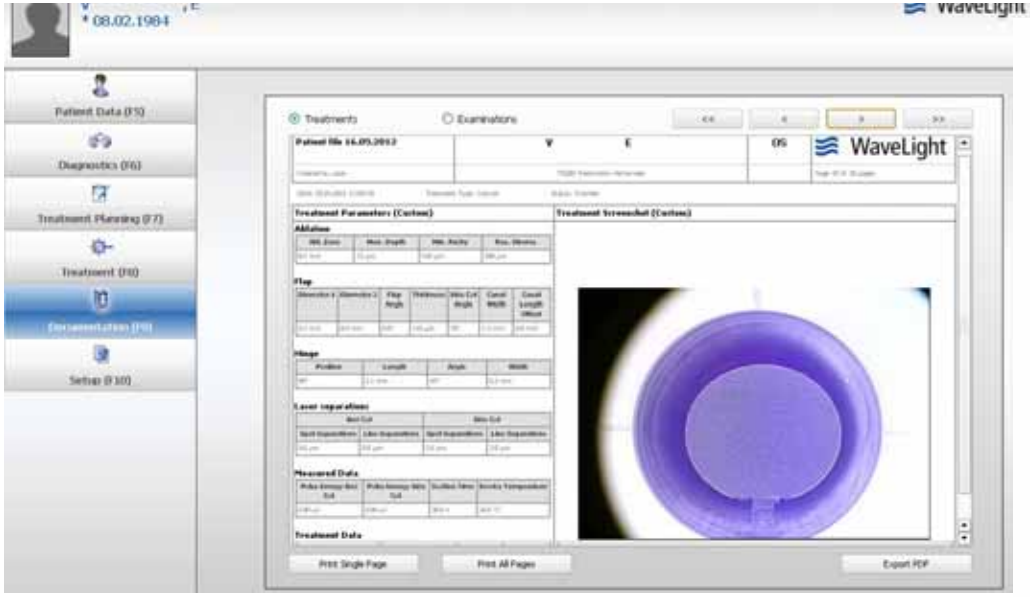


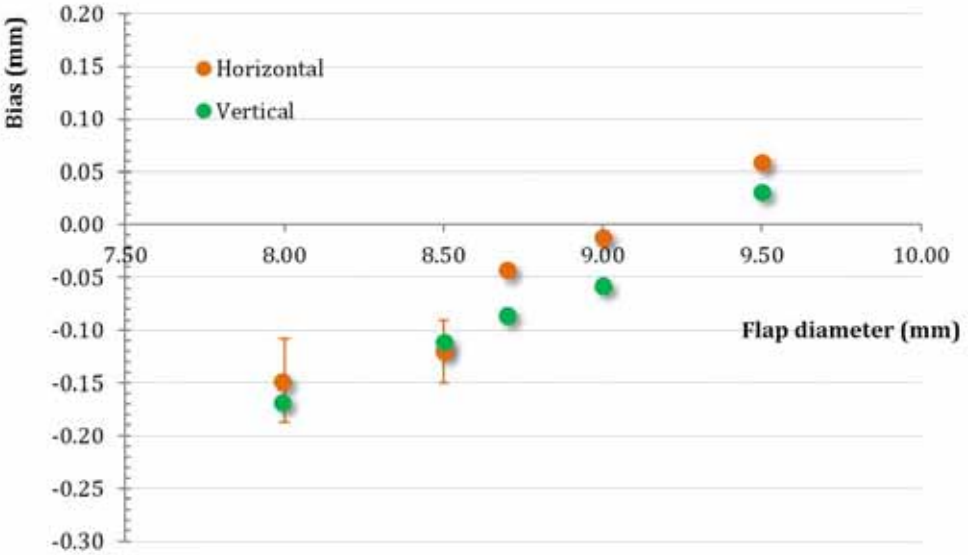
Methods:

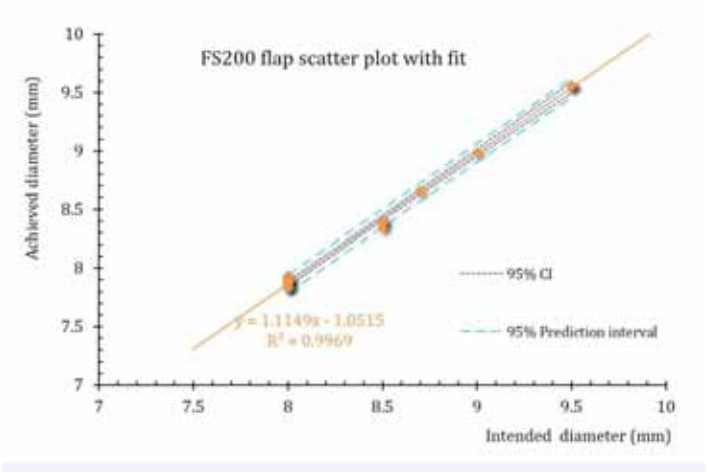
- 139 consecutive myopic and hyperopic LASIK patients were treated with the Alcon/Wavelight: 500Hz excimer and the FS 200 femtosecond lasers. Peri-operative refractive error, visual acuity, keratometric, topographic, flap dimensions and OBL were evaluated both intra-operatively as well as postoperatively utilizing a proprietary macroprocedure on a commercially available image processing software: the flap creation report image provided by the FS200 was analyzed digitally and calibrated on a scale converting pixels to mm. In a similar fashion, OBL occurrence was measured as a percentage of the actual flap surface area. Mean follow-up of 25 months (21-37).

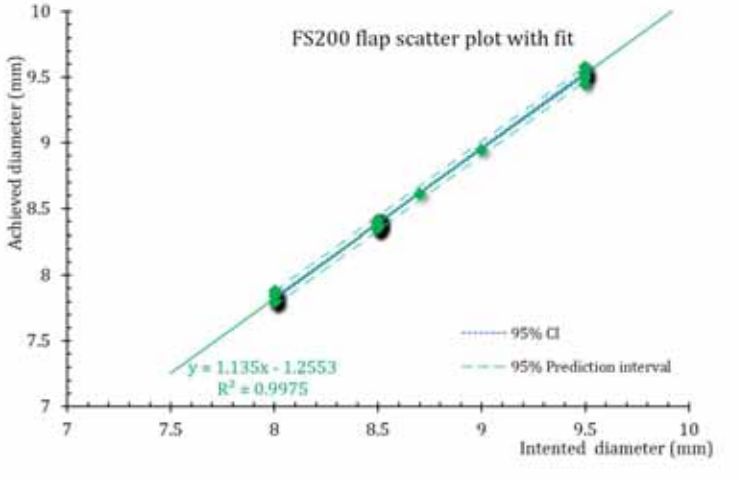
results

- Of the 101 flaps examined, as shown in Table 1, the majority (63) were intended to 8.50 mm diameter, while 19 were intended to have 8.00 mm diameter, one (1) 8.70 mm, one (1) 9.00 mm, and 17 to 9.50 mm diameter.
- As stated in the Methodology section, separate measurements were undertaken for the horizontal meridian (0° – 180°) and for the vertical meridian (90° – 270°). Overall correlation between horizontal intended vs. achieved size is shown in Figure 4 ($p < 0.0001$), while the correlation between the vertical intended vs. achieved size is shown in Figure 5 ($p < 0.0001$).
- Due to the nature of the measurements involved, ie grouped set of data, difference plots were drawn to demonstrate specific bias between intended vs. achieved size. Bland-Altman plots for the horizontal intended vs. achieved size is shown in Figure 6, and for the vertical intended vs. achieved size is shown in Figure 7. Specific per intended diameter study showing bias is presented in Figure 8.
- The OBL incidence was measured to have mean area 5.8%, standard deviation 6.32%, minimum 0%, and maximum 20.3%. No significant variation was found between OD and OS eyes (Table 3). Of the 101 flaps examined, 31 had absolutely no OBL presence. The histogram of OBL incidence is shown in Figure 9.
- Finally, of the 101 flaps examined in nine (9), corresponding to 8.91%, had noticeable 'burp' line incidence.









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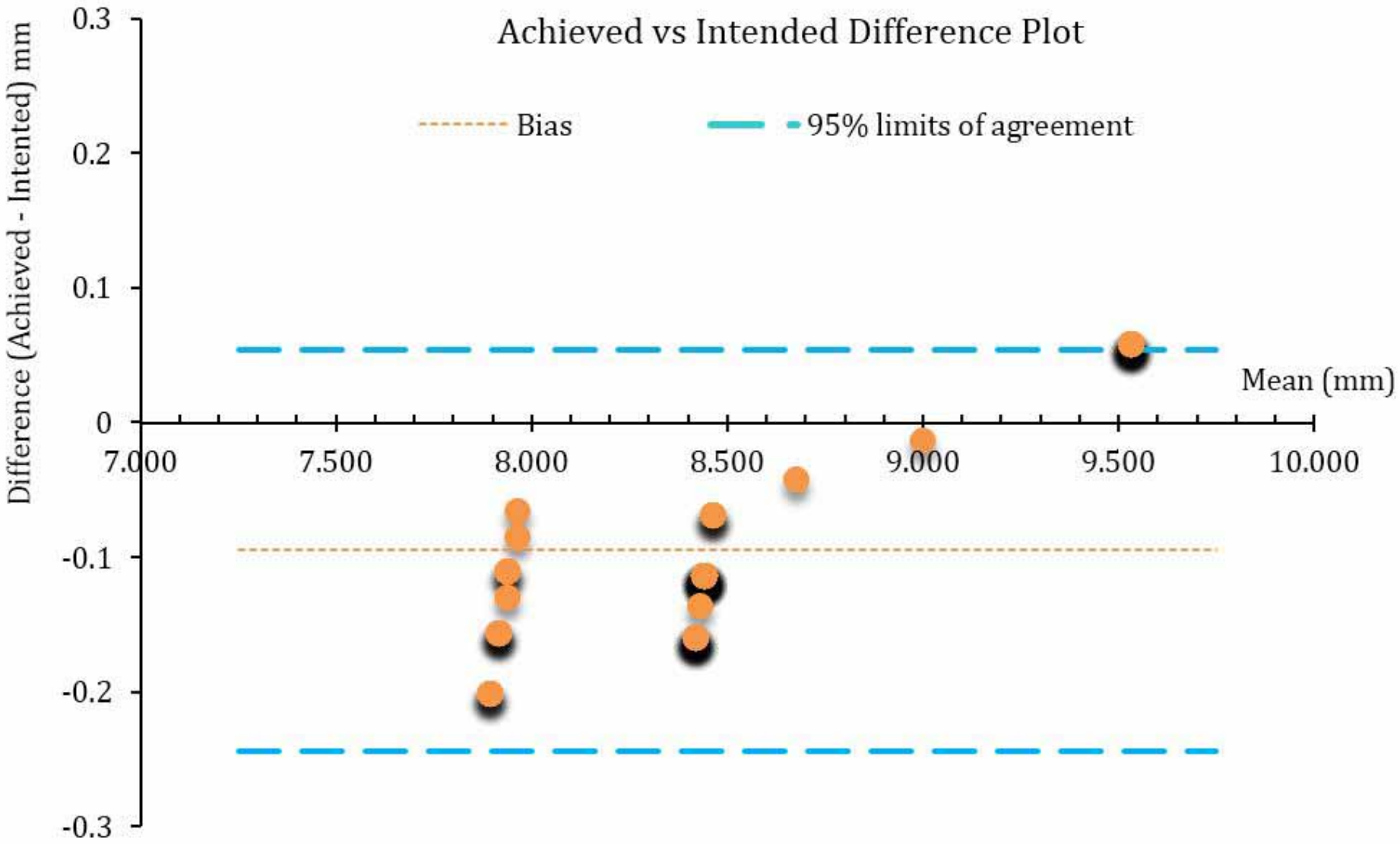

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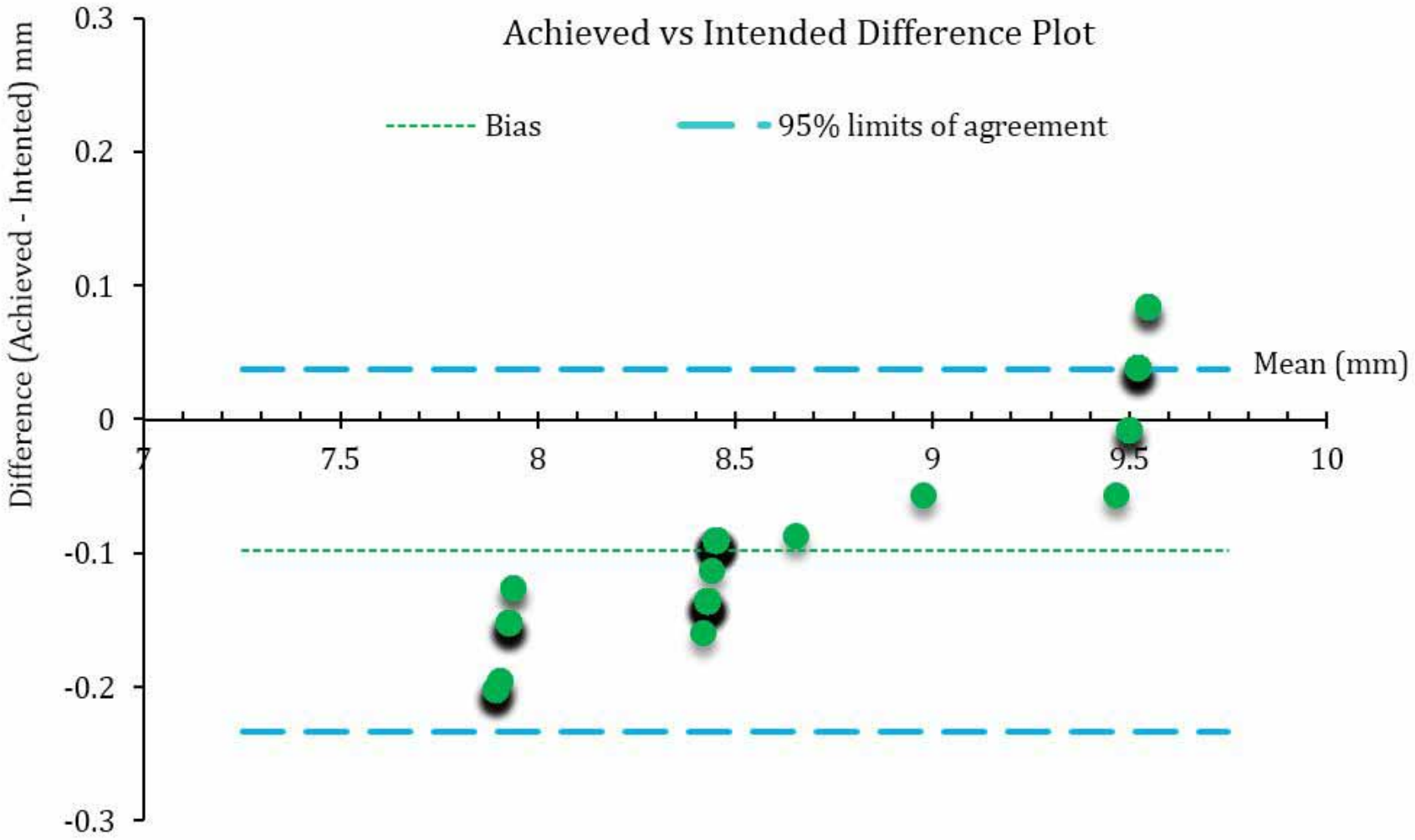
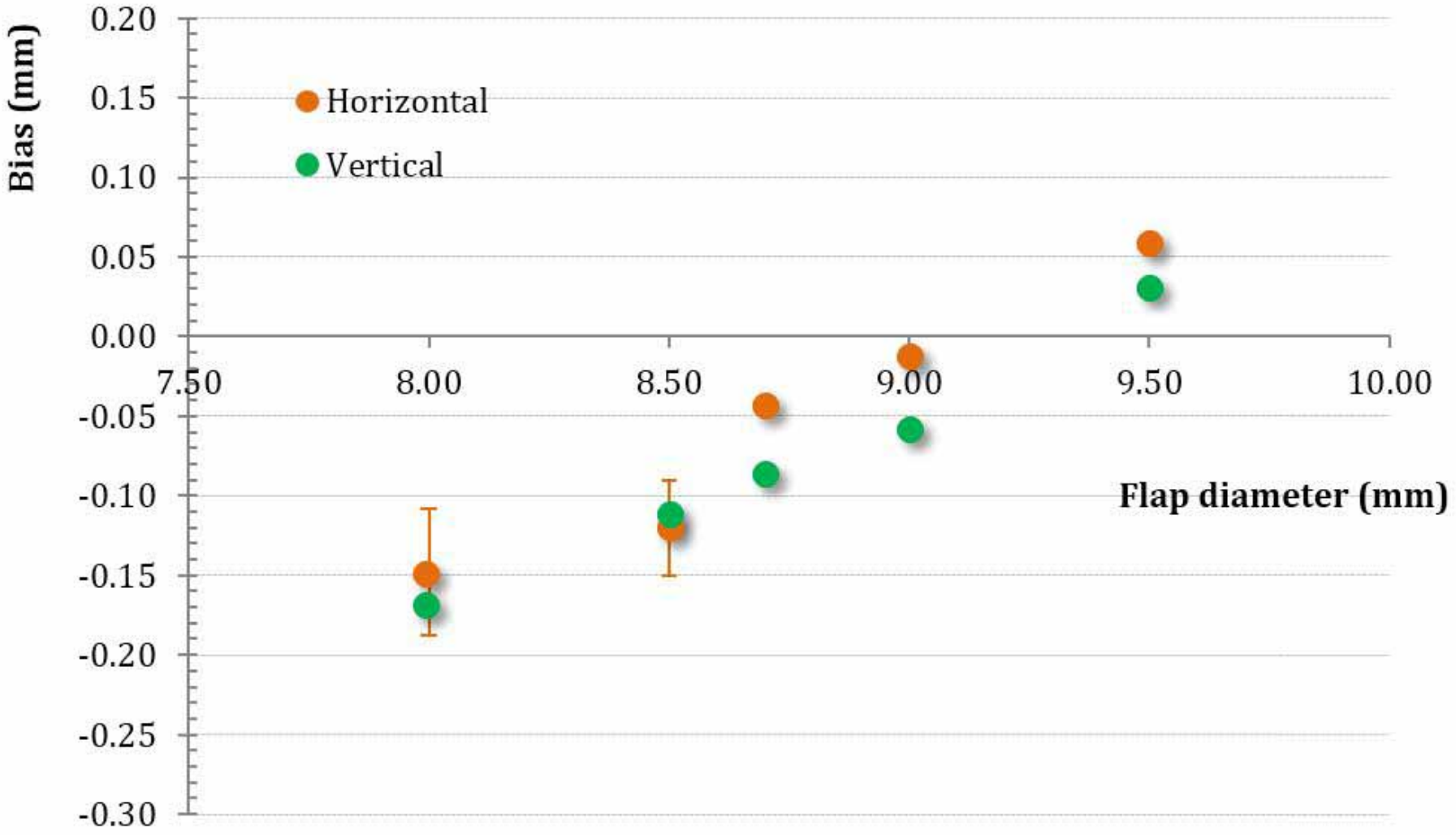

Achieved vs Intended Difference Plot
Bias
95% limits of agreement
Difference (Achieved - Intented) mm
0.3
0.2
0.1
0
-0.1
-0.2
-0.3
7
7.5
8
8.5
9
9.5
10
Mean (mm)



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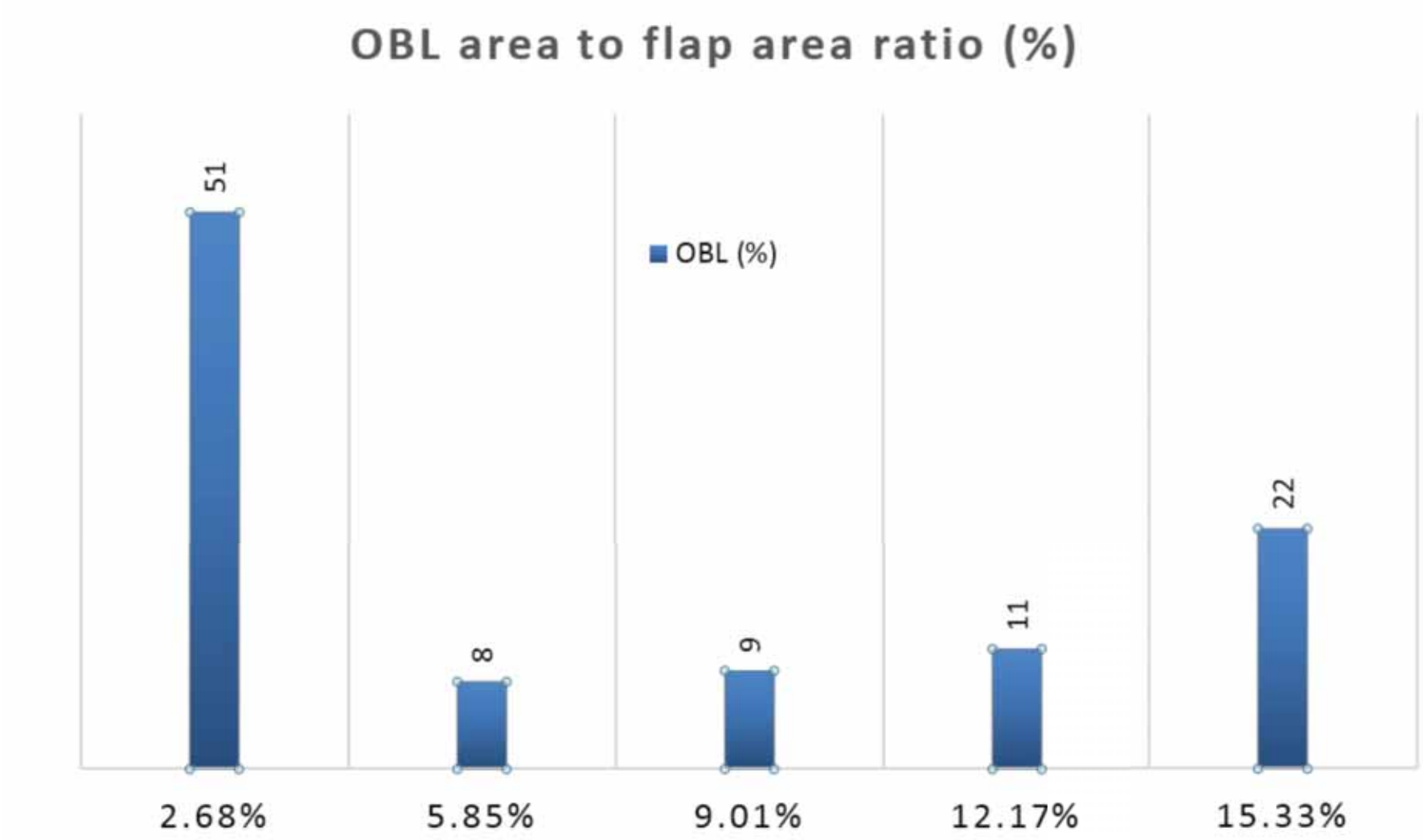

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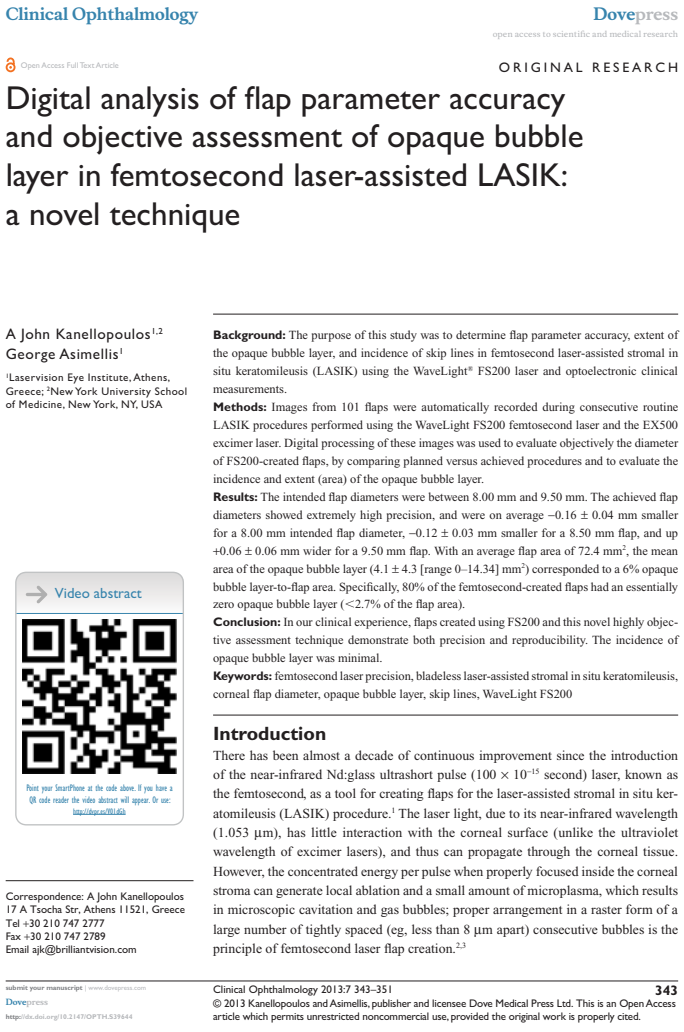
Conclusions:

- This novel validation model is very easy to perform and confirms the high reproducibility in flap parameters and small occurrence of OBL in both myopic and hyperopic LASIK cases with this femtosecond laser.
- Our study indicated an astounding accuracy (less than -0.12 mm, up to +0.06 mm) on the flap creation with the FS200 femtosecond laser. Flap precision was also outstanding in all groups with the most precise flaps being, those intended for 9.5 mm (± 0.00 mm to ± 0.04 mm for the horizontal and vertical meridian).



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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 mm^2, the mean area of the opaque bubble layer (4.1 ± 4.3 [range 0–14.34] mm^2) 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]

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ORIGINAL RESEARCH

Essential opaque bubble layer elimination with novel LASIK flap settings in the FS200 Femtosecond Laser

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Background: The purpose of this study is to evaluate the extent and incidence of opaque bubble layer (OBL) using laser-assisted in situ keratomileusis (LASIK) flaps created with the Alcon/WaveLight® FS200 femtosecond laser as a result of a recent change in flap programming parameters aiming to reduce further the incidence and extent of OBL.

Methods: Intraoperative digital images of flaps from 36 consecutive patients (72 eyes) subjected to bilateral femtosecond-assisted LASIK were analyzed using a proprietary computerized technique. The incidence and extent of OBL was measured and reported as a percentage of the entire flap area. Flap creation was performed with a 1.7 mm wide canal, implemented as an updated design intended to reduce the extent of OBL (group A). The same OBL parameters were investigated and compared in an age-matched and procedure-matched patients in whom the previous standard setting of a 1.3 mm wide canal was implemented (group B).

Results: In group A, the average extent of OBL was 3.69% of the flap area (range 0%–11.34%). In group B, the respective values were 6.06% (range 0%–20.24%). We found the difference to be statistically significant (one-tailed $P = 0.00452$).

Conclusion: This study suggests that there is a significant reduction in the incidence and extent of OBL when novel LASIK flap ventilation canal parameters of width and spot line separation are used.

Keywords: femtosecond laser flap, bladeless laser-assisted in situ keratomileusis, opaque bubble layer, Alcon/WaveLight FS200, spot line separation

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Introduction

Formation of opaque bubble layer (OBL) during creation of a laser-assisted in situ keratomileusis (LASIK) flap is a finding unique to use of femtosecond laser.[1] OBL occurs along the lamellar dissection plane during the flap creation,[2] and can be described simply as temporary stromal infiltration by compressed air generated by the intracorneal femtosecond laser action, that cannot escape.[3]

Although no serious complications have been reported as a result of its occurrence, OBL may temporarily obscure the pupil image used by most excimer laser trackers, in the subsequent excimer ablation. It may also interfere with reading of architectural landmarks on the iris used by some excimer laser trackers to compensate for cyclorotation, and may even obscure the patient's fixation target.

The purpose of this study was to compare quantitative differences in the presence and extent of OBL in flaps created using the FS200 femtosecond laser with a recently introduced wider venting canal design, and tighter line separation parameters, versus the predecessor design.

Table 1 Incidence of opaque bubble layer, expressed as a percentage of total flap area, with comparative results for the wide and narrow canal groups

	Wide canal group	Narrow canal group
Eyes (n)	72	72
Mean OBL area	3.69%	6.06%
Standard deviation	3.78%	6.58%
Minimum	0.00%	0.00%
Maximum	11.34%	20.34%

OBL in group A (wide canal) was digitally measured to have a mean area of 3.69% ± 3.78%, where the percentage indicates the fraction of the OBL area with respect to the total flap area. The maximum OBL percentage was 11.3%, and the minimum was 0%. Of the 72 flaps examined, 27 had no OBL present (that is, OBL area 0%). The comparative OBL incidence metrics for both groups are presented in Table 1, and histogram data and box plots for the incidence of OBL in both groups are shown in Table 2 and Figure 2, respectively. The one-tailed *t*-test was performed because the results were expanding only in the positive direction, and yielded a value of $P = 0.00452$ between the groups.

Table 2 Comparative OBL histogram data, expressed as % fraction of total flap area for the two groups in the study

OBL area (% of total flap area)	number of cases	
	group A wide canal group	group B wide canal group
0%–2%	35	32
2%–4%	2	5
4%–6%	6	4
6%–8%	17	5
8%–10%	8	4
10%–12%	4	5
12%–14%	0	3
14%–16%	0	7
16%–18%	0	7
>18%		2

Discussion

Creation of a LASIK flap with a femtosecond laser is considered advantageous to microceratome[7,8] for a more centered, higher controlled-geometry, both in depth[9] as well as diameter.[10] In an earlier effort to validate the precision and accuracy of flap creation, we had introduced a quantitative digital analysis technique for accurate measurement of flap diameter and extent of OBL for flaps created using the Alcon/WaveLight FS200 femtosecond laser during LASIK and prior to lifting of the flap.[10]

A major finding of this study was that OBL was rare and consistently of the "delayed" form, and that there was a "signature" of accumulation near the sides of the canal and towards the limbus (Figure 3). Our hypothesis to explain why

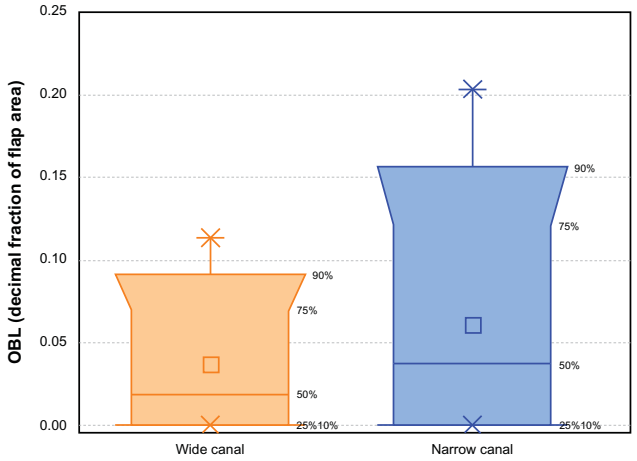

Figure 2 Box plots for OBL, expressed as fraction of the total flap area for the two groups, indicating the 99% point with the × sign, and the mean point with the sign.
Note: Vertical axis, range of extent of OBL as a fraction of total flap area.
Abbreviation: OBL, opaque bubble layer

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