FP 2873:

Digital analysis in flap accuracy and opaque bubble layer objective assesmenet in 100 cases of femto-assisted LASIK

ESCRS 2013

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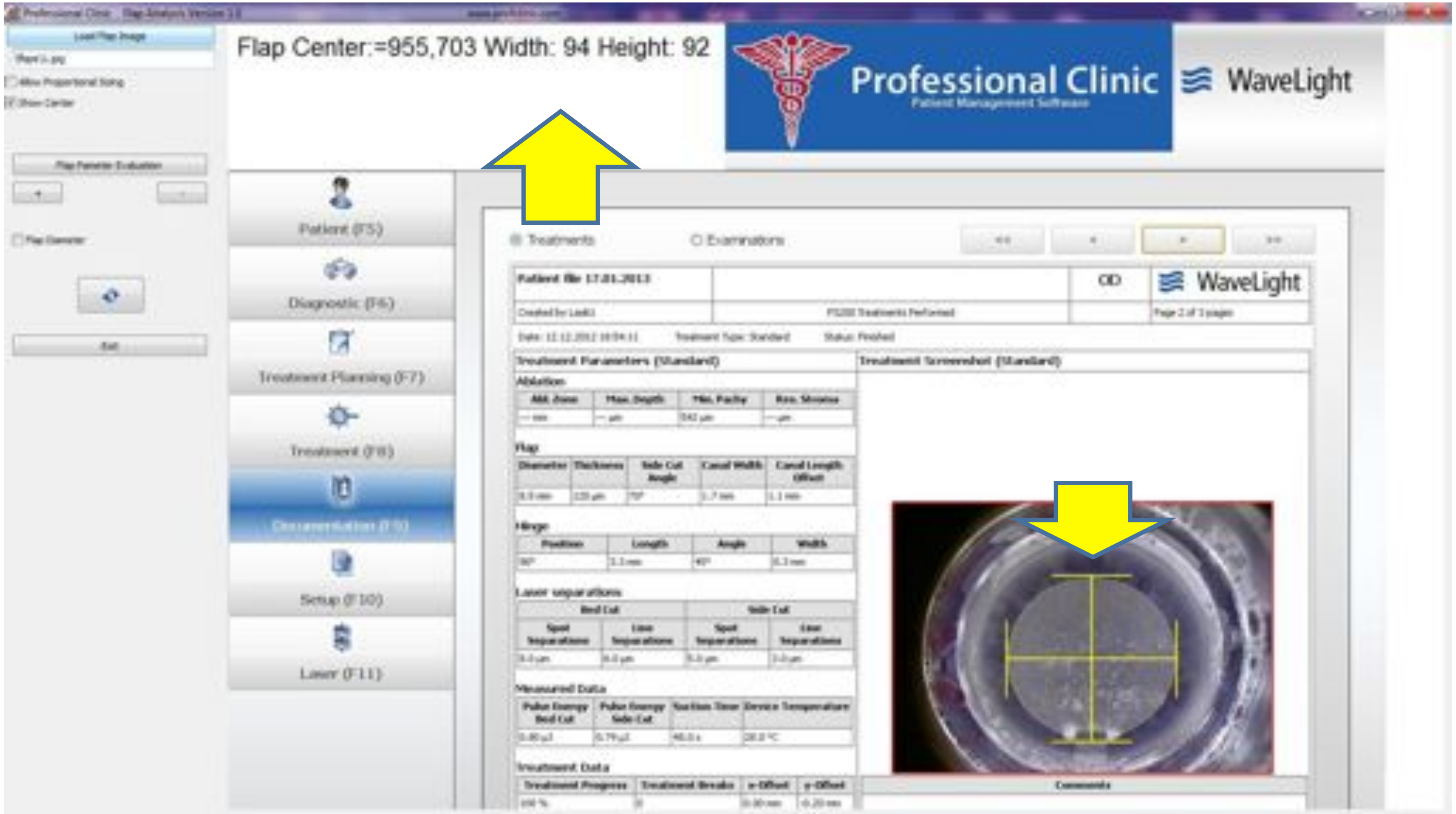
Step-1: Flap diameter objective determination
free from inter-examiner and intra-examiner potential bias
there is no examiner handling of patient privacy-sensitive data



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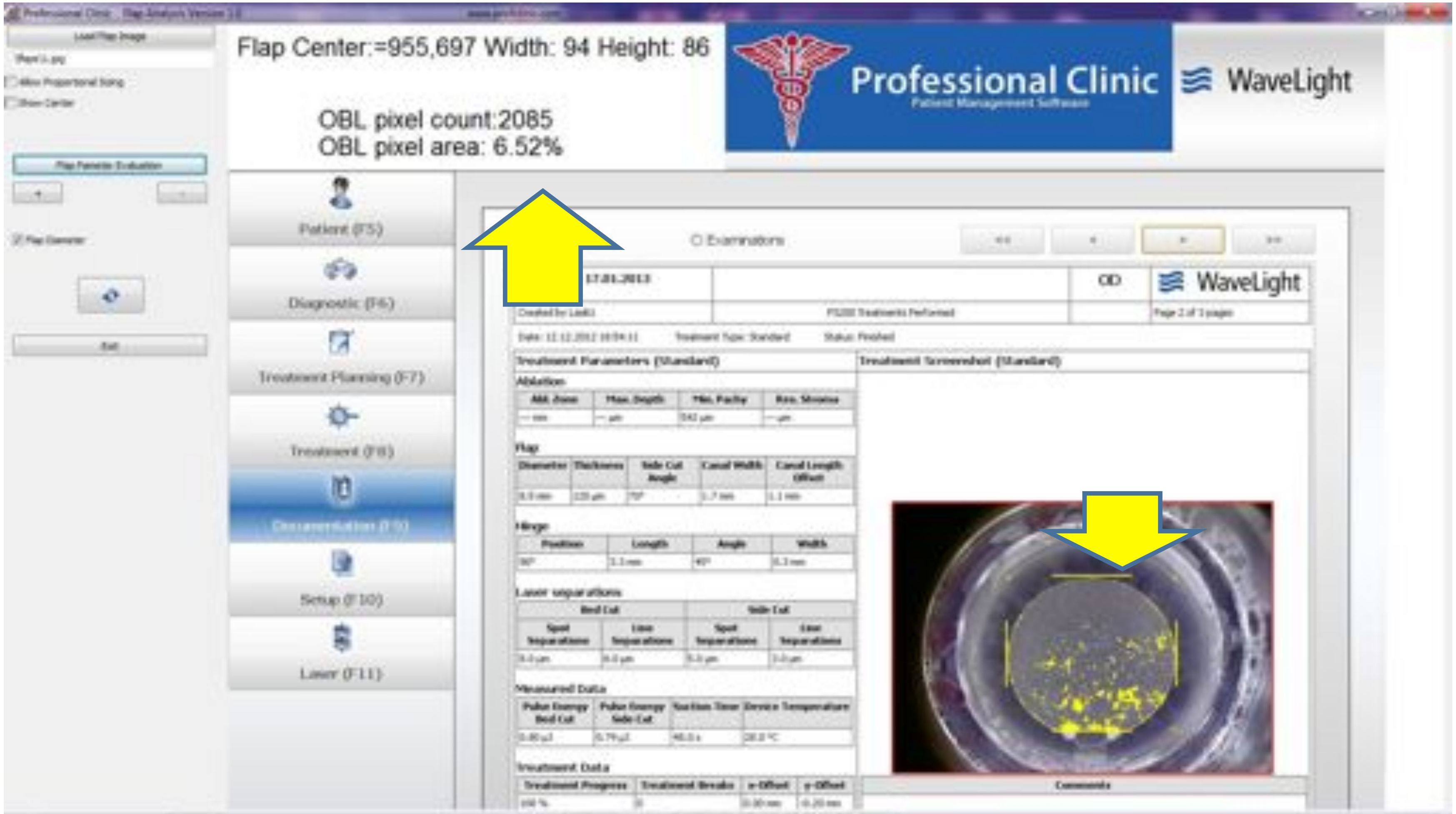
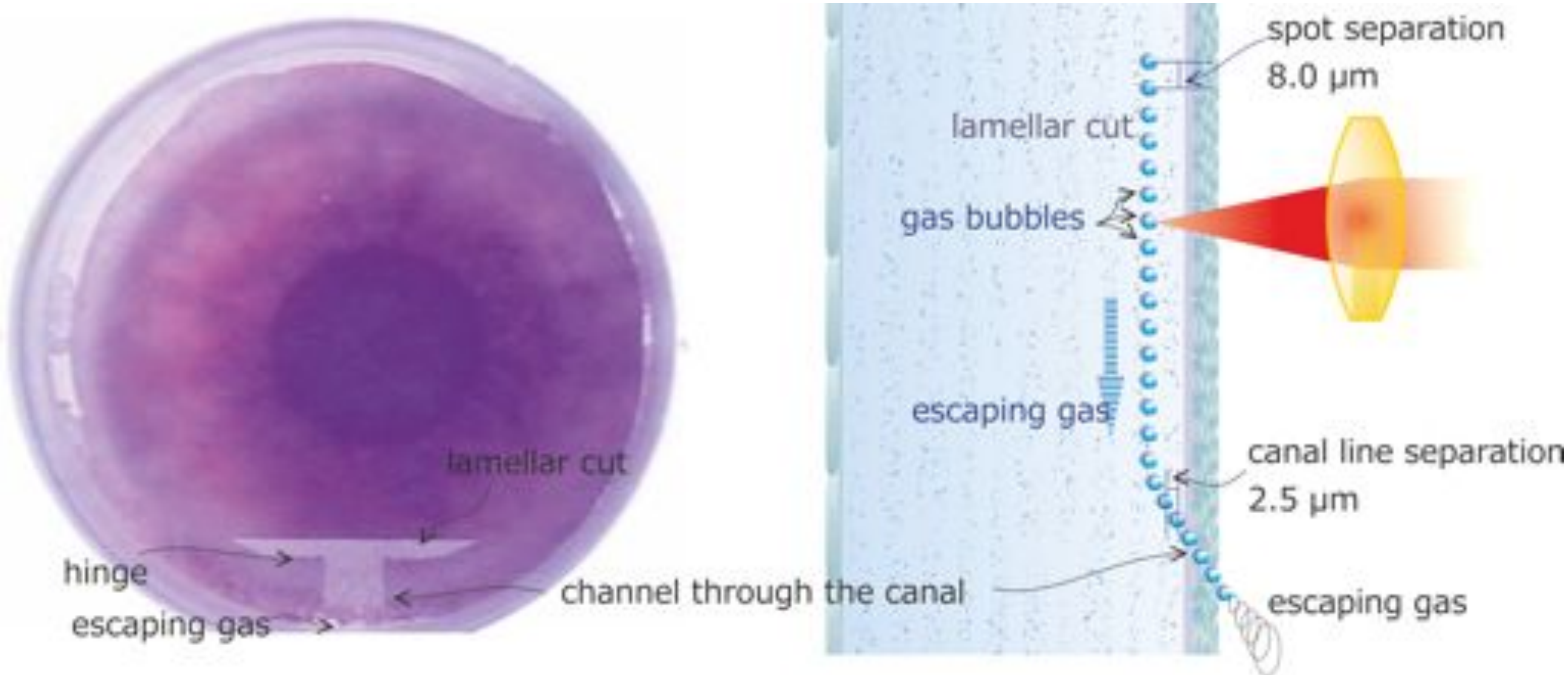
Step 2: OBL extent determination in relation to the actual flap surface achieved calculated in step 1



Are LASIK Flaps important?
Femto flap gas escape



Three-dimensional LASIK flap thickness variability: topographic central, paracentral and peripheral assessment, in flaps created by a mechanical microkeratome (M2) and two different femtosecond lasers (FS60 and FS200) J Clinical Ophthalmology, 2013

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ORIGINAL RESEARCH

Three-dimensional LASIK flap thickness variability: topographic central, paracentral and peripheral assessment, in flaps created by a mechanical microkeratome (M2) and two different femtosecond lasers (FS60 and FS200)

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Purpose: To evaluate programmed versus achieved laser-assisted in situ keratomileusis (LASIK) flap central thickness and investigate topographic flap thickness variability, as well as the effect of potential epithelial remodeling interference on flap thickness variability.

Patients and methods: Flap thickness was investigated in 110 eyes that had had bilateral myopic LASIK several years ago (average 4.5 ± 2.7 years; range 2–7 years). Three age-matched study groups were formed, based on the method of primary flap creation: Group A (flaps made by the Moria Surgical M2 microkeratome [Antony, France]), Group B (flaps made by the Abbott Medical Optics IntraLase™ FS60 femtosecond laser [Santa Ana, CA, USA]), and Group C (flaps made by the Alcon WaveLight® FS200 femtosecond laser [Fort Worth, TX, USA]). Whole-cornea topographic maps of flap and epithelial thickness were obtained by scanning high-frequency ultrasound biomicroscopy. On each eye, topographic flap and epithelial thickness variability was computed by the standard deviation of thickness corresponding to 21 equally spaced points over the entire corneal area imaged.

Results: The average central flap thickness for each group was 138.33 ± 12.38 μm (mean ± standard deviation) in Group A, 128.46 ± 5.72 μm in Group B, and 122.00 ± 5.64 μm in Group C. Topographic flap thickness variability was 9.73 ± 4.93 μm for Group A, 8.48 ± 4.23 μm for Group B, and 4.84 ± 1.88 μm for Group C. The smaller topographic flap thickness variability of Group C (FS200) was statistically significant compared with that of Group A (M2) ($P = 0.004$), indicating improved topographic flap thickness consistency – that is, improved precision – over the entire flap area affected.

Conclusions: The two femtosecond lasers produced a smaller flap thickness and reduced variability than the mechanical microkeratome. In addition, our study suggests that there may be a significant difference in topographic flap thickness variability between the results achieved by the two femtosecond lasers examined.

Keywords: Moria M2, IntraLase FS60, WaveLight® FS200, Allegretto Wave® Eye-Q, 400 Hz excimer, ultrasound biomicroscopy

Video abstract

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Introduction

We have previously reported, in agreement with many others, on the safety and accuracy of flap making with mechanical keratomes for correction of myopia and myopic astigmatism[1] as well as hyperopia.[2]

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Figure 1 Standard corneal analysis report used in our investigation.
Note: This specific flap has been created with the FS200 femtosecond laser.
Abbreviation: LASIK, laser-assisted in situ keratomileusis.

with an intended (programmed) thickness of 120 μm. Representative flap thickness maps from each group are shown in Figure 3.

Column 5 in Table 1 shows the grouped topographic flap thickness values, their range, and standard deviation.

As presented in the tabulated data and illustrated in Figure 4, the mean topographic flap thickness variability was 9.73 ± 4.93 μm for Group A, 8.48 ± 4.23 μm for Group B, and 4.84 ± 1.88 μm for Group C.

Paired comparisons between the three modalities (Table 2) show that there is a statistically significant flap thickness difference between the FS200 and M2 microkeratome groups ($P = 0.004$), while the other two pairs (FS200 and FS60; FS60 and M2) were not statistically different (paired sample t-test, $P = 0.078$ and 0.095, respectively).

Epithelial thickness and topographic variability

To determine any potential bias in these flap thickness and/or thickness variability measurements from epithelial masking, we investigated epithelial thickness. Results per group are reported in Table 3 and illustrated in Figure 5. The mean epithelial thickness was 51.50 ± 4.19 μm in Group A, 51.54 ± 4.16 μm in Group B, and 49.53 ± 4.28 μm in Group C. Topographic epithelial thickness variability for the three groups was 4.15 ± 1.53 μm in Group A, 5.11 ± 1.15 μm in Group B, and 3.97 ± 1.58 μm in Group C.

In our study, none of the cases showed a significant epithelial thickness deviation that suggested early ectasia, nor did

Mean epithelial thickness overall	55 μm
Minimum stromal thickness	374 μm
Minimum corneal thickness	433 μm
Mean corneal thickness @ 0~3 mm	447 μm
Mean corneal thickness @ 3~6 mm	519 μm
Minimum residual stroma	310 μm
Mean stromal component of flap	67 μm
Mean flap depth overall	122 μm
Mean flap depth @ 0~3 mm	125 μm
Mean flap depth @ 3~6 mm	124 μm

Figure 2 Detail from the lower-left table of the corneal analysis report depicted in Figure 1, showing data recorded for mean epithelial thickness, mean flap depth (0–6 mm), central flap depth (0–3 mm), and peripheral flap depth (3–6 mm).

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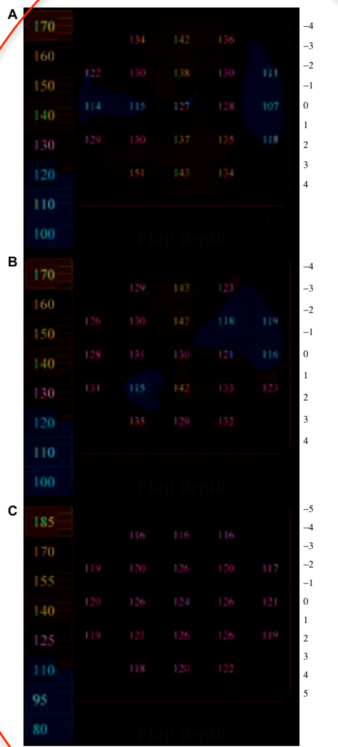

Figure 3 Three representative flap thickness maps (8 mm diameter) from flaps created with the modalities studied in this paper: **(A)** M2 microkeratome (Moria Surgical, Antony, France), **(B)** Intralase™ FS60 femtosecond laser (Abbott Medical Optics, Santa Ana, CA, USA), **(C)** WaveLight® FS200 femtosecond laser (Alcon, Fort Worth, TX, USA).
Note: The values over the 21 points are those used for the flap thickness mean and topographic flap thickness variability study.

the epithelium contribute to the flap thickness homogeneity differences found between the three groups.

Discussion

The importance of flap thickness

Flap parameter accuracy and homogeneity have been studied and debated at length by refractive surgeons globally over

Table 1 Flap thickness measurements, range, and topographic flap thickness variability statistics for the three groups examined

	0–6 mm	0–3 mm	3–6 mm	Flap thickness variability
Group A	**M2**			
Average	138.83	138.33	140.58	9.73
Maximum	159.00	159.00	159.00	17.05
Minimum	114.00	115.00	114.00	3.37
SD	12.38	12.85	12.09	4.93
Group B	**FS60**			
Average	128.46	130.31	128.15	8.48
Maximum	137.00	142.00	136.00	17.16
Minimum	119.00	120.00	119.00	2.94
SD	5.72	6.80	5.49	4.23
Group C	**FS200**			
Average	122.00	122.20	122.53	4.84
Maximum	135.00	137.00	136.00	7.96
Minimum	94.00	90.00	97.00	1.68
SD	5.64	6.11	5.47	1.88

Note: All values are expressed in micrometers (µm).
Abbreviation: SD, standard deviation.

the last 10 years. There appear to be variable differences reported in the basic surgical outcomes when comparing procedures with flaps created either with a mechanical microkeratome or a femtosecond laser.[16] For example, a study in hyperopic patients showed significantly better refractive results with femtosecond laser flaps than with microkeratome flaps.[17] Another study showed that clinically significant epithelial ingrowth after femtosecond LASIK is an infrequent complication, the incidence being less than reported for microkeratome LASIK.[18]

Despite the fact that multiple generations of femtosecond lasers for refractive surgery have been introduced so far, and while the "perfect LASIK flap" is becoming increasingly tangible, the field continues to welcome research on the comparative characteristics of the femtosecond laser versus mechanical microkeratome flap, including that on morphology, cut accuracy, flap thickness reproducibility, flap-edge quality, stromal-bed surface roughness, and histopathology.[19–25]

The femtosecond laser continues to be preferred for flap creation over the bladed mechanical microkeratome due to the increased safety, precision, and regularity this modality offers.[26,27]

Flap thickness is considered an important indicator of LASIK safety due to the critical importance of adequate residual stromal preservation, not only at the center of the cornea, but also for the overall area of the cornea affected. To ensure a thicker residual stroma, a thin flap is preferable in myopic treatments. A further benefit of a thin flap (in

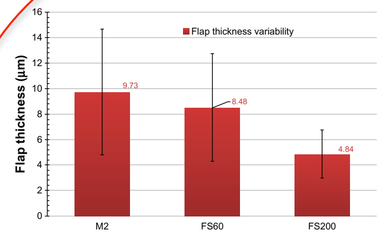

Figure 4 Postoperative topographic flap thickness variability for the three groups examined.
Notes: "FS60" refers to the IntraLase™ FS60 femtosecond laser manufactured by Abbott Medical Optics, Santa Ana, CA, USA; "FS200" refers to the WaveLight® FS200 femtosecond laser manufactured by Alcon, Fort Worth, TX, USA; "M2" refers to the M2 microkeratome manufactured by Moria Surgical, Antony, France.

addition to a smaller diameter) is reduced interference of the superficial "running" nerves within the corneal stroma, which can lessen postoperative dry-eye syndrome.[28] However, the risk in opting for a thin flap is that the flap may end up too thin – that is, a flap < 90 µm. Such a flap may be associated with flap slippage, striae, irregularity, astigmatism, buttonholes, free caps, and corneal haze.[29,30]

However, thicker flaps (for myopic treatment, a flap > 140 µm is acknowledged as being too thick) may lead to a dangerously thin residual stroma (after the excimer ablation), possibly compromising the biomechanical corneal strength and leading to iatrogenic corneal ectasia.[31]

However, the 140 µm flap has been considered by our team optimal for hyperopic ablation and its accompanying (large-diameter) blend zone, as a means to reduce epithelial ingrowth.[14]

Thus, to ensure safety of the procedure and enable borderline decisions to be made – such as in operations with relatively thin residual stroma – it is of ultimate importance that both a higher precision (intended vs achieved thickness) and increased accuracy (improved homogeneity, or else reduced thickness variability) of the lamellar flap cut or stromal tissue separation be sought when selecting a femtosecond laser.

Table 2 Paired sample *t*-tests (*P*) between the three pairs of flap-creation modalities examined

	FS200 and microkeratome	FS200 and FS60	FS60 and microkeratome
Flap thickness	0.004	0.078	0.095
Epithelial thickness	0.020	0.056	0.084

Table 3 Epithelial thickness measurements and statistics for the three groups examined

	Average overall epithelial thickness	Topographic epithelial thickness variability
Group A	**M2**	
Average	51.50	4.15
Maximum	57.00	7.51
Minimum	43.00	1.28
SD	4.19	1.53
Group B	**FS60**	
Average	51.54	5.11
Maximum	58.00	6.92
Minimum	44.00	3.42
SD	4.16	1.15
Group C	**FS200**	
Average	49.53	3.97
Maximum	56.00	7.56
Minimum	42.00	1.10
SD	4.28	1.58

Note: All values are expressed in micrometers (µm).
Abbreviation: SD, standard deviation.

Our results indicate that the postoperative flap thickness, as measured by the HF-UBM method, is larger than the programmed flap thickness and that there are differences between the peripheral and the central thickness. In Group A, overall flap thickness was thicker than planned by +8.83 µm (minimum, 114 µm – ie, a −6 µm average difference; maximum, 159 µm – ie, a +39 µm difference) with an average thickness standard deviation of 12.38 µm. In addition, we observe that this group had the largest topographic thickness variability (9.73 ± 4.93 µm), which is an indication of the inhomogeneity of the flap thickness produced by the microkeratome. We also observe that in this group, on average, the flaps were thicker in the periphery (average 140.58 µm in the 3–6 mm zone vs an average of 138.33 µm in the central 0–3 mm zone), owing to the so-called meniscus shape.[23]

In Group B, we also observe that the overall flap thickness was thicker than planned, by +8.46 µm. However, the range is smaller (minimum, 119 µm, maximum, 137 µm), and so is the standard deviation (6.80 µm). The flap thickness variability is smaller than that of Group A (8.48 ± 4.23 µm). In Group B, we observe that, on average, the flaps were thinner in the peripheral zone (average peripheral thickness, 128.15 µm) compared with in the central zone (average central thickness, 130.31 µm).

In Group C, we observe that the average postoperative flap thickness was just 2.00 µm thicker than programmed and that flaps in this group had the smallest topographic

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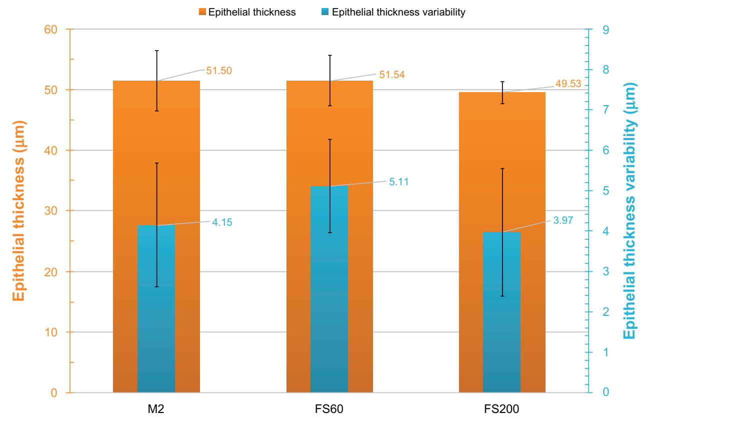

Figure 5 Postoperative epithelial thickness and topographic epithelial thickness variability for the three groups examined.
Notes: "FS60" refers to the Intralase™ FS60 femtosecond laser manufactured by Abbott Medical Optics, Santa Ana, CA, USA; "FS200" refers to the WaveLight® FS200 femtosecond laser manufactured by Alcon, Fort Worth, TX, USA; "M2" refers to the M2 microkeratome manufactured by Moria Surgical, Antony, France.

thickness variability (4.84 µm ± 1.88 µm). This group also had nonstatistically different peripheral and central flap thicknesses (central flap thickness, 122.20 ± 6.11; peripheral flap thickness, 122.53 ± 6.11 µm).

It is worth comparing our results to a similar recent study,[32] in which a handheld AS-OCT unit was used to measure postoperative flap thickness. In that study, the standard deviation for paracentral flap thickness and peripheral flap thickness was reported to be ±3.16 µm and ±3.26 µm, respectively, for the FS200 group and ±10.27 µm and ±10.35 µm for the Hansatome microkeratome, respectively.

Differences between the two femtosecond lasers in terms of flap thickness variability

An interesting finding of our study is that the measured topographic flap thickness variability was smaller for the FS200 group than for the FS60 and M2 microkeratome groups. The FS200 flaps appeared to be more uniform, with an average topographic thickness variability of 4.84 ± 1.88 µm, whereas this was 8.48 ± 4.23 µm for the FS60 group and 9.73 ± 4.93 µm for the M2 microkeratome group.

In addition, the FS200 flaps were associated with a statistically significant smaller epithelial average thickness (49.53 ± 4.28 µm, range 42–56 µm) over the other groups: the FS60 group had an average epithelial thickness of 51.54 ± 4.16 µm (range 44–58 µm) and the microkeratome group had an average epithelial thickness of 51.50 ± 4.19 µm (range 43–57 µm). The FS60 and M2 microkeratome were not statistically different in terms of epithelial thickness variability.

The difference between the flap thickness variability of the FS200 and the FS60 may stem from their different intraoperative gas-venting techniques and/or their different – active versus passive – intraoperative suction methods. Intraoperative gas buildup during creation of the lamellar part of the flap (opaque bubble layer)[33] may interfere with the precision of the femtosecond laser tissue separation. In contrast, variation in the stabilizing force to the cornea during this process, through the applanation pressure applied, may also result in tissue separation bias. The FS60 uses a passive syringe chamber-induced suction that is achieved prior to cornea applanation and maintained passively during the procedure, while the FS200 uses a tubing system that connects the suction ring to an active vacuum pump within the unit that monitors and maintains stable suction during the lamellar cut procedure.

The first step in creating the flap is the creation of an externalizing channel peripheral to the hinge of the flap, permitting the generated gas to diffuse outside of the cornea. The different initial steps in creating femtosecond laser-assisted flaps are illustrated in Figure 6 – the channel

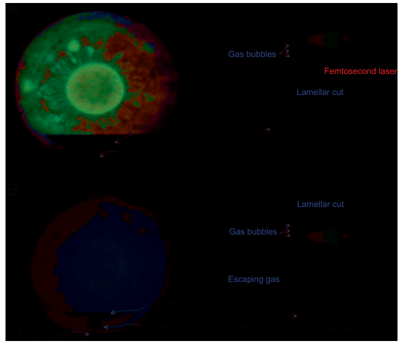

Figure 6 Schematic of the architectural differences between the (**A**) Intralase™ FS60 (Abbott Medical Optics, Santa Ana, CA, USA) and (**B**) WaveLight® FS200 (Alcon, Fort Worth, TX, USA) femtosecond lasers.
Notes: In the initial phase of flap creation with the FS60, a stromal "gas decompression" pocket is created, while, with the FS200, a channel through the hinge is created to help the gas escape.

is clearly shown in 6B (FS200), whereas there is no such channel in 6A (FS60).

We conclude that all three devices are very safe and offer great efficacy in flap making. Both femtosecond lasers appear to be more accurate in generating the desired central corneal flap thickness, as expected. However, the dramatic difference in overall flap thickness between the FS200 and the other two modalities studied herein may suggest that the FS200 has a better aberrations profile and better mesopic and scotopic visual functions. As our momentum in corneal imaging expands, we may come to explain and understand visual function parameters beyond acuity and refraction that may be significant in assessing modern refractive surgery.

Conclusion

Our study suggests that the WaveLight FS200 femtosecond laser has a statistically higher precision in planar flap thickness creation as flaps created with this laser have a statistically smaller flap thickness area variation when compared with the flaps produced by the IntraLase FS60 and M2 microkeratome. The difference between the FS200 and the FS60 may stem from their different intraoperative gas-venting techniques and/or their different – active versus passive – intraoperative suction methods.

Disclosure

AJK consults for Alcon. The authors declare no other conflicts of interest in this work.

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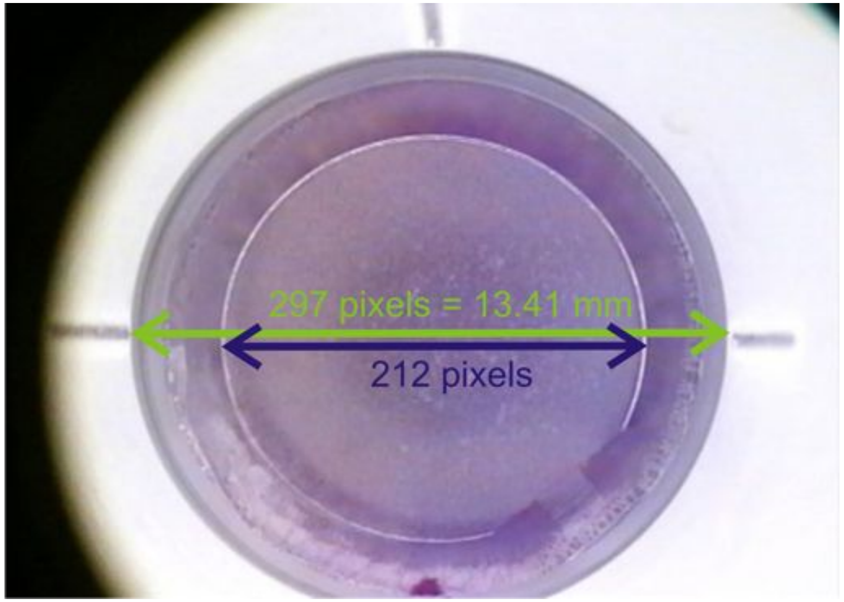
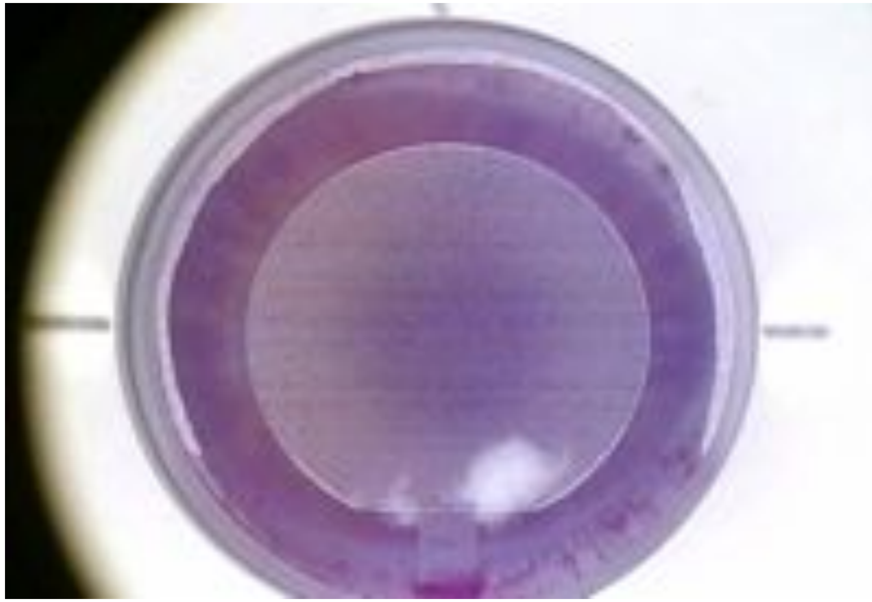
Images from one hundred and one flaps were automatically recorded during consecutive routine LASIK procedures performed with the Alcon – WaveLight (Fort Worth, TX)

FS200 femtosecond laser and the EX500 excimer laser. Digital processing of these images was employed to objectively evaluate the diameter of FS200-created flaps, by comparing planned Vs. achieved and to evaluate incidence and extent (area) of opaque bubble layer (OBL). Data were assessed using paired two-tailed t-tests, coefficient of determination (r2), trend line linearity, bias, and plots of differences against means.

Introduction:

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





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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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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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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

Video abstract

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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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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.

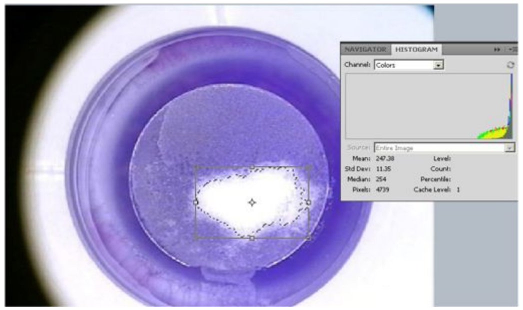

Figure 3 Methodology for measurement of opaque bubble layer area.
Notes: The area within the flap with white more than 50% is selected with the Magic Wand tool. The pixel area is determined by the histogram tool, and subsequently converted to metric units. This is the maximal opaque bubble layer encountered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

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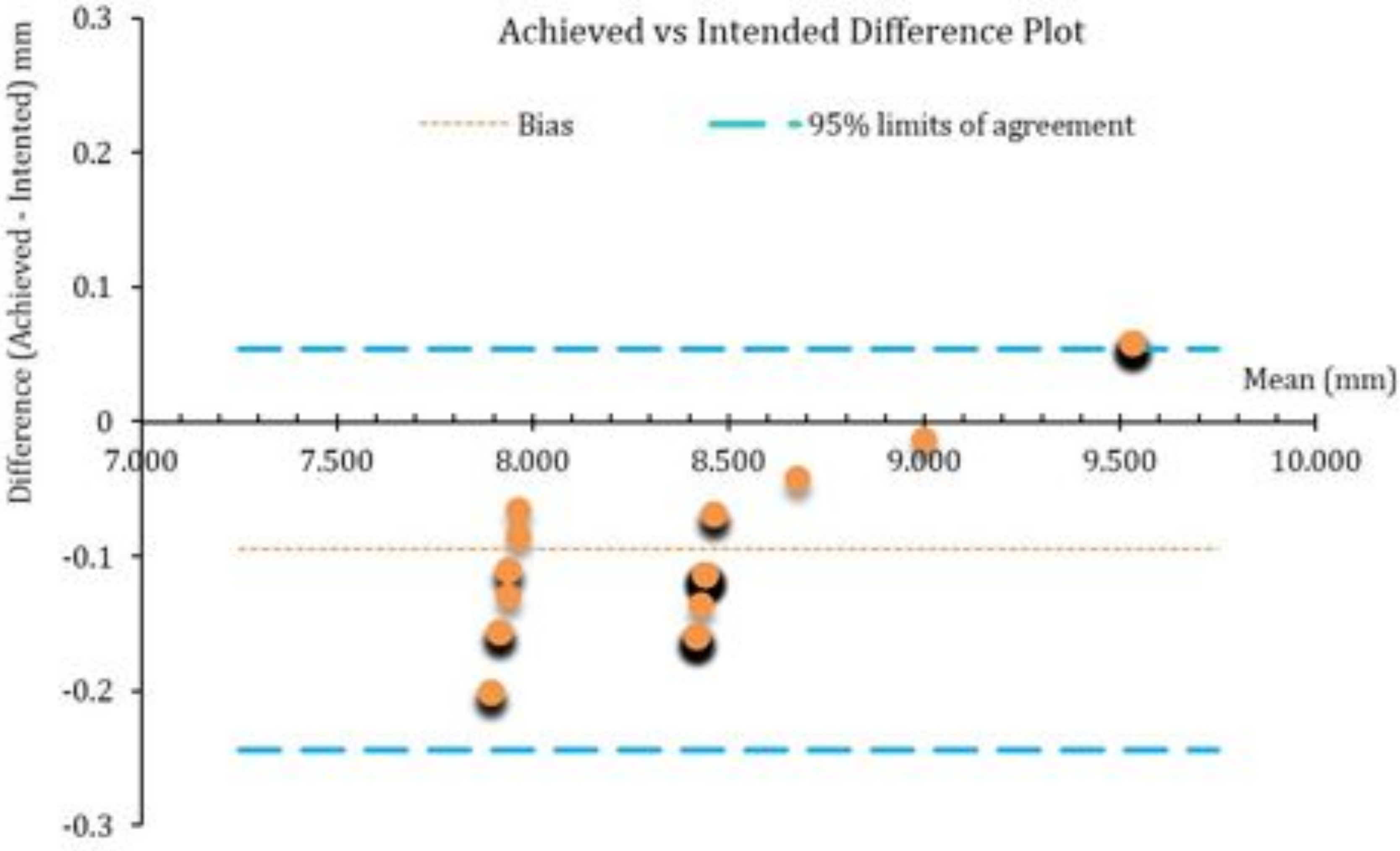
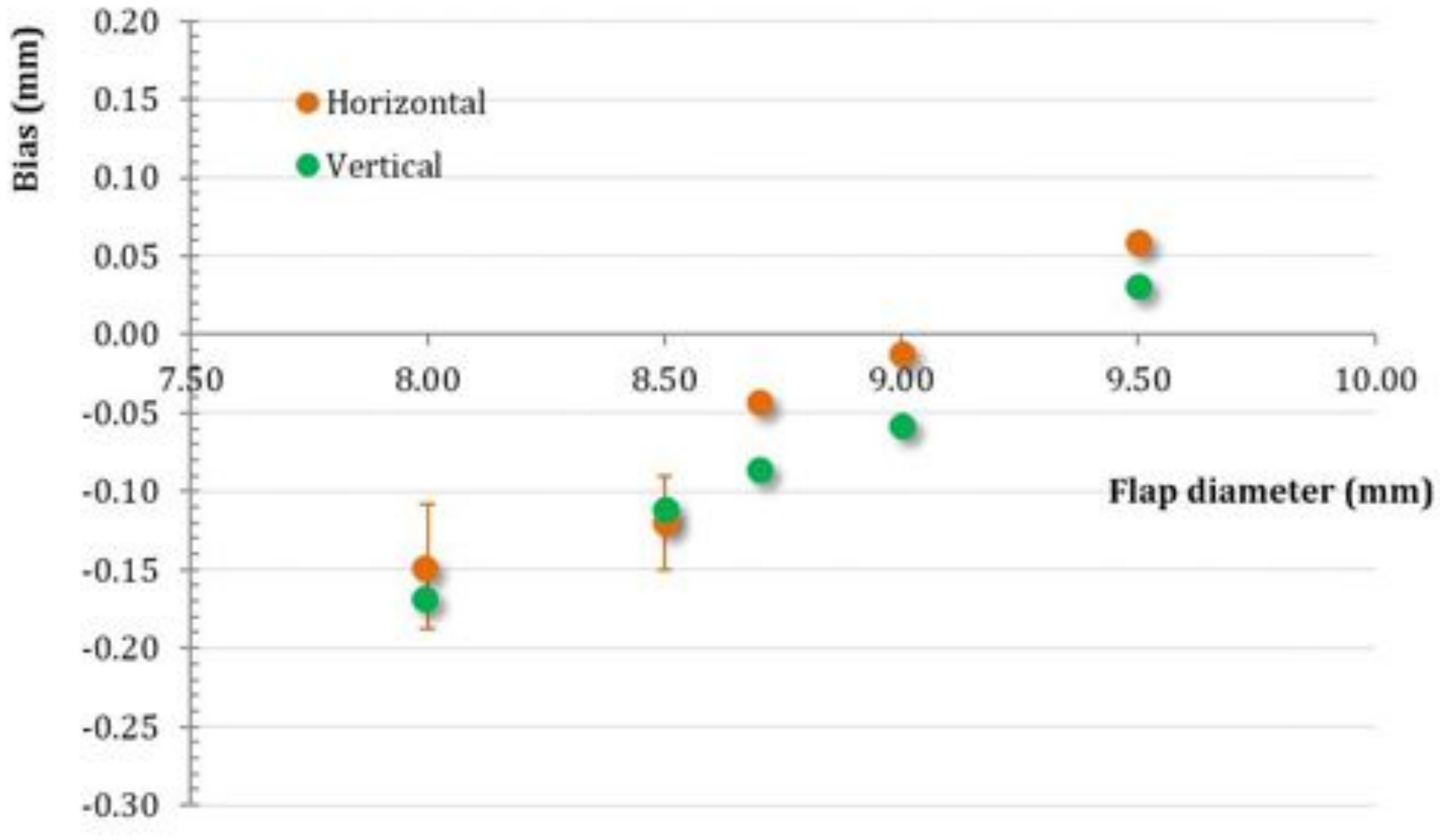
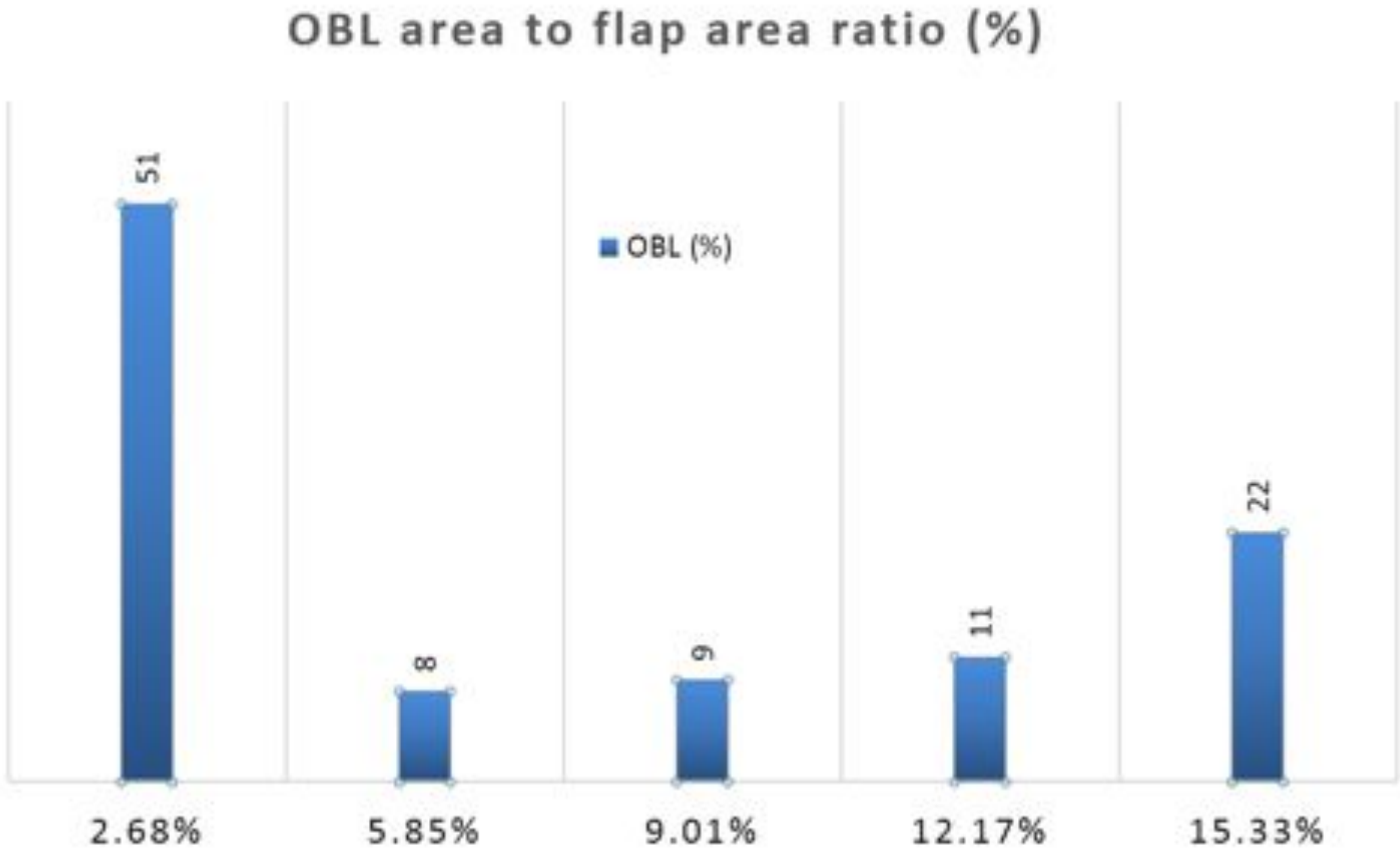

Achieved vs Intended Difference Plot
Bias
95% limits of agreement
Difference (Achieved - Intented) mm
Mean (mm)
0.3
0.2
0.1
0
-0.1
-0.2
-0.3
7.000
7.500
8.000
8.500
9.000
9.500
10.000


Bias (mm)
0.20
0.15
0.10
0.05
0.00
-0.05
-0.10
-0.15
-0.20
-0.25
-0.30
7.50
8.00
8.50
9.00
9.50
10.00
Horizontal
Vertical
Flap diameter (mm)



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New venting channel parameters and OBL reduction

Clinical Ophthalmology

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ORIGINAL RESEARCH

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

A John Kanellopoulos[1,2]
George Asimellis[1]

[1]Laservision.gr Eye Institute, Athens, Greece; [2]New York University School of Medicine, New York, NY, USA

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

Video abstract

Point your SmartPhone at the code above. If you have a QR code reader the video abstract will appear. Or use: http://dvpr.es/ZNk4F5

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.

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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.

Discussion

Creation of a LASIK flap with a femtosecond laser is considered advantageous to microceratome[7,8] for a more

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

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

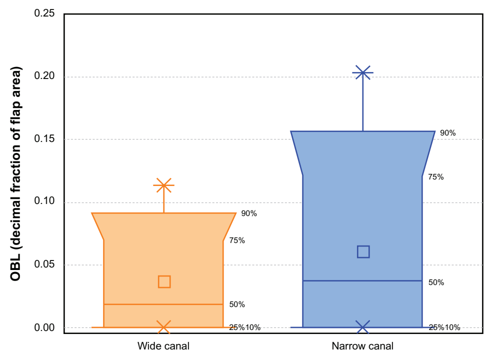

Figure 2 Box plots for OBL, expressed as fraction of the total flap area for the two groups, indicating the 99% point with the × sign, and the mean point with the sign.
Note: Vertical axis, range of extent of OBL as a fraction of total flap area.
Abbreviation: OBL, opaque bubble layer

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FS200 femtosecond laser LASIK flap digital analysis parameter evaluation: comparing two different types of patient interface applanation cones

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ORIGINAL RESEARCH

FS200 femtosecond laser LASIK flap digital analysis parameter evaluation: comparing two different types of patient interface applanation cones

A John Kanellopoulos[1,2]
George Asimellis[1]

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Purpose: To evaluate the safety and efficacy of a novel LASIK flap patient interface (PI) cone with our reported digital analysis and compare for potential differences with the standard metal and glass PI in flap parameters when used with the Alcon/WaveLight FS200 femtosecond laser.

Patients and methods: Thirty-six consecutive LASIK patients (72 eyes) subjected to a bilateral femtosecond assisted LASIK procedure with the novel clear cone PI FS200 1505 were examined for flap diameter and flap thickness over the entire flap area via digital analysis performed on intraoperation image (flap diameter) and anterior-segment optical coherence tomography image (flap thickness). This group was compared with an age- and procedure-matched group B from our practice, in which the standard metal and glass PI was employed.

Results: Horizontal flap diameter for group A (clear cone) was 7.87 mm ± 0.02 mm (range 7.89–7.84 mm) for 8.00 mm programmed, whereas for group B (metal and glass cone) was 7.85 mm ± 0.04 mm (range 7.93–7.80 mm). Likewise, along the vertical line, flap diameter for group A was 7.84 mm ± 0.02 mm (range 7.85–7.80 mm) and for group B was 7.83 mm ± 0.03 mm (range 7.87–7.80 mm). Central flap thickness for group A was 113.29 µm (±1.19 µm) for 110 µm planned, 122.1 µm (±2.10 µm) for 120 µm planned, and 133.50 µm (±0.71 µm) for 130 µm planned. Group B central flap thickness was, accordingly, 112.8 µm (±1.25 µm), 122.4 µm (±2.15 µm), and 132.50 µm (±0.90 µm). The data evaluated (paired group comparisons) between group A and group B did not show statistically significant differences.

Conclusion: This study indicates that two PIs in use with the FS200 femtosecond laser are safe and have highly reproducible and accurate flap parameter results, such as achieved diameter and flap thickness. The paired group comparisons between the two PIs' respective data do not show statistically significant differences.

Keywords: femtosecond laser precision, bladeless LASIK, corneal flap diameter, flap thickness, Alcon/WaveLight FS200, clear cone, patient interface, applanation cone, myopic laser correction, hyperopic laser correction

Introduction

A very precise optical path control system is a prerequisite in all femtosecond ophthalmic surgical platforms, in order to precisely and accurately focus the successive laser pulses to their programmed positions within the cornea.[1,2] For that purpose, the cornea is maintained to a defined shape via suction pressure facilitated by a patient interface (PI) or applanation cone. The patient interface for most femtosecond lasers is a flat clear surface that applanates the patient's cornea surface in order to achieve a reliable separation plane for LASIK flap creation. Some systems use a concave interface with less applanation required.[3] With the exception of intraocular pressure

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increase during flap creation,[4] very little has been published in the peer review literature regarding these critical elements in femtosecond refractive surgery.

The Alcon/WaveLight® FS200 1505 PI (Alcon Surgical, Fort Worth, TX, USA) is a clear cone interface that has recently been introduced by the manufacturer. It carries the advantages of having a lower cost and high reproducibility, it is recyclable, and it offers a wider intraoperative field of view for the surgeon.

It is sterile and patient contact disposable (ie, intended for single use), consisting of a tubing system with integrated suction ring and an applanation cone. The flat bottom of the cone is used as an applanation plate for the patient's cornea. The interface is indicated to be used with the FS200 femtosecond laser, consistent with the cleared indications for use for this refractive surgical laser.

The standard metal device was the interface 1504, the main differences being in the applanation cone. The applanation cone of the predicate device 1504 consists of a metal and glass cone with a bonded glass plate, whereas the applanation cone in interface 1505 is a one-piece molded plastic cone (Figure 1). We have recently implemented the use of clear cone interface 1505 in our practice.

In an effort to validate flap precision and accuracy, our team has introduced a digital analysis flap diameter technique during the LASIK operation and prior to flap lifting,[5] as well as a flap thickness study,[6] examining the FS200 flap thickness characterization achieved with the interface 1504.

Figure 1 The Alcon/WaveLight® FS200 patient interfaces 1504 (metal and glass, top) and 1505 (clear cone, bottom).

The purpose of this paper is to compare the differences in achieved flap diameter and thickness precision and accuracy created via the FS200 femtosecond laser with the recently introduced clear cone interface 1505 versus the metal and glass cone interface 1504 in the FS200 femtosecond laser.

Materials and methods

This case series study received approval by the ethics committee of our institution, adherent to the tenets of the Declaration of Helsinki. Informed consent was obtained from each subject at the time of the LASIK intervention or the first clinical visit. The study was conducted in our clinical practice on patients during the refractive operation and scheduled postoperative visits.

Patient inclusion criteria

The study group consisted of 36 consecutive patients (72 eyes) treated for bilateral primary myopic or hyperopic femtosecond assisted LASIK between October 2012 and January 2013 in our center using the interface 1505, forming the clear cone group A. Mean preoperative spherical equivalent for this group A was –4.23 D ± 1.22 D. Of the 72 flaps in the group, as shown in Table 1, the majority subgroup (48 flaps) were programmed to 8.00 mm diameter, whereas 22 flaps were programmed to 8.50 mm diameter, and two flaps were programmed to 9.50 mm diameter.

A second group of 36 patients (72 eyes) was randomly selected from a pool of patients previously treated (between March 2012 and October 2012) for bilateral primary myopic or hyperopic femtosecond assisted LASIK in our center using the interface 1504, with the intent to match the programmed flap diameter population of the study group A. This group formed the metal and glass cone reference group B. Mean preoperative spherical equivalent for this group B was –4.15 D ± 1.34 D.

In all procedures (performed by the same surgeon [AJK]), the LASIK flap was created with the Alcon/WaveLight FS200 femtosecond laser, and subsequent excimer ablation was provided by the Alcon/WaveLight EX500 excimer laser.[7,8]

The femtosecond laser settings were as follows: stromal bed cut spot separation 8 µm, line separation 8 µm, side cut bed separation 5 µm, line separation 3 µm, bed cut pulse energy 0.80 µJ, and side cut pulse energy 0.80 µJ.

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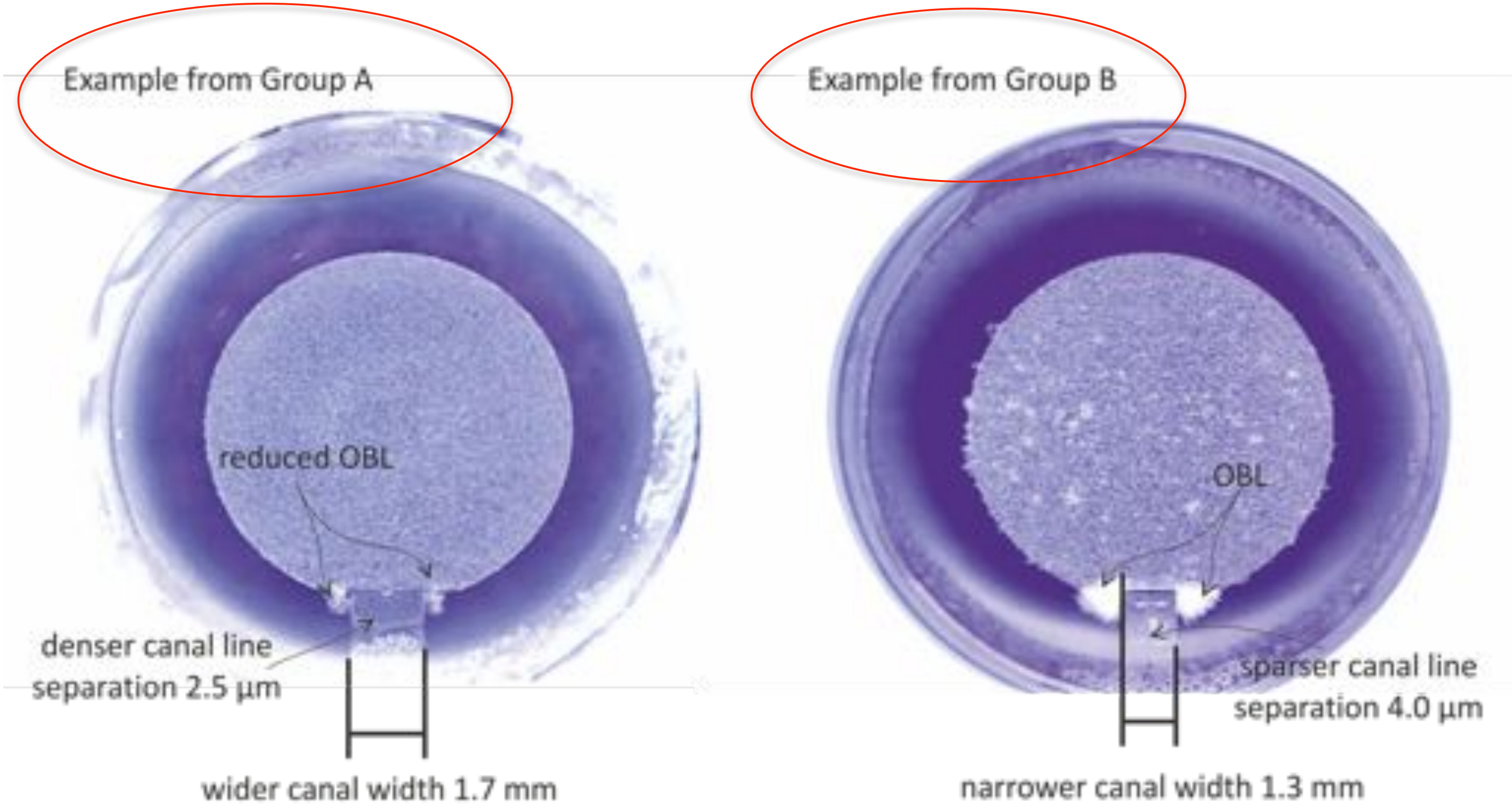
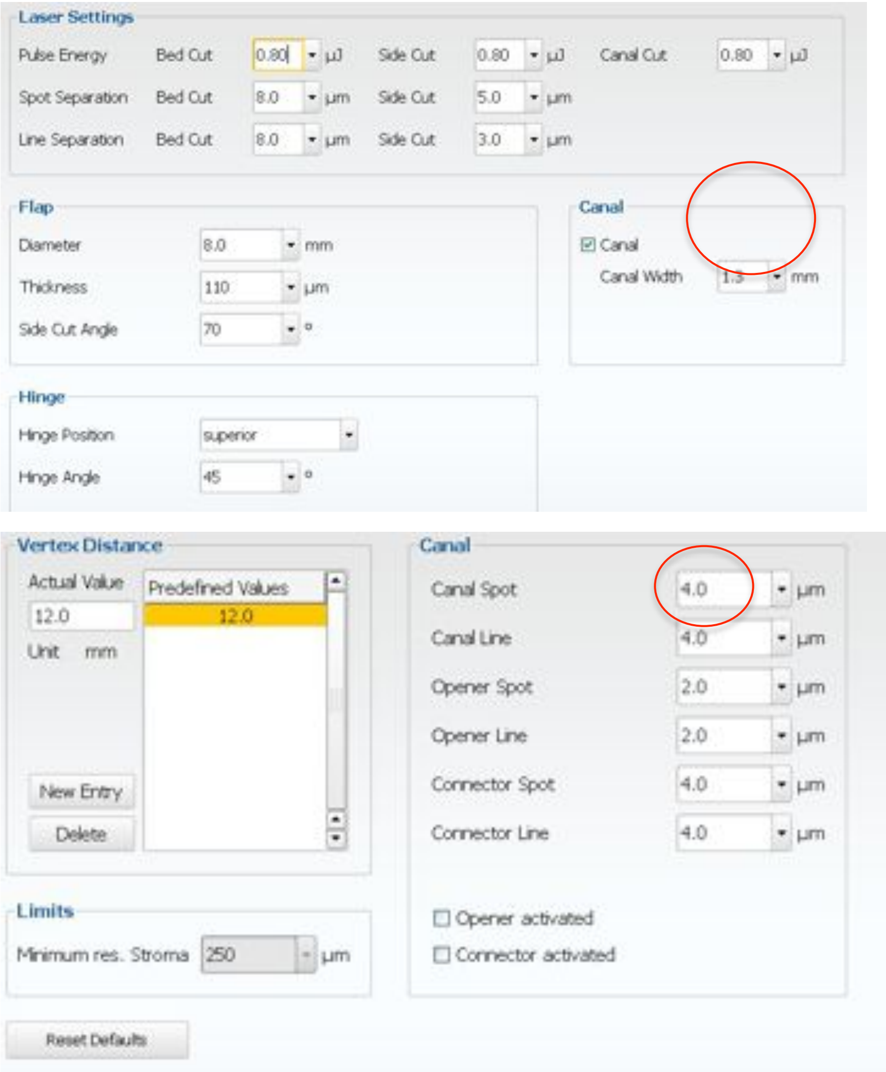
1.3mm Vs 1.7mm

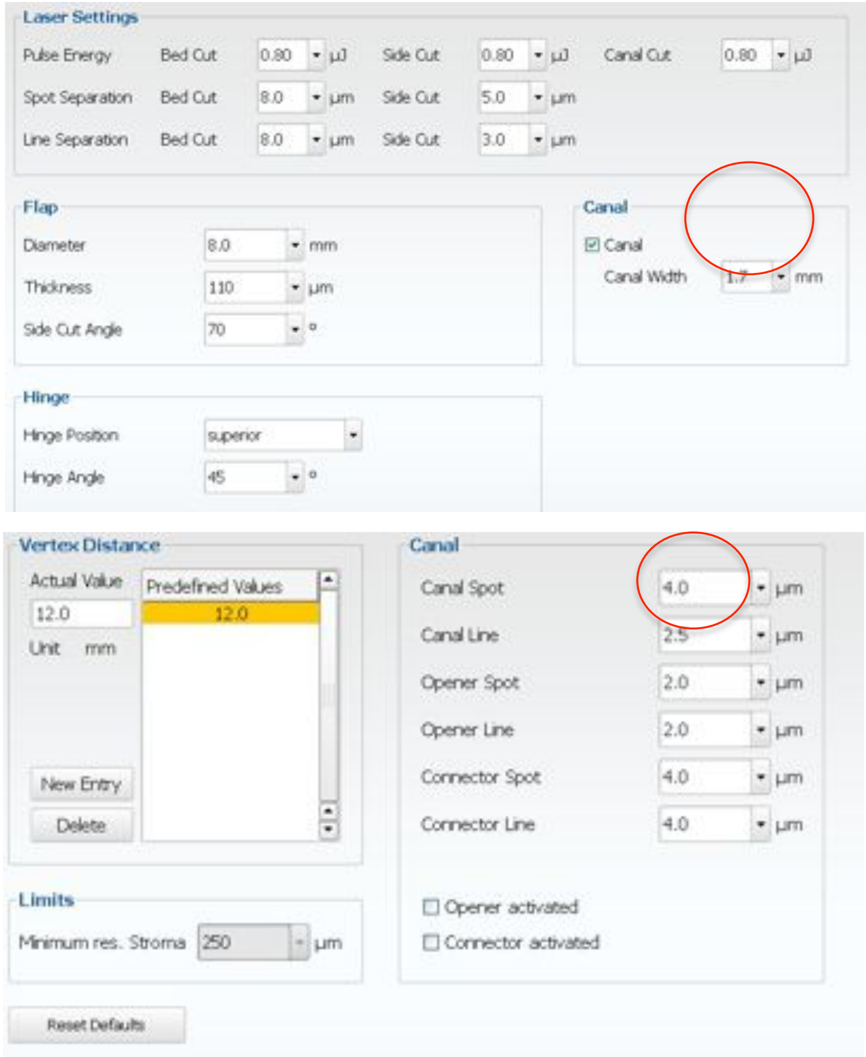


1.7mm 1.3mm

Channel parameters length up to end of applanation to max 1.3mm (the S. Lemonis technique)

1.3mm Vs. 1.7mm





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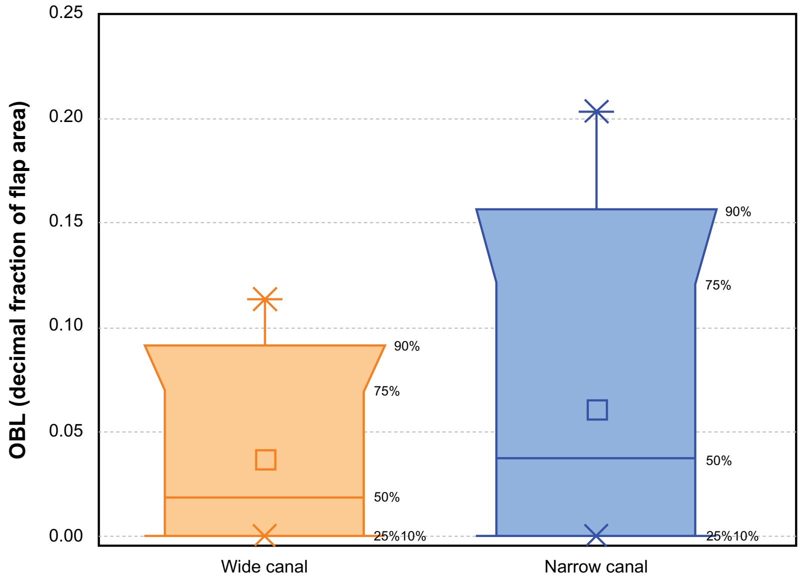

Figure 2 Box plots for OBL, expressed as fraction of the total flap area for the two groups, indicating the 99% point with the × sign, and the mean point with the sign.
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16%–18%	0	7
>18%		2

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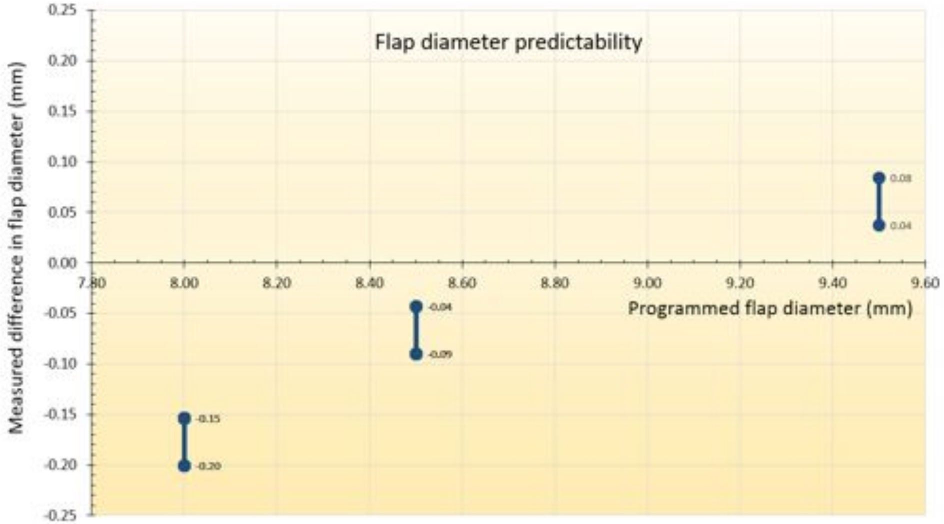
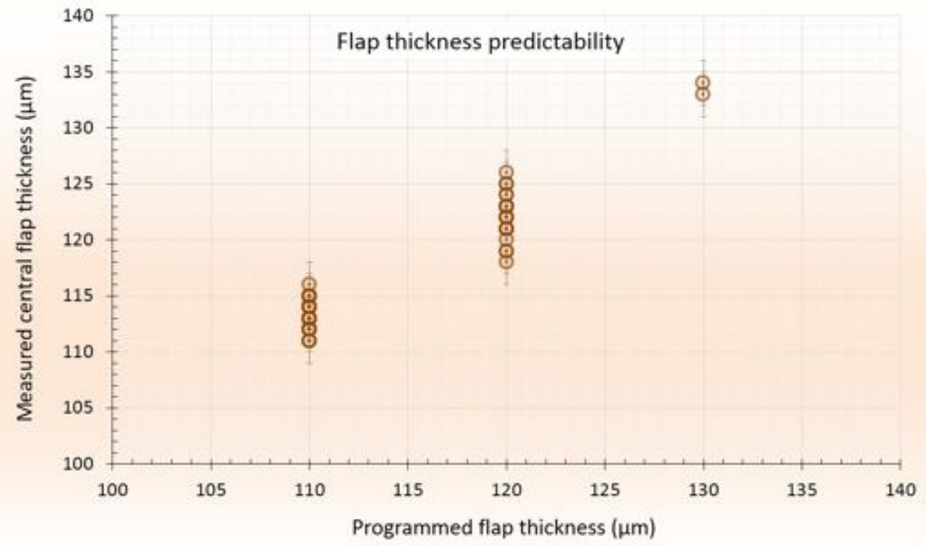
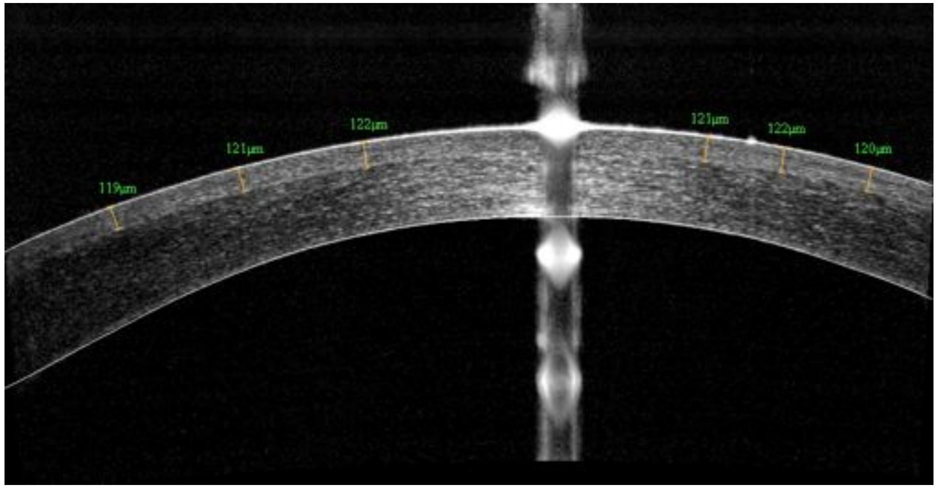

Flap diameter predictability
Measured difference in flap diameter (mm)
Programmed flap diameter (mm)
0.25
0.20
0.15
0.10
0.05
0.00
-0.05
-0.10
-0.15
-0.20
-0.25
7.80
8.00
8.20
8.40
8.60
8.80
9.00
9.20
9.40
9.60
0.08
0.04
-0.04
-0.09
-0.15
-0.20


Flap thickness predictability
Measured central flap thickness (µm)
Programmed flap thickness (µm)
140
135
130
125
120
115
110
105
100
100
105
110
115
120
125
130
135
140


119µm
121µm
122µm
121µm
122µm
120µm

The intended flap diameters were between 8.00 to 9.50 mm.

The achieved flap diameters depicted extremely high precise translation, and were on average just -0.16 mm (± 0.04) smaller for the 8.00 mm intended flap diameter, -0.12 mm (± 0.03) smaller for the 8.50 mm, and up +0.06 mm (±0.06) wider for the 9.50 mm flap respectively. With an average flap area 72.4 mm2, the average OBL area was 4.1 ± 4.3 mm2 (Max, 14.34 mm2 , Min 0), corresponding to a 6% OBL-to-flap area. Specifically 80% of the femtosecond created flaps had essentially zero OBL (0 to under 2.7% of the flap area.

We are introducing and novel benchmark in LASIK flap parameter assessement

The FS200 (Alcon, Wavelight, Ft. Worth, TX) femtosecond laser created flaps, in our clinical experience and with this novel highly objective assessment technique, demonstrate both extreme precision and reproducibility. OBL incidence was minimal.

Athens, September 14th, 2013 next year October 4th, 2014

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