FS200 flap thickness Z adjustment

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Financial interests consultant for:

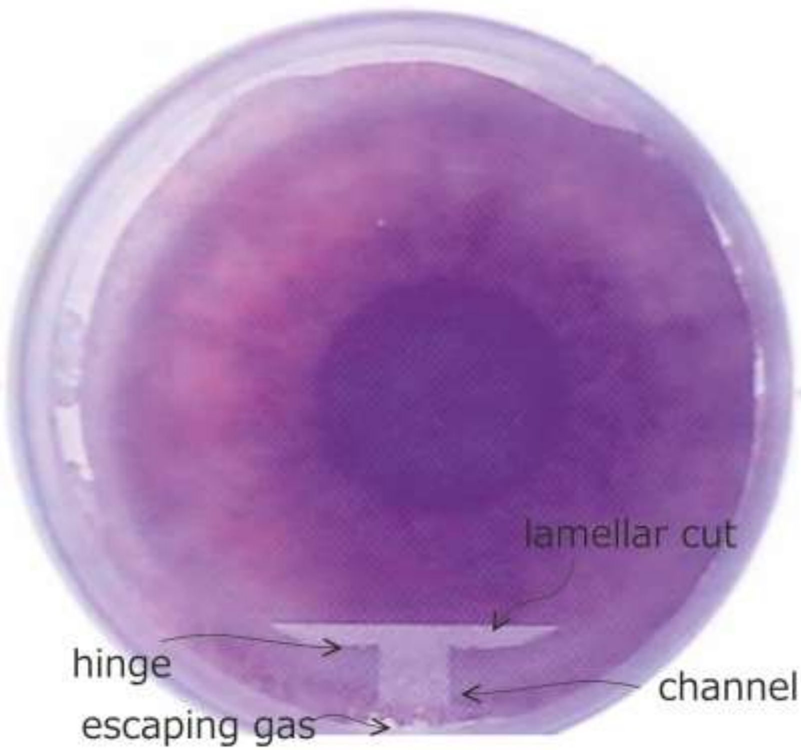
- Alcon
- Avedro
- iOptics
- Oculus
- Optovue
- Ocular Therapeutix

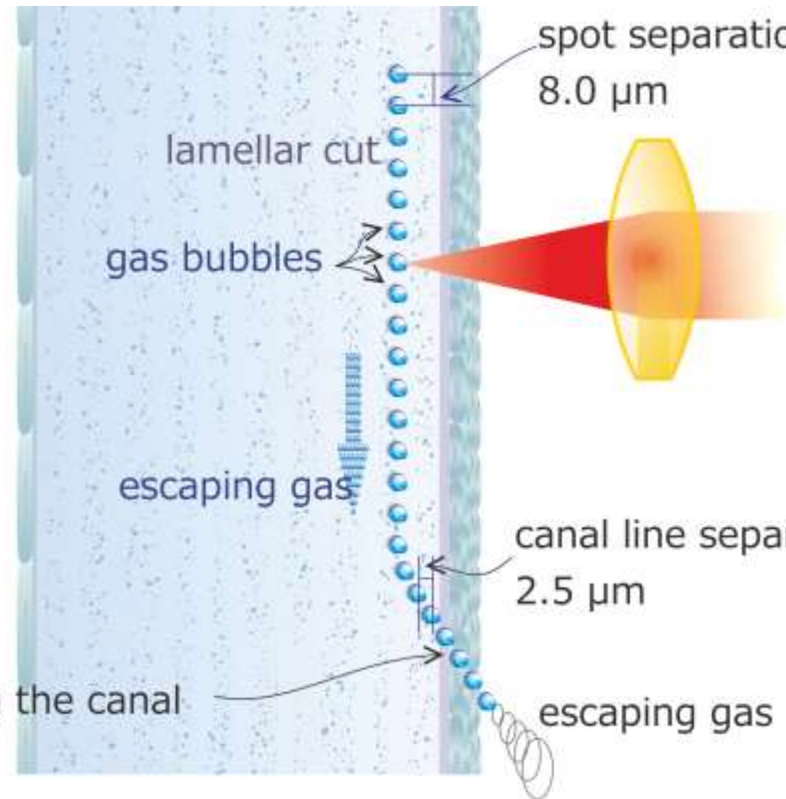
Clinical and investigative interests

- Keratoconus
- Laser (femto and nanosecond) cataract surgery
- Biometry limitations
- Epithelial cornea imaging
- Collagen cross-linking
- LASIK stability
- Light diffraction after cornea and lens refractive procedures
- Natural UV light exposure

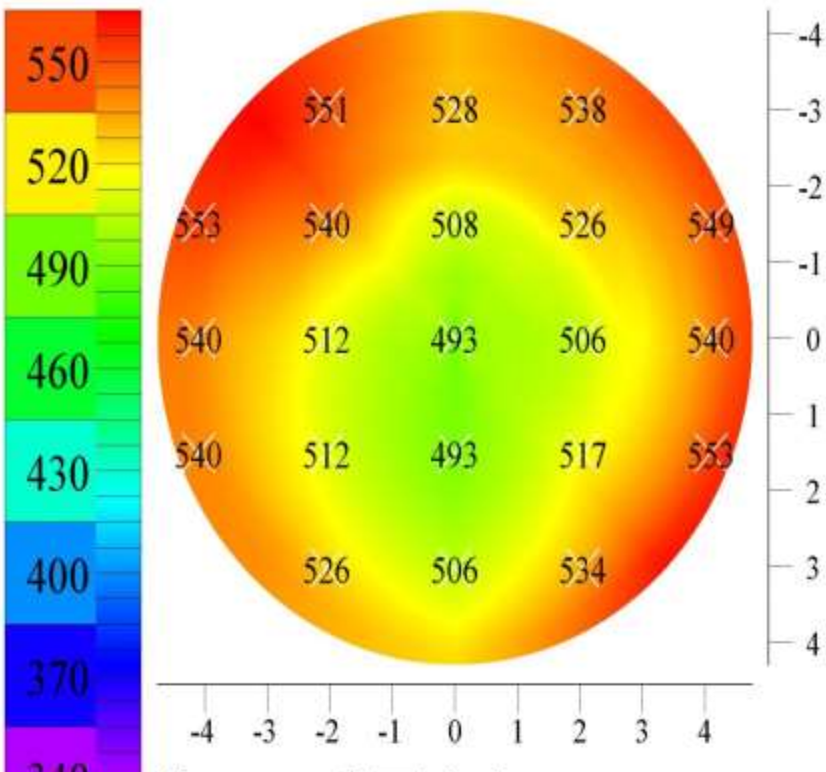
Refractive lens rehabilitation

Femto flap gas escape

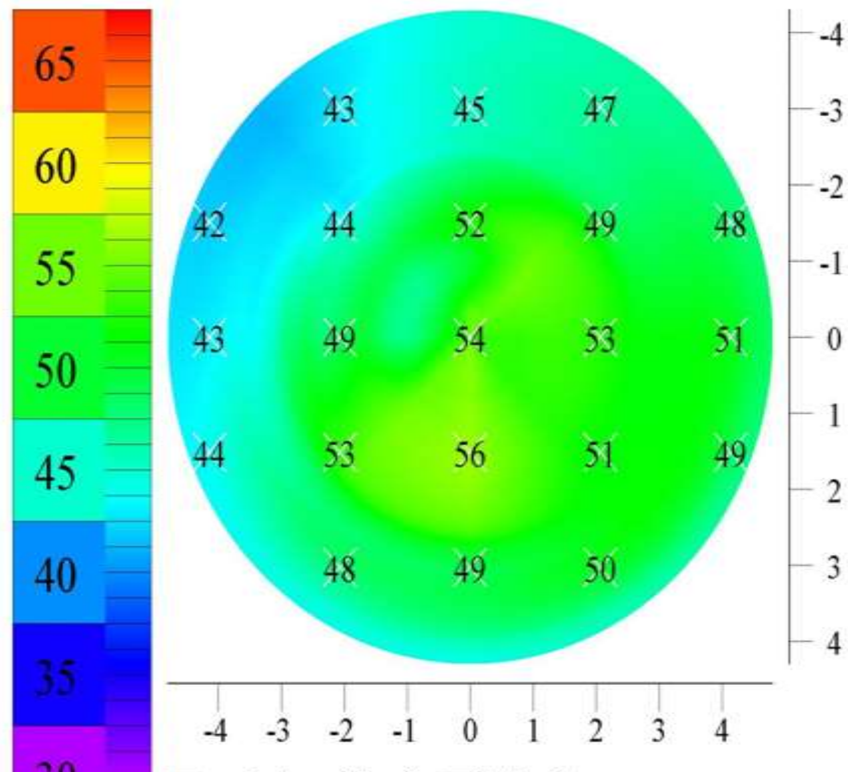




Stromal and Epithelial Imaging



Stromal Thickness



Epithelial Thickness

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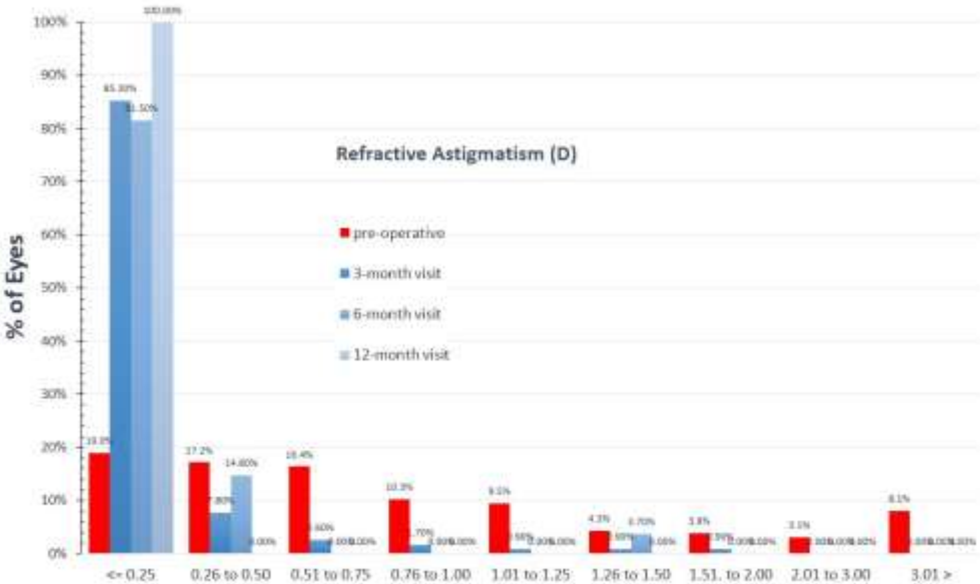
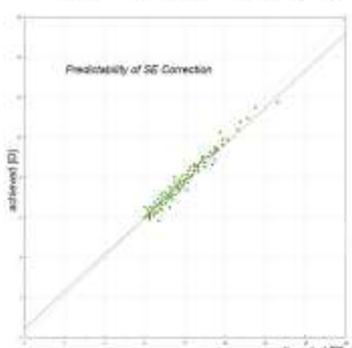
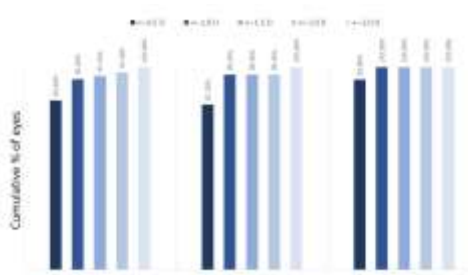
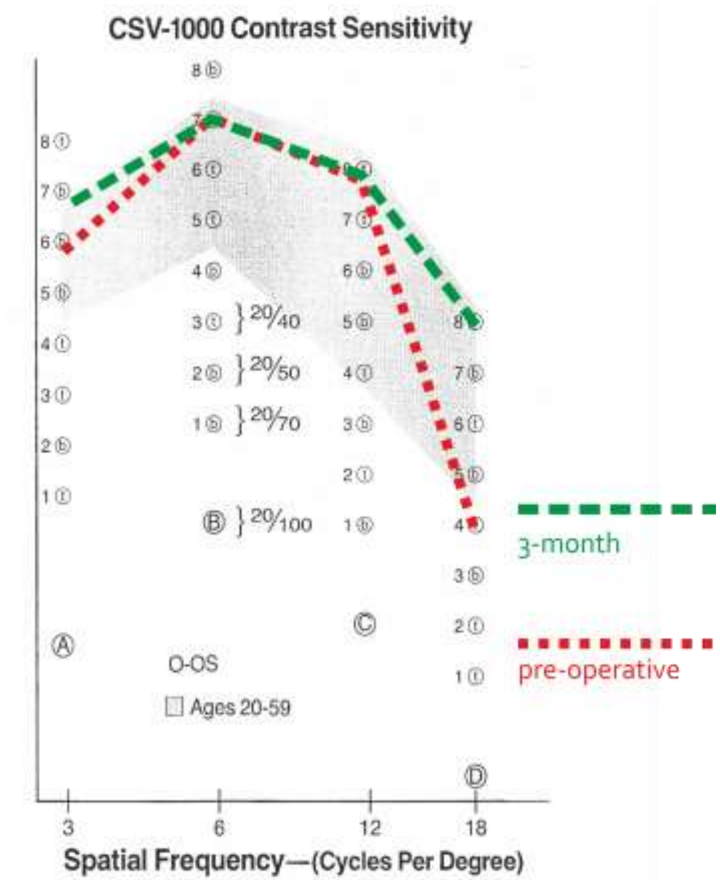
High myopia one-year refractive and keratometric stability in LASIK with high-frequency femtosecond and excimer lasers.









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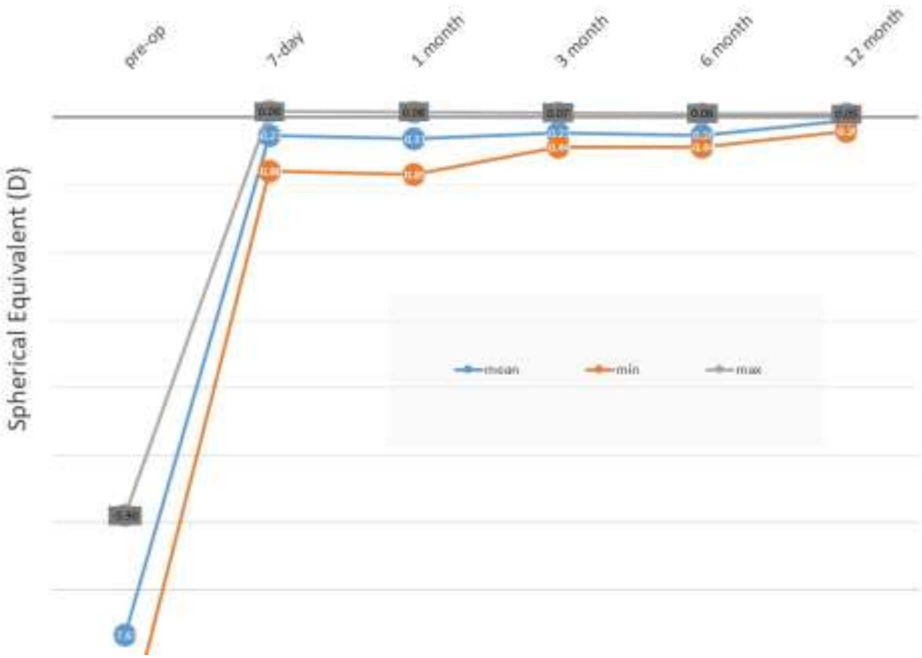
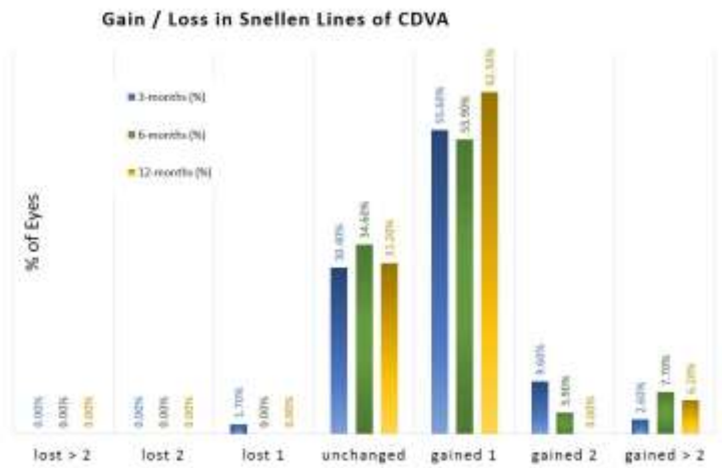
Stability-safety





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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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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]

http://dx.doi.org/10.2147/OPTH.S40762

Clinical Ophthalmology 2013:7 675–683

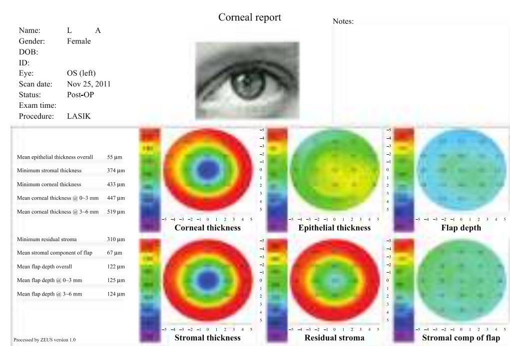

Figure 1 Standard corneal analysis report used in our investigation.
Note: This specific flap has been created with the FS200 femtosecond laser.
Abbreviation: LASIK, laser-assisted in situ keratomileusis.

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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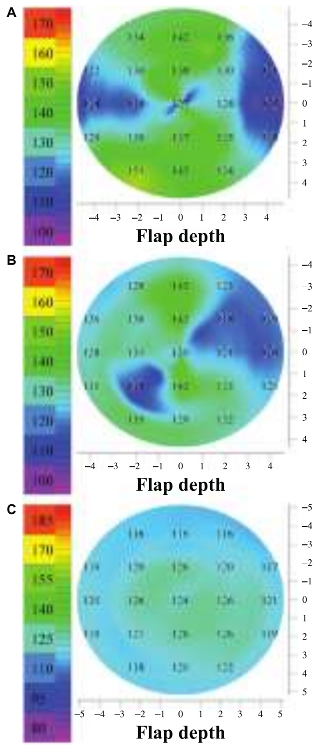

Figure 3 Three representative flap thickness maps (8 mm diameter) from flaps created with the modalities studied in this paper: (**A**) M2 microkeratome (Moria Surgical, Antony, France), (**B**) Intralase™ FS60 femtosecond laser (Abbott Medical Optics, Santa Ana, CA, USA), (**C**) WaveLight® FS200 femtosecond 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

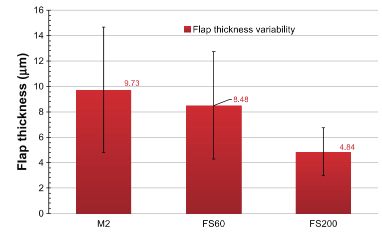

Figure 4 Postoperative topographic flap thickness variability for the three groups examined.
Notes: "FS60" refers to the IntraLase™ FS60 femtosecond laser manufactured by Abbott Medical Optics, Santa Ana, CA, USA; "FS200" refers to the WaveLight® FS200 femtosecond laser manufactured by Alcon, Fort Worth,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

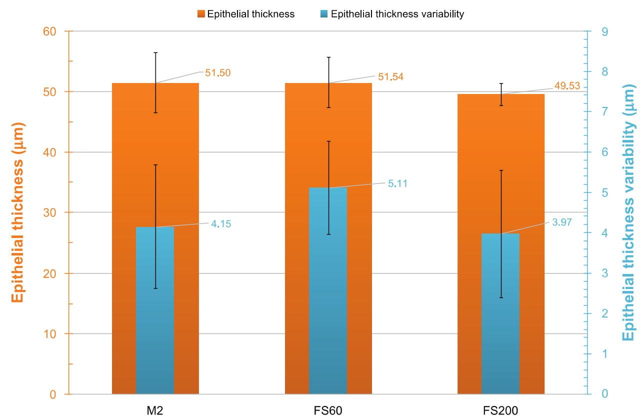

Figure 5 Postoperative epithelial thickness and topographic epithelial thickness variability for the three groups examined.
Notes: "FS60" refers to the Intralase™ FS60 femtosecond laser manufactured by Abbott Medical Optics, Santa Ana, CA, USA; "FS200" refers to the WaveLight® FS200 femtosecond laser 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

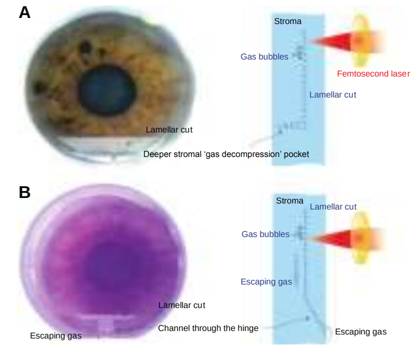

Figure 6 Schematic of the architectural differences between the (**A**) Intralase™ FS60 (Abbott Medical Optics, Santa Ana, CA, USA) and (**B**) WaveLight® FS200 (Alcon, Fort Worth, TX, USA) femtosecond lasers.
Notes: In the initial phase of flap creation with the FS60, a stromal "gas decompression" pocket 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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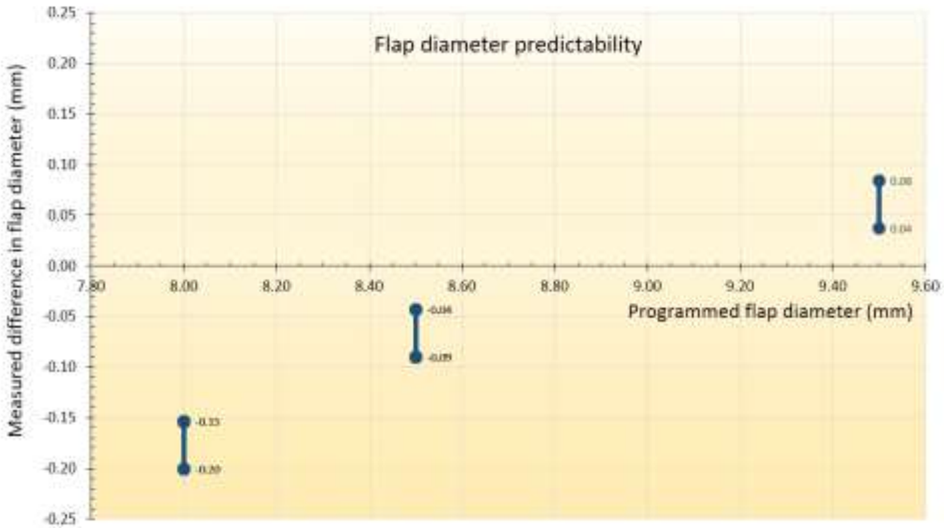
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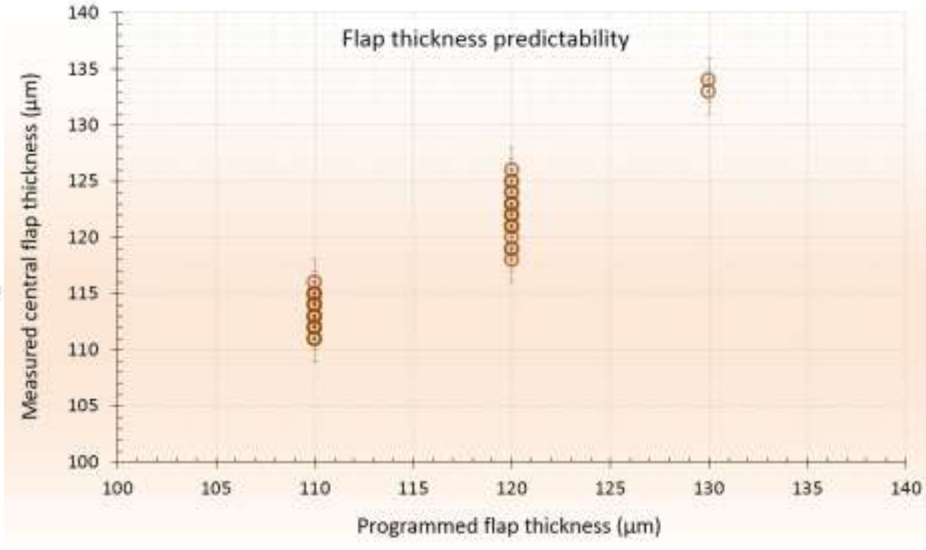
Flap thickness predictability
Measured central flap thickness (µm)
Programmed flap thickness (µm)
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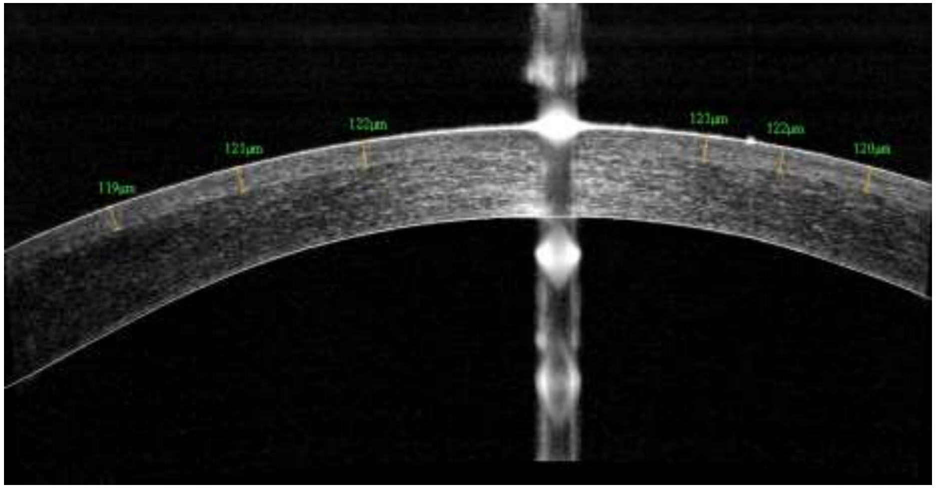
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120µm

video

Software development for FS200 Flap Diameter and OBL real-time objective assessment

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Clinical Professor of Ophthalmology

Medical Director: The Laservision.gr Institute, Athens Greece

and the Athens team

New York University School of Medicine

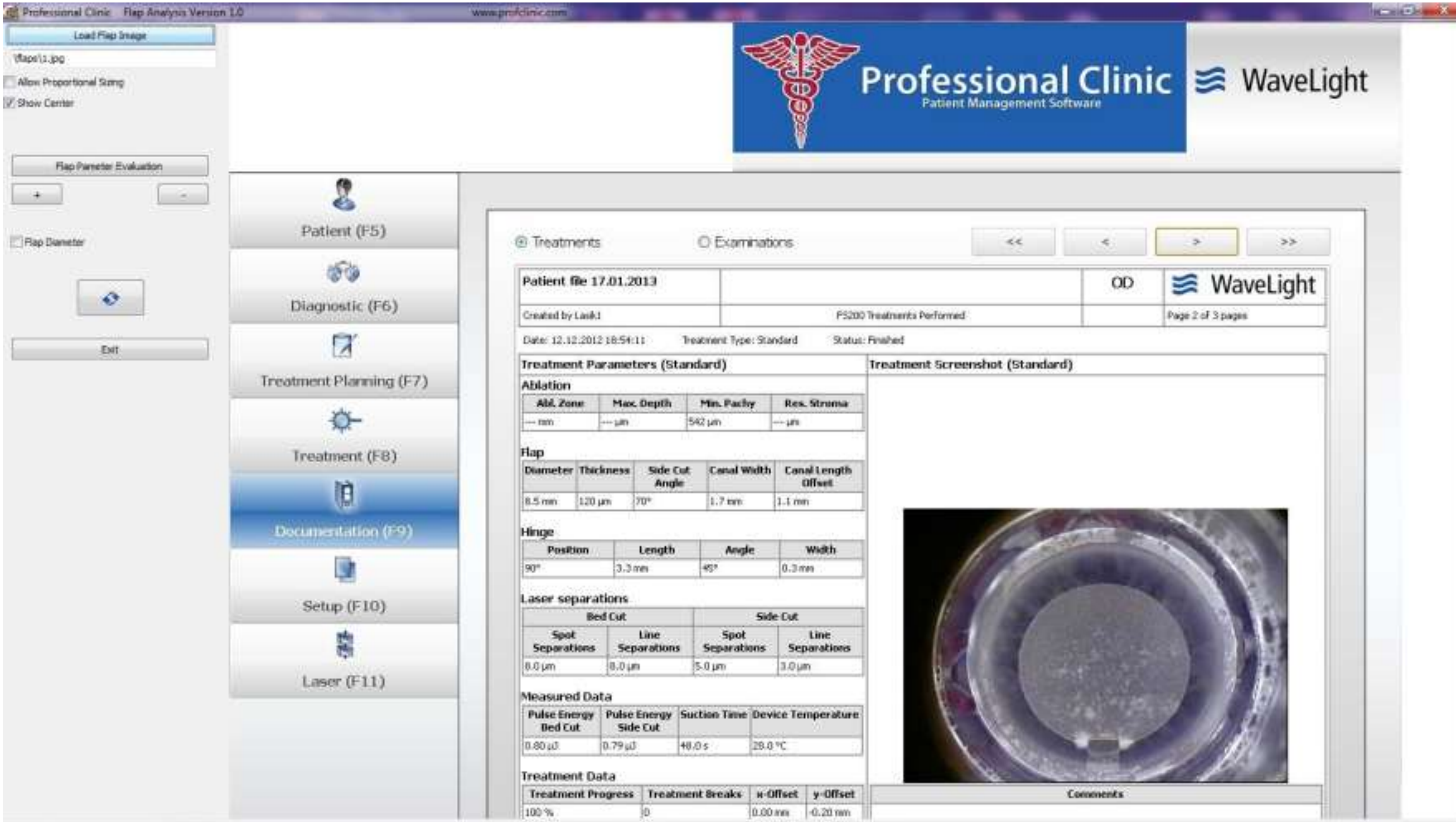
Kanellopoulos,MD

LaserVision.gr Institute for laser

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

Initial flap image-imported to the software



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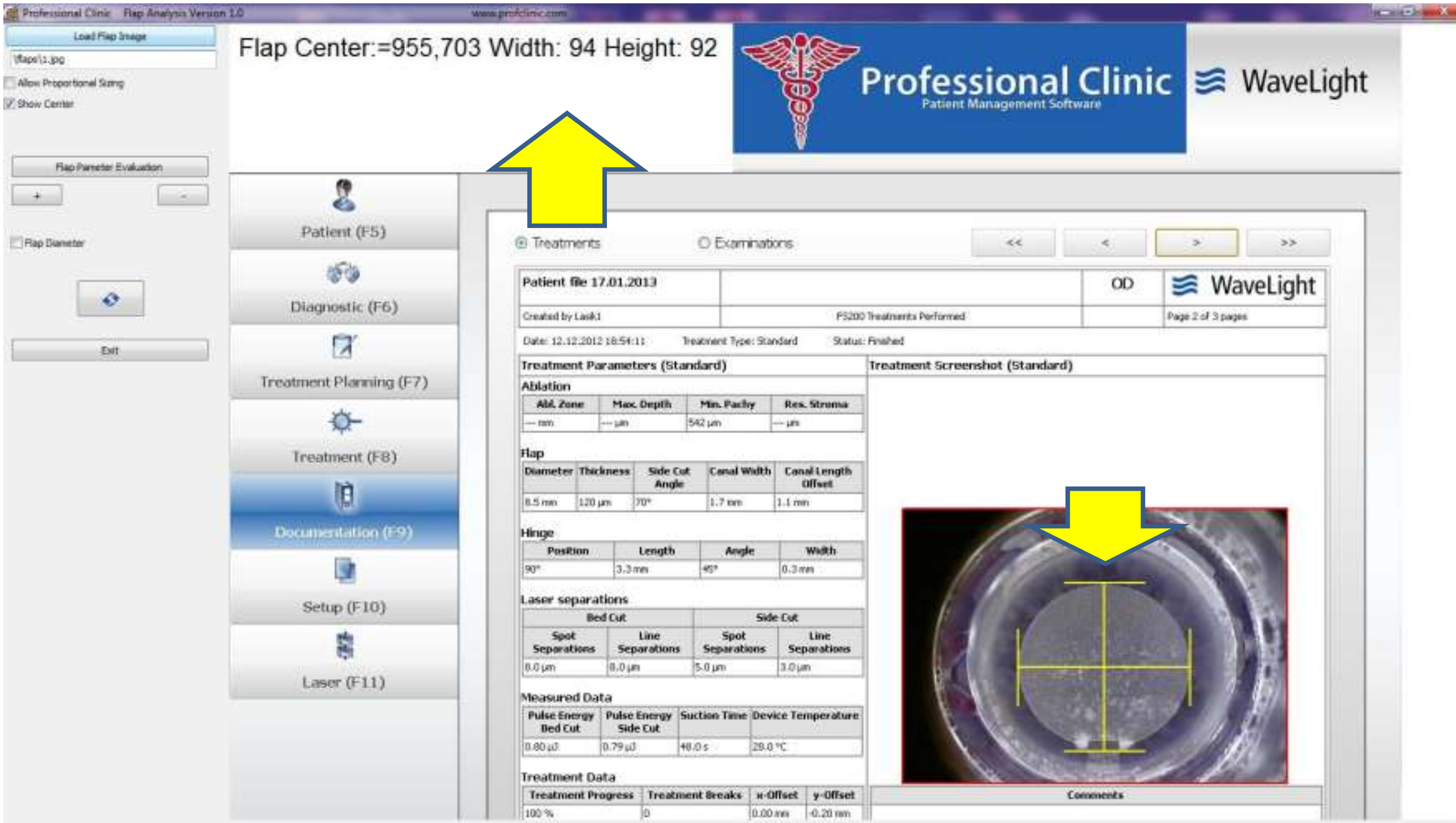
Step-1: Flap diameter objective determination
free from inter-examiner and intra-examiner potential bias
there is no examiner handling of patient privacy-sensitive data



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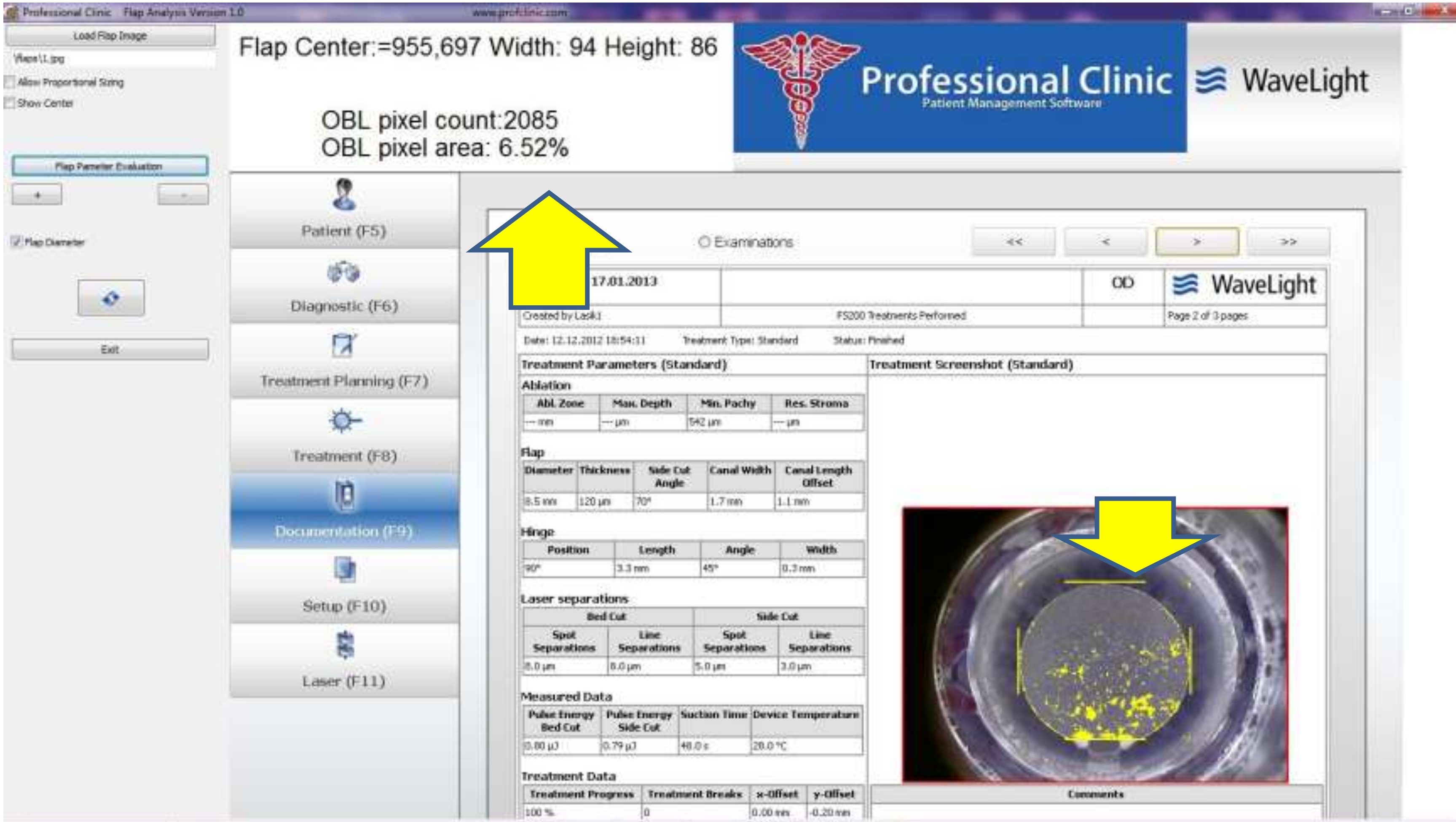
Step 2: OBL extent determination in relation to the actual flap surface achieved calculated in step 1



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Invitation

Femtosecond & Nanosecond Laser Cataract surgery, Cross-linking, and Cornea Imaging: Video Surgery Workshop and Wetlab

Saturday September 14th, 2013, 5:00-8:00pm, dinner 8:30-10:00pm

Tsocha 15-17 at the Laservision.gr Eye Institute auditorium (Free parking)

Course director: Professor Kanellopoulos, MD, NYU Medical School, New York, NY

Femtosecond and Nanosecond laser applications in cornea, refractive and cataract surgery

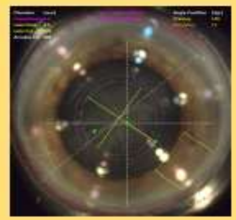
FS200 Femtosecond Laser,
LenSx Femtosecond Cataract Laser,
Cetus Nanosecond Cataract Laser.

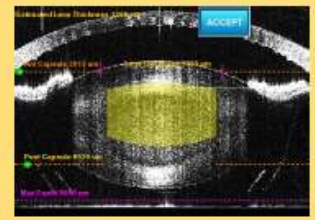
Collagen cross-linking (CXL)

our introduced techniques and future ideas:
Higher fluence,
Pulsing,
Customized CXL and the Athens Protocol
Refractive CXL results (new technology KXL II)
LASIK Xtra (myopia and hyperopia).

Cornea Imaging

Scheimpflug Imaging Pentacam,
Placido Topography,
Interferometric Pachymetry,
Modern Aberrometry,
Contrast Sensitivity and Contrast Acuity,
Anterior-Segment OCT,
High-Frequency Ultrasound,
Pupillometry Centroid Shift Studies.





Physician tuition: please inquire at (210) 7472777, physicians-in-training: no registration fee

LaserVision.gr Eye Institute   Saturday, September 14th, 2013

Thank you