

FS200 flap studies

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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

- Precise, digital analysis of flap dimensions (diameter) before flap lifting through the FS200 documentation
- Analysis of OBL presence and % extent with regard to flap area
- Impressive precision displayed on achieved diameter (-0.2 mm to +0.05 mm)
- Maximum OBL area 15%, in less than one in five FS200 created flaps.

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 $+0.06 \pm 0.06$ 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 ($1.053 \mu\text{m}$), 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 $8 \mu\text{m}$ apart) consecutive bubbles is the principle of femtosecond laser flap creation.^{2,3}



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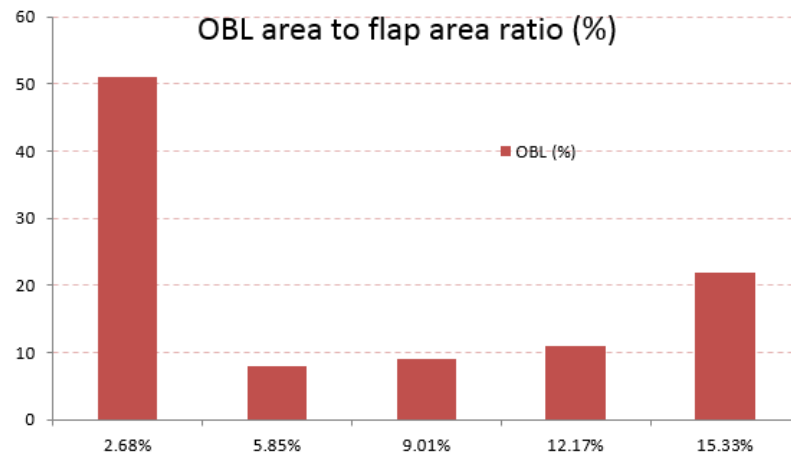
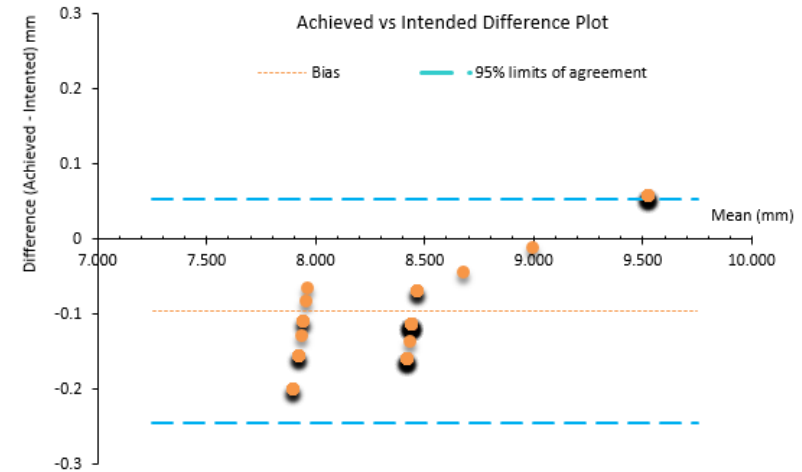
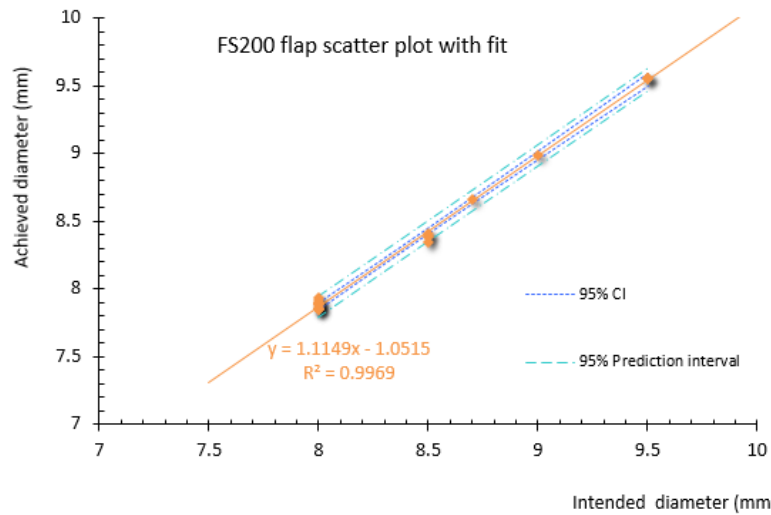
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Digital analysis of flap parameter accuracy and objective assessment of opaque bubble layer in femtosecond laser-assisted LASIK: a novel technique



Essential Opaque Bubble Layer elimination with novel LASIK flap settings in the FS200 Femtosecond Laser.

- Mechanism of OBL creation investigated
- Implementation of improved channeling with wider chimney and denser line spacing
- Analysis of OBL presence and % extent with regard to flap area enables assessment of OBL reduction
- Maximum OBL area 7%, in less than one in eight FS200 created flaps.

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

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Clinical Ophthalmology
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A John Kanellopoulos^{1,2}
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¹LaserVision.gr Eye Institute, Athens, Greece; ²New 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



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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

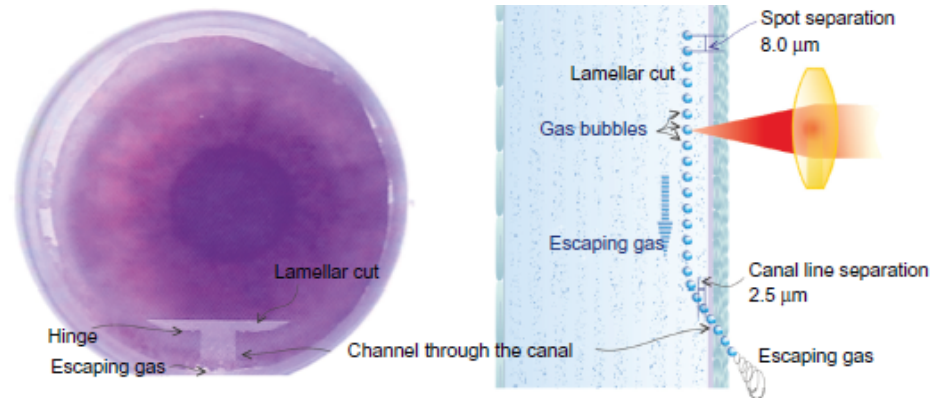
Although no serious complications have been reported as a result of its occurrence, OBL may temporarily obscure the pupil image used by most excimer laser trackers, in the subsequent excimer ablation. It may also interfere with reading of architectural landmarks on the iris used by some excimer laser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

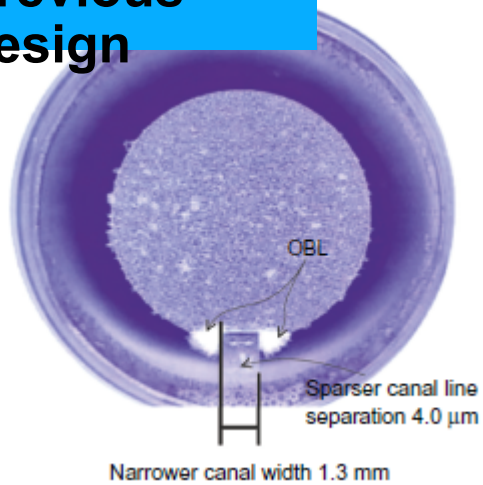


Digital analysis of flap parameter accuracy and objective assessment of opaque bubble layer in femtosecond laser-assisted LASIK: a novel technique

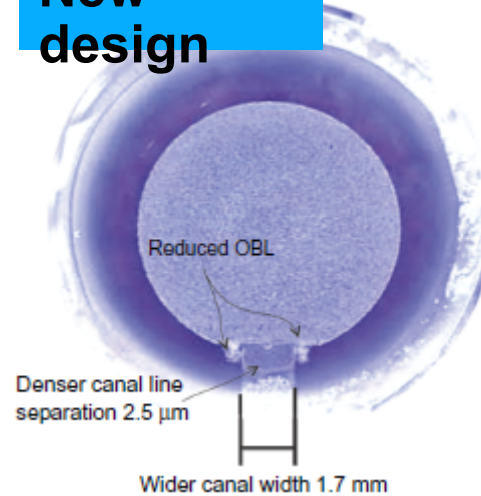
Mechanism



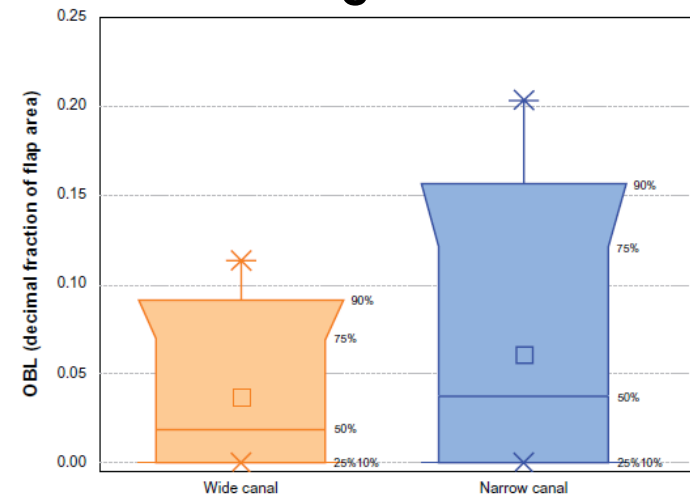
Previous design



New design



difference



Software development for flap diameter and OBL assessment

- Reads standard FS200 flap creation reports
- Identifies flap, measures diameter digitally
- Identifies OBL, measures OBL % area (to flap) digitally
- Fast, objective, repeatable
- Designed and developed by Laservision.gr

Initial flap image

The screenshot shows the 'Professional Clinic Flap Analysis Version 1.0' software interface. The main window displays patient information for 'Patient file 17.01.2013', created by 'Laski', with 'FS200 Treatments Performed' and 'Status: Finished'. The 'Treatment Parameters (Standard)' section includes a table for 'Flap' parameters:

Parameter	Value
Abbl. Zone	---
Misc. Depth	542 µm
Mix. Pachy	---
Res. Stroma	---
Flap Diameter	6.5 mm
Flap Thickness	120 µm
Side Cut Angle	70°
Canal Width	1.7 mm
Canal Length Offset	1.1 mm

The 'Hinge' section shows a table with columns for Position, Length, Angle, and Width. The 'Laser separations' section includes a table for 'Bed Cut' and 'Side Cut' parameters. The 'Measured Data' section shows 'Pulse Energy' and 'Suction Time' values. A circular image of a flap is displayed on the right side of the interface.

Flap diameter determination

Professional Clinic Flap Analysis Version 1.0 www.profclinic.com

Flap Center:=955,703 Width: 94 Height: 92

Professional Clinic Patient Management Software WaveLight

Load Flap Image
|flaps\1.jpg
 Allow Proportional Sizing
 Show Center

Flap Pamer Evaluation
+ -

Flap Diameter

Exit

Patient (F5)
Diagnostic (F6)
Treatment Planning (F7)
Treatment (F8)
Documentation (F9)
Setup (F10)
Laser (F11)

Treatments Examinations

Patient file 17.01.2013 OD WaveLight
Created by Lasik1 F5200 Treatments Performed Page 2 of 3 pages
Date: 12.12.2012 18:54:11 Treatment Type: Standard Status: Finished

Treatment Parameters (Standard) Treatment Screenshot (Standard)

Ablation

Abl. Zone	Max. Depth	Min. Pachy	Res. Stroma
--- mm	--- µm	542 µm	--- µm

Flap

Diameter	Thickness	Side Cut Angle	Canal Width	Canal Length Offset
8.5 mm	120 µm	70°	1.7 mm	1.1 mm

Hinge

Position	Length	Angle	Width
90°	3.3 mm	45°	0.3 mm

Laser separations

Bed Cut		Side Cut	
Spot Separations	Line Separations	Spot Separations	Line Separations
8.0 µm	8.0 µm	5.0 µm	3.0 µm

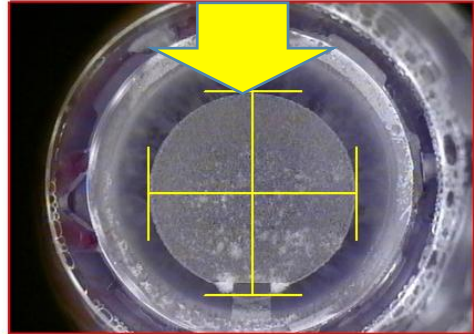
Measured Data

Pulse Energy Bed Cut	Pulse Energy Side Cut	Suction Time	Device Temperature
0.80 µJ	0.79 µJ	48.0 s	28.0 °C

Treatment Data

Treatment Progress	Treatment Breaks	x-Offset	y-Offset
100 %	0	0.00 mm	-0.20 mm

Comments



OBL extent determination

Professional Clinic Flap Analysis Version 1.0 www.profclinic.com

Flap Center:=955,697 Width: 94 Height: 86

OBL pixel count:2085
OBL pixel area: 6.52%

Professional Clinic Patient Management Software WaveLight

Flap Parameter Evaluation

Load Flap Image
Y:\flaps\1.jpg

Allow Proportional Sizing
Show Center

Flap Diameter

Exit

Patient (F5)

Diagnostic (F6)

Treatment Planning (F7)

Treatment (F8)

Documentation (F9)

Setup (F10)

Laser (F11)

Comments

Examinations

Patient file 17.01.2013

Created by Lasik1 FS200 Treatments Performed

Date: 12.12.2012 18:54:11 Treatment Type: Standard Status: Finished

OD WaveLight

Page 2 of 3 pages

Treatment Parameters (Standard)

Ablation			
Abl. Zone	Max. Depth	Min. Pachy	Res. Stroma
--- mm	--- µm	542 µm	--- µm

Flap

Diameter	Thickness	Side Cut Angle	Canal Width	Canal Length Offset
8.5 mm	120 µm	70°	1.7 mm	1.1 mm

Hinge

Position	Length	Angle	Width
90°	3.3 mm	45°	0.3 mm

Laser separations

Bed Cut		Side Cut	
Spot Separations	Line Separations	Spot Separations	Line Separations
8.0 µm	8.0 µm	5.0 µm	3.0 µm

Measured Data

Pulse Energy Bed Cut	Pulse Energy Side Cut	Suction Time	Device Temperature
0.80 µJ	0.79 µJ	48.0 s	28.0 °C

Treatment Data

Treatment Progress	Treatment Breaks	x-Offset	y-Offset
100 %	0	0.00 mm	-0.20 mm

Treatment Screenshot (Standard)

Comments

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

- Comparison of achieved vs programmed flap diameters
- Aluminum-and-glass applanation cone compared to the newly introduced all-plastic applanation cone

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

A John Kanellopoulos^{1,2}
George Asimellis¹

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

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 \pm 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 \pm 0.04 mm (range 7.93–7.80 mm). Likewise, along the vertical line, flap diameter for group A was 7.84 mm \pm 0.02 mm (range 7.85–7.80 mm) and for group B was 7.83 mm \pm 0.03 mm (range 7.87–7.80 mm). Central flap thickness for group A was 113.29 μ m (\pm 1.19 μ m) for 110 μ m planned, 122.1 μ m (\pm 2.10 μ m) for 120 μ m planned, and 133.50 μ m (\pm 0.71 μ m) for 130 μ m planned. Group B central flap thickness was, accordingly, 112.8 μ m (\pm 1.25 μ m), 122.4 μ m (\pm 2.15 μ m), and 132.50 μ m (\pm 0.90 μ m). 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

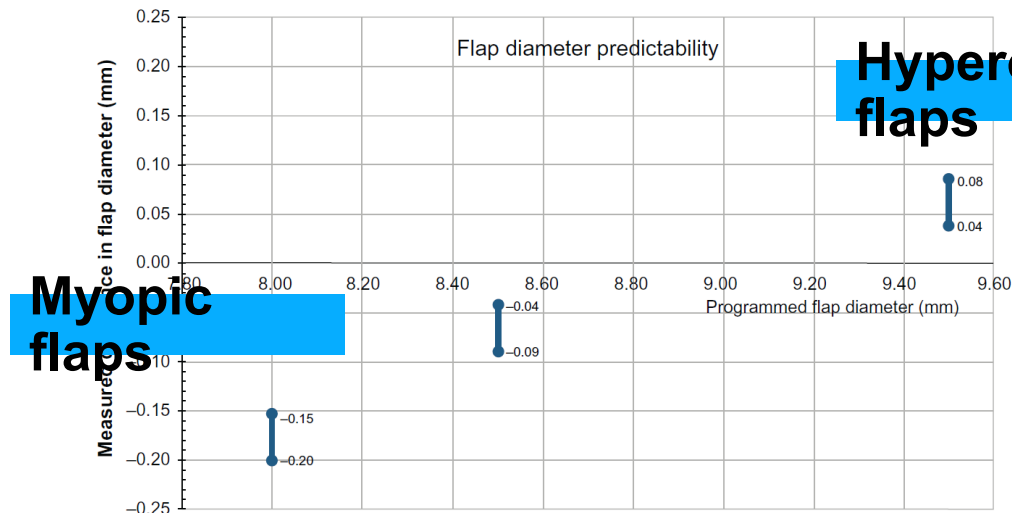
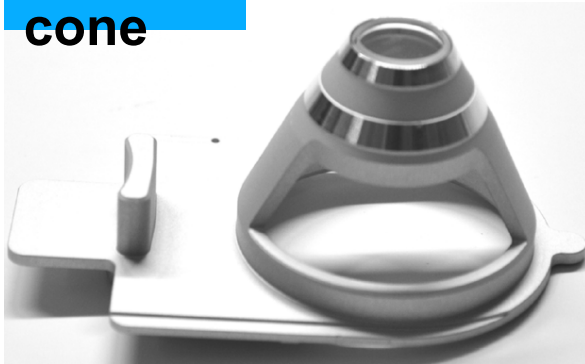
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FS200 femtosecond laser LASIK flap digital analysis parameter evaluation; comparing two different types of patient interface applanation cones

Old cone



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)

- Comparison of flap thickness and topographic variability of flap
- M2, FS60 and FS200
- Three-dimensional thickness maps produced by high-frequency scanning ultrasound
- FS200 flaps more uniform, statistically significant

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 $138.33 \pm 12.38 \mu\text{m}$ (mean \pm standard deviation) in Group A, $128.46 \pm 5.72 \mu\text{m}$ in Group B, and $122.00 \pm 5.64 \mu\text{m}$ in Group C. Topographic flap thickness variability was $9.73 \pm 4.93 \mu\text{m}$ for Group A, $8.48 \pm 4.23 \mu\text{m}$ for Group B, and $4.84 \pm 1.88 \mu\text{m}$ 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



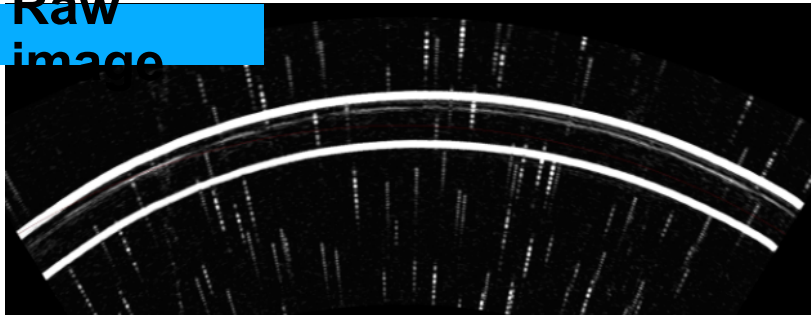
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Introduction

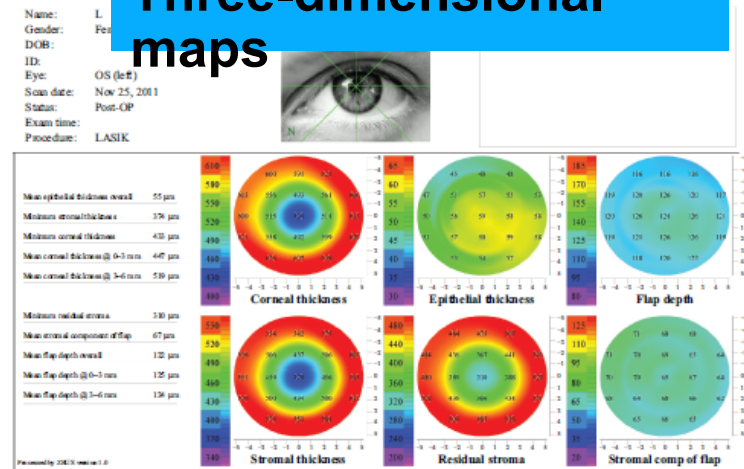
We have previously reported, in agreement with many others, on the safety and accuracy of flap making with mechanical keratomes for correction of myopia and myopic astigmatism¹ as well as hyperopia.²

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)

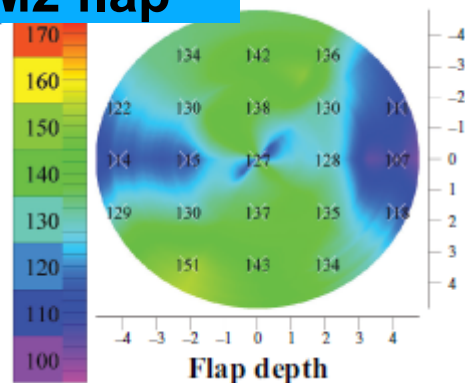
Raw image



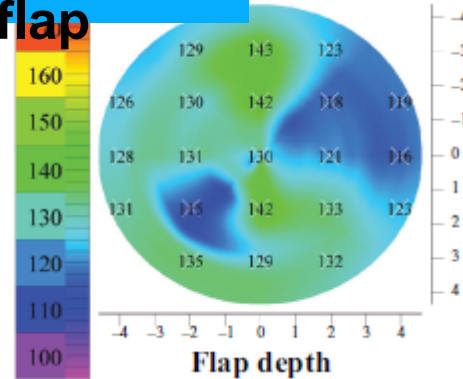
Three-dimensional maps



M2 flap



FS60 flap



FS200 flap

