

Digitized evaluation of femtosecond laser-assisted LASIK flap parameters (x and y diameter, thickness) and Opaque Bubble Layer extent

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Background

- Myopia, hyperopia, and astigmatism can be treated by laser in-situ keratomileusis (LASIK) via 2 steps¹
 - **Corneal flap creation** with a mechanical microkeratome or a femtosecond laser
 - **Corneal reshaping** with an excimer laser
- LASIK can be performed using the upgraded WaveLight® Refractive Suite
 - FS200 Femtosecond Laser: improves precision of LASIK flaps by reducing optical aberrations and enhancing predictability of the procedure^{2,3}
- An opaque bubble layer (OBL) is a temporary stromal infiltration by compressed air generated by the intracorneal femtosecond laser action, that cannot escape during creation of a LASIK flap, and occurs along the lamellar dissection plane⁴

WaveLight® FS200 Femtosecond Laser



1. Watson SL, et al. Improved safety in contemporary LASIK. *Ophthalmology*. 2005;112:1375-1380. 2. Chan A, et al. Comparison of the femtosecond laser and mechanical keratome for laser in situ keratomileusis. *Arch Ophthalmol*. 2008;126:1484-1490. 3. Stonecipher K, et al. Advances in refractive surgery: microkeratome and femtosecond laser flap creation in relation to safety, efficacy, predictability, and biomechanical stability. *Curr Opin Ophthalmol*. 2006;17:368-372. 4. Kanellopoulos AJ, et al. Essential opaque bubble layer elimination with novel LASIK flap settings in the FS200 Femtosecond Laser. *Clin Ophthalmol*. 2013; 7: 765-770.

Purpose

- To determine the precision and accuracy of flap parameters (x and y diameter and thickness) in comparison with programmed settings
- To evaluate the extent of OBL in femtosecond laser-assisted myopic LASIK
- To compare results between two centers

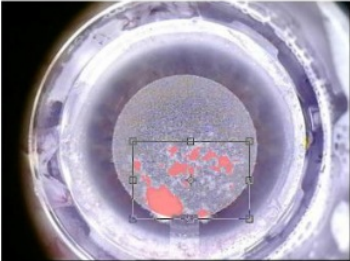
○ Treatments ○ Examinations << >>

Patient file 20.12.2012 , M

Created by Leski FS200 Treatments Performed


Date: 20.12.2012 16:17:25 Treatment Type: Standard Status: Finished

Treatment Parameters (Standard)				Treatment Screenshot (Standard)			
Ablation							
Abl. Zone	Max. Depth	Min. Pachy	Res. Stroma				
8.7 mm	116 µm	549 µm	31.3 µm				
Flap							
Diameter	Thickness	Side Cut Angle	Canal Width	Canal Length	Offset		
8.0 mm	120 µm	70°	1.7 mm	1.3 mm			
Hinge							
Position	Length	Angle	Width				
90°	3.1 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				
0.82 µJ	0.82 µJ	37.0 s	27.0 °C				
Treatment Data							
Treatment Progress	Treatment Breaks	x-Offset	y-Offset	Comments			
100 %	0	0.00 mm	-0.10 mm				

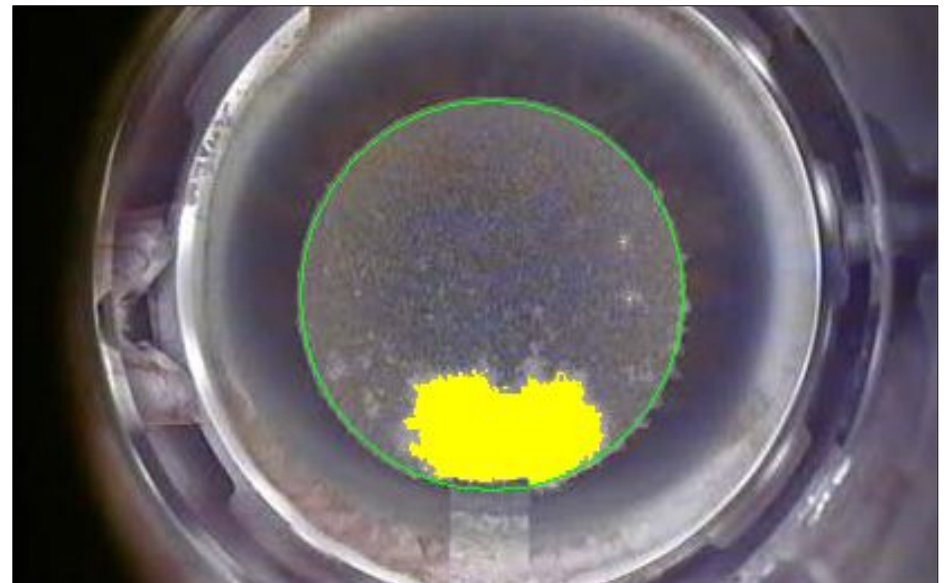


NAVIGATOR HISTOGRAM INFO

Channel: Luminosity



Source: Entire Image
Mean: 166.75 Level:
Std Dev: 7.02 Count:
Median: 168 Percentiles:
Pixels: 2688 Cache Level: 1



Study Design and Methods

- Dual-center study
- US site-1: 48 consecutive eyes (24 OD, 24 OS) with 8.50 mm diameter flaps were investigated
- GR site-2: 36 consecutive eyes (16 OD, 20 OS) with 8.50 mm diameter flaps were investigated
- GR site-2: 48 consecutive eyes (24 OD, 24 OS) with 8.00 mm diameter flaps were investigated
- Central flap thickness (planned 110- μ m) was investigated in all GR site-2 eyes

Methods

- Flaps (programmed diameter, 8.00 mm or 8.50 mm) were created with the FS200 femtosecond laser and were imaged intra-operatively with a built-in digital camera
- Image processing was used to document flap diameter accuracy (vertical and horizontal) to the 100 μm sensitivity level, and OBL occurrence and extent of flap area
- Central flap thickness (planned 110 μm) was measured using anterior-segment OCT meridional scans acquired one-month post-operatively

Results

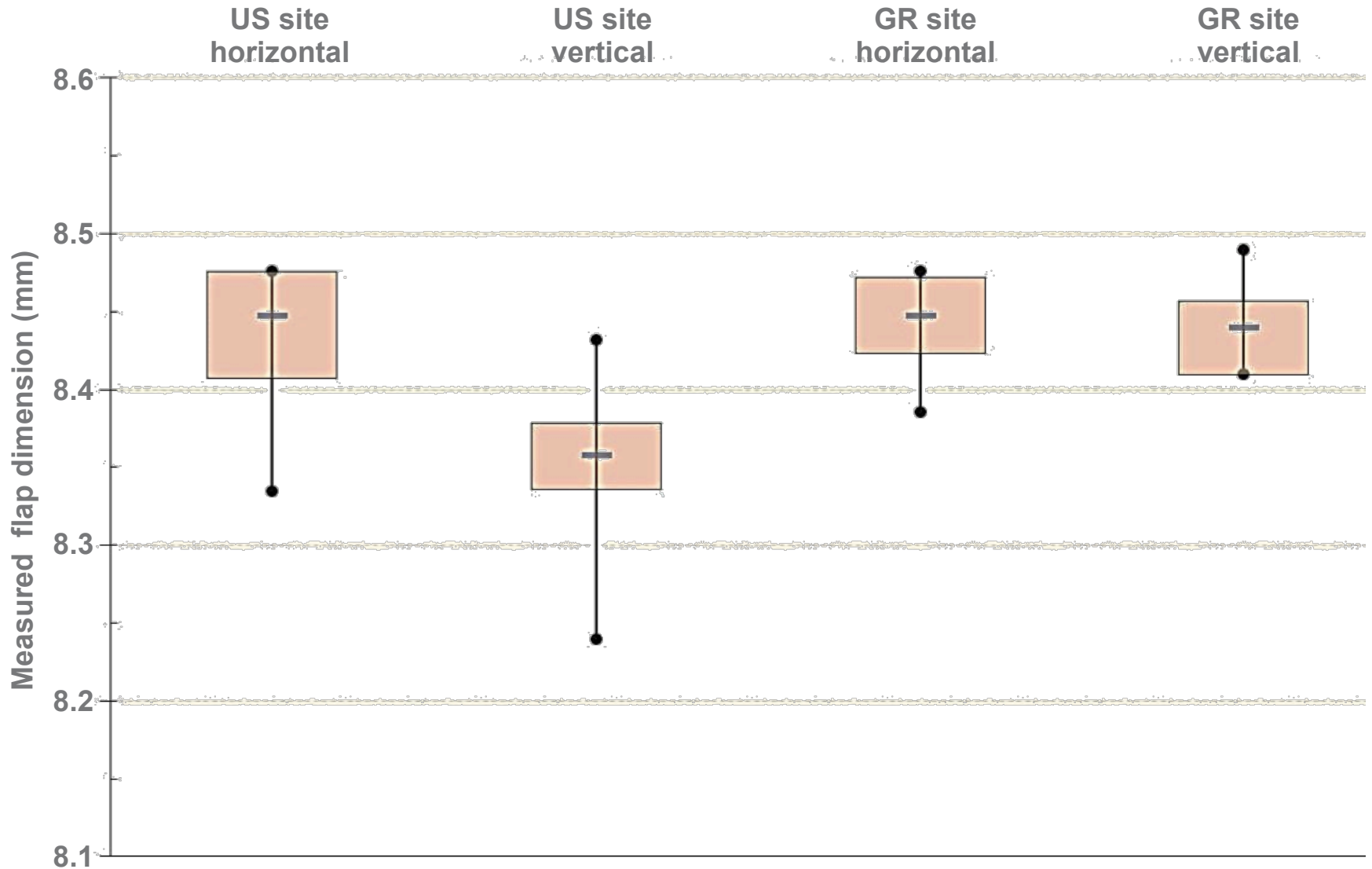
8.50-mm Programmed Flaps

- US site-1
 - Horizontal diameter: 8.44 ± 0.02 SD (8.35-to-8.45) mm
 - Vertical diameter: 8.32 ± 0.05 (8.24-to-8.43) mm
 - OBL extent: 5.48 ± 8.25 (0.00-to-26.64) % of flap area

- GR site-2
 - Horizontal diameter: 8.43 ± 0.03 (8.39-to-8.48) mm
 - Vertical diameter: 8.43 ± 0.03 (8.41-to-8.49) mm
 - OBL extent was 5.33 ± 7.59 (0.00-to-26.44) % of flap area

Results

8.50-mm Planned Flaps



Results

8.00-mm Programmed Flaps and Flap Thickness

- 8.00-mm programmed flaps (GR site-2 only)
 - Horizontal diameter: 7.87 ± 0.02 (7.84-to-7.89) mm
 - Vertical diameter: 7.84 ± 0.02 (7.80-to-7.85) mm
 - OBL extent: 4.89 ± 7.52 (0.00-to-22.64) % of flap area

- Flap thickness (GR site-2 only, 84 flaps)
 - Measured central thickness: 113.54 ± 1.39 (111-to- 119) μm
 - Intra-flap thickness variation: <5 (1-4) μm in all cases

Conclusions

- This study uses an objective digital analysis to document and confirm that FS200 demonstrates high precision, accuracy and reproducibility for flap creation
- Revised treatment parameters (venting channel dimensions, spot separation and energy settings) may offer significant reduction in clinical OBL occurrence
- Results were comparable between the two centers