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A. John Kanellopoulos, MD
Clinical Professor of Ophthalmology
Medical Director: The Laservision.gr Institute, Athens Greece
and the Athens team

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

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

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

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

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Correspondence: A John Kanellopoulos
17 A Tsocha Str, Athens 11521, Greece
Tel +30 210 747 2777
Fax +30 210 747 2789
Email ajk@brilliantvision.com

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]

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.

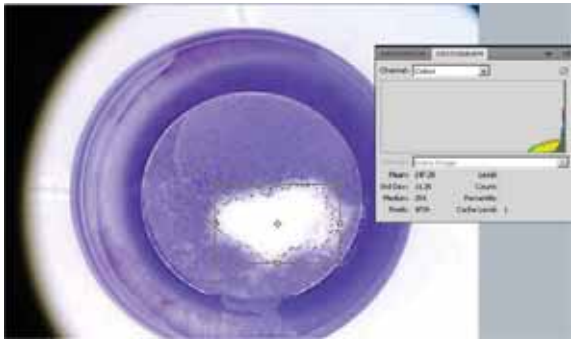

Figure 3 Methodology for measurement of opaque bubble layer area.
Notes: The area within the flap with white more than 50% is selected with the Magic Wand tool. The pixel area is determined by the histogram tool, and subsequently converted to metric units. This is the maximal opaque bubble layer encountered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

New York University School of Medicine Kanellopoulos,MD

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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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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)

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

[1]Laservision.gr Institute, Athens, Greece; [2]NYU Medical School, New York, USA

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Correspondence: A John Kanellopoulos
Laservision.gr Institute,
17 Tsocha Street, Athens,
Greece 11521
Tel +30 210 7472777
Fax +30 210 7472789
Email ajk@brilliantvision.com

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

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]

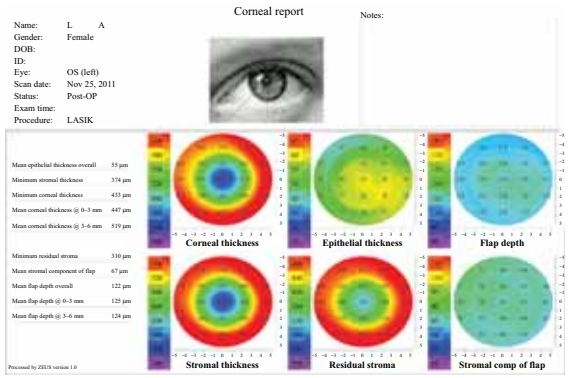

Figure 1 Standard corneal analysis report used in our investigation.
Note: This specific flap has been created with the FS200 femtosecond laser.
Abbreviation: LASIK, laser-assisted in situ keratomileusis.

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).

New York University School of Medicine Kanellopoulos,MD

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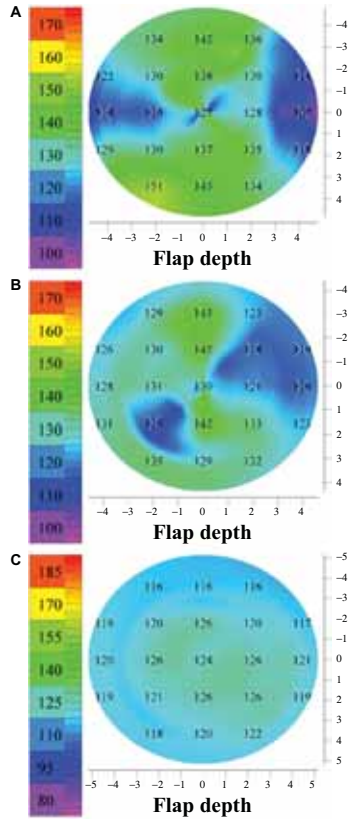

Figure 3 Three representative flap thickness maps (8 mm diameter) from flaps created with the modalities studied in this paper: (**A**) M2 microkeratome (Moria Surgical, Antony, France), (**B**) Intralase™ FS60 femtosecond laser (Abbott Medical Optics, Santa Ana, CA, USA), (**C**) WaveLight® FS200 femtosecond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

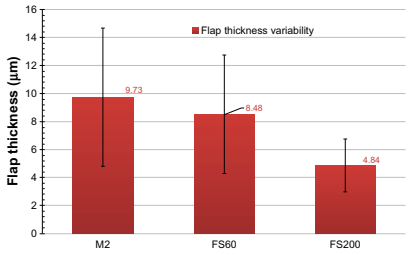

Figure 4 Postoperative topographic flap thickness variability for the three groups examined.
Notes: "FS60" refers to the IntraLase™ FS60 femtosecond laser manufactured by Abbott Medical Optics, Santa Ana, CA, USA; "FS200" refers to the WaveLight® FS200 femtosecond laser manufactured by Alcon, Fort Worth,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

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

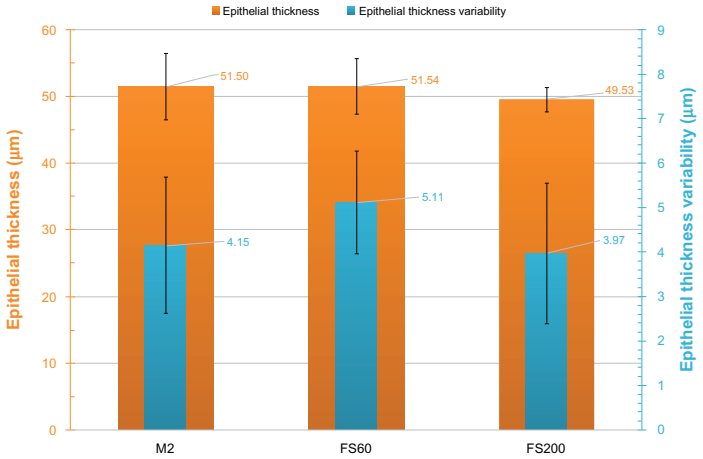

Figure 5 Postoperative epithelial thickness and topographic epithelial thickness variability for the three groups examined.
Notes: "FS60" refers to the Intralase™ FS60 femtosecond laser manufactured by Abbott Medical Optics, Santa Ana, CA, USA; "FS200" refers to the WaveLight® FS200 femtosecond laser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

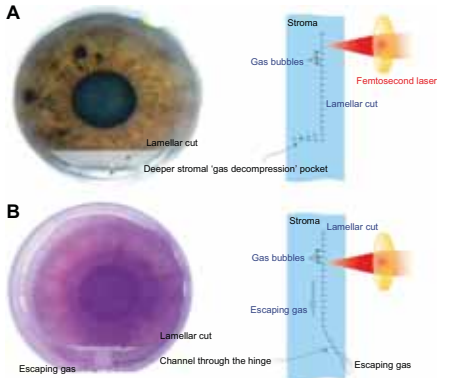

Figure 6 Schematic of the architectural differences between the (**A**) Intralase™ FS60 (Abbott Medical Optics, Santa Ana, CA, USA) and (**B**) WaveLight® FS200 (Alcon, Fort Worth, TX, USA) femtosecond lasers.
Notes: In the initial phase of flap creation with the FS60, a stromal "gas decompression" pocket 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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Long-term bladeless LASIK outcomes with the FS200 Femtosecond and EX500 Excimer Laser workstation: the Refractive Suite

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Long-term bladeless LASIK outcomes with the FS200 Femtosecond and EX500 Excimer Laser workstation: the Refractive Suite

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

[1]Laservision.gr Institute, Athens, Greece; [2]NYU Medical School, NY, USA

Purpose: The evaluation of the safety, efficacy, and long-term stability of LASIK procedures utilizing novel platform comprising a femtosecond and excimer laser and multiple networked diagnostics.

Setting: Private clinical ophthalmology practice.

Patients and methods: In consecutive cases of myopic LASIK procedure with a novel refractive platform (FS200 Femtosecond and EX500 Excimer Laser), 190 eyes (from 109 different patients) were evaluated pre- and postoperatively for the following parameters: refractive error, best corrected distance visual acuity, uncorrected distance visual acuity, topography (Placido-disc based) and tomography (Scheimpflug-image based), wavefront analysis, pupillometry, and contrast sensitivity. Follow-up visits were conducted for at least 12 months.

Results: The change from pre- to postoperative mean refractive error was from −5.29 ± 2.39 diopters (D) (range −8.0 to −0.50 D) to −0.27 ± 0.09 D at the 3-month visit, −0.27 ± 0.10 D at the 6-month visit, and −0.39 ± 0.08 D at the 1-year visit. The change from pre- to postoperative refractive astigmatism was −1.07 ± 0.91 D (range −4.25 to 0 D) to −0.14 ± 0.04 D at 3 months, −0.15 ± 0.04 at 6 months, and −0.16 ± 0.04 at the 1-year visit. The proportion of the eyes with postoperative astigmatism within 0.5 D ranged between 95.6% and 99%. The proportion of eyes achieving uncorrected distance visual acuity of 1.0 (decimal) was 93.0%.

Conclusion: The myopic LASIK clinical results with the FS200 Femtosecond Laser and EX500 Excimer Laser showed outstanding efficacy, great safety, and long-term stability.

Keywords: bladeless LASIK flap, femtosecond laser, myopic correction, long-term stability, regression, astigmatism correction, post-LASIK refraction

Video abstract

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Correspondence: A John Kanellopoulos
Laservision.gr Eye Institute, 17 Tsocha Street, Athens, Greece, 11521
Tel +30 21 0747 2777
Fax +30 21 0747 2789
Email ajk@brilliantvision.com

Introduction

Laser-assisted in situ keratomileusis (LASIK) is a widely accepted method for correcting the refractive error,[1,2] as evidenced by the long number of publications in the peer-reviewed literature.

In recent years, the use of bladeless LASIK surgery utilizing a femtosecond laser (named for its ultrashort pulses, with duration of few femtoseconds or quadrillionths of a second) for lamellar flap creation, as an alternative option to the mechanical microkeratome,[3,4] has been studied as well.

A second laser involved in the procedure, the excimer provides the ablation and has also evolved significantly over the course of the past 10 years. Contemporary generation excimer lasers for refractive surgery operate with high pulse repetition (more than 400 Hz)[5,6] and scanning spot[7] and can provide customized ablation, including aspheric ablation profiles,[8] wavefront-guided,[9,10] or topography-guided[11,12] treatments.

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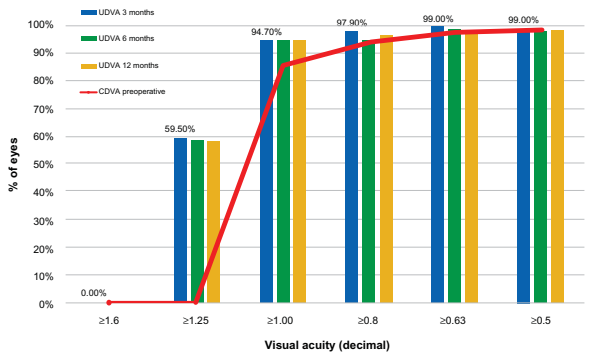

Figure 1 Postoperative uncorrected distance visual acuity at the 3-, 6-, and 12-month visits (clustered columns) versus preoperative best corrected visual acuity (stacked red line).
Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, best corrected visual acuity.

were unchanged, while 59.2% of the eyes gained one Snellen line and 6.4% gained two or more Snellen lines. The proportion of eyes losing one line was less than 2%, and so was the proportion of eyes losing two Snellen lines.

Refractive stability and predictability

The refractive stability is demonstrated by the SE correction, at the 12-month postoperative visit (Figure 3). Defocus equivalent results are presented in Figure 4.

Predictability is demonstrated in Figure 5, where the achieved SE versus attempted SE (in D) was plotted, for gate = 0.5 D. Of the 190 eyes shown, one eye (0.5%) is marked with red, indicating overcorrection, 180 (95%) are marked with green (indicating individual outcomes where the achieved spherical correction was within the gate, that is, 0.5 D of the attempted correction), and nine eyes (5%) are marked with blue, indicating undercorrection. The data have a linearity a = 1.00, with bias b = −0.16, and the regres-

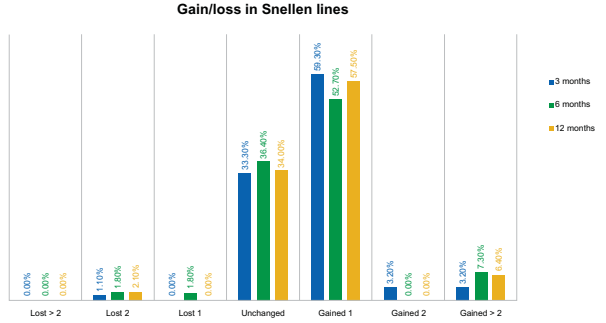

Figure 2 Safety distance visual acuity graph (% of eyes with gain/loss in Snellen lines), at the 3-, 6-, and 12-month visits.

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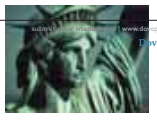


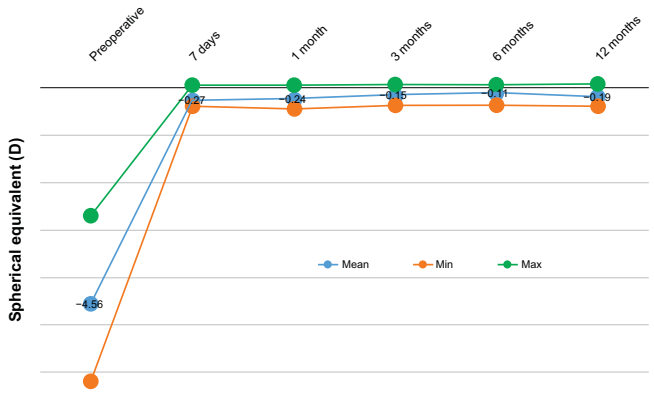


Figure 3 Stability of spherical equivalent for up to 12 months postoperatively.
Abbreviation: D, diopter.

sion coefficient (r) = 0.98. Likewise, in the 6-month follow-up visit, the linearity was a = 1.02, and for the 12-month postoperatively follow-up visit, the linearity was a = 0.99.

In a similar fashion, the SE refraction is depicted in Figure 6, where SE during the 3-month, 6-month, and 12-month postoperatively follow-up visits are shown.

Keratometric and astigmatic changes and stability

The comparison between postoperative and preoperative refractive astigmatism is demonstrated by the percentage of eyes within 0.25 D of postoperative refractive astigmatism.

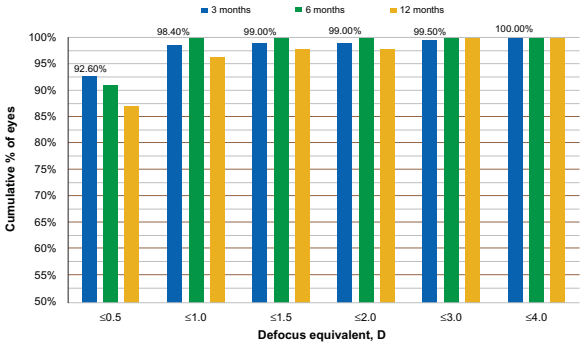


Figure 4 Defocus equivalent results at the 3-, 6-, and 12-month visits.
Abbreviation: D, diopter.

As shown in Figure 7, at the 3-month visit, 94.7% of the eyes showed astigmatism less than 0.25 D, at the 6-month visit, and 97.9% showed less than 0.5 D refractive astigmatism at the 12-month visit.

Of interest is the comparison between postoperative and preoperative refractive astigmatism, in the form of a double angle-cylinder scatterplot of the surgically induced astigmatism minus the target-induced astigmatism, an example of which is shown in Figure 8.

The keratometric changes and stability is demonstrated by the K-flat and K-steep average values during the 1-, 3-, 6-, and 12-month postoperative visits (Figure 9).

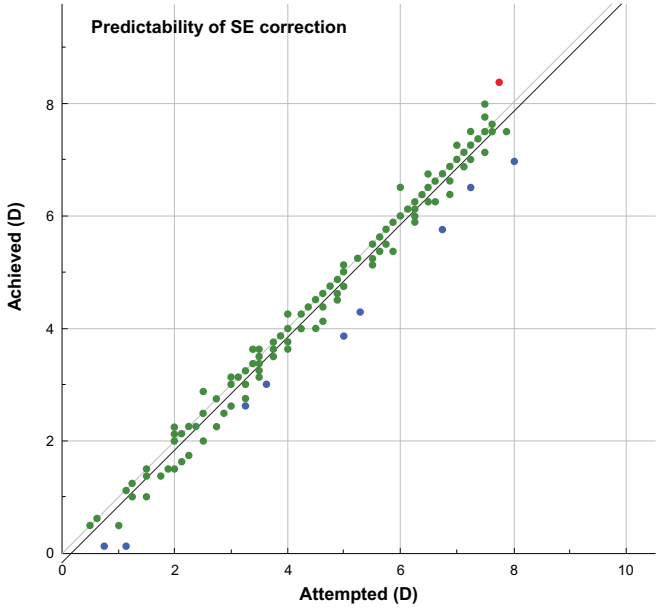


Figure 5 Predictability of spherical equivalent (SE) correction, showing achieved SE versus attempted SE.
Abbreviation: D, diopter.

Discussion

In clinical practice, we used the combined WaveLight refractive surgery laser platform comprising the FS200 Femtosecond Laser,[16] the EX500 Excimer Laser, and the series of networked diagnostic devices (including Vario Placido topography, Oculyzer II Scheimpflug topography imaging, a Tscherning wavefront system, and the OB820 biometer), that together constitute the Refractive Suite®.[17]

Clinical results and features of the previous generations of the WaveLight excimer series (200 Hz Allegretto and 400 Hz Eye Q) have been reported by our team.[12,19]

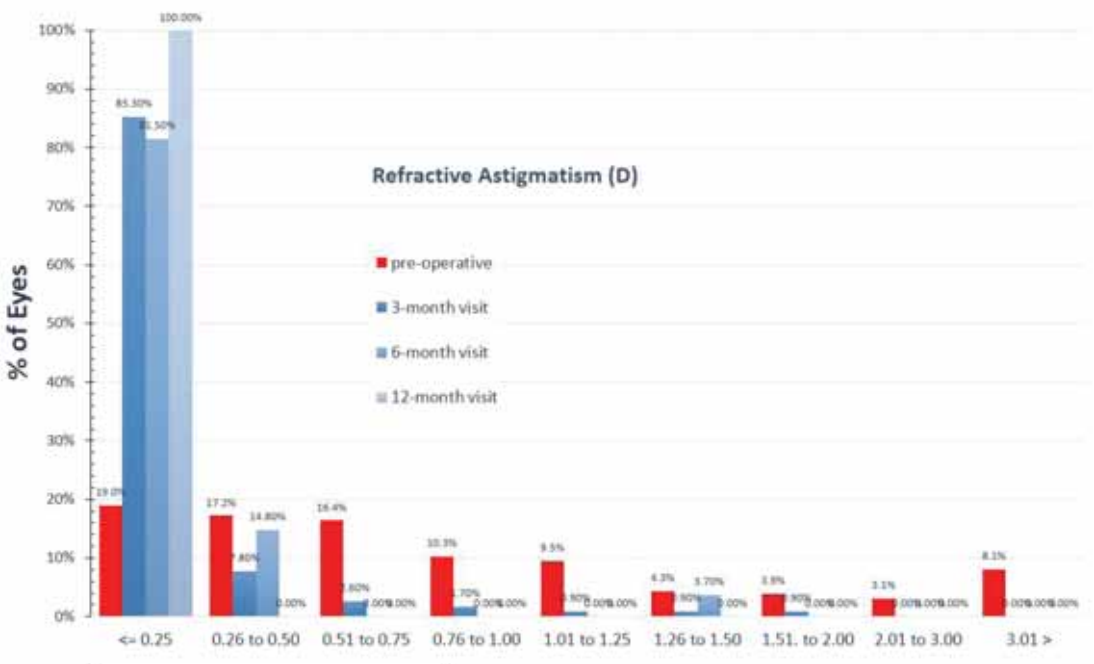
The EX500 laser, the latest evolution of the aforementioned excimer lasers, employs a 1050 Hz multidimensional active tracker (with estimated response time [latency] of 2 milliseconds and ability to track pupil size from 1.5 to 8 mm), online optical pachymetry (enabling central cornea pachymetric measurements immediately following flap removal and during the LASIK procedure) to dynamically assess tissue removal, an onboard nitrogen generator (making the unit self-sufficient for nitrogen), and a 500 Hz laser pulse frequency that enables the treatment of each D of myopia in 1.4 seconds (based on a 6.0 mm optical zone of treatment). This enhanced speed may reduce stromal dehydration, flap shrinkage, sensitivity to eye movements, and patient fixation fatigue.[20]

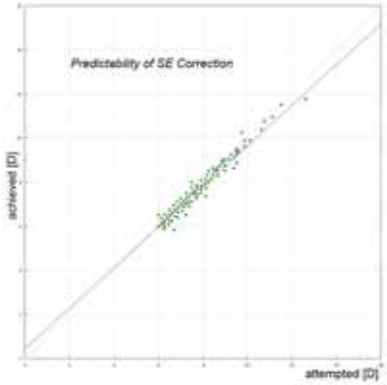
The flying spot in the excimer allows only one pulse in five to overlap and optimizes temporal and spatial shot distribution. Additional pulses are sent to the periphery to compensate for energy loss, reducing the potential for nighttime glare.

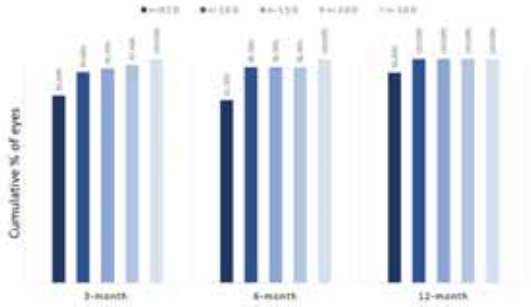
The Refractive Suite operates on its own Ethernet network and allows the import of diagnostic data from networked screening devices into the planning software tools of both lasers. For example, the Suite offers the ability to import the topometry data from the Oculyzer II into the laser treatment planning mode and to accordingly customize the excimer treatment to the cornea (for eg, topography-guided treatment).[12]

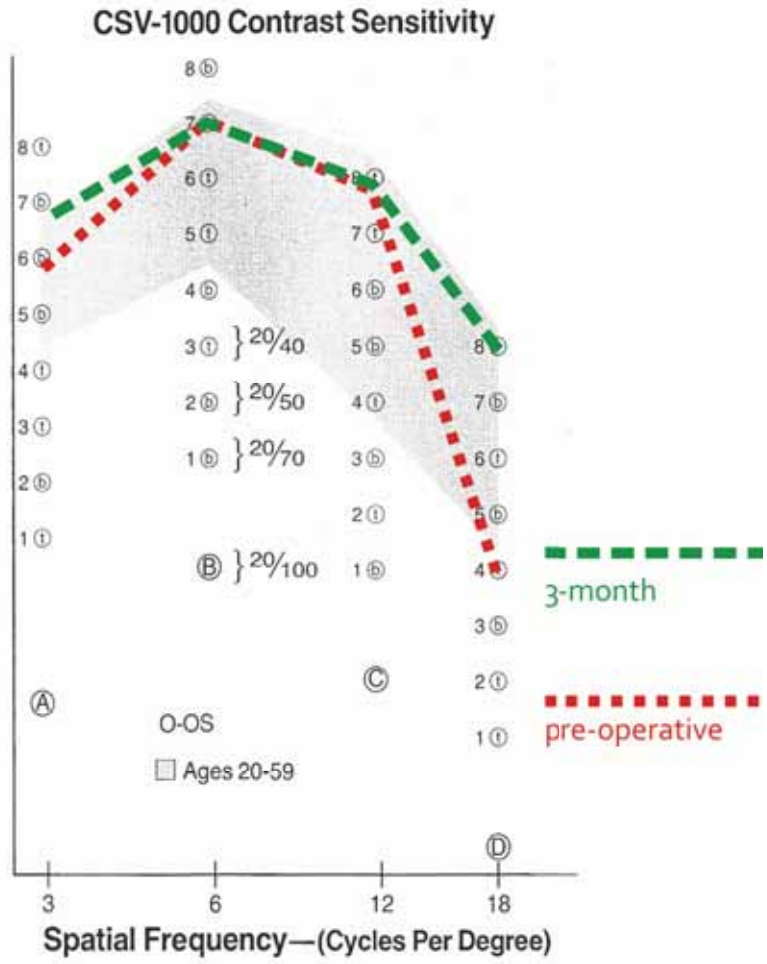
The long-term clinical results with the systems described above reported here show impressive refractive outcome,

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









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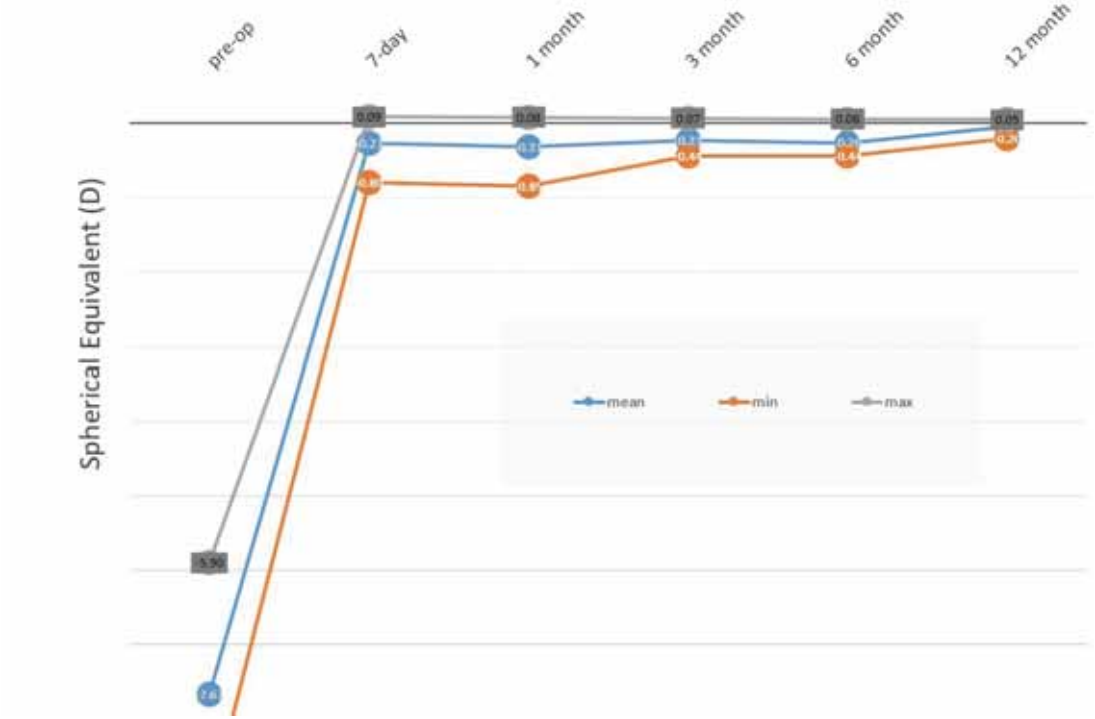
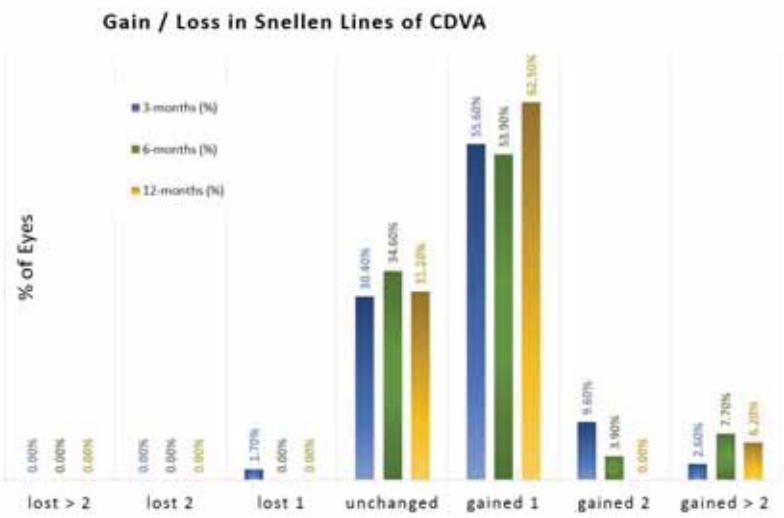
Stability-safety





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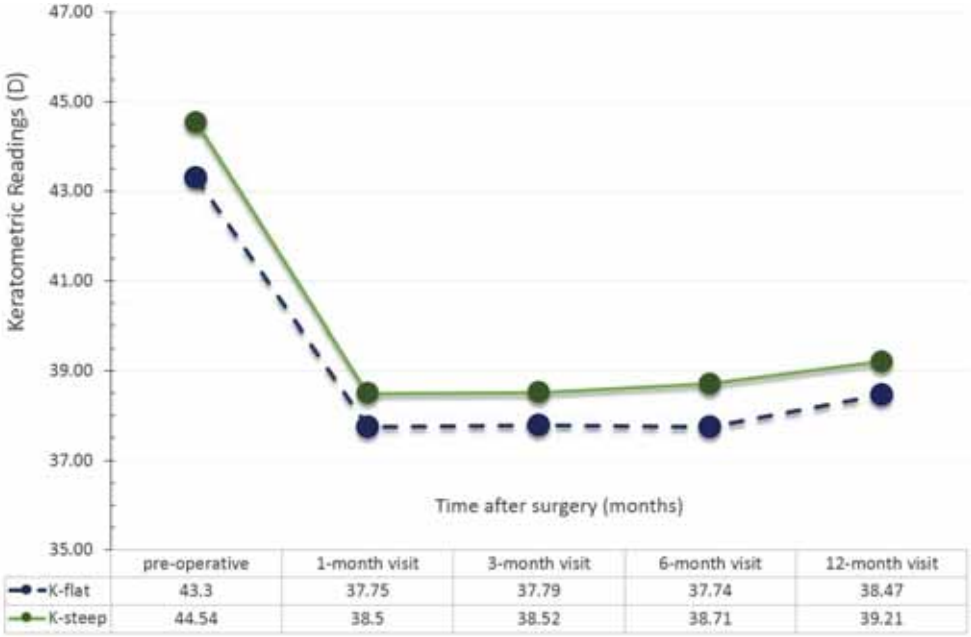
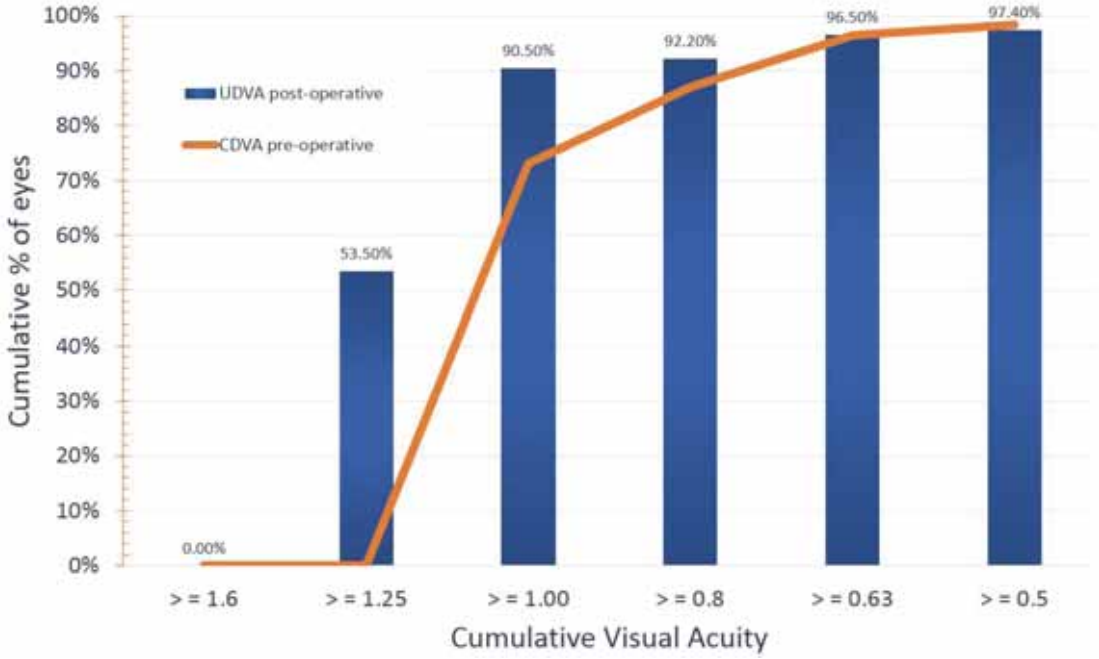
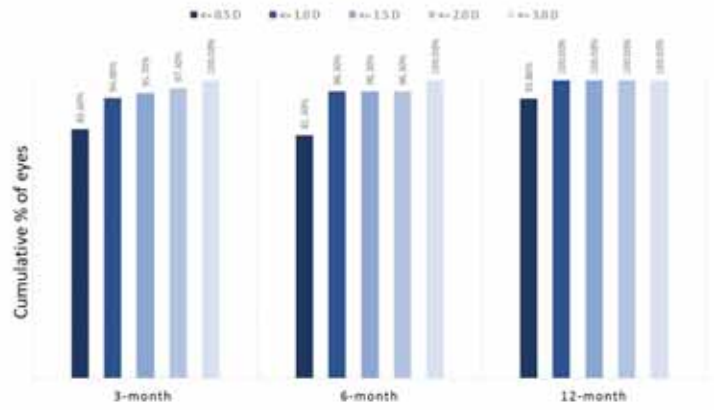


	pre-operative	1-month visit	3-month visit	6-month visit	12-month visit
K-flat	43.3	37.75	37.79	37.74	38.47
K-steep	44.54	38.5	38.52	38.71	39.21





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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]

[1]LaserVision.gr Eye Institute, Athens, Greece; [2]New 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 ± 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 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.

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.

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

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

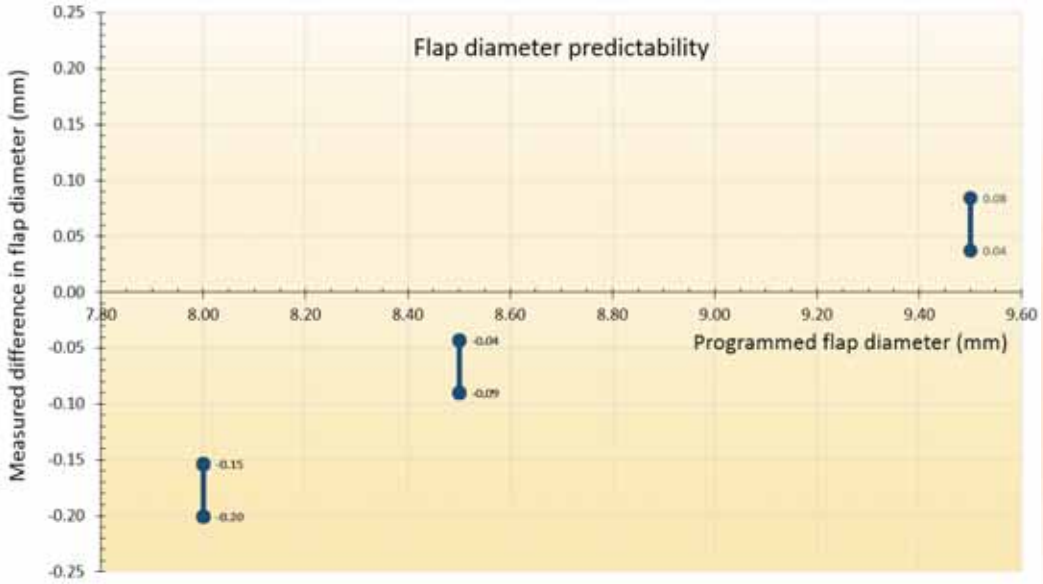
The study group consisted of 36 consecutive patients (72 eyes) treated for bilateral primary myopic or hyperopic femtosecond assisted LASIK between October 2012 and January 2013 in our center using the interface 1505, forming the clear cone group A. Mean preoperative spherical equivalent for this group 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.

Correspondence: A John Kanellopoulos
Laservision.gr Institute,17A Tsocha str,
Athens 11521, Greece
Tel +30 210 747 2777
Fax +30 210 747 2789
Email ajk@brilliantvision.com


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
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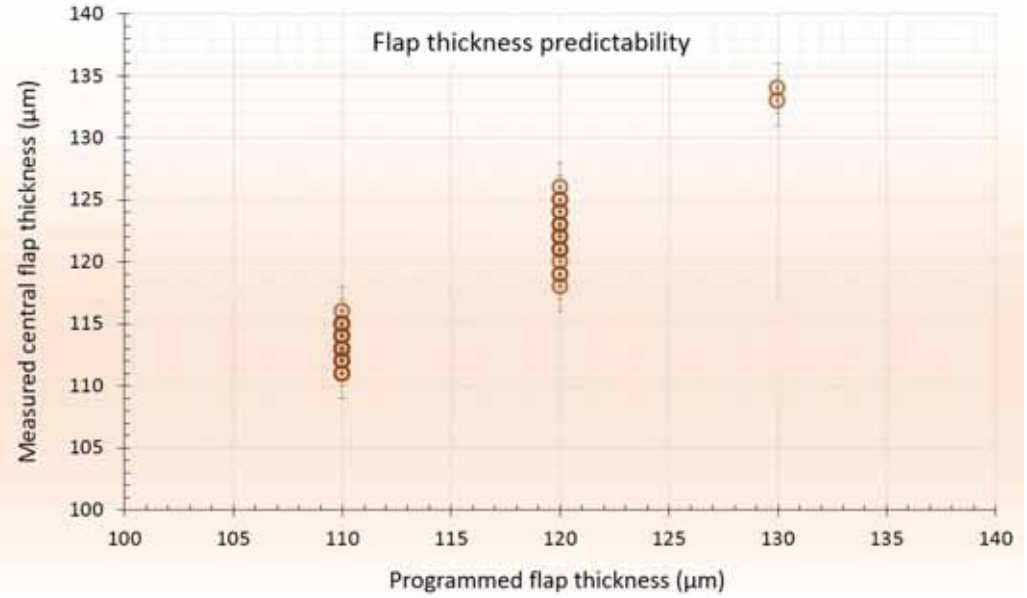
Flap thickness predictability
Measured central flap thickness (µm)
Programmed flap thickness (µm)
140
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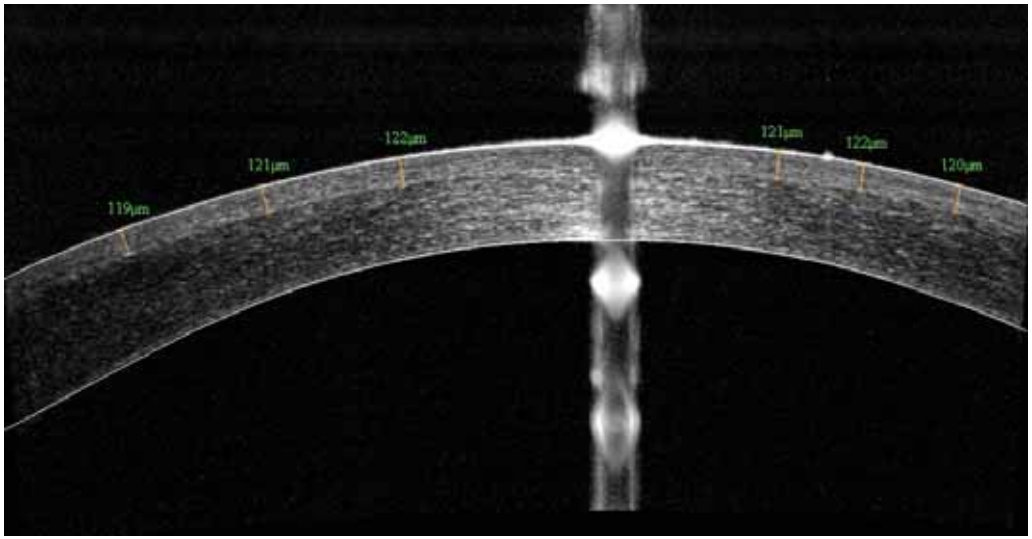
119µm
121µm
122µm
121µm
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120µm

New venting channel parameters and OBL reduction

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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

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Correspondence: A John Kanellopoulos
Laservision.gr Eye Institute
17A Tsocha Str, Athens, Greece 11521
Tel +30 210 747 2777
Fax +30 210 747 2789
Email ajk@brilliantvision.com

Introduction

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

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

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

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

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

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

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 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

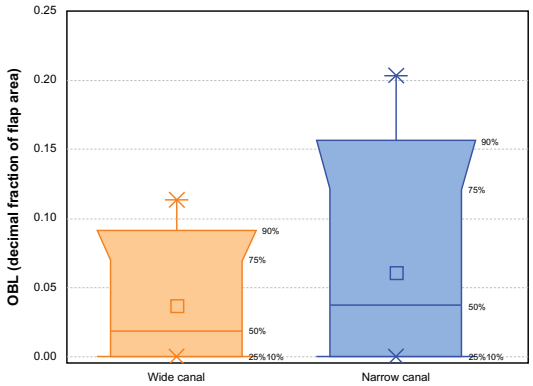
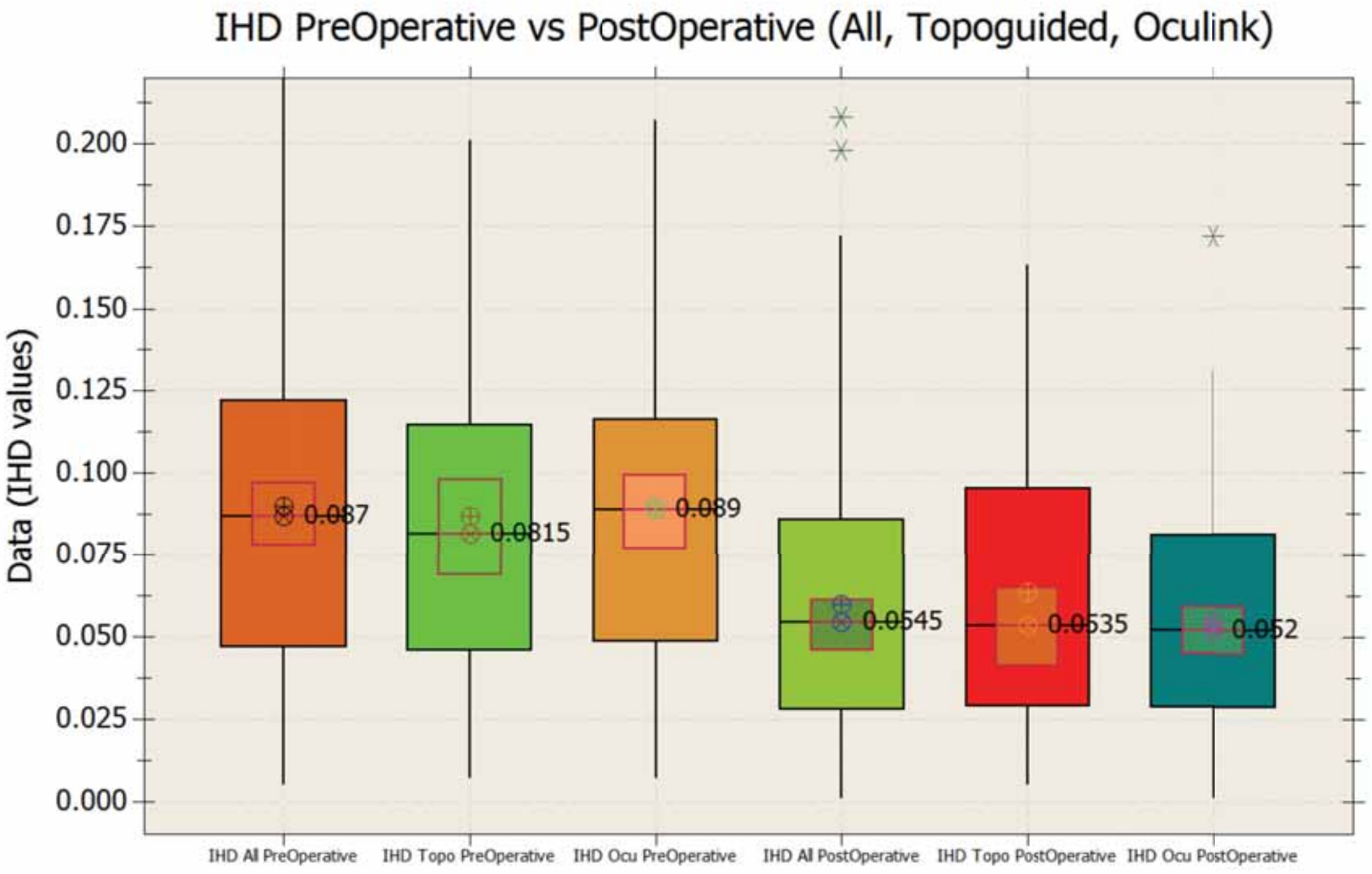
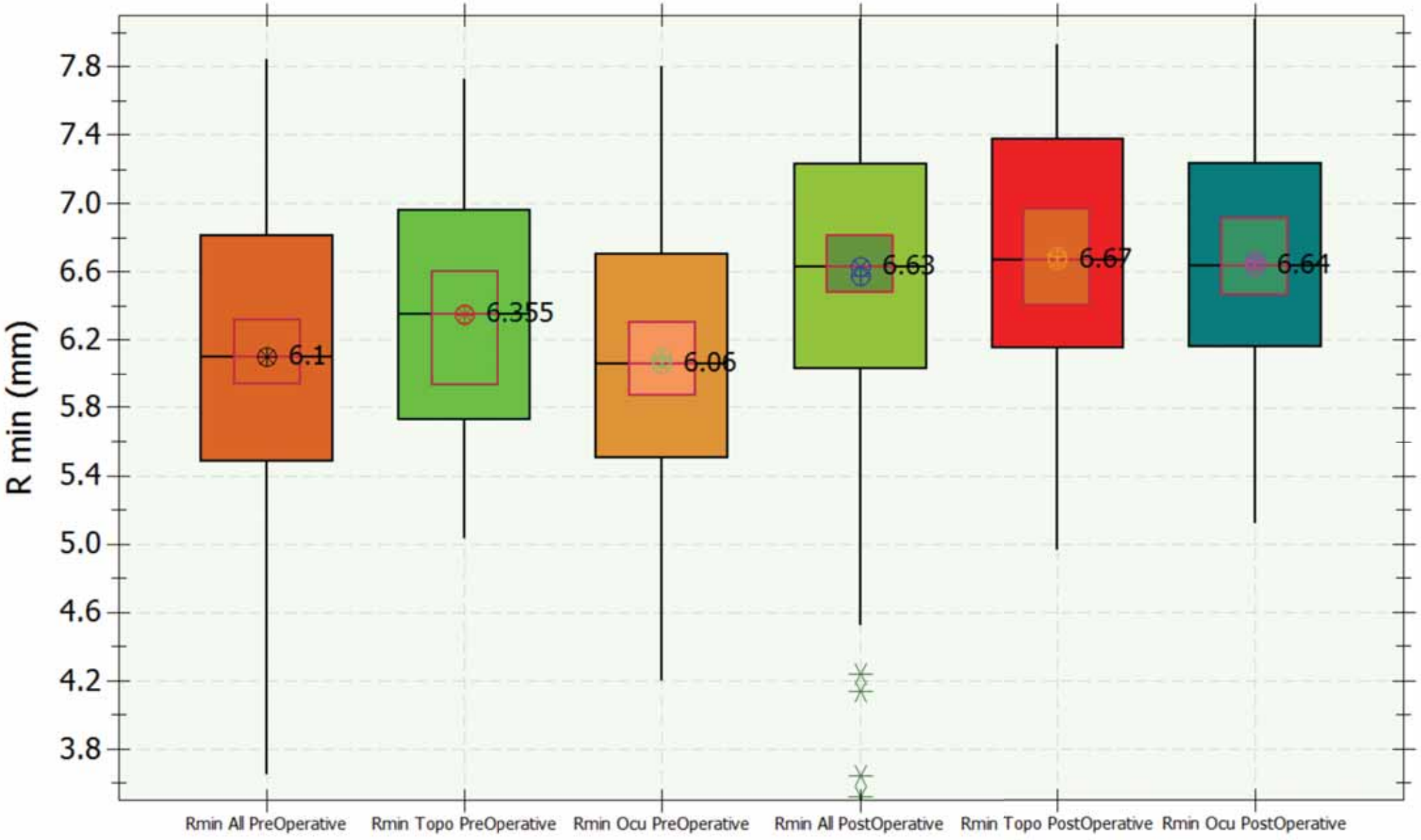


Figure 2 Box plots for OBL, expressed as fraction of the total flap area for the two groups, indicating the 99% point with the × sign, and the mean point with the sign.
Note: Vertical axis, range of extent of OBL as a fraction of total flap area.
Abbreviation: OBL, opaque bubble layer

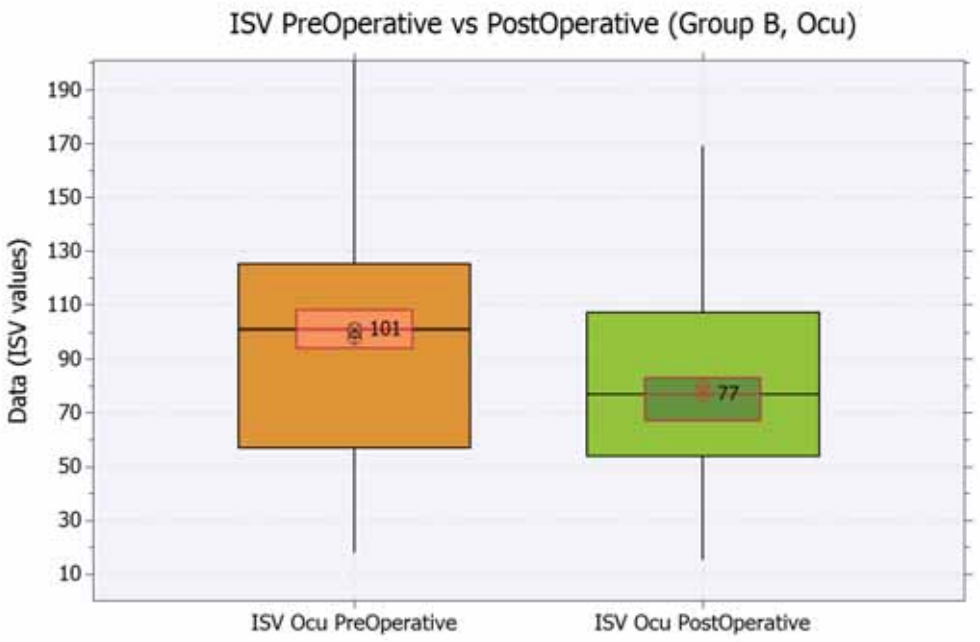
Comparison of Placido disc Vs Scheimpflug image-derived topography-guided excimer laser surface normalization used combined with CXL (the Athens Protocol) in progressive keratoconus cases (500!).

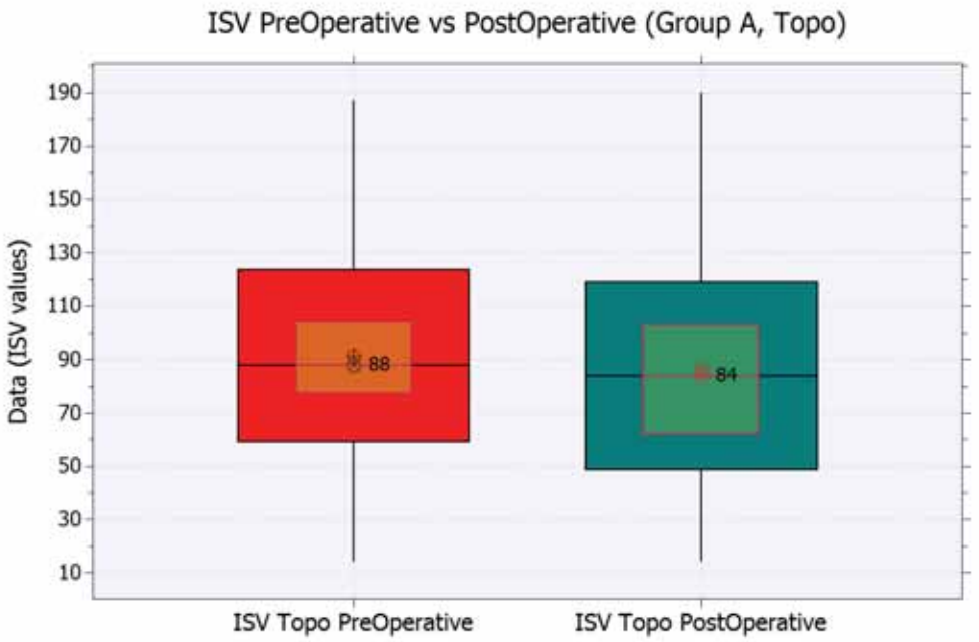


R min PreOperative vs PostOperative (All, Topoguided, Oculink)



Oculink Vs Topolink in Athens Protocol





Oculink is BETTER!

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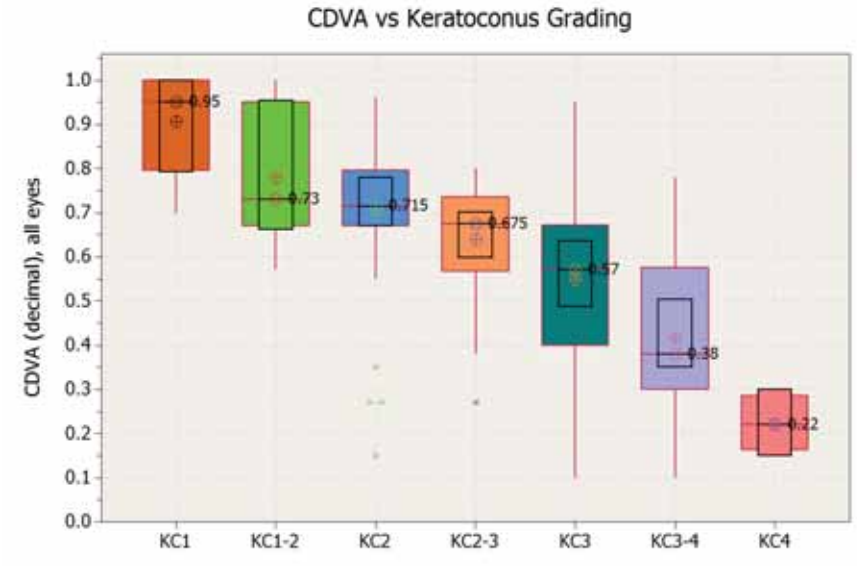
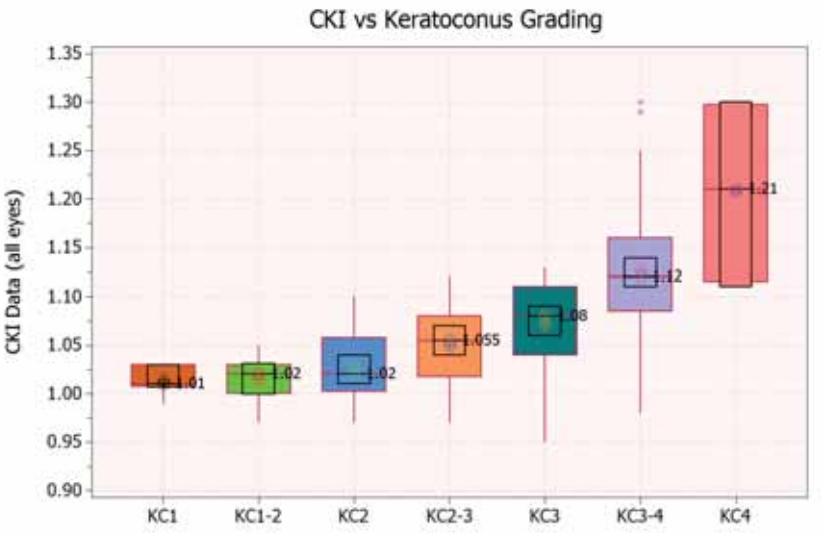
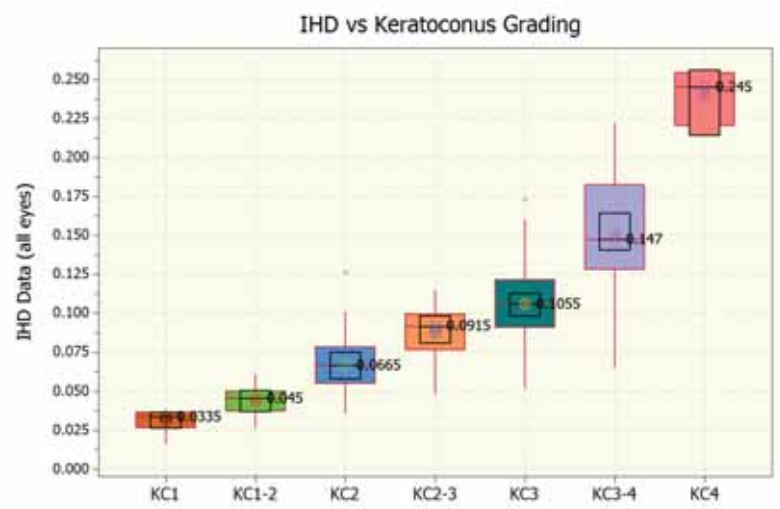
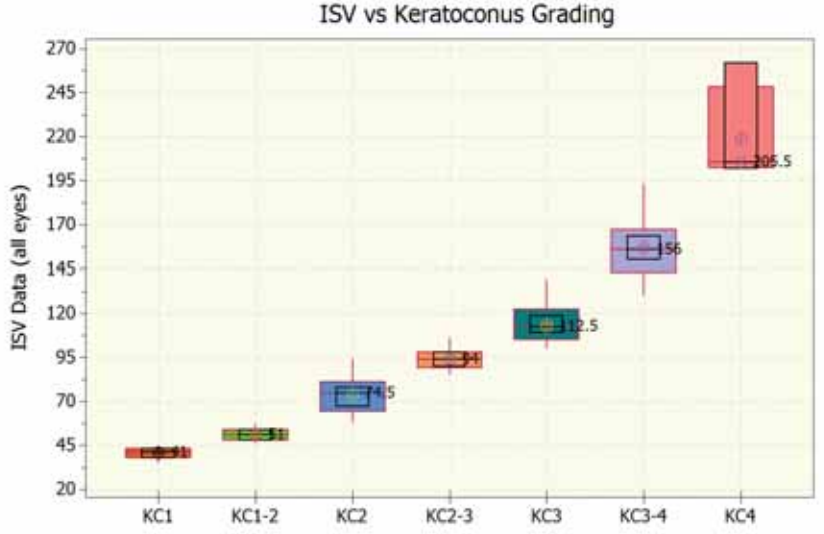
Vision, Ks=waste of time in 700 KCN cases test ISV and IHD!









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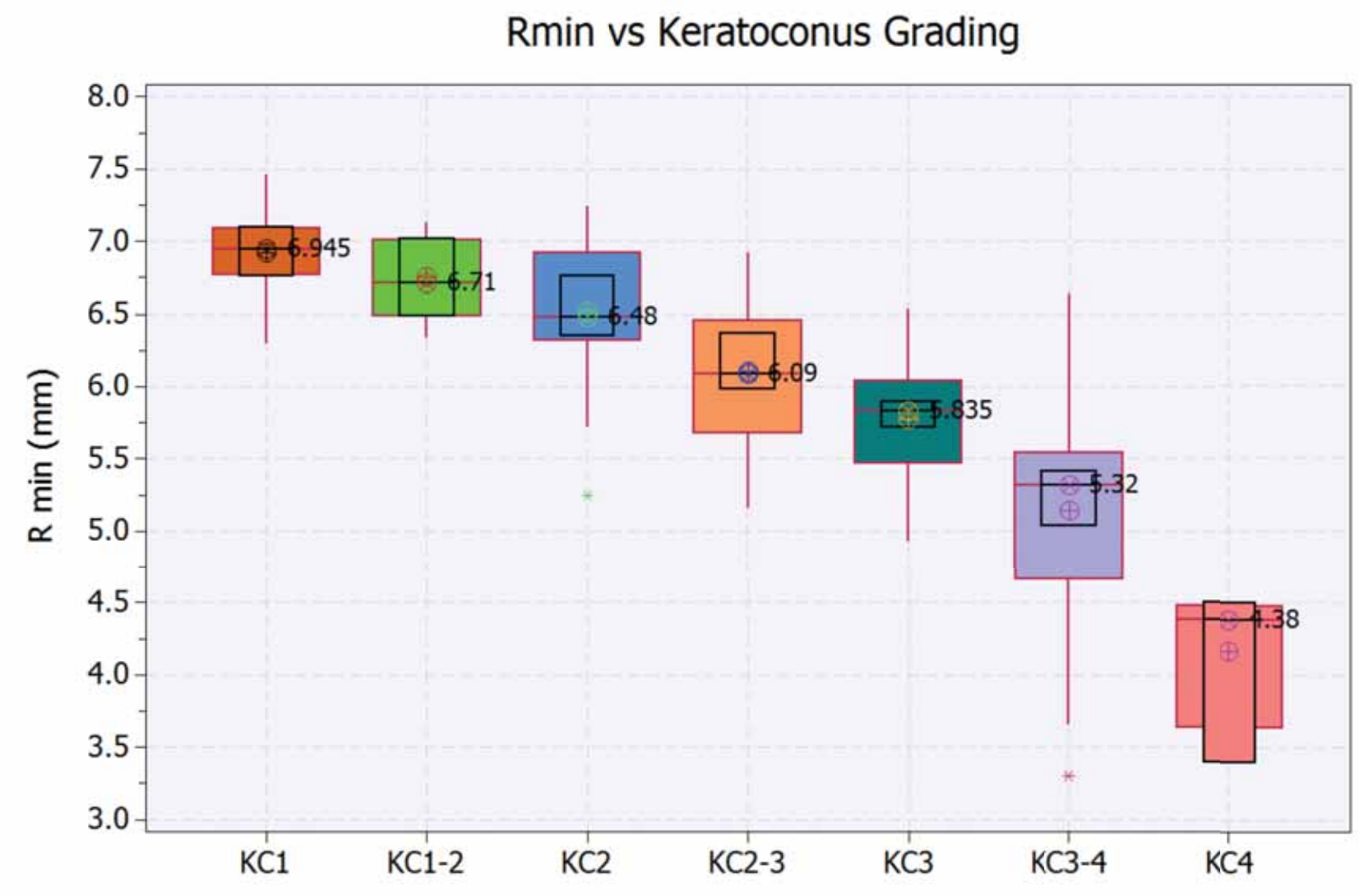

Rmin vs Keratoconus Grading
R min (mm)
8.0
7.5
7.0
6.5
6.0
5.5
5.0
4.5
4.0
3.5
3.0
6.945
6.71
6.48
6.09
5.835
5.32
4.38
KC1
KC1-2
KC2
KC2-3
KC3
KC3-4
KC4

2-Sample t Test for Treat plan - OCT vs Treat plan - Oculyzer 1 month

Summary Report

Do the means differ?

P = 0.000

The mean of Treat - OCT is significantly different from the mean of Treat - Ocul ($p < 0.05$).

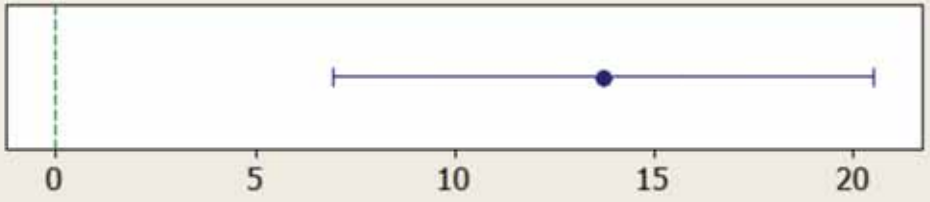
Statistics	Treat - OCT	Treat - Ocul
Sample size	21	21
Mean	2.7433	-10.971
95% CI	(-1.380, 6.867)	(-16.596, -5.3460)
Standard deviation	9.0585	12.357

Difference between means*	13.714
95% CI	(6.9334, 20.495)

* The difference is defined as Treat - OCT - Treat - Ocul.

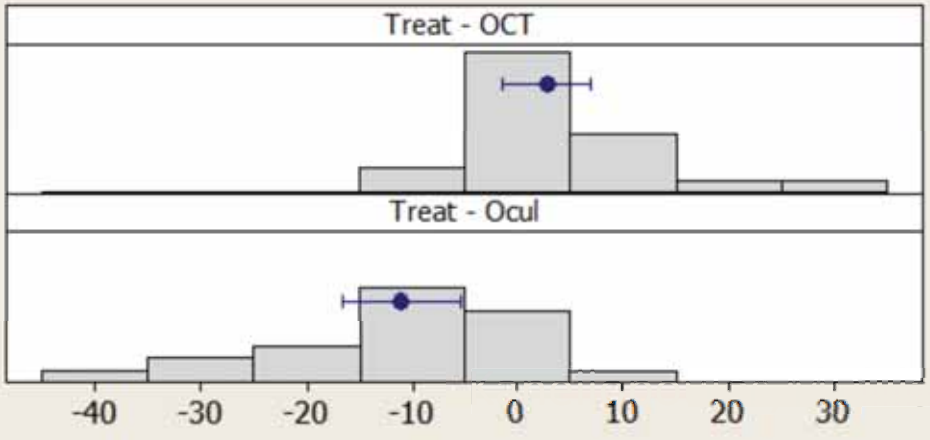
95% CI for the Difference

Does the interval include zero?



Distribution of Data

Compare the data and means of the samples.



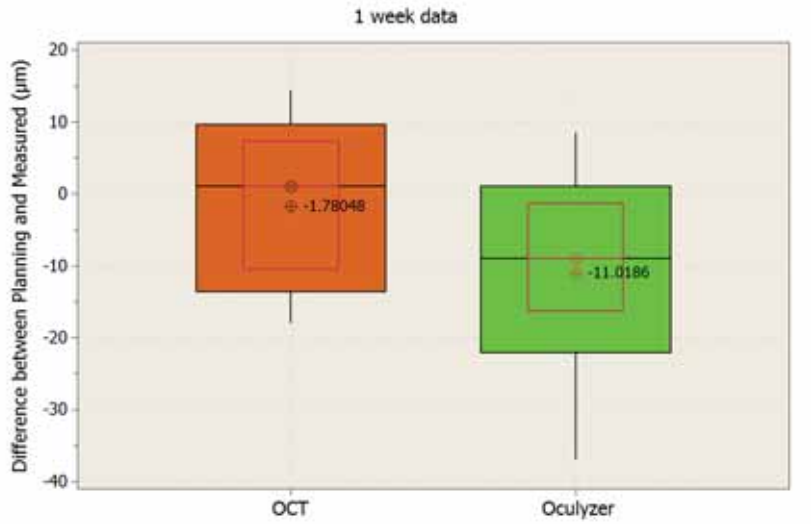
Comments

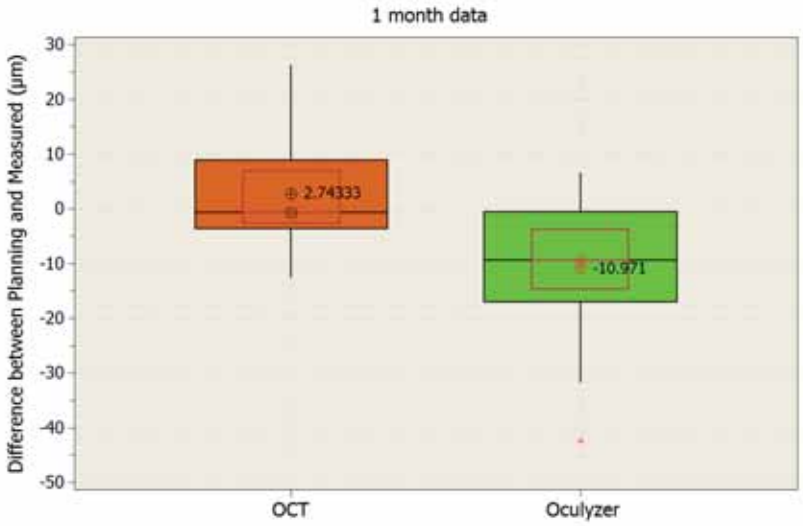
-- Test: You can conclude that the means differ at the 0.05 level of significance.

-- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 95% confident that the true difference is between 6.9334 and 20.495.

-- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

Planned Vs acchieved ablation depth in LASIK with the Refractive Suite: OCT and Scheimpflug





1 week

1 month

Bottom line: OCT says -2.5um, Pentacam +12um

Correlation Between Central Corneal Thickness, Anterior Chamber Depth, and Corneal Keratometry as Measured by Oculyzer II and WaveLight OB820 in Preoperative Cataract Surgery Patients

ORIGINAL ARTICLE

Correlation Between Central Corneal Thickness, Anterior Chamber Depth, and Corneal Keratometry as Measured by Oculyzer II and WaveLight OB820 in Preoperative Cataract Surgery Patients

A. John Kanellopoulos, MD; George Asimellis, PhD

ABSTRACT

PURPOSE: To compare and correlate central corneal thickness (CCT), anterior chamber depth (ACD), and keratometric (flat and steep K) measurements using two anterior segment imaging methods, a Scheimpflug camera system (Oculyzer II [Oculus Optikgeräte GmbH]), and a partial coherence biometry system (WaveLight OB820 [Alcon Laboratories Inc]) in eyes undergoing cataract surgery.

METHODS: Ninety patients (mean age: 66±13 years [range: 32 to 88 years]) underwent preoperative measurement of central corneal thickness, anterior chamber depth, and keratometric measurements by Scheimpflug tomography (Oculyzer II) and optical low coherence reflectometry (WaveLight OB820). Interdevice agreement and correlation between the two techniques were assessed.

RESULTS: All measurements were highly correlated, and showed no clinically significant difference between methods. Mean CCT was 554.21±39.07 μm and 546.59±37.75 μm for the Oculyzer II and WaveLight OB820, respectively (R^2=0.9268). Mean ACD was 2.63±0.44 mm and 2.63±0.43 mm for the Oculyzer II and WaveLight OB820, respectively (R^2=0.9488). The principal meridian keratometric values were also highly correlated. Mean flat K was 42.88±1. 50 diopters (D) and 42.96±1.40 D for the Oculyzer II and WaveLight OB820, respectively (R^2=0.8741). Mean steep K was 44.08±1.79 D and 44.26±1.95 D for the Oculyzer II and WaveLight OB820, respectively (R^2=0.9159).

CONCLUSIONS: Our data show that the Oculyzer II and WaveLight OB820 provide measurements that are in agreement with published values for CCT and ACD in patients. Excellent agreement for CCT and ACD was found between the two devices, as demonstrated by a high degree of correlation and linearity, in addition to minimal bias. Thus, CCT, ACD, and K measurements by these instruments can both be used in clinical preparation, and their agreement is an ensuring precision factor for cataract and refractive surgeons. [*J Refract Surg.* 2012;xx(x):xxx-xxx.]

doi:10.3928/1081597X

Biometry is a basic and necessary examination that must be performed prior to cataract surgery. Ongoing improvement of intraocular lens (IOL) design (accommodating, multifocal, aspheric, astigmatic, etc) requires high precision biometry calculations.[1] Therefore, increased precision and accuracy of biometry measurements is essential in any preoperative measurement.

Biometry determines the refractive power of the IOL as well as its effective lens position and helps achieve the targeted postoperative refraction. To this aim, several preoperative data have to be collected to be included in formulae such as the Olsen,[2] Haigis-L,[1,3] Holladay 2,[4,5] and Hoffer Q.[6] These data include corneal refractive power (by measuring steep and flat meridian keratometry [K]) and ocular axial length. In addition, central corneal thickness (CCT, defined as the distance between the anterior corneal surface and posterior corneal surface) and aqueous or anterior chamber depth (ACD, defined as the distance between the anterior corneal surface and anterior crystalline lens surface) are also measured by biometry devices.

Central corneal thickness measurement is important for ensuring proper intraocular pressure correction in individuals with increased glaucoma risk, and ACD measurement is important for its correlation with axial length and its association with increased risk for angle closure if the anterior angle is shallow, particularly for hyperopic individuals.

BIOMETRY DEVICES

The IOLMaster (Carl Zeiss Meditec, Jena, Germany) was the first US Food and Drug Administration–approved noncontact, optical biometry device to use partial coherence in-

From Laservision Eye Institute, Athens, Greece (Kanellopoulos, Asimellis); and New York University School of Medicine, New York, New York (Kanellopoulos).

Dr Kanellopoulos is a consultant to Alcon Wavelight. Mr Asimellis has no financial interest in the materials presented herein.

Correspondence: A. John Kanellopoulos, MD, 17 A. Tsocha St, Athens, Greece 11521. Tel: 30 210 747 2777; Fax: 30 210 747 2789; E-mail ajk@brilliantvision.com

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Posted online:

TABLE 2

Comparative Statistics Between Oculyzer II and WaveLight OB820 Data

Statistic	CCT	ACD	Flat K	Steep K
Correlation coefficient (R^2)	0.9268	0.9786	0.8741	0.9159
Linearity	0.9302	0.9488	0.9443	1.0383
Two-tailed *P* value	<.0001	<.0001	<.0001	<.0001
Bias	7.60 μm	0.008 mm	−0.135 D	−0.182 D
Corresponding to % of average value	1.38%	0.30%	−0.31%	−0.41%
LoA @ 95% CI (lower - upper)	−13.1 μm 28.3 μm	−0.122 mm 0.138 mm	−1.098 D 0.829 D	−1.30 D 0.93 D

CCT = corneal thickness, ACD = anterior chamber depth, K = keratometry LoA = limits of agreement, CI = confidence interval

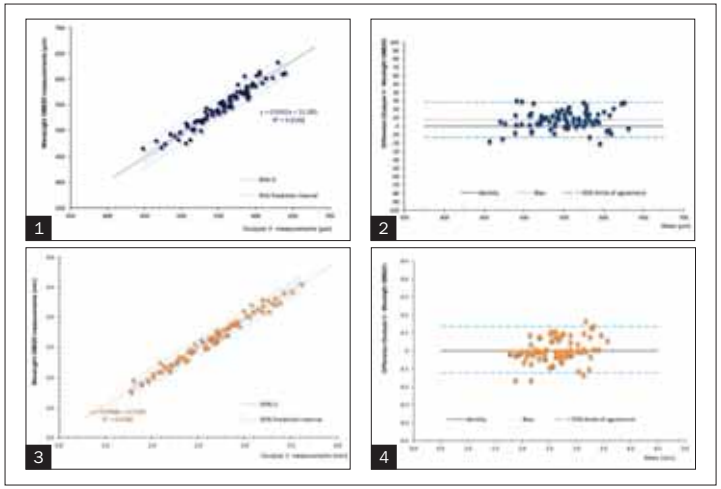

Figure 1. Scatterplot depicting correlation between Oculyzer II and WaveLight OB820 central corneal thickness measurements with linearity coefficient and coefficient of determination (R^2) (CI = confidence interval). **Figure 2.** Bland-Altman plot comparing central corneal thickness measurements between Oculyzer II and WaveLight OB820 with bias and 95% limits of agreement. **Figure 3.** Scatterplot depicting correlation between Oculyzer II and WaveLight OB820 anterior chamber depth measurements with linearity coefficient and coefficient of determination (R^2) (CI = confidence interval). **Figure 4.** Bland-Altman plot comparing Oculyzer II and WaveLight OB820 anterior chamber depth measurements with bias and 95% limits of agreement.

RESULTS

As shown in Tables 1 and 2, there was excellent correlation between the two devices for all studied parameters. Specific data for all parameters are presented in Figures 1-8.

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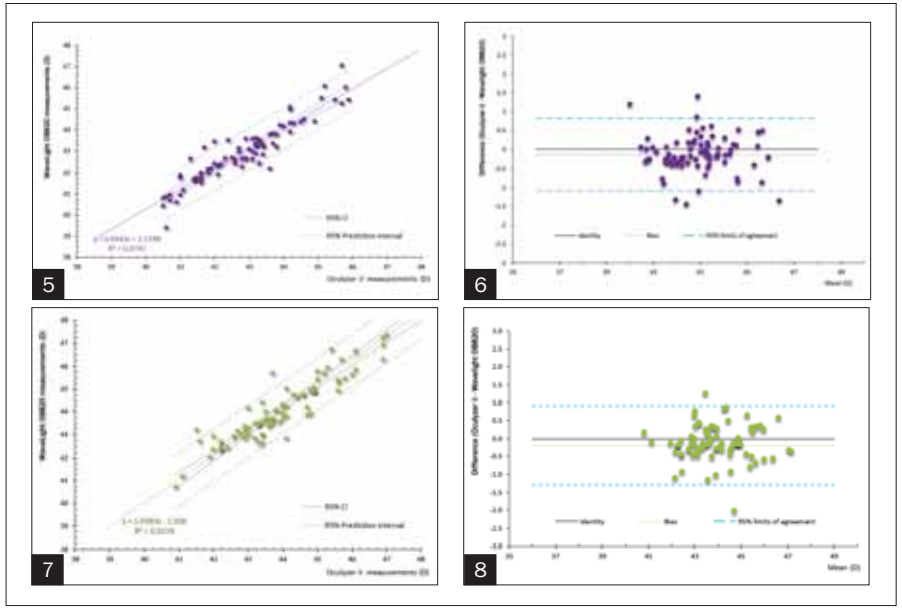

Figure 5. Scatterplot depicting correlation between Oculyzer II and WaveLight OB820 flat keratometry measurements with linearity coefficient and coefficient of determination (R^2) (CI = confidence interval). **Figure 6.** Bland-Altman plot comparing Oculyzer II and WaveLight OB820 flat keratometric measurements with bias and 95% limits of agreement. **Figure 7.** Scatterplot depicting correlation between Oculyzer II and WaveLight OB820 steep keratometry measurements with linearity coefficient and coefficient of determination (R^2). CI = confidence interval **Figure 8.** Bland-Altman plot comparing Oculyzer II and WaveLight OB820 steep keratometry measurements with bias and 95% limits of agreement.

DISCUSSION

Our data show that the Oculyzer II and WaveLight OB820 provide measurements that are in agreement with published values for CCT,[14-16] ACD, and K-values[17-24] in normal and preoperative cataract surgery patients. Literature suggests that mean CCT normally varies among Caucasian people with an average of 540 to 550 µm, which is in agreement with our data: WaveLight OB820 mean 546.59 µm, Oculyzer II mean 554.21 µm. The average young adult eye has ACD of 3.15 mm,[25] but it is commonly accepted that it decreases by 0.01 mm per year. This is in excellent agreement with our findings, as shown in Figure 9, where the linear fit line of both Oculyzer II and WaveLight OB820 ACD versus age is displayed. (The data are highly normalized, as demonstrated by the standardized residual plots and normal fit shown in Figure 10 for the Oculyzer II ACD measurements.) Thus, for the mean patient age of 66 years in the current study, an ACD of 2.5 mm is considered representative (our data: WaveLight OB820 mean 2.63 mm, Oculyzer II mean 2.63 mm). In addition, the average corneal refractive K value is reported at 43.00 to 44.00 D (our data: WaveLight OB820 mean 42.96/44.26 D, Oculyzer II mean 42.88/44.08 D, for flat/steep meridians, respectively).

We find that in the set of measurements provided by both systems (ie, CCT, ACD, and K), an excellent degree of correlation with minimal bias exists. Of the two modalities examined, the Oculyzer II features the largest number of acquired images per scan (although we used 25 in the present study per our protocol, there is an option to acquire 50 images) compared to the 9 for the WaveLight OB820. It is, therefore, expected that the most detailed and accurate pachymetry maps result from the Oculyzer II; however, the comparison is valid only for the corneal apex, provided that precise pupil centering was achieved during acquisition.

It is encouraging that the most positively correlated

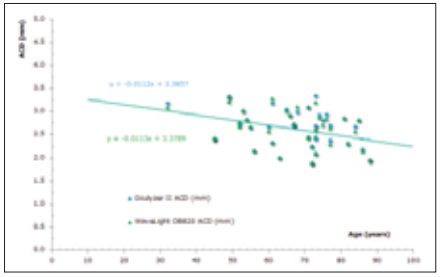

Figure 9. Scatterplot depicting correlation between anterior chamber depth (ACD) and age. The negative slope of the trend lines (−0.0104 and −0.0106 for the Oculyzer II and WaveLight OB820, respectively) are indicative of the rate at which the ACD decreases per year.

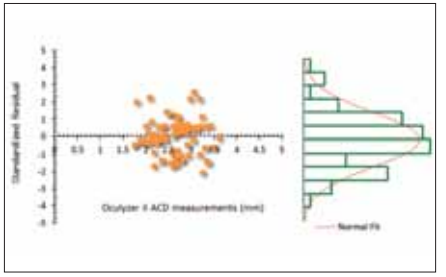

Figure 10. Anterior chamber depth (ACD) measurements via the Oculyzer II showing normalization.

set of data, featuring the lowest bias, was measured for ACD. Precise ACD measurement is essential not only for patient selection to ensure a safe distance of the lens from the iris and other anterior anatomical elements, but is also an important parameter to consider in phakic IOL calculation formulae. In our set of data, the bias (Oculyzer II–WaveLight OB820) was only 8 µm (0.008 mm, corresponding to 0.3% of the average ACD and 0.0035 D target refractive error according to the Haigis formula), LoA was likewise very tight (−0.122 to 0.138 mm), the linearity of the trend line was excellent (WaveLight OB820 measurements=0.9488×Oculyzer measurements), and the coefficient of correlation was almost unity (R^2=0.9786).

Previous studies of ACD measurements comparing Pentacam to other traditional devices such as the IOLMaster (Carl Zeiss Meditec) and ultrasound have yielded mixed results. In one study, the Pentacam differed significantly from the IOLMaster, with the Pentacam bias by approximately 0.05 mm,[25] while in another by 0.10 mm.[26] This range of ACD uncertainty (0.05 to 0.1 mm) corresponds to a refractive error discrepancy of 0.025 to 0.05 D for a standard posterior chamber IOL.

The CCT measurements were also highly correlated. In our set of data the bias (Oculyzer II–WaveLight OB820) was only 7.6 µm (0.0076 mm, corresponding to 1.37% of the average CCT), LoA was likewise close (−13.1 to 28.3 µm), the linearity of the trend line was excellent (WaveLight OB820 measurements=0.93×Oculyzer measurements), and the coefficient of correlation was almost unity (R^2=0.93).

On the other hand, of the four pairs of data sets, the least correlated data (although still very well correlated), were found among the keratometric data. This can be explained by the fact that the Oculyzer II obtains refractive maps from the entire corneal surface and computes specific K readings for each zone of 3-, 5-, and 7-mm diameter. It is quite unusual that any cornea will have the exact keratometric readings (including, but not limited to, shift of the principal meridian) in all three zones. On the other hand, the keratometric values reported by WaveLight OB820 are considered a more "average" reading.

Our data show that the Oculyzer II and WaveLight OB820 provide measurements that are in agreement with published values for CCT and ACD in patients. Excellent agreement for CCT and ACD was found between the two devices, as demonstrated by a high degree of correlation and linearity, in addition to minimal bias. Thus, CCT, ACD, and K measurements from these instruments can be used in clinical preparation and their agreement is an ensuring precision factor for any cataract or refractive surgeon.

AUTHOR CONTRIBUTIONS

Study concept and design (A.J.K., G.A.); data collection (G.A.); analysis and interpretation of data (A.J.K., G.A.); drafting of the manuscript (G.A.); critical revision of the manuscript (A.J.K.); statistical expertise (G.A.); obtained funding (A.J.K.); administrative, technical, or material support (A.J.K.); supervision (A.J.K.)

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2. Olsen T. Prediction of the effective postoperative (intraocular lens) anterior chamber depth. *J Cataract Refract Surg.* 2006;32(3):419-424.
3. Haigis W. Intraocular lens calculation after refractive surgery for myopia: Haigis-L formula. *J Cataract Refract Surg.* 2008;34(10):1658-1663.
4. Bang S, Edell E, Yu Q, Pratzer K, Stark W. Accuracy of intraocular lens calculations using the IOLMaster in eyes with long axial length and a comparison of various formulas. *Ophthalmology.* 2011;118(3):503-506.

Interpolated Pre-Op Shift and Int Post-Op Shift 2-Sample t Test

Do the means differ?

The mean of Int Pre-Op S is not significantly different from the mean of Int Post-Op (p > 0.05).

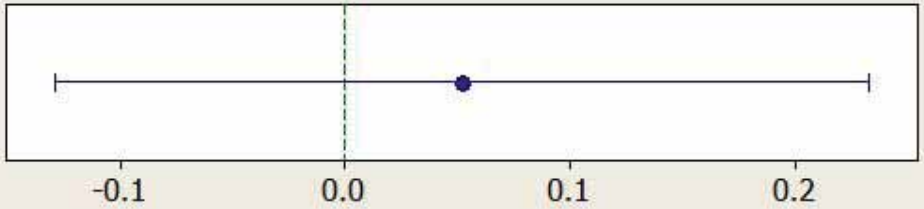
Statistics	Int Pre-Op S	Int Post-Op
Sample size	12	12
Mean	0.29083	0.23917
95% CI	(0.1174, 0.4642)	(0.17659, 0.30174)
Standard deviation	0.27291	0.098485

Difference between means*	0.051667
95% CI	(-0.12928, 0.23261)

* The difference is defined as Int Pre-Op S - Int Post-Op .

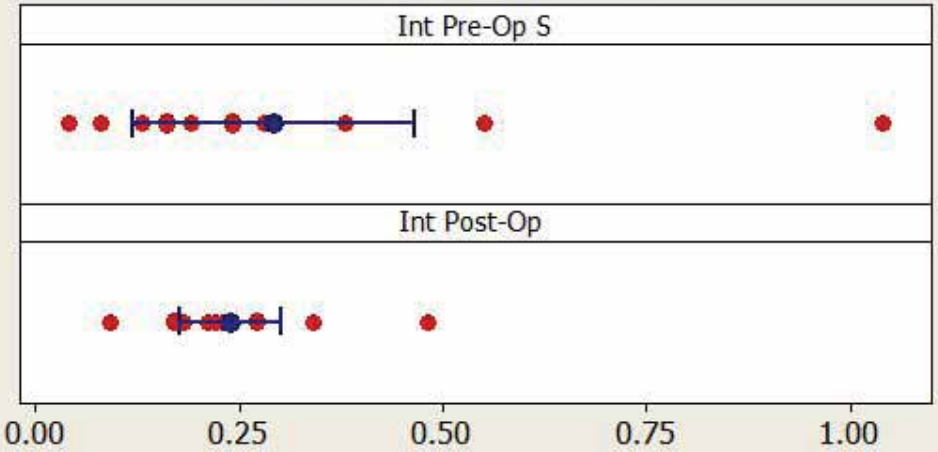
95% CI for the Difference

Does the interval include zero?



Distribution of Data

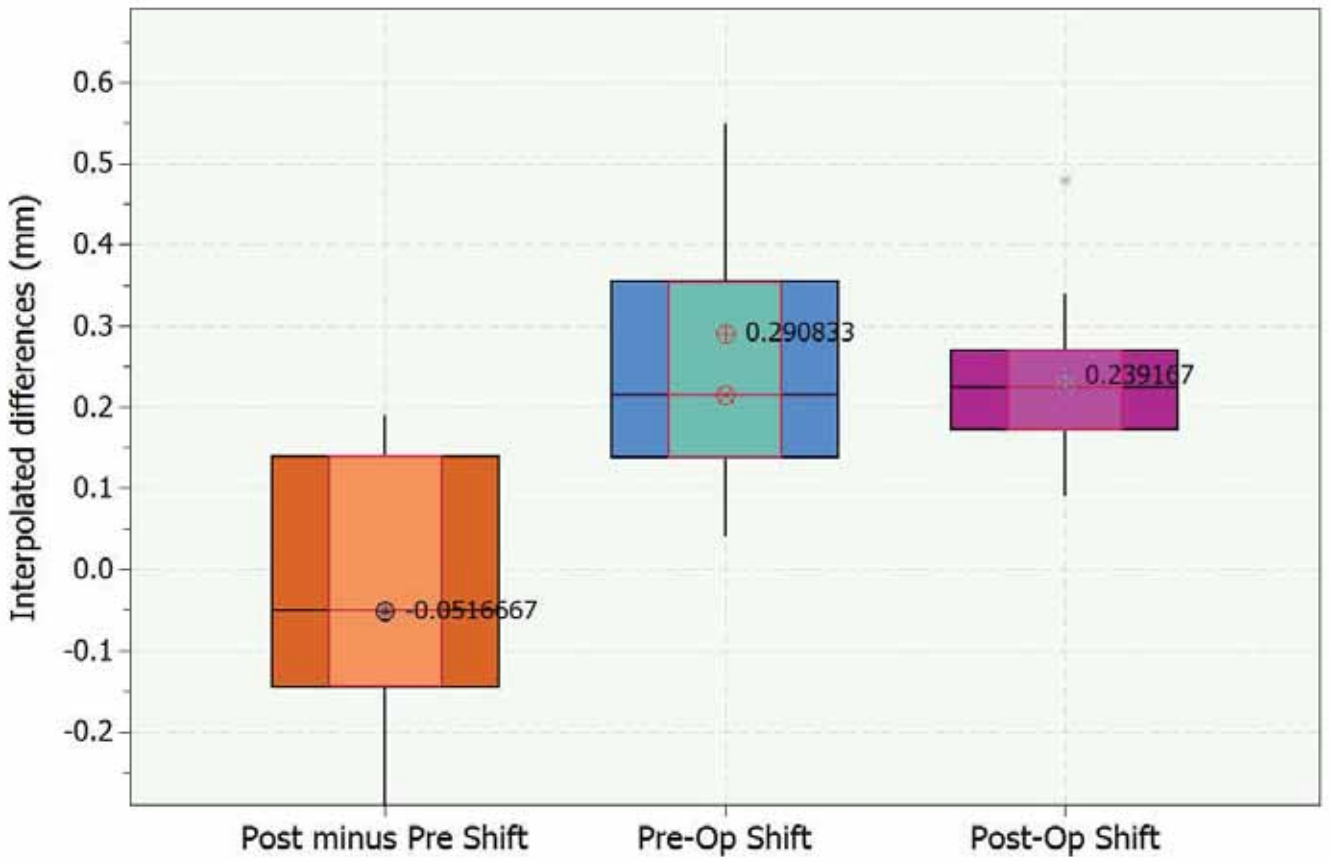
Compare the data and means of the samples.



Comments

-- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
-- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 95% confident that the true difference is between -0.12928 and 0.23261.
-- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

Centroid shift pre-post clear cornea cataract surgery



Bottom line: we should center the IOL in the photopic pre axis

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

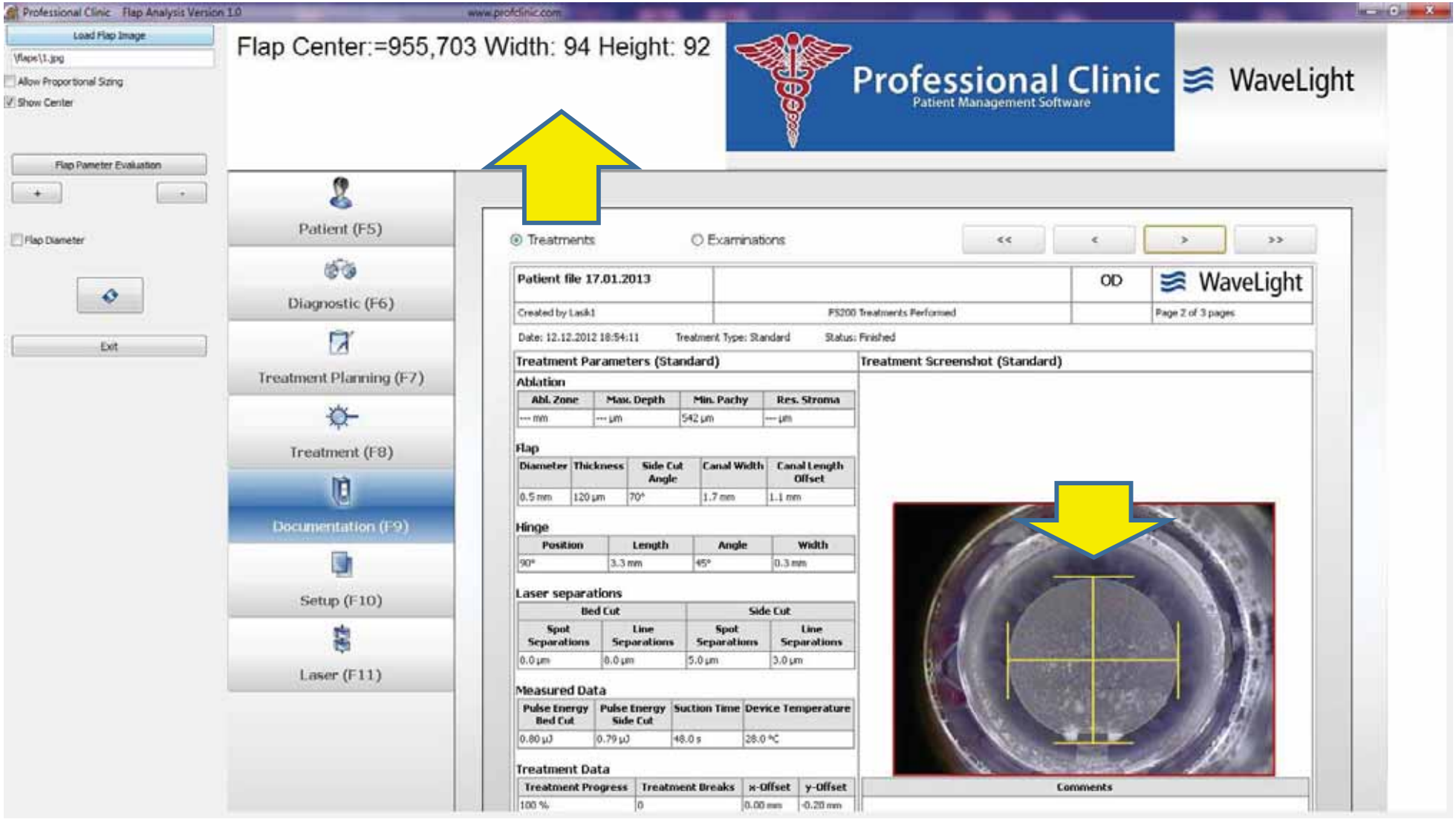
A. John Kanellopoulos, MD
Clinical Professor of Ophthalmology
Medical Director: The Laservision.gr Institute, Athens Greece
and the Athens team

Objective:

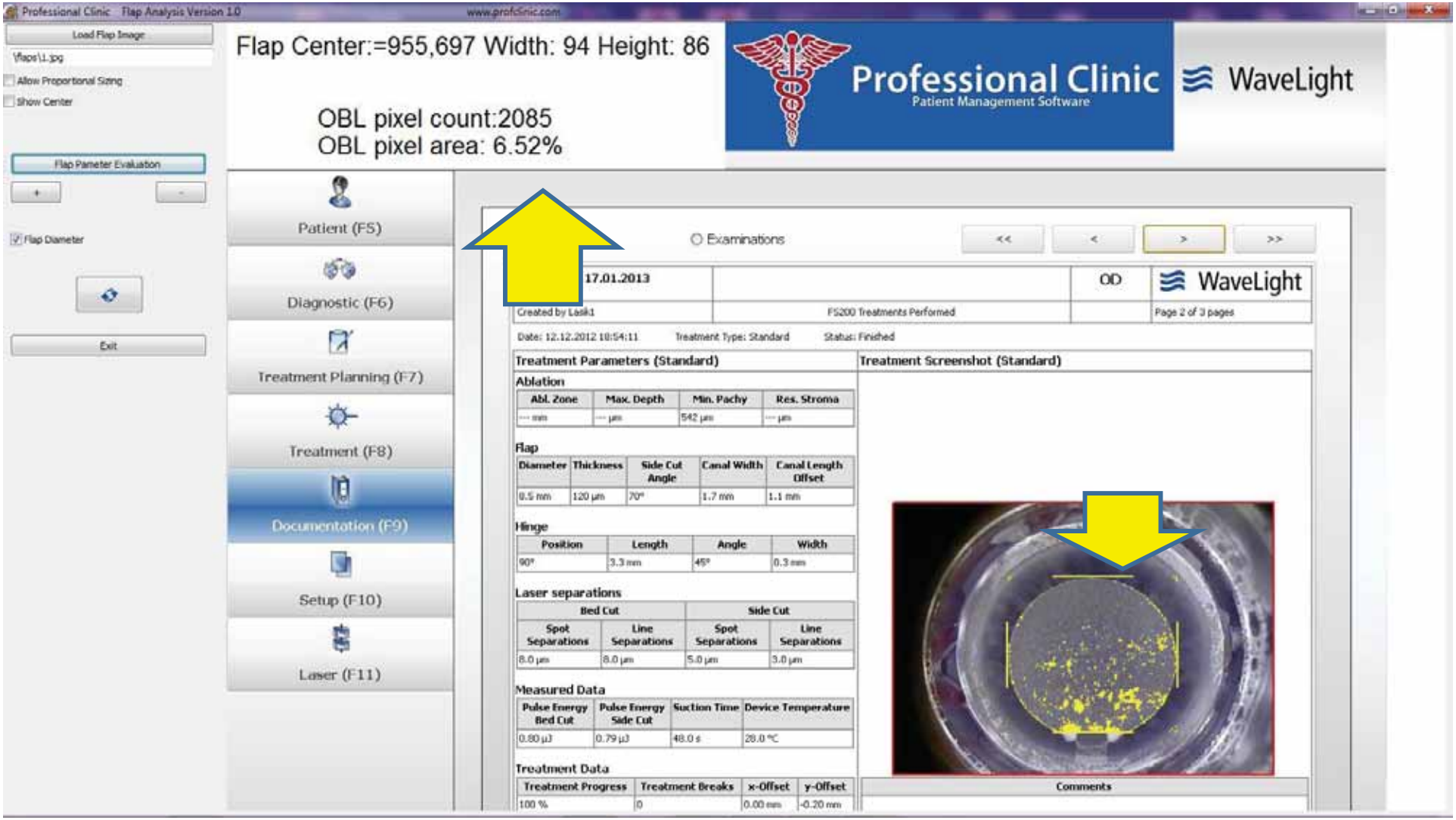
- To digitally, objectively, and investigator-bias free measure achieved flap diameter and opaque bubble layer extent
- Only the jpeg report provided b the FS200 at the end of the procedure will be proccessed seamlessly through this software for objective flap parameter and OBL measurement
- This project 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

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



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



New York University School of Medicine Kanellopoulos,MD

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