Predictability of Tunnel Depth for Intrastromal Corneal Ring Segments Implantation Between Manual and Femtosecond Laser Techniques

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ABSTRACT

PURPOSE: To compare the predictability of intrastromal tunnel depth creation for intrastromal corneal ring segments (ICRS) implantation between manual dissection and femtosecond laser using a high-resolution anterior segment optical coherence tomography (AS-OCT).

METHODS: This multicenter study included patients with keratoconus who had Ferrara-type ICRS implantation at Hospital de Braga using manual dissection and at the Fernandez-Vega Ophthalmological Institute using the femtosecond laser technique. The intended depth of implantation was compared to the achieved postoperative ICRS depth of each case, measured using a swept-source AS-OCT (CASIA SS-1000; Tomey Corporation, Nagoya, Japan) at three points (proximal, central, and distal end of the implant).

RESULTS: The study included 105 eyes in the manual group and 53 eyes in the femtosecond laser group. The differences of the intended versus the achieved depth were statistically higher in the manual group for all positions measured (Wilcoxon ranked-sum, $P < .001$). In the manual group, there were significant differences between the mean values of intended and achieved depth after surgery for the three locations measured (Wilcoxon signed-rank, $P < .05$), whereas there were no significant differences in the femtosecond laser group. In the manual group, the proximal part of the stromal tunnel was significantly shallower (-40.87 ± 69.03 μm) than the central (-25.54 ± 71.00 μm) and distal (-26.52 ± 73.22 μm) parts (Friedman test, $P < .05$).

CONCLUSIONS: ICRS implantation assisted by a femtosecond laser provides a more precise procedure considering dissection depth when compared with the manual dissection technique. Such an advantage may provide more predictable clinical results and safer procedures with the femtosecond laser.

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Intrastromal corneal ring segments (ICRS) implantation is a surgical procedure used for the treatment of keratoconus, enabling both a therapeutic and refractive improvement.[1-3] Both the safety and the refractive efficacy of the implant depend on the correct selection of the implant features and a precise intrastromal surgical implantation. Shallower intrastromal tunnels are associated with complications such as implant exposure due to corneal thinning over the implant, segment migration and extrusion, astigmatism overcorrection, or corneal melting.[4-6] Deeper tunnels can be associated with corneal perforation or endothelial cell damage and a minor refractive and topographic effect on the cornea.[7] Therefore, a precise and predictable tunnel depth creation is crucial for this surgical procedure. The tunnel can be created with manual dissection or assisted by a femtosecond laser device. Previous publications regarding this aspect present conflicting results, but most studies report shallower depth than predicted and no difference between manual or femtosecond laser–assisted surgery[8-12]; all studies but one were performed with Intacs ICRS (Addition Technology Inc., Des Plaines, IL). The reasons for such differences reported arise mainly because the methods of measurement differ, whether regarding the device being used (Scheimpflug tomography or optical coherence tomography) or the location used for the measurement.

The purpose of this study was to compare the precision and predictability of intrastromal tunnel creation for Ferrara-type

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ICRS implantation between the manual mechanical technique and femtosecond laser–assisted surgery using a novel high-resolution swept-source AS-OCT. To our knowledge, this is the first study to compare the intended versus achieved tunnel depth for Ferrara ICRS implantation using OCT and measuring three different locations for each segment with two different surgical techniques.

PATIENTS AND METHODS

The tenets of the Declaration of Helsinki were followed and full ethical approval was obtained from both institutions. After receiving a detailed explanation of the nature and possible consequences of the study and surgery, all patients gave their informed consent. The study included Ferrara-type ICRS implantation in 158 eyes of 158 patients with keratoconus and was conducted at the Ophthalmology Department of Hospital de Braga, Braga, Portugal, and the Fernandez-Vega Ophthalmological Institute, Oviedo, Spain. The criteria required for inclusion in the study were the presence of keratoconus (diagnosis based on the slit-lamp examination and confirmed by Scheimpflug tomography [Pentacam; Oculus Optikgeräte, Wetzlar, Germany]), contact lens intolerance, and a clear cornea, together with a minimum corneal thickness of greater than 400 µm at the optical zone involved in the implantation (a general criterion for surgery). In addition, keratoconus had to be stage I to II according to the Amsler–Krumeich keratoconus classification. The exclusion criteria defined for this study were previous corneal or intraocular surgery, a history of herpetic keratitis, diagnosed autoimmune disease, systemic connective tissue disease, endothelial cell density of less than 2,000 cells/mm^2, cataract, a history of glaucoma or retinal detachment, macular degeneration or retinopathy, neuro-ophthalmic disease, or a history of ocular inflammation.

Data collected were patient gender and age, operated eye, ICRS arc length and thickness, intended depth thickness, and achieved postoperative ICRS depth as measured by a swept-source AS-OCT (CASIA SS-1000; Tomey Corporation, Nagoya, Japan) at three points for each segment (proximal, central, and distal end of the implant). For each point of measurement, we calculated two values: the tunnel depth achieved and the mean difference between intended and achieved depth of implantation, designated as the "delta" value for each location. The delta value was expressed as "relative delta" and "absolute delta." The relative delta is the difference between achieved and intended (a negative value means a superficial implant and a positive value means a deeper implant than intended). The absolute delta is the value of delta without negative or positive signal; it means the overall difference between depths, with no indication regarding superficial or deeper implant.

Ferrara-type ICRS (Mediphacos, Belo Horizonte, Brazil) were implanted in all eyes studied. These polymethylmethacrylate Ferrara-type ICRS have a triangular cross-section that induces a prismatic effect on the cornea. Their apical diameter is 6 mm (flat basis width = 800 mm), with variable thicknesses (150, 200, 250, and 300 mm) and arc lengths (90, 120, 150, and 210 degrees); ICRS implanted was chosen according to the Mediphacos nomogram previously published.[13]

Manual Mechanical Technique

The ICRS implantation surgeries with the manual technique were all performed at the Ophthalmology Department of Hospital de Braga and by the same surgeon (TM). The visual axis was marked by pressing the Sinskey hook on the central corneal epithelium while asking the patient to fixate on the corneal light reflex of the microscope light. Using a marker tinted with gentian violet, a 6-mm optical zone and incision site were aligned to the desired axis in which the incision would be made. The incision site was always performed at the steepest topographic axis of the cornea given by the topographer. A square diamond blade was set at 80% of the thinnest point along the implantation optical zone track and this blade was used to make the incision. Corneal thickness was measured intraoperatively with ultrasonic pachymetry. Using a "stromal spreader," a pocket was formed on each side of the incision. Two (clockwise and counterclockwise) 270 degrees semicircular dissecting spatulas were consecutively inserted through the incision and gently pushed with some quick rotary "back and forth" tunneling movements. Following channel creation, the ring segments were inserted using modified McPherson forceps. The rings were properly positioned with the aid of a Sinskey hook.

Femtosecond Laser–Assisted Surgery

The center of the pupil was marked and four cardinal spots at 4 (for ICRS 5-mm optical zone) or 5 (for ICRS 6-mm optical zone) mm were also placed on the cornea with a caliper to better centrate the laser spot location regarding the visual axis and to avoid pupillary shift after the pressure was applied. The corneal thickness at the area of implantation (5- or 6-mm diameter) was measured with ultrasonic pachymetry and a disposable suction ring was centered on the pupil. A tunnel was subsequently created at 70% of the corneal thickness, using a 60-KHz infrared neodymium glass femtosecond laser (Intralase FS; Abbott Medical Optics, Inc., Abbott Park, IL) at a wavelength of 1,053 nm. The 3-mm diameter (spot size) laser beam was optically focused by computer scanners at a predetermined intrastromal depth ranging from 90 to 400 mm from the anterior corneal surface. The beam formed cavitations and water vapor by photodisruption, with an interconnected series of microbubbles of carbon dioxide forming a dissection plane. The laser software was programmed to an inner diameter of 5 or 6 mm and an outer diameter of 6 to 7.2 mm for a channel width of 1.1 mm and an incision length of 1.7 mm on the steepest topographic axis. The power used to create the channel and the incision was 5 mJ in all eyes. This part of the procedure lasted approximately 15 seconds. The ICRS were implanted 5 minutes later after the gas bubbles had dissolved, with a dedicated forceps and under fully aseptic conditions. The segments were placed in their final position with the aid of a Sinskey hook that engaged the two positioning holes, one at each end of the segment. All femtosecond laser–assisted ICRS surgeries were performed by the same surgeon (JFA).

Postoperative treatment was similar for both surgical procedures and consisted of a combination of antibiotic (tobramycin, 3 mg/mL) and steroid (dexamethasone, 1 mg/mL) eye drops (Tobradex; Alcon Laboratories, Inc., Fort Worth, TX) administered three times daily for 2 weeks, with tapering of the dose over the following 2 weeks.

AS-OCT Examination

AS-OCT was performed using a swept-light source Fourier-domain OCT system (CASIA SS-1000); all examinations were performed and analyzed by the same operator (TM). A high-speed swept-laser source operating at 1,310-nm wavelength can achieve an axial resolution of 10 µm or less and a transverse resolution of 30 µm or less at a rate of 30,000 axial scans (A-scans) per second. Sixteen radial cross-sectional images are therefore obtained for 0.34 second (each cross-sectional image consists of 512 telecentric A-scans). Three scans were analyzed for each segment in relation to the incision site. The first, second, and third measurements were at the proximal, central, and distal portions of the segment, respectively (**Figure A**, available in the online version of this article). The depth was measured as the distance from the corneal epithelial layer to the external border of the segment adjacent to the hyperreflective line depicting the location of the intrastromal tunnel (**Figures B-C**, available in the online version of this article). The meridian of the incision and the scan location differed for each patient because, for each eye, the incision was made in the steepest meridian in reference to the corneal topography. In patients with two segments implanted, only the temporal inferior implant was measured. The ICRS depth measurement was performed 6 months after the ICRS surgery.

Statistical Analysis

The continuous data are presented as the mean ± standard deviation or the median and interquartile range, as appropriate. The normality of quantitative data was checked by the Shapiro–Wilk test. For normally distributed data, the *t* test was used to compare the two treatment groups. The Wilcoxon test was used for comparison of independent samples if normality was not observed. For the delta value of differences between the three points of measurement, a Friedman test analysis of variance was used. When statistically significant differences were found, post hoc tests were performed for multiple comparisons. A P value less than .05 was considered statistically significant. All calculations were performed using SPSS software (version 20; SPSS, Inc., Chicago, IL).

RESULTS

We included 105 eyes of 105 patients in the manual group and 53 eyes of 53 patients in the femtosecond laser group. The mean intraoperative corneal thickness was 514.13 ± 35.43 µm in the manual group and 525.38 ± 36.31 µm in the femtosecond laser group (*t* test, $P < .05$).

Comparison Between Manual and Femtosecond Laser–Assisted Surgery

When comparing the delta difference between both groups for each of the three locations measured, the delta difference was significantly higher in the manual group for all locations measured (**Table 1**) in terms of relative and absolute delta (*t* test, $P < .05$ for all values compared).

Manual Group

The difference between intended versus achieved intrastromal depth was significantly shallower in the manual group, for all three locations (Friedman test, $P < .05$, **Table 2** and **Figure DA**, available in the online version of this article). The proximal part of the stromal tunnel was significantly shallower than the central and distal parts (**Table 3** and **Figure DB**). A total of 57.14% of eyes had a superficial implantation shallower than 10 µm from the intended; 27.61% of eyes had a deeper implantation above 10 µm from the intended; and only 15.24% of eyes reached an achieved depth within ±10 µm from the intended (**Figure 1**).

Femtosecond Laser Group

The difference between intended versus achieved intrastromal depth was not significantly different for all three locations (Friedman test, $P > .05$, **Table 2** and **Figure EA**, available in the online version of this article); the dis-

TABLE 1
Values of Relative and Absolute Delta, the Differences Between Achieved and Intended Depth of Implantation[a]

Value	Manual	Femtosecond Laser	*P*
Proximal relative delta	-40.86 ± 69.02 (-263 to 74)	-4.24 ± 11.89 (-27 to 25)	.0004
Proximal absolute delta	56.98 ± 56.32 (0 to 263)	10.01 ± 7.58 (0 to 27)	< .0001
Central relative delta	-25.54 ± 71.00 (-218 to 136)	-3.26 ± 10.58 (-26 to 22)	.01
Central absolute delta	56.70 ± 49.54 (0 to 218)	8.69 ± 6.76 (0 to 26)	< .0001
Distal relative delta	-26.52 ± 73.21 (-211 to 136)	-8.09 ± 11.90 (-56 to 20)	.03
Distal absolute delta	60.02 ± 49.32 (1 to 211)	10.43 ± 9.87 (0 to 56)	< .0001

[a]*Values are presented as mean ± standard deviation (range).*

TABLE 2
Depth of ICRS Implantation Intended and Achieved After Surgery for the Proximal Central and Distal Location of the Implant

	Manual		Femtosecond Laser	
Depth	Mean ± SD (Range) (μm)	*P*[a]	Mean ± SD Range (μm)	*P*[a]
Incision intended	409.14 ± 25.70 (320 to 480)	–	368.28 ± 25.34 (273 to 413)	–
Central	383.60 ± 73.06 (204 to 586)	.001	365.01 ± 28.85 (275 to 417)	.54
Distal	382.61 ± 74.21 (227 to 551)	.0007	360.18 ± 27.70 (280 to 410)	.12
Proximal	368.27 ± 68.23 (181 to 524)	< .0001	364.03 ± 28.53 (277 to 410)	.42

ICRS = intrastromal corneal ring segments; SD = standard deviation
[a]*P value was calculated for the difference between the intended versus achieved depth in each technique for the three different locations measured.*

TABLE 3
Difference Between Achieved Versus Intended for Both Groups in Terms of Relative Delta

	Manual				Femtosecond Laser			
Relative Delta	N	Mean ± SD (Range) (μm)	Comparison	*P*	N	Mean ± SD (Range) (μm)	Comparison	*P*
Central	105	-25.54 ± 71.01 (-218 to 136)	Central vs distal	.38	53	-3.26 ± 10.58 (-26 to 22)	Central vs distal	.003
Distal	105	-26.52 ± 73.21 (-211 to 136)	Central vs proximal	.0002	53	-8.09 ± 11.91 (-56 to 20)	Central vs proximal	.25
Proximal	105	-40.87 ± 69.03 (-263 to 74)	Distal vs proximal	.001	53	-4.24 ± 11.89 (-27 to 25)	Distal vs proximal	.01

SD = standard deviation

tal part of the stromal tunnel was significantly shallower than the central and proximal parts (**Table 3** and **Figure EB**). A total of 22.64% of eyes had a superficial implantation shallower than 10 µm from the intended; 9.44% of eyes had a deeper implantation above 10 µm from the intended; and 67.92% of eyes reached an achieved depth within ±10 µm from the intended (**Figure 1**).

DISCUSSION

Safety and efficacy of ICRS implantation for keratoconus treatment depend on their precise implantation in the corneal stroma. To the best of our knowledge, this is the first study to compare the predictability and accuracy of intrastromal tunnel depth performed by manual dissection technique versus femtosecond laser. Our study found that ICRS implantation assisted by a femtosecond laser is a more accurate and predictable procedure when compared with manual dissection technique, even when the latter is performed by an experienced surgeon.

Most of the previous studies[9,10,12,14] published about this subject report on the use of Intacs ICRS and do not

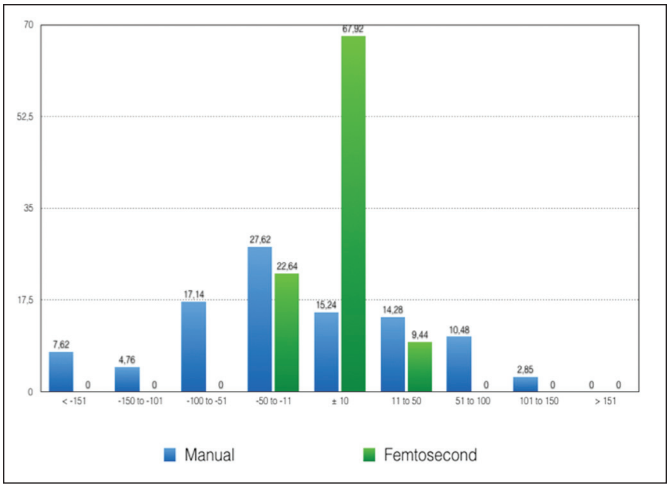

Figure 1. Distribution of patients according to different intervals of the delta between intended and achieved depth at the central location of the stromal tunnel. Values shown in % of total number of eyes.

compare both techniques. Barbara et al.[10] studied with OCT the depth of implantation of Intacs ICRS after manual surgery. Our results, with a larger sample, confirm those reported in this previous study, in which the authors found a shallower than planned intrastromal tunnel performed by mechanical dissection (308 µm instead of the expected 461 µm; $P < .05$). The tunnel depth achieved after surgery was shallower than intended at three different locations (proximal, central, and distal; $P < .05$). At the same line, results in the study by Naftali and Jabaly-Habib.[14] showed a shallower implantation than intended by 120 µm: segment depth was 360 µm, corresponding to 60% of corneal thickness. In a study by Lai et al.,[12] it was suggested that shallow implantation can cause stronger anterior stromal compression and might result in more complications, such as epithelial and stromal breakdown or ring extrusion.

Gorgun et al.[9] also measured with OCT the depth of Ferrara ICRS from the corneal apex in a group of patients who had femtosecond laser–assisted surgery. On average, the segments were implanted 97 µm shallower than intended. However, in a subgroup of eyes with available intraoperative measured tunnel depth data (and before the ICRS implantation), the authors could observe that the tunnel depth achieved was similar to the target depth programmed in the femtosecond laser (336.7 ± 23.5 vs 336.6 ± 25.0 µm, respectively). These subgroup results are equal to and corroborate our results of 53 eyes treated with femtosecond laser–assisted surgery, in which we did not observe any significant difference. Furthermore, it has also been shown that flap thickness is predictable in LASIK with a femtosecond laser.[15] Therefore, we have interpreted this phenomenon as the apex of the ICRS having a pushing and compacting effect on the intrastromal collagen lamellae overlying the implant.

The only published study to date comparing the manual and the femtosecond laser surgery was by Kouassi et al.[8] The authors implanted Intacs ICRS for keratoconus. The results demonstrate a shallower implantation than intended in both groups: 76 µm in the manual and 86 µm in the femtosecond laser–assisted surgery, concluding that there was no difference between the two techniques concerning segment depth. Although their study has some similarities to our study, it is of note that the ICRS rings were of an earlier design with a hexagonal cross-section and the methods of measurement of the tunnel depth were distinct. In our study, the tunnel depth was directly measured by high-resolution OCT after identification of the hyperreflectivity line in the corneal stroma that depicts its presence. This method of evaluation is independent of the corneal stroma compression induced by the ICRS, as mentioned by Gorgun et al.[9]

Another disadvantage observed in previous studies is the method used for intrastromal tunnel depth measurement. The depth is predicted from the distance of the corneal apex to the outer surface of the ICRS or from the distance of the corneal apex to the inner or middle surface of the implant. This method of calculation is indirect and strongly influenced by the corneal stroma compression induced by the ICRS. In our opinion, this is the main reason why all studies demonstrated a statistically and clinically relevant difference between the intended and achieved depth of implantation, which does not correlate with what is observed (for the past decade) in clinical practice and reported in published studies about visual and topographic outcomes of the technique.[16-18] We think that the calculated depth has to derive from a direct measurement of the intrastromal tunnel. To achieve this objective, it is mandatory to use a higher resolution corneal OCT and to identify the line of hyperreflectivity adjacent to the outer border of the implant, which represents the intrastromal tunnel. The AS-OCT used for this study, the CASIA SS-1000, is a new generation Fourier-domain OCT with an axial and transverse resolution of 10 and 30 µm, respectively. The Visante OCT (Carl Zeiss Meditec, Jena, Germany), used in most of the studies published, has a weaker resolution of 18 and 60 µm, respectively, for the axial and transverse cuts. In our study, we observed a mean difference between intended and achieved depth below 10 µm for all three locations measured and in all of the eyes analyzed. In the case of manual mechanical dissection, the achieved depth of implantation was significantly shallower than intended for all measurements: more than half of the eyes (57.14%) had an implantation shallower than 10 µm from intended and almost one-third (29.52%) had a shallower difference of 50 µm or more from intended. As mentioned before, the precision of intrastromal tunnel dissection is critical in achieving a good therapeutic and refractive result. In cases of inadequate ICRS implantation, there is a higher probability of mechanical complications (migration or extrusion), worse visual and refractive outcomes, and weaker topographic and aberrometric improvements.

Another aspect discussed previously is the variability of ICRS tunnel depth along the same path, from the proximal to the distal part of the implant. Our cohort of patients had a statistically significant difference in the manual group: the proximal depth being shallower than the central and distal parts. No difference was found between the central and distal locations of the tunnel. We observed an opposite result in the femtosecond laser group: a significant difference between the distal location when compared to both the central and proximal locations; however, we consider these differences to be clinically irrelevant because they were all less than 10 µm.

A previous study by Lai et al.[12] using AS-OCT to examine the depth of Intacs intracorneal ring segments, which were implanted with the aid of mechanical dissectors, showed that the tunnel depth decreased with increasing distance from the incision site. The authors hypothesized that the weaker and more flexible inferior cornea might bow downward ahead of the mechanical dissector, causing the channel to be progressively shallow during the dissection process. In another study by Kamburoglu et al.[11] intrastromal depth of Intacs ICRS implanted with the aid of a femtosecond laser were measured using Pentacam and the tunnel depth was similar across different points.

Higher precision and predictability of intrastromal tunnel creation are associated with a better safety profile of the procedure. Most mechanical complications of ICRS implantation are associated with shallow implantation in the corneal stroma.[5-7,19] An easier identification of an ICRS implanted more superficially than intended (by a non-invasive, rapid, and reproducible method such as the AS-OCT) will help the surgeon to monitor patients with superficial implants and recognize the need to explant the ICRS to avoid spontaneous extrusion after epithelial breakdown, stromal melting, or even infectious keratitis. A superficial ICRS is the most important risk factor for future implant extrusion or corneal melting.[20]

The implantation of ICRS for keratoconus is a more precise and predictable procedure if performed with the assistance of a femtosecond laser. The importance of a correct implantation regarding the ICRS depth cannot be overemphasized because this fact is crucial for both the achievement of the intended refractive, visual, and topographic results and because it is a guarantee of lower incidence of mechanical complications in the long term, such as ICRS migration or extrusion.

AUTHOR CONTRIBUTIONS

Study concept and design (TM, JFA, NF, FF-C, RA, DM-C); data collection (TM, NF, FF-C, RA, DM-C); writing the manuscript (TM); critical revision of the manuscript (TM, JFA, NF, FF-C, RA, DM-C); supervision (JFA)

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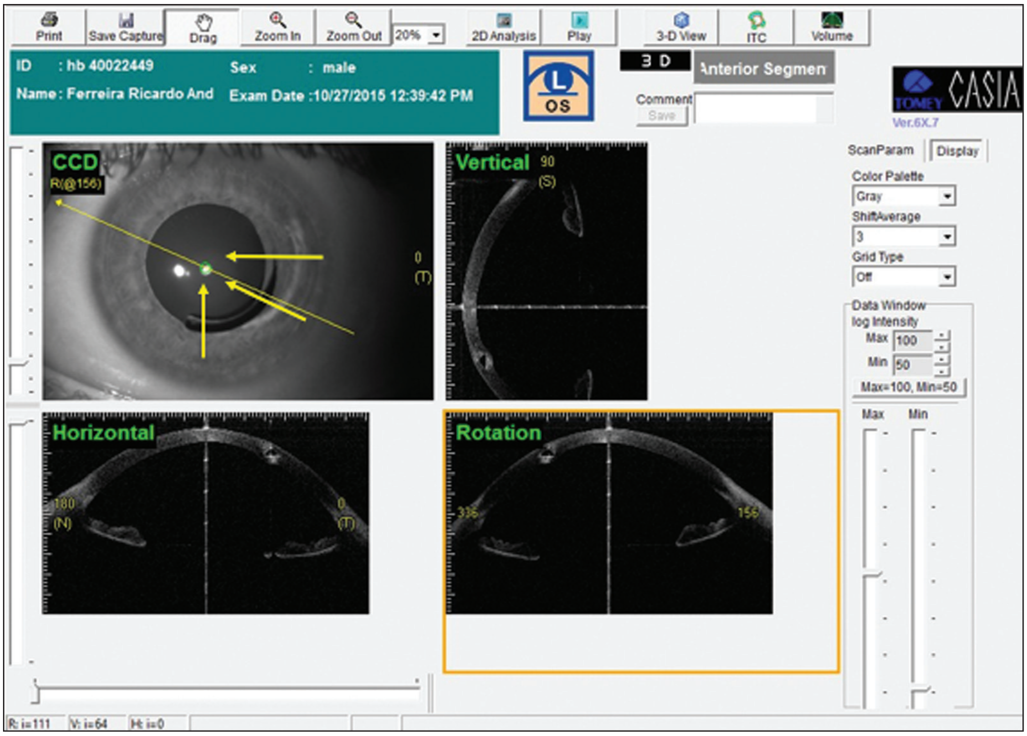

Figure A. Example of an examination performed at three locations in the same eye.

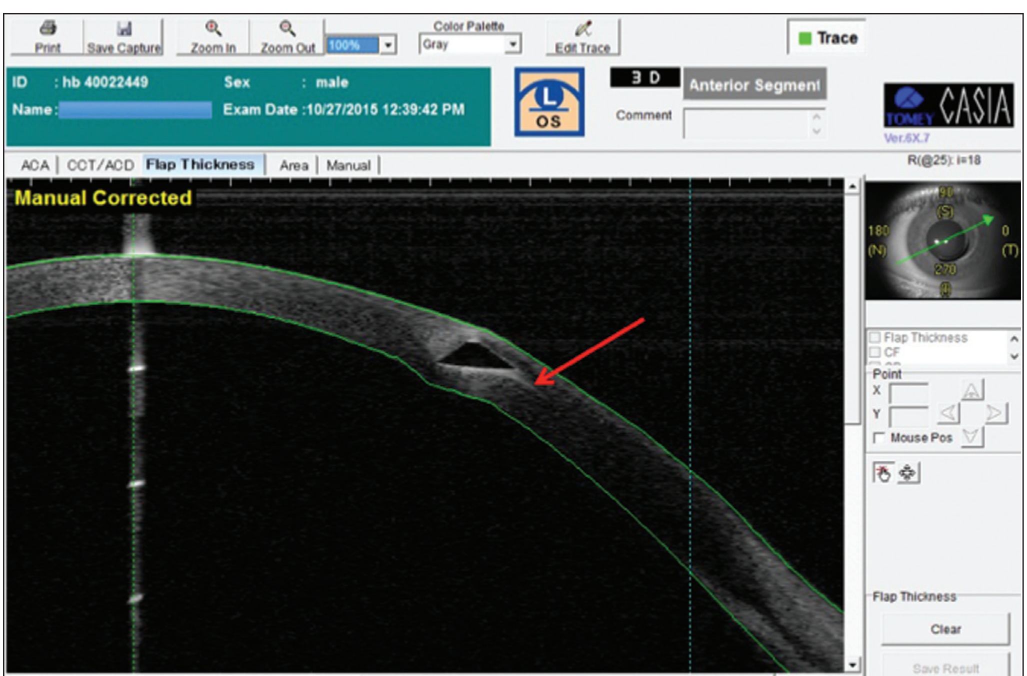

Figure B. Line of hyperreflectivity.

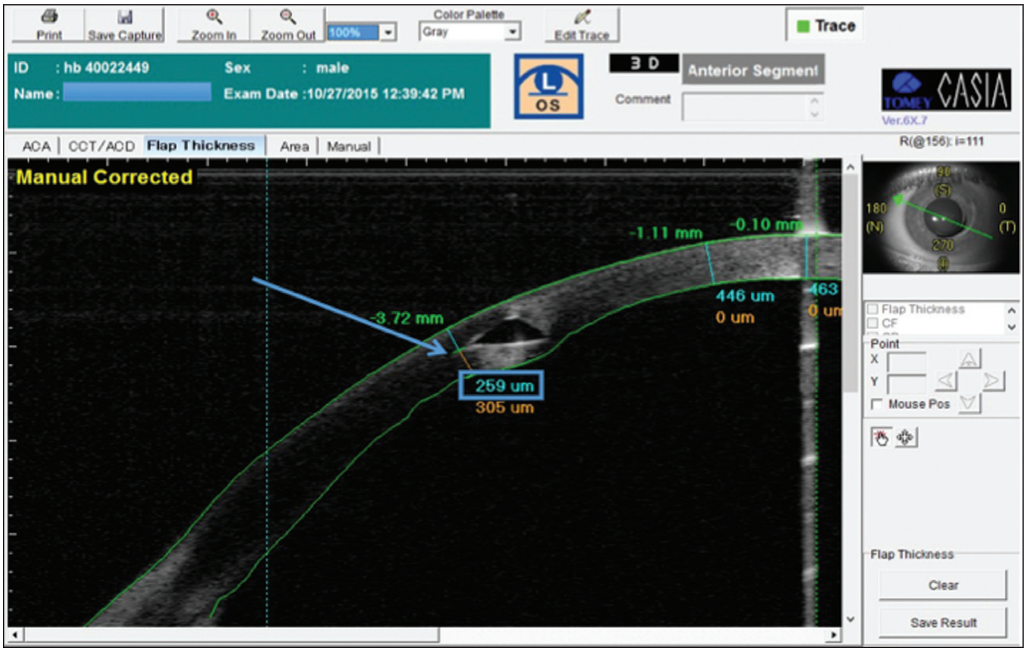

Figure C. Measurements of the tunnel depth with the flap analysis module.

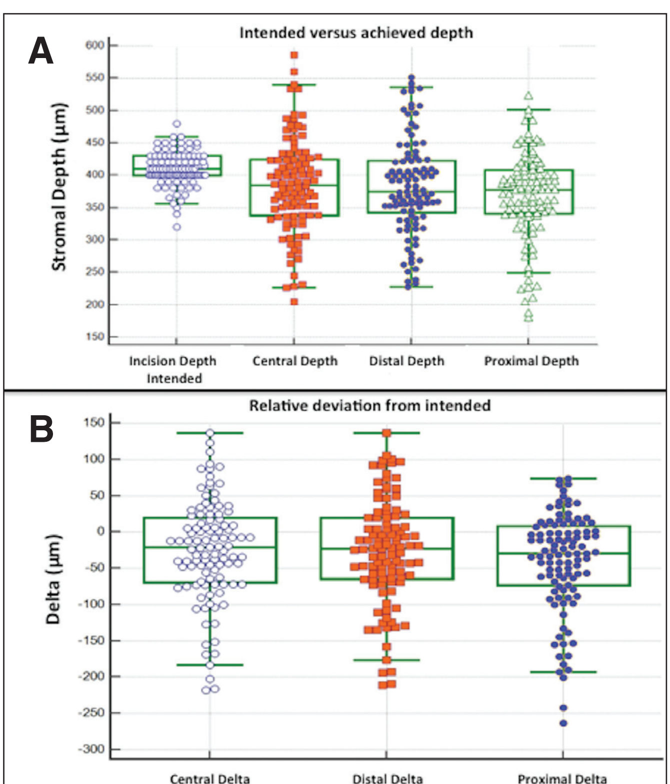

Figure D. Manual technique group. (A) Distribution of intended versus achieved depth of intrastromal corneal tunnel for intrastromal corneal ring segments implantation. All measurements at central, proximal and distal locations were shallower than intended. (B) Distribution of delta values between intended versus achieved for central, distal, and proximal locations.

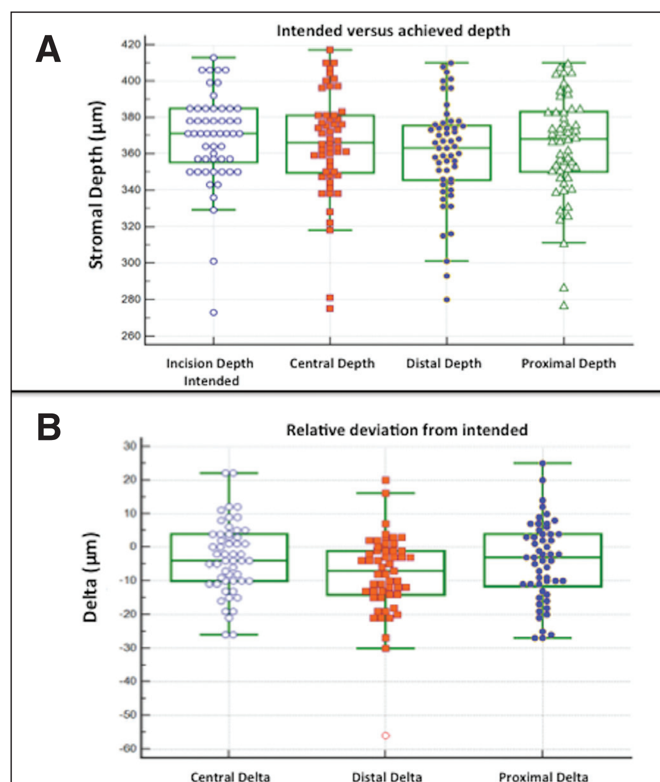

Figure E. Femtosecond laser technique group. (A) Distribution of intended versus achieved depth of intrastromal corneal tunnel for intrastromal corneal ring segments implantation. All measurements at central, proximal, and distal locations were similar to the intended value (*P* > .05). (B) Distribution of delta values between intended versus achieved for central, distal, and proximal locations.