New Technique of Femtosecond Laser-Assisted Intracorneal Ring Segment Implantation

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Purpose: To describe a new technique of femtosecond laser-assisted intracorneal ring segment implantation.

Methods: The study included 6 eyes of 5 patients. Software of the LDV Z6 femtosecond laser was modified to create a 110-degree reverse side cut between the corneal surface and incision instead of the conventional 90 degree angle (which changed the angle between the incision and tunnel from conventional 90–70 degrees) and 2 disjointed tunnels separated by 10 degrees arc length at the proximal and distal ends.

Results: One-year postoperatively, there were no cases of segment extrusion or touch/overlap. Anterior segment optical coherence tomography showed appropriate position of the rings in all eyes postoperatively. Improvement was also found in visual, refractive, keratometric, and asphericity parameters.

Conclusions: The results of this pilot study are promising. A comparative prospective study with more eyes and longer follow-up may confirm whether this technique is better than the conventional femtosecond laser-assisted one.

Key Words: intracorneal ring segment, reverse side cut, disjointed tunnels, LDV Z6 femtosecond laser

(*Cornea* 2017;0:1–5)

Intracorneal ring segment (ICRS) implantation is being used as an effective and safe treatment for patients with keratoconus and post–laser-assisted in situ keratomileusis ectasia.[1,2] The procedure involves implantation of an ICRS in the deep corneal stroma using mechanical or femtosecond laser-assisted methods with the aim of modifying corneal curvature and inducing refractive changes.[3] The mechanical method involves making an initial 90-degree incision (using a diamond blade) followed by the creation of a tunnel using semicircular lamellar dissectors.[4] The procedure results in good visual and refractive outcomes[5–7]; however, intraoperative and postoperative complications may occur.[1,5,8–10]

The use of femtosecond laser technology in ICRS implantation has resulted in a precise tunnel and keratotomy depth, width, and location,[5,8] and minimized intraoperative and postoperative complications (decreased risk of epithelial defects, stromal edema, and corneal perforations; and less postoperative discomfort) resulting in improved surgeon confidence.[8,10–12] Earlier concerns about nonlamellar cuts are now settled with increasing availability of data to support the safety of femtosecond laser-assisted tunnel creation.[2,13,14] Although an appropriate depth, which is believed to be one of the most important factors to reduce migration, was addressed by femtosecond laser-assisted tunnel creation,[12] migration resulting in extrusion is still observed[5,13,15] and is probably the most common complication of ICRS implantation.[6,16]

The femtosecond laser allows precision crafting of the length, angle, and shape of corneal incisions.[17] Different types of incisions are possible with the use of a femtosecond laser, which otherwise were not conventionally possible with a blade. As such, the femtosecond laser can be used advantageously to improve the technique of ICRS tunnel creation and potentially decrease the incidence of extrusion. One such technique modification could be making the angle between the incision and tunnel more acute instead of the conventional 90 degree angle, thereby preventing segment extrusion. Furthermore, the incidence of segment touch/overlap can be addressed by making separate (disjointed) tunnels for 2 segments. In this study, we describe a new technique of ICRS implantation with a femtosecond laser to potentially reduce the incidence of the most common complications of ICRS implantation like segment extrusion and touch/overlap.

MATERIALS AND METHODS

The current prospective, interventional pilot study included 6 eyes of 5 patients who underwent ICRS implantation for grade 2 to grade 3 keratoconus (Amsler–Krumeich classification) at Instituto de Ojos Oftalmosalud, Lima, Peru. The cone was inferior in 2 eyes and asymmetric in 4 eyes. The eyes included in the study did not have any corneal scar, Descemet tears, or history of any other ocular disease or ocular surgery.

The Ferrara nomogram was used for selecting ring size(s) based on the type of keratoconus, its location in the cornea, corneal asphericity (Q), topographic astigmatism, and pachymetry. All subjects included in the study required

Received for publication December 9, 2016; revision received February 16, 2017; accepted March 1, 2017.
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The authors have no funding or conflicts of interest to disclose.
Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.corneajrnl.com).
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implantation of two 160-degree ICRSs (Ferrara rings; Mediphacos, Belo Horizonte, Brazil). The study protocol complied with the provisions of the Declaration of Helsinki and was reviewed and approved by the ethics committee of the institution. Informed consent was obtained from all the subjects before the procedures were performed.

Surgical Technique

The LDV Z6 (Ziemer Ophthalmic Systems, Port, Switzerland) femtosecond laser was used for the creation of incision(s) and tunnel(s) for ICRS implantation. The procedure was performed under topical anesthesia using 0.5% proparacaine sterile eye drops. A disposable suction ring was placed and centered with respect to the pupil center to avoid decentration.

Instead of the conventional single 90-degree incision and a 360-degree tunnel, 2 disjointed tunnels with separate incisions were performed for double segment implantation (Fig. 1). A new program in the femtosecond laser LDV Z6 was used to make 2 incisions that were aligned 5 degrees on either side of the steepest topographic meridian (thereby achieving a separation of 10 degrees between both incisions). Instead of the conventional 90 degree angle between the corneal surface and incision, a 110-degree reverse side cut was made, which changed the angle between the incision and tunnel from the conventional 90 to 70 degrees (Fig. 1). Because all patients (in this study) underwent implantation of 160-degree ring segments; 170-degree tunnels were created, thereby allowing a separation of 10 degrees between the distal ends of the tunnels (see Video 1, Supplemental Digital Content 1, http://links.lww.com/ICO/A525). The inner diameter of the tunnel was set at 4.35 mm, and the outer diameter was set between 5.75 and 5.77 mm based on the thickness of the ring segment to be implanted (information preset in the laser system). The tunnel width and incision length were equivalent depending on inner and outer diameters of the ring segment chosen for implantation. The tunnel depth was chosen based on 80% thickness of the thinnest pachymetry (range: 324–409 μm) in the 5- to 6-mm area. Laser beam of spot size <2 μm was used. The power of the laser was set at 100% for creation of both tunnel and incision. The laser procedure was completed within approximately 10 seconds.

Implantation of ICRSs was performed under a microscope. ICRSs were implanted immediately after the creation of tunnels under full aseptic conditions. A Sinskey hook was used to place the ring segments in the final position. The 160-degree ring segments were centered in the tunnel of arc length 170 degrees so that the space of 5 degrees arc length was left between proximal and distal ends of the tunnel and ring segment. No sutures were placed. At the end of the procedure, 0.3% tobramycin and 0.1% dexamethasone eye drops were applied. No intraoperative complications were observed. Postoperative treatment included a combination of an antibiotic (tobramycin 0.3%) and a steroid (dexamethasone, 0.1%) 4 times daily for 1 week. Lubricants were also administered postoperatively.

Postoperative assessment included uncorrected distance visual acuity and corrected distance visual acuity (Snellen chart), Pentacam (OCULUS Optikgerate GmbH, Wetzlar, Germany), anterior segment optical coherence tomography (Visante; Carl Zeiss Meditec, Germany), slit-lamp biomicroscopy, and corneal photography. The main outcome measure was the corneal ring position. Additional data analyzed at preoperative and 6-month and 1-year postoperative levels were uncorrected distance visual acuity, corrected distance visual acuity, and Scheimpflug data (keratometry, pachymetry, and asphericity).

Statistical Analysis

Statistical analysis was performed using SPSS software (version 17.0; SPSS Inc, Chicago, IL). The Shapiro–Wilk test and quantile–quantile plots were used to check the normality of the data. To analyze the change from the preoperative level to postoperative 6 months and postoperative 6 months to 1 year, repeated-measures analysis of variance followed by post hoc Bonferroni statistics was used for normally distributed

FIGURE 1. Ziemer (LDV Z6) femtosecond laser system display showing the plan for making disjointed tunnels with separate incisions (highlighted red) such that the 110-degree reverse side cut was created between the corneal surface and the incision instead of the conventional 90-degree angle (which changed the angle between incision and tunnel from the conventional 90–70 degrees).

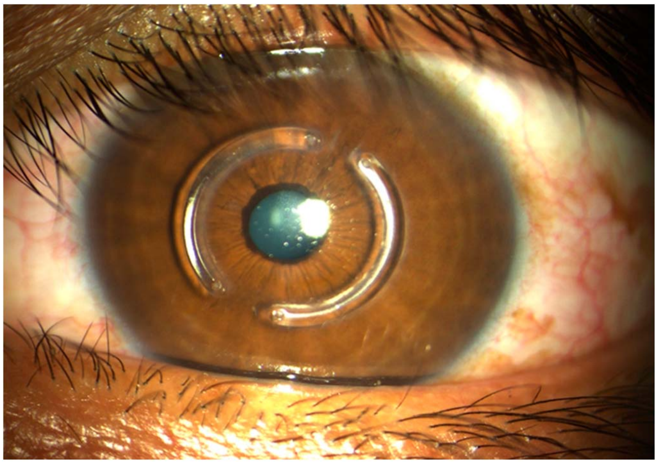

FIGURE 2. Slit-lamp photograph of the left eye of a patient 1 year after ICRS implantation showing disjointed tunnels with separate incisions (superotemporally).

data; otherwise corresponding nonparametric tests, that is, Friedman/Wilcoxon signed-rank test, were used. Differences with $P < 0.05$ were considered statistically significant.

RESULTS

A total of 5 patients (6 eyes) were recruited into the study. The mean age of the patients was 29 years (range: 27–33). All the patients were followed up for at least 1 year. The mean depth of ICRS implantation was 386.2 ± 27.4 μm (range, 335–409 μm).

One-year postoperatively, ICRSs in all eyes were well positioned (Fig. 2); there were no complications, particularly no cases of segment extrusion or touch/overlap. Six eyes in the current pilot study demonstrated good improvement in visual acuity, refraction, keratometry, and asphericity index at 6 months postoperatively compared with the preoperative levels. All outcomes remained stable at 1-year postoperatively (Table 1). Optical coherence tomography of one of the study eyes showing 2 separate angled incisions with corresponding tunnels is shown in Figure 3. Figure 4 demonstrates preoperative and postoperative 1-year topography of one of the study eyes revealing adequate central flattening.

DISCUSSION

In this study, we introduced a new technique of femtosecond laser-assisted ICRS implantation to potentially avoid the complications of segment extrusion and touch/overlap. Plausible reasons for ICRS extrusion include superficial segment placement and minimal separation between the proximal end of the ring segment and incision.[16,18] Review of the literature shows that migration and extrusion of the ring segments have been observed with both methods of tunnel creation, that is, mechanical and femtosecond laser-assisted. Seven studies (304 eyes; follow-up time: ≥1 yr) involving mechanical implantation of ICRSs showed extrusion rates ranging from 1.8% to 19.4%[5,6,19–23]; in comparison, 3 studies of femtosecond laser-assisted ICRS implantation (148 eyes; follow-up time: 6 mo–1 yr) reported extrusion rates between 0% and 4.8%.[5,6,24] The lower incidence of extrusion in the studies involving femtosecond laser-assisted ICRS implantation seems to correlate well with the ability of the femtosecond laser to create tunnels with a precise and predictable depth. However, future studies with longer follow-up time are needed to confirm these findings.

Despite the apparent decrease in the rate of extrusion with femtosecond-assisted ICRS implantation, extrusion continues to remain the most common ICRS complication.[5,6,24] The literature documenting the long-term data of ICRS implantation reports stable keratometry and topographic outcomes, indicating the potential of the ICRS to halt keratoconus progression, and therefore deferring the need for keratoplasty.[25] In view of that, extrusion of the ICRS can significantly change the disease course of corneal ectasia and may necessitate keratoplasty early on. It is therefore warranted that different ways that can prevent ICRS extrusion be explored and incorporated into clinical practice. Surgical technique modifications, particularly with femtosecond laser-assisted ICRS implantation, can be one such way which can be used to precisely modify the tunnel anatomy, potentially decreasing the risk of extrusion.

TABLE 1. Comparison of Visual Acuity, Refractive, and Keratometric Parameters—Preoperative Versus Postoperative 6 Months; Preoperative Versus Postoperative 12 Months; and Postoperative 6 Months Versus 1 Year

	Preoperative	6 Month	12 Month	*P*		
Parameters (N = 6)	Mean ± SD	Mean ± SD	Mean ± SD	Preoperative Versus 6 Month	Preoperative Versus 12 Month	6 Versus 12 Month
UDVA, logMAR	0.83 ± 0.61	0.44 ± 0.42	0.43 ± 0.30	0.373	0.313	1
CDVA, logMAR	0.14 ± 0.13	0.07 ± 0.07	0.05 ± 0.06	0.203	0.066	0.18
Sphere	−1.83 ± 2.16	−0.75 ± 2.14	−0.67 ± 2.01	0.102	0.209	1
Cylinder	−6.25 ± 1.54	−1.96 ± 1.27	−2.04 ± 1.38	0.027	0.006	1
MRSE	−4.96 ± 1.60	−1.73 ± 2.41	−1.69 ± 2.30	0.028	0.006	1
Steep K	50.72 ± 1.53	46.77 ± 2.94	46.90 ± 2.88	0.014	0.013	0.545
Flat K	44.82 ± 2.42	43.40 ± 2.40	43.73 ± 2.61	0.046	0.373	0.677
Asphericity Q value	−1.21 ± 0.24	−0.62 ± 0.37	−0.65 ± 0.36	0.08	0.092	1

CDVA, corrected distance visual acuity; MRSE, manifest refraction spherical equivalent; N, number of eyes; UDVA, uncorrected distance visual acuity.

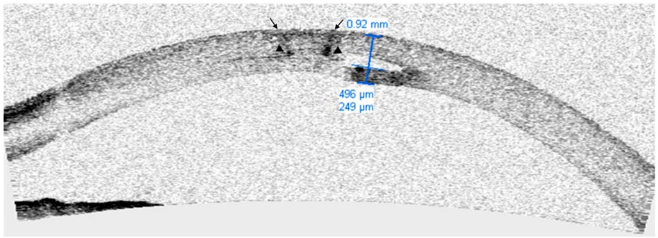

FIGURE 3. Corneal optical coherence tomography showing 2 separate incisions with corresponding tunnels. The entry point of incision from the corneal epithelial side is marked by arrows and 70-degree angle between the incision and tunnel is marked by arrow heads.

The new technique described in this study modifies software of the LDV Z6 femtosecond laser to create a 110-degree reverse side cut (instead of the conventional 90 degrees), thereby making an autosealed valve (by changing the angle between the incision and tunnel from the conventional 90–70 degrees), which the authors believe will decrease the risk of ICRS extrusion. In this study, no cases of ring segment extrusion and touch or overlap were observed during the 1-year follow-up period. In addition, other kinds of postoperative complications were also not observed. Expectedly, the visual, refractive, and topographic outcomes of this study were comparable to the results obtained in previous studies with mechanical and conventional femtosecond laser-assisted techniques.[5–7,13,26] Similarly, the asphericity Q value decreased postoperatively as reported in previous studies.[27,28]

Theoretically, construction of 2 incisions would increase the exposed surface of the cornea and thus may increase the risk of infection. However, we found better apposed incisions with 110-degree reverse side cuts with no case of infection. Furthermore, making an acute angle between the incision and tunnel may be expected to necessitate higher tissue manipulation for ring segment implantation and consequent tissue damage. However, in this study, implantation of the ring segment through 110-degree reverse side cut did not result in any undue tissue manipulation or trauma at the incision site and no case of corneal epithelial defects or corneal stromal edema[9] was observed. In fact, in the authors' experience, implantation of ring segments through separate incisions required less manipulation than implanting both segments through a single incision. Although this study used 110-degree reverse side cuts in all the cases; if needed, the angle between the incision and tunnel can be made less or more acute but the higher degree of acuteness must be balanced against the potential of increased tissue manipulation.

Two disjointed tunnels were constructed for implantation of 2 ring segments. At the proximal end, 2 separate reverse side cut incisions (110 degrees) were constructed, which were separated by the tissue barrier (10 degrees arc length). The tunnels were also separated distally by the tissue barrier of arc length 10 degrees. Theoretically, creation of 2 tunnels separated by a tissue barrier at both proximal and distal ends could increase the risk of extrusion, as it will make the proximal edge of the ring considerably closer to the incision. However, in the authors' experience, 110-degree reverse side cuts resulted in better apposed incision walls, potentially balancing the proximity of the incision. Within the 1-year follow-up period, we did not find any such complication; however, longer-term studies are needed to confirm these findings. As such, the technique can be modified to implant the segments more toward the distal end of the

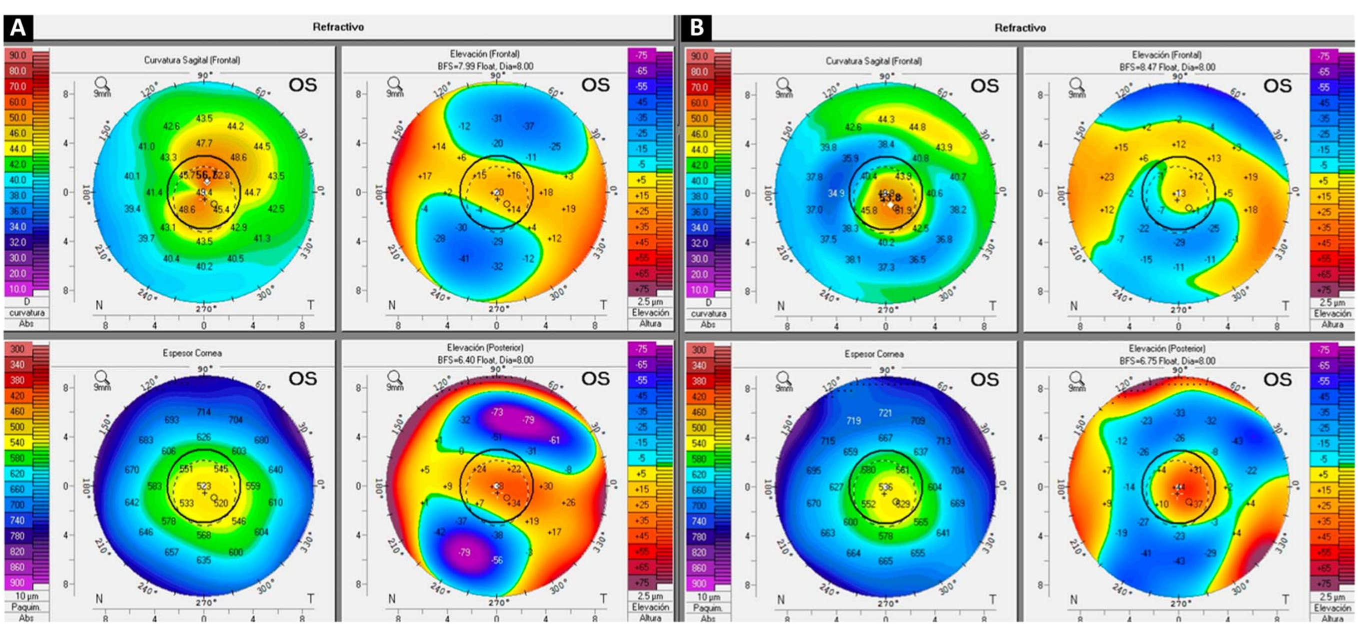

FIGURE 4. Preoperative (A) and 1 year postoperative (B) refractive maps of the left eye of the patient from the Pentacam (Oculus, Oculus Optikgerate GmbH). There was regularization of the corneal topography postoperatively showing marked reduction in both steep K (preoperative = 49.5 D, postoperative = 43.4 D) and flat K (preoperative = 42.9 D; postoperative = 40.1 D).

tunnels (as a 5-degree distance was left between the distal end of the ICRS and tunnel), potentially increasing the separation between incisions and the proximal end of the ring segments. In fact, the separation can be managed more effectively for an ICRS of arc length shorter than 160 degrees. In addition, the inferior tissue barrier arc length can be shortened to 5 degrees; the increased tunnel length thus created could be used to further increase the separation between the incision and proximal edge of the ring segment.

Extrusions of the ring segments can occur as early as the first postoperative day and even after several years of ICRS implantation; however, review of the literature shows that the most common time period for ICRS extrusion is between postoperative 1 and 12 months.[5,6,20–22] Overall, the 1-year results of this new technique in a small cohort of patients are promising; however, longer-term studies are needed to confirm the preliminary findings we are presenting with this technique article. This pilot study should be followed by a comparative prospective study with more eyes and longer follow-up to confirm whether this technique is better than the conventional femtosecond technique.

ACKNOWLEDGMENTS

Raman Bedi, MD, critically reviewed the manuscript. IrisARC—Analytics, Research & Consulting (Chandigarh, India) provided writing, editing, and statistics assistance.

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