Innovative intra-corneal ring-supported graft surgery for treatment of keratoconus and cornea regeneration: Surgical technique and case report

Khosrow Jadidi1, Seyed Aliasghar Mosavi1,2, Farhad Nejat1,2, Hosein Aghamolaei3, Shiva Pirhadi4

Therapeutic options for corneal ectasia are evolving, with emphasis on the intra-stromal corneal ring for delaying or eliminating the need for penetrating keratoplasty. A 33-year-old man with grade 4 keratoconus and rising intolerance of the hard contact lens underwent a combination of a new innovative ring and graft with suture in the left eye. Excellent structural support and stability of the cornea were observed immediately post-operatively and 12 months after surgery. It appears as a feasible and safe therapy option for keratoconus eyes with reference to the instability and asymmetry of the cornea. Hence, as a safe and effective technique, it can be performed easily.

Key words: Corneal graft, femtosecond-assisted, intra-stromal ring, keratoconus

Keratoconus is a chronic escalating non-inflammatory eye disorder caused by thinning of the cornea and its irregular deformation. Various treatment options have been suggested for the management of keratoconus, including corneal collagen cross-linking (CXL), intra-stromal corneal ring (ICR) implantation, and lamellar or penetrating keratoplasty. Based on a biomechanical perspective, the corneal tissue is an elastic material capable of structural alternations and deforms under a force like intra-ocular pressure. However, sometimes biomechanical structural changes related to keratoconus lead to progression of the disease.

Several studies mentioned the effectiveness of the rings to improve visual acuity and declining the refractive error and the mean keratometry (K) value in patients with keratoconus. ICR, settled as an additive refractive surgical method for low to moderate myopia, is advanced into a main instrument for management of corneal ectatic disorders such as keratoconus, pellucid marginal degeneration, and post-laser-assisted in situ keratomileusis (LASIK) ectasia.

Although ICR has shown to provide some improvement in treatment of keratoconus and its progression, still there is a need for ways to better re-shape the cornea, further improve visual acuity, and halt the progression in keratoconus disorder.

Corneal lenticule insertion alone in treating keratoconus, despite having no graft folds or interface complications during a 5-year follow-up, was not effective, which may point to the lack of limbal support and visible change in biomechanics of the cornea. Moreover, ICR can be only used for mild to moderate keratoconus and is not a solution for all keratoconus cases, and therefore, development of new devices and methods can provide further help for treating keratoconus on a wider scale. With these problems in mind, we designed a coupling method to achieve more posterior cornea stress comfort for ectatic disorders.

Innovation

The innovative surgical procedure was conducted at Bina eye Hospital, Tehran, Iran, and approved by the ethics committee (registered number of IR.SEMUM.REC.1398.316). The informed and written consent was taken. The surgical procedure shown in the Video [Supp 2] had the following steps:

First, a corneal lenticule is created as a graft from the donor eye. Before surgery, using a blade (number 15), the donor eye was trephined, a corneal lenticule is created, and a corneal strip was inserted. A 5-mm diameter donor corneal lenticule was cut from the left eye and inserted into the prepared bed.

Video available on: www.ijo.in

For reprints contact: WKHLRPMedknow_reprints@wolterskluwer.com

Cite this article as: Jadidi K, Mosavi SA, Nejat F, Aghamolaei H, Pirhadi S. Innovative intra-corneal ring-supported graft surgery for treatment of keratoconus and cornea regeneration: Surgical technique and case report. Indian J Ophthalmol 2022;70:3412-5.
epithelium of the donor eye was removed from the whole globe. Afterward, a corneal lenticule is created with an exact diameter and thickness as desired by VICTUS Femtosecond Laser (Bausch + Lomb). Then, our innovative ring characterized as a full circle with two spherical side surfaces defining its thickness, an inner and an outer rim defining its width with a plurality of holes, preferably 12, distributed around the ring pass through the side surfaces [Fig. 1]. The ring is sutured to the natural corneal graft lenticule mentioned above via the holes such that it is uniformly stretched flat by the suture and fills the inside of the ring (see the video as the supplementary material). The ring, the suture, and the graft together define a cohesive part acting in unison, named Ring Graft in this innovation [Fig. 1]. The Ring Graft is inserted in the corneal stroma using superior scleral tunnel incision. The Ring Graft suturing was performed using a 10-0 nylon suture. The diameter of ring holes is slightly larger than that of the suture to allow the biological interaction between cornea layers on the two sides of the ring. The ring side surfaces have a curvature in alignment with that of the cornea with a base angle of 20–25 degrees. These provisions are intended to prevent corneal melting at the cornea ring interface.

Afterward, a corneal pocket was created in the recipient’s eye as follows:

Local anesthesia was used in the recipient’s eye using tetracaine 0.5% anesthesia eye drops (Sina Darou Company) three times in 5 min intervals before and as needed during operation. Then, peritomy was performed from the superior part of the cornea, and an incision was made in the sclera 1.5 mm from the limbus. The length of the incision was approximately 6 mm. The incision was extended as the scleral tunnel into the mid-stromal part of the cornea manually using the Melles hook. The pocket was mid-stromal, 1 mm larger than the outer rim diameter (9.4 mm for an 8.4 mm ring). The pocket was separated from the underlying stromal layer with the aid of a Melles hook.

Subsequently, Ring Graft was inserted in the corneal pocket. Next, the pocket was irrigated with BSS, and the conjunctiva was stuck in place using cautery without the suture. Finally, a silicone-hydrogel bandage contact lens (Alcon Laboratories, Inc., Fort Worth, TX, USA) was used to cover the cornea. Ciprofloxacin antibiotic 0.3% (Sina Darou Company) was administered one drop every 6 hours for 1 week. Betamethasone (Sina Daroo Company) was administered one drop every 4 hours for 1 week and tapered gradually for 6 months, with artificial tear drops or a lubricant. The contact lens was removed after 2 days when the wound was healed. Furthermore, using corneal visualization Scheimpflug technology (Corvis-ST, CST), corneal biomechanical examination was performed.

Then, the pre- and post-examination results were compared. The impact of the novel surgical device and method for treating keratoconus in the left eye of a 33-year-old man with grade 4 keratoconus, with rising intolerance of the hard contact lens, was investigated.

### Before intervention
The severity of keratoconus (grade 4) was evaluated based on the grading system of the Pentacam, Belin ABCD progression display [Supp 1]. The left eye of the patient was treated with a refraction of -7.4 × 120°. The corrected distance visual acuity (CDVA) was 4/10, and the uncorrected distance visual acuity (UDVA) was 5/100. The topography before surgery is exhibited in Fig. 3b. The highest and central K-values were 60 and 50 D, respectively, at the steepest and 44.70 D at the flattest meridian (mean 47.20 D). Also, at the thinnest point, the thickness of the cornea was 463 μm. Meanwhile, UDVA and CDVA of the right eye were 2/10 and 6/10 decimal, respectively, with a refraction of -2.3 × 45°.

### After implantation
One year after implantation of the new ring-supported graft, the eye was white and quiet, and the graft was clear [see Fig. 4]. UDVA was 2/10 and CDVA was 8/10 decimal with a refraction of -2.3 × 100° [Table 1]. Fig. 2 shows corneal keratometry of the eye after the procedure of the present innovation demonstrating a decrease in the mean topographic K values [Fig. 3c]. K max reduced from 60 dioptries to 50 dioptries in 1 year.

After providing the intervention, no graft folds or interface-related problems were found [Fig. 3a]. The patient was highly satisfied and did not mention any problem (during either
the day or night). Moreover, the corneal stiffness increased 3 times post-operatively. Anterior and posterior corneal aberrometry revealed a significant decrease in higher-order aberrations, spherical aberration, primary coma, and trefoil 1 year after surgery. Because our patient was pleased with his vision, no more augmentation was performed.

Discussion

ICR was developed as an additive approach for managing myopia by shortening the central arc length and therefore flattening the central portion of the anterior corneal surface. Nevertheless, a particularly asymmetrical form of the cornea in advanced keratoconus still is a major challenge.

The presented procedure intended to treat keratoconus through an intra-corneal implant-supported graft allows a new degree of modification in the ICR therapeutic concept, that is, using the implant as a secondary limbus. Therefore, the aforementioned coupling procedure can be used not only to cover an extended arc length but also for forming increased constructive support. The authors believe that the added thickness, strength, and limbal style support of the cornea by Ring Graft of the present innovation may provide a safe method to prevent the progression of keratoconus.

In keratoconus cases, corneal irregularity causes glare and halo as a major complaint. Clinical studies by the authors showed improvement in irregularity and reduction of glare and halo after Ring Graft implantation which is not reported yet. Furthermore, aberrometric parameters showed a significant decrease that may explain corneal regularization, which is consistent with improvement in CDVA.

There are many advantages using Ring Graft as follows:

First, the ring with its plurality of distributed holes, spherical shell profile, or angle, in relation to or in cooperation with a human cornea, allows benefitting from its high stiffness. Second, the suturing of the ring and graft are better capable of securing the determined location of the ICR, with no

| Table 1: Changes in visual acuity, Corvis parameters, and aberrometry findings before and after Ring Graft insertion |
|---------------------------------------------------------------|
| **PRE-OP** | **6 MONTH POST-OP** | **ONE YEAR POST-OP** |
| UCVA (decimal unit) | 5/100 | 1/10 | 2/10 |
| REFRACTION (l) | -7.4 x 120 | -2.2.5 x100 | -2.3 x100 |
| BSCVA (decimal unit) | 4/10 | 7/10 | 8/10 |
| CORVIS-ST HRC (mm) | 5.46 | 5.95 | 5.90 |
| CORVIS-ST MDA (mm) | 1.29 | 1.13 | 1.10 |
| CCT (µm) | 463 | 526 | 525 |
| IOP (mm Hg) | 10.5 | 15 | 14 |
| HO TOTAL (µm) | 1.942 | 0.267 | 0.207 |

MDAR=Maximum Deformation Amplitude, HRC=Highest Radius of Curvature, HO=Higher-Order Aberrometry, IOP=Intra-Ocular Pressure, BSCVA=best spectacle corrected visual acuity

Figure 3: (a): Slit lamp photograph 5 days after corneal Ring Graft insertion; (b) Corneal topography prior to Ring Graft insertion; (c) Corneal topography 1 year after corneal Ring Graft insertion

Figure 4: (a) Slit lamp photograph before corneal Ring Graft insertion; (b) Slit lamp photograph after corneal Ring Graft insertion; (c) Slit lamp photograph of RE
negative impacts of migration, which potentially can decline consequences of extrusion. Another advantage of the Ring Graft is its insertion in the stroma layer of the cornea using superior scleral tunnel incision that avoids any incision on the cornea to maintain its integrity and biomechanics. Additionally, the present method reduces the chance of corneal melting because the 20–25-degree base angle prevents corneal melting observed in conventional cornea implants.

Eventually, the present technique provides treatment for any level of keratoconus. The authors successfully treated severe keratoconus cases in their clinical studies which will be reported soon.

**Conclusion**

In conclusion, options to manage corneal ectasia are continuously developing with several intermediate therapeutic choices prior to penetrating keratoplasty. The adjustments suggested in the present study can potentially improve keratoconus treatment; however, more research with a longer follow-up period and a larger sample size are needed to provide decisive evidence regarding the efficacy and safety of the aforementioned procedure and its role in managing the advancement of keratoconus. The study continues, still, and more findings will be reported soon.

**Acknowledgment**

The authors would like to acknowledge the staff of the Eye Clinic in Bina Eye Hospital Research Center for their invaluable help during the entire process of this study.

**Availability of data and materials**

The datasets generated and/or analyzed during the current study are not publicly available since all relevant data are included in the manuscript. The datasets are available from the corresponding author on reasonable request.

**Ethics approval and consent to participate**

The research protocol was in accordance with the Helsinki’s Declaration and approved by the Ethics Committee in Human Research at Bina Eye Hospital Research Center (registered number of IR.SEMUM.REC.1398.316). Also, an informed consent was signed by the study participant.

**Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

**References**

1. Rabinowitz YS. Keratoconus. Surv Ophthalmol 1998;42:297‑319.
2. Blackburn BJ, Jenkins MW, Rollins AM, Dupps WJ. A review of structural and biomechanical changes in the cornea in aging, disease, and photochemical crosslinking. Front Bioeng Biotechnol 2019;7:66.
3. Burris TE. Intrastomal corneal ring technology: Results and indications. Curr Opinion Ophthalmol 1998;9:9-14.
4. Piñero DP, Alio JL. Intracorneal ring segments in ectatic corneal disease–a review. Clin Exp Ophthalmol 2010;38:154-67.
5. Dauwe C, Touboul D, Roberts CJ, Mahmoud AM, Kérautret J, Fournier P, et al. Biomechanical and morphological corneal response to placement of intrastromal corneal ring segments for keratoconus. J Cataract Refract Surg 2009;35:1761‑7.
6. Piñero DP, Alio JL, Morbelli H, Uceda-Montanes A, El Kady B, Coskunseven E, et al. Refractive and corneal aberrometric changes after intracorneal ring implantation in corneas with pellucid marginal degeneration. Ophthalmology 2009;116:1656‑64.
7. Kymionis GD, Tsiklis AI, Pallikaris AI, Kounis G, Diakonis VF, Astyrakakis N, et al. Long-term follow-up of Intacs for post-LASIK corneal ectasia. Ophthalmology 2006;113:1909‑17.
8. Jadidi K, Mosavi SA. Keratoconus treatment using femtosecond-assisted intrastromal corneal graft (FAISCG) surgery: A case series. Int Med Case Rep J 2018;11:9-15.
9. Daxer A, Mahmoud H, Venkateswaran RS. Intracorneal continuous ring implantation for keratoconus: One-year follow-up. J Cataract Refract Surg 2010;36:1296‑302.
10. Jadidi K, Mosavi SA, Nejat F, Alishiri A. Complications of intrastromal corneal ring implantation (keraring 355) using a femtosecond laser for channel creation. Int J Kerat Ect Cor Dis 2014;3:53-6.
**Supp 1:** Belin ABCD progression display. The ABCD parameters are graphically displayed over time. The exams from a patient with known keratoconus show progression of the anterior surface and thinning of the cornea beyond the 95% confidence interval (keratoconic database) and of the posterior surface above the 80% confidence interval. The black and white checkered line when Ring Graft was inserted with subsequent improvement posttreatment (Oculus Pentacam)
Supp 2: The Video clip of the surgical procedure of Ring Graft insertion