



## Toric implantable collamer lens for treating refractive error in post-radial keratotomy, post-penetrating keratoplasty pseudophakic eye

Karolinne M. Rocha<sup>\*</sup>, Colin E. Brown, Kareem Sioufi, Larissa Gouvea

Storm Eye Institute, Medical University of South Carolina, Charleston, SC, USA

### 1. Introduction

Patients with prior history of a multiple ocular surgeries can prove a challenge in attempting to achieve optimal refractive outcomes. As the ocular anatomy and optics change in these eyes, different treatment modalities should be considered to address significant residual refractive errors. Typically, laser corrective surgery is well tolerated and widely utilized to correct postoperative refractive error.<sup>1</sup> However, in eyes with significant residual refractive error or ocular pathologies not amenable to spectacle and contact lens therapies or laser corrective surgery, a secondary intraocular lens (IOL) placement or IOL exchange could be an alternative surgical option.<sup>1-3</sup> Secondary IOLs such as the Sulcoflex (Rayner Intraocular Lenses Lt., United Kingdom) and, more recently, the off-label use of a standard Visian Implantable Collamer lens (Visian ICL, STAAR Surgical, Inc., Monrovia, CA, USA) have demonstrated good refractive outcomes for the correction of pseudophakic ametropias.<sup>4,5</sup> Herein, we report a case of a pseudophakic patient with multiple anterior segment surgeries, resulting in significant residual refractive error managed with a toric implantable collamer lens (TICL V4) implantation.

### 2. Methods

A 71-year old male was referred to cornea service of the Storm Eye Institute, Medical University of South Carolina for management of aniseikonia and high residual refractive error in the setting of contact lens intolerance. The patient had undergone multiple anterior segment surgeries including bilateral 8-incision radial keratotomy (RK) 30 years prior, bilateral phacoemulsification with toric intraocular lens (IOL) implantation, and subsequent bilateral penetrating keratoplasties (PK) due to high irregular astigmatism and corneal ectasia after RK (Fig. 1).

The uncorrected distance visual acuity (UDVA) was counter finger (CF) in both eyes, the distance-corrected visual acuity (DCVA) was 20/60 in the right eye (OD) and 20/50-2 in the left eye (OS), with a manifest

refraction of  $-14.50 + 5.50 @ 115$  OD and  $-13.50 + 4.00 @ 28 = 20/50-2$  OS. On slit-lamp exam, corneal grafts were clear without residual sutures and no signs of rejection, posterior chamber toric IOLs in the capsular bag at the  $60^\circ$  axis OD and  $130^\circ$  axis OS. Fundoscopy in both eyes (OU) revealed myopic fundus with posterior vitreous detachment, with no holes or tears.

Scheimpflug corneal tomography (Pentacam®, Oculus, Germany) showed pachymetry at the thinnest point of  $551 \mu\text{m}$  OD and  $572 \mu\text{m}$  OS, corneal astigmatism of  $7.0\text{D} @ 128.1$  OD with Km of  $43.0\text{D}$ , and  $4.4\text{D} @ 13.9$  OS with a Km of  $45.9\text{D}$ , anterior chamber depth (ACD) of  $4.52 \text{ mm}$  OD and  $4.83 \text{ mm}$  OS, and white-to-white (WTW) measurements of  $12.0 \text{ mm}$  OD and  $12.0 \text{ mm}$  OS (Fig. 2). Optical biometry (IOL Master® 700, Carl Zeiss, Germany) revealed ACD of  $5.23 \text{ mm}$  OD and  $5.42 \text{ mm}$  OS, and WTW measurements of  $12.2 \text{ mm}$  in both eyes. Manual WTW measurements performed with calipers were  $12.1 \text{ mm}$  OD and  $12.3 \text{ mm}$  OS. The average endothelial cell count was  $1798 \mu\text{m}^3$  OD and  $2182 \mu\text{m}^3$  OS.

After extensive discussion regarding surgical options, which focused primarily on the implantation of a secondary IOL given the significant residual refractive error, the patient underwent uncomplicated bilateral implantation of a toric Visian ICL (TICL V4). We calculated the appropriate power and vault of the implant based on manifest refraction and anterior chamber depth using the calculator provided by the company (<https://ocos.staar.com/staarocos/rdefault.asp>). A TMICL 13.2, power  $-16.0/4.0/123$  at the  $172$ -degree axis OD, and a TMICL 13.7, power  $-15.5/4.0/035$  at the  $173$ -degree axis OS were implanted (Fig. 3).

On postoperative day 1, UDVA was  $20/70$  OD and  $20/100$  OS. One month postoperatively, UDVA was  $20/40$  OD and  $20/25 + 2$  OS, with a manifest of  $-1.50 + 6.00 @ 125 = 20/25$ - (SE:  $+1.50$ ) OD and  $-1.50 + 4.50 @ 40 = 20/20-2$  (SE:  $+0.75$ ) OS. At 3 months postoperatively, UDVA was  $20/40$  OD and  $20/40$  OS, DCVA was  $20/25$  OD and  $20/20$  OS with a manifest of  $-1.0 + 5.0 @ 125$  (SE:  $+1.50$ ) OD and  $-1.0 + 3.75 @ 95$  (SE:  $+0.875$ ) OS. After removal of one suture at the incision site on each eye, DCVA at 6 months postoperatively was  $20/30$  OD with a manifest refraction of  $-0.75 + 3.00 @ 123$ , and  $20/25$  OS with a

<sup>\*</sup> Corresponding author. 167 Ashley Avenue, Charleston, SC 29425, USA.  
E-mail address: [rochak@musc.edu](mailto:rochak@musc.edu) (K.M. Rocha).

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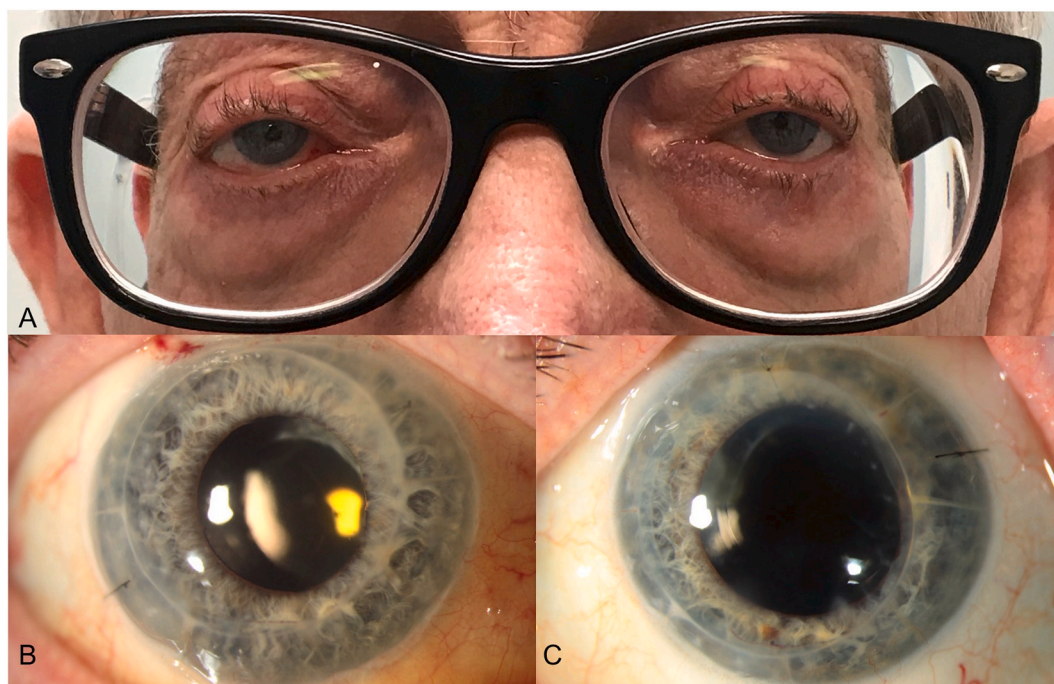
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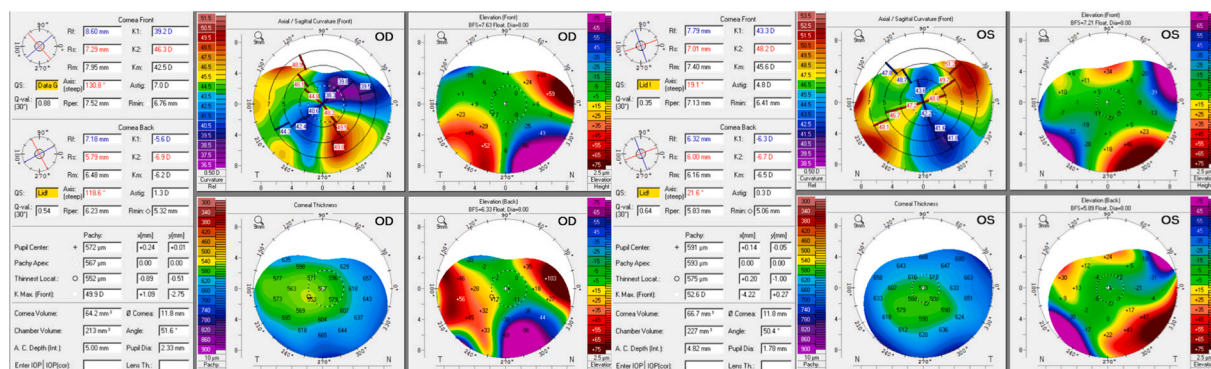
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**Fig. 1.** 71 year old male with history of bilateral 8-incision radial keratotomy (RK) 30 years prior, bilateral phacoemulsification with toric intraocular lens (IOL) implantation and subsequent bilateral penetrating keratoplasties (PK). (A) External photo of the patient with spectacles demonstrating minification effect secondary to high negative sphere lenses. Slit lamp photo of the right eye (OD) (B) and left eye (OS) (C) showing evidence of prior keratoplasty following complete removal of corneal sutures.



**Fig. 2.** Scheimpflug corneal tomography (Pentacam®, Oculus, Germany).

manifest refraction of  $-1.200 + 2.50 @ 95$ . We did not observe ICL rotation postoperatively.

Anterior segment optical coherence tomography using Spectralis Heidelberg (Heidelberg Engineering, Heidelberg Germany) showed ICL well positioned in sulcus with a 500µm vault in both eyes (Fig. 4).

**2.1. Surgical technique**

The ICL power was calculated using the software provided by STAAR Surgical, Inc, with a target refraction for emmetropia. The size of the ICL was determined based on the horizontal white-to-white distance and true anterior chamber depth measured with Scheimpflug tomography (Pentacam®, Oculus, Germany) and optical biometry (IOL MASTER 700®, Carl Zeiss, Germany). Nd:YAG laser iridotomy was performed preoperatively. Surgery was performed by one experienced surgeon (KMR) through a 3 mm temporal tunneled clear corneal incision. The anterior chamber was filled with viscoelastic material (OcuCoat, Bausch&Lomb, Canada). The toric ICL was loaded into the cartridge and injected slowly to allow controlled slow lens unfolding. An ICL

manipulator was used to place the lens footplate haptics within the posterior chamber and the lens was rotated to 172° OD and 173° OS. Viscoelastic material was removed with bimanual irrigation and aspiration. The main incision was sutured with a 10-0 nylon. Patient was treated postoperatively with prednisolone acetate 1% eye drops (Pred Forte; Allergan, Inc.) four times daily, moxifloxacin 0.5% eye drops (Vigamox; Apotex, Inc.) four times daily and ketorolac 0.5% (Acular; Akorn, Inc.) four times daily. The moxifloxacin and ketorolac drops were used until gone, while the prednisolone acetate 1% drops were tapered weekly by 1 drop over a period of 3 additional weeks.

**3. Discussion**

The surgical technique of ICL implantation in pseudophakic eyes is essentially the same as in phakic patients. Eissa et al.<sup>5</sup> advocated for assurance of sulcus patency and posterior capsular stability prior to ICL loading and implantation. In this case, additional dispersive viscoelastic was used to protect the corneal graft with the use of bimanual irrigation and aspiration behind the ICL implant to avoid postoperative intraocular

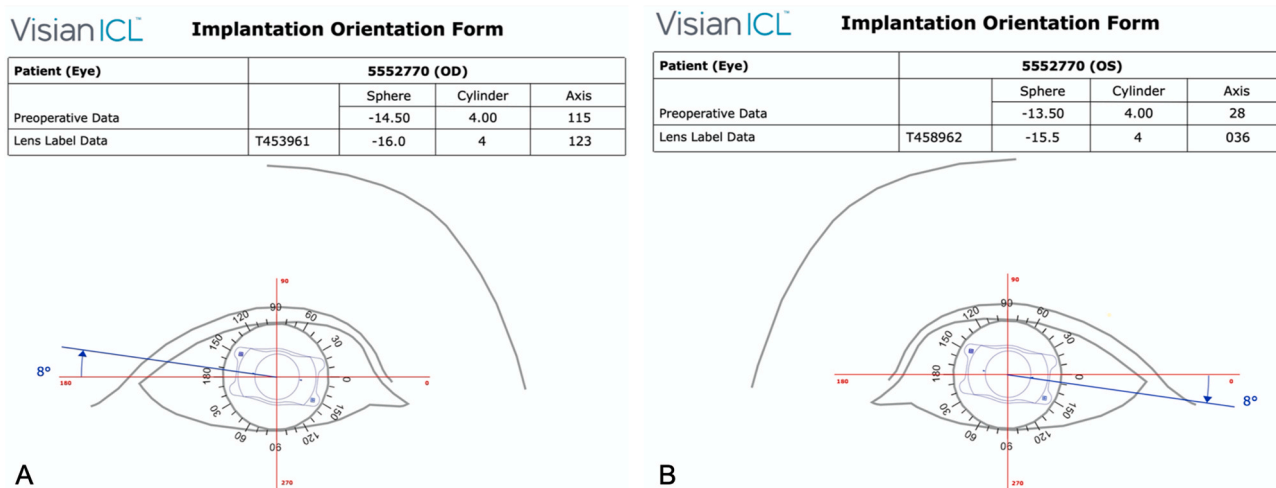


Fig. 3. Online ICL calculation form with toric alignment suggested axis (A: right eye; B: left eye).

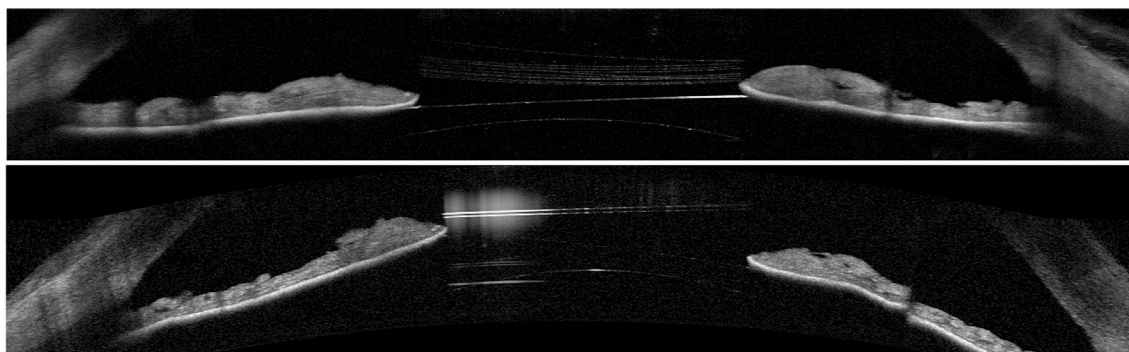


Fig. 4. On follow up, anterior segment optical coherence tomography (AS-OCT) was obtained demonstrating the toric implantable collamer lens (TICL) well positioned in the sulcus.

pressure spikes.

Residual refractive error following intraocular surgery can cause frustrations to patients and surgeons. Small amounts of residual refractive error can be treated with spectacles, contact lenses, and laser-based corrective surgeries. In cases with large amounts of residual refractive error, treatment options include IOL exchange or secondary IOL implantation. Compared to IOL exchange, secondary IOLs may reduce the risk of zonular damage, cystoid macular edema, vitreous loss, and corneal endothelial damage.<sup>5</sup> Supplementary IOL implantation using ICLs have been reported with satisfactory results.<sup>4,5,7-12</sup>

The non-toric Visian ICLs have been FDA approved since 2005 for patients 21–45 years of age for the treatment of myopia, ranging from −3.0D to −20.0D with less than or equal to 2.5D of astigmatism at the spectacle plane. These ICLs are produced in a variety of sizes and refractive powers, making secondary IOL positioning more secure and postoperative refractive outcomes more predictable.<sup>7</sup> However, recent FDA approval for the toric version of the Visian ICL, in September 2018, allows surgeons to target an even broader range of refractive correction, with myopic correction parameters remaining the same and cylinder parameters of 1.0D to 4.0D of astigmatism at the spectacle plane.

Previous studies have illustrated the effectiveness of phakic IOL implantation to alleviate residual refractive error. Martín-Escuer et al.<sup>13</sup> presented a retrospective, non-comparative, interventional case-series involving 6 eyes of 4 patients that underwent phakic IOL implantation to correct residual refractive error following radial keratotomy. The authors found that overall, the refractive outcomes were satisfactory without loss of lines of vision. Additionally, rotational stability has been found to be excellent with toric ICL implantation,<sup>14</sup> although cases of

post-operative ICL rotation have been reported.<sup>15</sup> If a post-operative toric ICL patient has a sudden change in refractive outcome, one must consider the possibility of toric ICL rotation.

Alfonso et al.<sup>6</sup> described 15 phakic eyes that underwent ICL implantation following penetrating keratoplasty for treatment of refractive error. Twenty-four months following phakic ICL implantation, the mean Snellen decimal UDVA was  $0.51 \pm 0.30$  (SD). The UDVA was 20/40 or better in 7 eyes (46.6%). The mean CDVA was  $0.79 \pm 0.22$ . The CDVA was 20/40 or better in 12 eyes (80%) and 20/25 in 6 eyes (40%). The safety index (1.58) was satisfactory and none of the enrolled eyes lost lines of vision following phakic IOL implantation. Additionally, Mehta et al.<sup>16</sup> presented a case-series in which 3 eyes (2 phakic, 1 pseudo-phakic) underwent ICL implantation to attempt to alleviate anisometropia resulting from post-keratoplasty changes. Their data showed a mean preoperative SE in the operative eye of  $-8.75 \pm 5.17D$  ( $-4.00$  to  $-14.25D$ ), improving to a postoperative SE of  $+0.29 \pm 1.21D$  ( $0.75$  to  $-1.625D$ ,  $P = 0.09$ ), with an improvement of spherical correction from  $-4.95D$  to  $+0.75D$  ( $P = 0.08$ ). The data also revealed an improvement in the anisometropia, from  $6.37 \pm 2.59D$  preoperatively to  $2.09 \pm 1.37D$  postoperatively.

Early postoperative complications after ICL include increased intraocular pressure related to high vaulting, but it can also be related to retained viscoelastic and non-functioning peripheral iridotomies (V4 model) leading to pupillary block or angle closure.<sup>5,7</sup> While cataract formation is very unlikely, Gimble, et al.<sup>17</sup> demonstrated a 0.23% incidence in 857 eyes implanted according to FDA age and ACD indications (age  $\leq 45$ ; ACD  $\geq 3.0mm$ ), having a low postoperative vault is a risk factor for developing lens opacities in phakic patients. However, this is

not of major concern for pseudophakic eyes. In fact, a lower vault may lessen the chance of angle closure or pupillary block in pseudophakic patients. One of the reasons leading to vaulting issues may be the discrepancies in ACD measurements with different devices. We used the true ACD measurements from the Pentacam HR (from the corneal endothelium to the anterior lens capsule), which explains the difference found in ACD measurements between the IOL Master 700 and Pentacam HR. Furthermore, we noticed that by adding the corneal thickness to the Pentacam ACD measurements, or subtracting the corneal thickness from the IOL Master ACD measurements, would result in similar measurements. We decided to use the measurements extracted from the biometer due to its high accuracy and repeatability.<sup>18</sup>

Considering endothelial cell loss from supplementary ICL implantation in pseudophakic patients, Eissa et al.<sup>5</sup> noted that over the first 12 months following ICL implantation, there was a statistically significant decrease in endothelial cell density from  $2878.57 \pm 15.03$  cells/mm<sup>2</sup> preoperatively to  $2725.71 \pm 147.62$  cells/mm<sup>2</sup> after 12 months ( $P < 0.001$ ). However, at the 18-month postoperative appointment, there was a trend towards more physiologic rates of endothelial cell density loss that was not statistically significant ( $P = 0.171$ ). The use of ICLs in our post RK, post toric IOL implantation and PK case is considered “off-label,” but multiple studies support the safety and efficacy of ICL implantation for treatment of refractive error in pseudophakic patients.<sup>4,5,7–12,6,13,16</sup> Thus far, our patient gained four lines of DCVA postoperatively and has not shown any evidence of short-term complications from this surgical procedure.

#### 4. Conclusion

Toric ICL may be a safe and effective option to correct high residual refractive errors and enhance satisfaction in pseudophakic patients who are not candidates for corneal-based procedures.

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#### Declaration of competing interest

All authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence

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