Axis Alignment and Rotational Stability
After Implantation of the Toric Implantable Collamer Lens for Myopic Astigmatism

Ayman N. Hashem, MD, FRCS; Alaa M. El Danasoury, MD, FRCS; Hamed M. Anwar, MD, FRCS

ABSTRACT

PURPOSE: To assess axis alignment and stability of the Toric Implantable Collamer Lens (TICL; STAAR Surgical Co) over time.

METHODS: Thirty-five consecutive eyes of 19 patients received the TICL for treatment of myopic astigmatism. Manifest refraction spherical equivalent (MRSE) and manifest refractive cylinder were measured preoperatively and at 3 months postoperatively. The axis alignment of the TICL was measured using the internal OPD map obtained with the OPD-Scan II (NIDEK Co Ltd).

RESULTS: Mean refractive cylinder was reduced from 2.80±1.45 diopters (D) preoperatively to 0.63±0.75 D at 3 months postoperatively; MRSE was −7.61±4.02 D preoperatively and −0.14±0.38 D at 3 months. Mean absolute value of the measured axis misalignment from baseline (day 1) to 1 month was 2.90±2.11° and from 1 month to 3 months was 4.6±11.2°. Mean absolute value of the measured changes in axis misalignment from baseline to 3 months was 2.68±2.11° (after excluding one eye that required repositioning due to TICL rotation). At 3 months postoperatively, 96.8% (30/31) eyes had ≤8° and 90.3% (28/31) had ≤5° of axis misalignment.


A stigmatism is a common refractive error with several modalities available for correction, such as spectacles and contact lenses. Although a safe method, optical correction is frequently not suitable for patients due to occupational hazards or for cosmetic reasons.

Corneal refractive surgery including LASIK, photorefractive keratectomy, and astigmatic keratotomy are relatively safe, widely used techniques but may be associated with corneal ectasia, low predictability, regression, and poor quality of vision.1,2

Toric phakic intraocular lens (IOL) implantation is an alternative when safety or predictability of corneal refractive surgery is a concern. Although several studies have demonstrated effective treatment of astigmatism using iris-fixated toric phakic IOLs,3-5 concerns exist regarding endothelial cell loss and surgically induced astigmatism by implantation of a rigid, polymethylmethacrylate (PMMA) lens through a 5.3-mm incision.3,6

A relative paucity of studies on misaligned Toric Implantable Collamer Lens (TICL; STAAR Surgical Co, Monrovia, Calif) exist in the literature.7,8 To our knowledge, only one study reported axis misalignment identified by slit-lamp microscopy2 and another study that assessed axis alignment after implantation.9 The aim of our prospective study was to objectively measure the axis alignment of implanted TICLs and to study the rotational stability of the lens over time.

PATIENTS AND METHODS

This prospective study consisted of 35 consecutive eyes of 19 patients implanted with the TICL. All patient treatment and...
Follow-up occurred at the Magrabi Eye & Ear Hospital, Saudi Arabia. Follow-up was 1 day and 1 and 3 months postoperative.

The TICL is a posterior chamber phakic IOL designed to vault anteriorly, intended to have minimal contact with the crystalline lens, and is made from a new generation of IOL material termed “collamer,”10,11 which is composed of hydrophilic porcine collagen (<0.1%) hydroxyethyl methacrylate (HEMA) copolymer into which an ultraviolet-absorbing chromophore is incorporated in the polymer chain.

The study inclusion criteria were phakic patients with myopia and astigmatism ranging from 1.00 to 5.00 diopters (D), a stable refraction for the past 12 months as documented by previous records, no history of ocular surgery, glaucoma, ocular hypertension, keratoconus and/or any ophthalmic or non-ophthalmic condition that may preclude study completion, endothelial cell count >2300/mm², and anterior chamber depth >2.75 mm measured with the IOLMaster (Carl Zeiss Meditec Inc, Dublin, Calif).

Ocular examination, including uncorrected visual acuity (UCVA), Snellen best spectacle-corrected visual acuity (BSCVA), manifest refraction, applanation tonometry, slit-lamp microscopy, dilated fundus examination, and noncontact specular microscopy (EM 3000; Tomey Corp, Nagoya, Japan), was performed in all eyes before surgery.

The TICL power and size were calculated using the software provided by the manufacturer and horizontal white-to-white was measured by Orbscan II (Bausch & Lomb, Salt Lake City, Utah). If a discrepancy of >0.2 mm was noted between the right and left eyes or in those eyes with small (<11.2 mm) or large (>12.2 mm) horizontal white-to-white measurement, the measurements were confirmed with a caliper as the planned axis of implantation for the TICL was ≤15° from the horizontal meridian.

The internal OPD map from the OPD-Scan II (NIDEK Co Ltd, Gamagori, Japan) was used to assess the axis of induced internal astigmatism by TICL and hence assessed the axis alignment and the rotational stability. The internal OPD map is a color-coded, refractive wavefront map displaying the refractive power of the eye plotted in diopters after subtracting the refractive power of the anterior corneal surface (Fig 1). To compensate for possible cyclorotation during examination, the axis of the steepest Sim K obtained from the axial map (at day 1) of the OPD-Scan II was used as a baseline to compensate for any cyclorotation during examination that would induce error. The OPD-Scan II examinations were considered valid only if obtained with a mesopic pupil size ≥6 mm.

Phenylephrine hydrochloride 2.5% (2.5% Mydfrin; TABLE 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Result</th>
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<tbody>
<tr>
<td>Number of eyes</td>
<td>35</td>
</tr>
<tr>
<td>Mean age (range) (y)</td>
<td>26.49±6.52 (19 to 43)</td>
</tr>
<tr>
<td>Gender (eyes)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (18)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (17)</td>
</tr>
<tr>
<td>Mean spherical equivalent refraction (range) (D)</td>
<td>−7.61±4.02 (−1.00 to −16.25)</td>
</tr>
<tr>
<td>Mean refractive cylinder (range) (D)</td>
<td>2.80±1.45 (0.75 to 5.50)</td>
</tr>
</tbody>
</table>

Figure 1. Internal OPD map showing the induced internal astigmatism after implantation of the Toric Implantable Collamer Lens at A) baseline (day 1), B) 1 month after surgery, and C) 3 months after surgery.
alcon Laboratories Inc, Ft Worth, Tex) eye drops were used to dilate the pupil if the desired pupil size was not obtained normally (one drop initially and examined 20 minutes later). Only 10 eyes of 5 patients required pharmacological pupil dilation. Examination at day 1 was considered the baseline for axis alignment. All eyes were examined at 1 and 3 months, at which time UCVA, BSCVA, axis alignment, and manifest refraction were measured.

**Surgical Technique**

On the day of surgery, topical dilating and cycloplegic drops were instilled. All 35 eyes were implanted with a V4 model TICL under topical anesthesia. The horizontal axis was marked at the slit to account for cyclotorsion once the patient was supine. During surgery, the Mendez ring (Rhein Medical, Tampa, Fla) was used to mark the intended axis of alignment of the TICL. A 3-mm corneal incision was placed at the planned TICL axis to minimize intraocular rotation, followed by delivery of sodium hyaluronate 1% viscoelastic material (Healon; Abbott Medical Optics Inc, Santa Ana, Calif) into the anterior chamber. The TICL was injected slowly into the anterior chamber allowing for slow unfolding, and injection was not finished until the leading footplates were completely unfolded. The four footplates were inserted behind the iris using a modified intraocular spatula by gentle posterior pressure combined with slight rotation, which was performed through the main wound for the proximal footplates and through a second incision for the distal footplates. If needed, adjustment of the implant was performed by gently manipulating the lens at the haptic–optic junction. The viscoelastic material was removed and the final position of the lens was checked before an intraocular miotic was used to decrease pupil size. A peripheral iridectomy was performed using the vitrectomy mode of the INFINITI Vision System (Alcon Laboratories Inc) with 300-mmHg vacuum and 10-second cutting rate; the probe was introduced into the anterior chamber after viscoelastic injection at the desired iridectomy site. Following iridectomy, the viscoelastic material was washed using an irrigation/aspiration cannula, an antibiotic (vancomycin) was delivered intraocularly, and the wound was secured by stromal hydration.

**Results**

Mean patient age was 26.49±6.52 years (range: 19 to 43 years). At 1 and 3 months postoperatively, 31 (88.6%) of 35 eyes were available for follow-up; the remaining 4 eyes were lost to follow-up. All eyes had preoperative myopia ranging from 1.00 to 16.00 D and preoperative cylinder ranging from 1.00 to 5.50 D. Baseline clinical characteristics are presented in Table 1.

**Manifest Refraction Cylinder**

Table 2 and Figure 2 present the manifest refraction cylinder before and 3 months after implantation of the TICL. Preoperatively, 8.6% (3/35) of eyes had ≤1.00 D refractive cylinder and 87.1% (27/31) of eyes had ≤1.00 D refractive cylinder at 3 months. No eyes had ≤0.50 D refractive cylinder preoperatively.

**Table 2**

<table>
<thead>
<tr>
<th>Cylinder (D)</th>
<th>Preoperative (n/N) (%)</th>
<th>3 Months Postop (n/N) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤0.25</td>
<td>0/35 (0)</td>
<td>17/31 (54.8)</td>
</tr>
<tr>
<td>≤0.50</td>
<td>0/35 (0)</td>
<td>18/31 (58.0)</td>
</tr>
<tr>
<td>≤1.00</td>
<td>3/35 (8.6)</td>
<td>26/31 (83.8)</td>
</tr>
<tr>
<td>≤1.50</td>
<td>8/35 (22.8)</td>
<td>30/31 (96.8)</td>
</tr>
<tr>
<td>≤2.00</td>
<td>11/35 (31.4)</td>
<td>30/31 (96.8)</td>
</tr>
<tr>
<td>≤3.00</td>
<td>18/35 (51.4)</td>
<td>30/31 (96.8)</td>
</tr>
<tr>
<td>≤4.00</td>
<td>24/35 (68.5)</td>
<td>31/31 (100)</td>
</tr>
<tr>
<td>≤5.00</td>
<td>30/35 (85.7)</td>
<td>31/31 (100)</td>
</tr>
<tr>
<td>≤6.00</td>
<td>35/35 (100)</td>
<td>31/31 (100)</td>
</tr>
<tr>
<td>Mean±standard deviation</td>
<td>2.80±1.45</td>
<td>0.63±0.75</td>
</tr>
<tr>
<td>Range</td>
<td>0.75 to 5.50</td>
<td>0 to 3.75</td>
</tr>
</tbody>
</table>
whereas 61.3% (19/31) of eyes had \( \leq 0.50 \) D and 54.8% (17/31) of eyes had \( 0.25 \) D refractive cylinder at 3 months. At 3-month follow-up, 96.8% (30/31) of eyes had \( 2.00 \) D refractive cylinder compared with 37.1% (13/35) of eyes preoperatively. One (3.2%) eye showed a change of manifest refractive cylinder from \( 0.50 \) D at 1 month to \( 3.75 \) D at 3 months secondarily to TICL rotation (Fig 3). Mean manifest refraction cylinder changed from \( 2.80 \pm 1.45 \) D preoperatively to \( 0.63 \pm 0.75 \) D at 3 months postoperatively.

**MANIFEST REFRACTION SPHERICAL EQUIVALENT**

Mean manifest refraction spherical equivalent (MRSE) improved from \(-7.61 \pm 4.02\) D to \(-0.14 \pm 0.38\) D at 3 months. Preoperatively, no eyes had MRSE within \( 1.50 \) D of emmetropia; however, 96.8% (30/31) of eyes had MRSE within \( 1.50 \) D at 3 months postoperative. One eye had residual myopia of \(-1.25\) D. In this eye, the TICL implanted was \( 1.00 \) D less than the lens that was required to achieve emmetropia due to the necessary manufacture time, which was not suitable for the patient’s schedule; therefore, he consented to implanta-
tion of a TICL that would leave him partially myopic.

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tion of a TICL that would leave him partially myopic.

**DISCUSSION**

In our study, TICL implantation decreased refractive cylinder by 77.5%, which is supported by results of other studies reporting reductions of 70.1% and 73.6%. We found the majority of eyes (96.8%) had MRSE within \( 1.50 \) D of emmetropia. These results indicate the TICL was predictable at reducing astigmatism from \( 1.00 \) to \( 5.00 \) D.

One key factor in determining refractive outcome after TICL implantation is postoperative rotation. Rotation of the TICL was found to decrease the cylinder correction in a previous study. Theoretical analysis and clinical results have reported a steady loss of cylinder correction as the toric IOL rotates off-axis. In our study, we objectively measured the TICL axis alignment using the internal OPD map obtained, which is different from previous studies that measured axis alignment using slit-lamp digital camera and slit-lamp assessment. Cyclotorsion was compensated for in this study by measuring the difference (between different examinations) in axis of the steepest corneal meridian displayed on the axial map of the OPD-Scan II, which was not addressed in the previously mentioned studies. For example, Park et al. measured axis misalignment from the intended axis at 6 months postoperatively, yet they did not assess the rotational
stability as the measured axis misalignment could either be due to TICL rotation or an incorrect alignment intraoperatively. The results of our study of axis misalignment at 3 months are supported by previous investigations. For example, we found mean absolute value of axis misalignment was 2.68°/H11006 2.11° (excluding the one eye that rotated) in the current study compared with 2.20°/H11006 5.50° reported by Sanders et al11 and 1.30°/H11006 5.15° reported by Park et al9; the lower value of the standard deviation in the current study reflects the more accurate measurements obtained by the OPD-Scan II compared with other previously used methods. One eye rotated significantly by 66°, which required repositioning, and this eye regained MRSE within 0.50 D after repositioning.

The limitation of our study is the small number of eyes and short follow-up. We are currently completing a longer-term follow-up study, the results of which will be reported in the future.

AUTHOR CONTRIBUTIONS

Study concept and design (A.N.H., A.E.D.); data collection (A.N.H., H.M.A.); interpretation and analysis of data (A.N.H., A.E.D.); drafting of the manuscript (A.N.H., H.M.A.); critical revision of the manuscript (A.E.D.)

REFERENCES