Rotational stability of the V4b implantable collamer lens

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PURPOSE: To assess rotational stability from corneal and refractive astigmatism vectorial decomposition after Toric Implantable Collamer Lens (TILC) V4b model implantation.

SETTING: Fernández-Vega Ophthalmological Institute, Oviedo, Spain

METHODS: Thirty-five eyes of twenty patients implanted with TICL V4b model were evaluated. Refraction and keratometry were measured in all patients preoperatively and 3, 6 and 12 months post-surgery.

RESULTS: No statistically significant differences were found in corneal astigmatism vectorial decomposition (J0 and J45) between the preoperative evaluation and each postoperative visit (p > 0.05). However, statistically significant differences in refractive astigmatism vectorial decomposition (J0 and J45) were found between preoperative and postoperative measurements (p < 0.05). Refractive astigmatism vectorial decomposition remained stable in each pair of visits during the 12-month follow-up with no statistically significant differences (p > 0.05).

CONCLUSIONS: These outcomes suggest high rotational stability of the TICL model V4b, with no significant rotation or axis misalignment in any eye at 12-month follow-up. In addition, no eyes required TICL repositioning in this period.

SUMMARY: The Toric Implantable Collamer lens V4b model showed high rotational stability after implantation in eyes with low and high astigmatism in a vectorial decomposition analysis during a 12-month follow-up.

footplate-position of TICL and vault value may both be possible risks factors for TICL rotation.

The aim of this study was to assess the rotational stability of the V4b model of TICL from corneal and refractive astigmatism vectorial decomposition during a 12-month follow-up.

PATIENTS AND METHODS

This prospective study comprised patients with TICL V4b model implantation for the correction of low and high astigmatism at Fernández-Vega Ophthalmological Institute, Oviedo, Spain. All patients provided written informed consent after the nature and possible consequences of the study were fully explained, in accordance with the Declaration of Helsinki. Institutional review board approval was obtained.

Inclusion criteria were corrected distance visual acuity (CDVA) of 20/40 or better, stable refraction, and a clear central cornea. The exclusion criteria included age less than 22 years, anterior chamber depth less than 2.8 mm, endothelial cell density less than 2,000 cells/mm², cataract, history of glaucoma or retinal detachment, macular degeneration or retinopathy, neuroophthalmic disease, and history of ocular inflammation.

Before surgery, all patients had a full ophthalmologic examination. The evaluation included manifest and cycloplegic refractions, keratometry, corneal topography, endothelial cell density, pachymetry, slit lamp microscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy through a dilated pupil.

Phakic intraocular lens size and power calculation

The Visian Toric Implantable Collamer lens is a plate-haptic single-piece lens designed to be implanted in the posterior chamber with support on the ciliary sulcus. It is partly made from collamer, a flexible, hydrophilic, biocompatible material. The lens has a central convex/concave optic zone and a cylinder component to correct astigmatism. To minimize rotation, the surgeon cannot rotate the pIOL more than 10° from the horizontal meridian. In this study, we analysed the TICL V4b model. The previous model (V4 model) was stored in NaCl solution, while this new lens model (V4b model) is stored in balanced salt solution (BSS), making the lens power closer to spectacle refraction. The TICL has a guide showing the amount and direction of rotation from the horizontal axis required to align the pIOL cylinder axis to the required cylinder correction. Apart from the need to mark the horizontal axis and rotate the toric pIOL in some cases, the surgical technique was the same as for the spherical model of the pIOL. To control for potential cyclotorsion when the patient was supine, the surgeon marked the zero horizontal axis at the slit lamp with the patient in an upright position.

The surgeon also used a Mendez ring to measure the required rotation from horizontal during the surgical procedure. Phakic IOL power calculation was performed using software provided by the manufacturer. The target refraction was emmetropia in all cases.

Surgical Technique

All surgeries were performed by the same experienced surgeon (JFA) through a 3.2 mm clear corneal tunnel incision in the horizontal meridian using peribulbar anesthesia. Intraoperative iridectomy was performed 1 week before surgery. Thirty minutes before surgery, tropicamide and phenylephrine eyedrops were instilled. Five minutes before surgery, povidone iodine 5% (Betadine®) was applied. The anterior chamber was filled with sodium hyaluronate 1% (Provisc®), which was completely removed at the end of surgery. Tobramycin and dexamethasone 0.1% eyedrops were used 4 times a day for 10 days, after which diclofenac sodium eyedrops were started 4 times a day for 2 weeks. In cases of bilateral implantation, the second eye was operated on within 1 week of surgery in the first eye.

Follow-up

Periodic check-ups were performed in all patients after surgery at 3, 6 and 12 months. The examinations included keratometry, slit lamp examination, tonometry, and objective vault assessment through optical coherence tomography, using the Visante OCT (Carl Zeiss Meditec AG). Manifest refractions in conventional script notation (S [sphere], C [cylinder], a [axis]) and corneal astigmatism (taken from keratometric data) were converted to power vector coordinates using the following formula17:

\[ M = S + C/2 \]

\[ J0 = (-C/2) \times \cos(2\alpha) \]

\[ J45 = (-C/2) \times \sin(2\alpha) \]

M is equal to the spherical equivalent (SE) of the given refractive error and J0 and J45 are the 2 Jackson Cross cylinders equivalent to the conventional cylinder.

Outcomes

Assessment of outcomes was based on corneal and refractive vectorial decomposition changes preoperatively and at each follow-up visit post-surgery to check rotational stability.

Statistical Analysis

Data analysis was performed using SPSS statistical software (version 20.0, SPSS, Inc.). Comparison of means was performed using the nonparametric Wilcoxon signed-rank test. Differences were considered statistically significant when the P value was less than 0.05.
RESULTS

The present study involved 35 eyes of 20 patients. The mean age (± standard deviation) of the patients at the time of surgery was 28.26 ± 3.65 years (range: 22 to 38). The mean sphere was −5.46 ± 4.17 diopters (D) (range: +3 to −12 D), and the mean cylinder was −3.14 ± 1.19 D (range: −1.50 to −6).

Rotation stability

Table 1 shows the distribution of corneal and refractive astigmatism after vector conversion before and after surgery. For corneal astigmatism, the power vectors did not change before and after surgery and remained stable over time. No statistically significant differences in corneal J0 and J45 components between the preoperative evaluation and each pair of visits were found (Wilcoxon test: p > 0.05). In contrast, for refractive astigmatism, the power vectors decreased significantly between the preoperative and postoperative measurements (Wilcoxon test: p < 0.05); but both remained stable over time after surgery. No statistically significant differences in refractive J0 and J45 components between each pair of visits during the 12-month follow-up period were found (Wilcoxon test: p > 0.05).

Analyzing the refractive astigmatism J0 and J45 vectors between patients, there were 7 eyes (20%) that showed slight differences between the 3 and 6-month follow-up; 5 of these eyes continued to change between the 6 and 12-month follow-up periods. However, these differences were not statistically significant (p > 0.05) and did not affect visual acuity outcomes. No eyes had lost any line of visual acuity after surgery in follow-up visits.

Figures 1-4 show the corneal and refractive astigmatic components of the power vector represented by the two-dimensional vector (J0, J45) preoperatively and 3, 6 and 12 months after surgery, respectively. Corneal astigmatism distribution data remained stable between the preoperative evaluation and the 12-month follow-up period. However, post-surgery, the distribution of points of refractive astigmatism are closer to zero than the preoperative data.

Mean differences in vault over the follow-up period were small and not statistically significant (p > 0.05, Wilcoxon test). Mean vault was 567.7 ± 128.3 µm (range: 350 to 860 µm), 541.5 ± 179.5 µm (range: 200 to 1,020 µm) and 594.3 ± 155.9 µm (range: 200 to 810 µm), at the 3, 6 and 12-month follow-up visits, respectively.

DISCUSSION

In this study, we evaluated corneal and refractive astigmatism vectorial decomposition after TICL implantation. The aim was to analyze rotation stability from astigmatism vectorial decomposition over 1 year of follow-up.

Astigmatism vectorial decomposition analyzed in the present study showed high rotational stability. Corneal astigmatism was not troublesome and it did not change between the preoperative evaluation and the follow-up periods. In contrast, as expected, refractive astigmatism changed significantly immediately after surgery, but it remained stable during the post-surgery follow-up periods.

### Table 1. Mean values of refractive and corneal astigmatism vectorial decomposition before and after ICL implantation.

<table>
<thead>
<tr>
<th>Component</th>
<th>Preoperative</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal J0</td>
<td>0.33 ± 1.27</td>
<td>0.44 ± 1.03</td>
<td>0.34 ± 1.03</td>
<td>0.29 ± 1.19</td>
</tr>
<tr>
<td>Corneal J45</td>
<td>0.053 ± 0.78</td>
<td>−0.09 ± 1.05</td>
<td>0.13 ± 1.05</td>
<td>0.02 ± 0.89</td>
</tr>
<tr>
<td>Refractive J0</td>
<td>0.16 ± 1.32</td>
<td>0.05 ± 0.27</td>
<td>0.04 ± 0.27</td>
<td>0.00 ± 0.18</td>
</tr>
<tr>
<td>Refractive J45</td>
<td>−0.26 ± 1.03</td>
<td>0.04 ± 0.24</td>
<td>0.003 ± 0.23</td>
<td>−0.01 ± 0.17</td>
</tr>
</tbody>
</table>

J0= Jackson Cross cylinder, axes 180 degrees and 90 degrees; J45= Jackson Cross cylinder, axes at 45 degrees and 135 degrees.
Figure 1. Scatterplot of preoperative corneal and refractive astigmatic vectors (J0 = Jackson cross-cylinder, axes at 180° and 90°; J45 = Jackson cross-cylinder, axes at 45° and 135°).

Figure 2. Scatterplot 3-month postoperative corneal and refractive astigmatic vectors. The more central location of postoperative data around 0 represents a reduction in refractive astigmatism after toric pICL implantation (J0 = Jackson cross-cylinder, axes at 180° and 90°; J45 = Jackson cross-cylinder, axes at 45° and 135°).

Figure 3. Scatterplot 6-month postoperative corneal and refractive astigmatic vectors. The more central location of postoperative data around 0 represents a reduction in refractive astigmatism after toric pICL implantation (J0 = Jackson cross-cylinder, axes at 180° and 90°; J45 = Jackson cross-cylinder, axes at 45° and 135°).

Figure 4. Scatterplot 12-month postoperative corneal and refractive astigmatic vectors. The more central location of postoperative data around 0 represents a reduction in refractive astigmatism after toric pICL implantation (J0 = Jackson cross-cylinder, axes at 180° and 90°; J45 = Jackson cross-cylinder, axes at 45° and 135°).
Several studies have analyzed the rotational stability of TICLs. Sanders et al. assessed 210 eyes with TICL implantation. They found that the mean of the absolute value of misalignment based upon slit lamp examination was between 1.2° to 2.2° for all intervals tested. Less than 96% of patients had a misalignment of 15° or less between 6 and 12 months after TICL implantation. No eyes reported misalignment greater than 30° between the 1 to 3, 3 to 6 and 6 to 12-month ranges. One patient needed repositioning TICL one day after surgery. Kamiya et al. found 10° of rotation in 5 eyes (8.9%), and deteriorating visual acuity or changing refraction in 4 eyes one day after surgery and in 1 eye after 1 week. All eyes required TICL repositioning. Alfonso et al. reported mean absolute rotation on slit lamp examination after TICL implantation of between 10° and 25° at all postoperative visits. Mean misalignment was 2.5 ± 4° between the 6 and 12-month follow-up visits; during that period, misalignment was 10° or less in 53 eyes (96.4%). No eye had TICL rotation greater than 30°. Hashem et al. measured the axis misalignment of the TICL using the internal OPD map obtained with the OPD-scan II. At 3 months, the mean absolute value of axis misalignment from baseline was 2.68 ± 2.11° and more than 96% of eyes had 8° axis misalignment or less. Park et al. evaluated the rotational stability of the TICL through a digital anterior segment photograph. They found that the mean of the absolute value of difference between the intended and achieved cylinder axes was 4.03 ± 3.39° (range: 0 to 11°). After mean follow-up, all eyes were 11° or less from the intended axis. Indeed, no eye required a second procedure to rotate the TICL back in position. Mori et al. assessed the factors affecting rotation of TICL; the toric pIOL axis was analyzed by calculating the ocular internal cylinder power and axis from the total refractive cylinder and corneal astigmatism using vector analysis (Jaffe and Clayman method). At 6 months, the mean rotation was 4.82 ± 6.98°, only one eye had a large rotation that required exchanging the primary pIOL for a larger one. Recently, Sheng et al. studied axis alignment, rotational and footplate stability through digital anterior segment photographs and ultrasound biomicroscopy. They found that the mean difference between intended and achieved TICL axes was 6.96 ± 8.37° at 8.6 months follow-up. In addition, 98.2% of eyes had 15° misalignment or less from the intended axes and one patient required TICL repositioning for this reason. All authors reported good rotation stability of TICLs, a low percentage of eyes showed high pIOL rotation or axis misalignment and a few patients required pIOL repositioning.

In conclusion, the outcomes of the present study suggest that there was no significant rotation or axis misalignment in any eye implanted with TICL model V4b throughout the 12-month follow-up. In addition, no eyes required pIOL repositioning in this period. Although slight changes in refractive astigmatism vectorial decomposition could be seen between 3 and 6 months of follow up, they did not affect the visual performance. During TICL implantation, it is imperative to have the lens axis aligned with the preoperative corneal marks to avoid residual astigmatism from misalignment. The higher the cylindrical power, the greater the residual astigmatism caused by misalignment.

REFERENCES


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