Introduction

Modern cataract surgery aims not only to remove lens opacities but also to achieve correction of any refractive error. In addition to restoration of uncorrected visual acuity, correction of preexisting astigmatism is also important, and treatment options for this purpose include corneal limbal relaxing incisions, excimer laser photoablation and toric intraocular lens (IOL) implantation. Shimizu et al. were the first to report the benefit of toric IOL implantation for correction of pre-existing astigmatism, and they emphasized that postoperative IOL rotational stability is crucial for astigmatic correction. Subsequent reports were also concerned with postoperative IOL rotational stability. Smaller corneal incisions have minimized surgery-induced astigmatism, and technical advances have been beneficial in reducing postoperative IOL rotation in the capsular bag.

In recent years, single-piece toric IOLs with acrylic optics materials have become available. However, fixation of the single-piece acrylic IOL in the capsular bag has not been as popular as the use of the 3-piece lens. When the posterior capsule is ruptured, use of a 3-piece lens is more advantageous for insertion. The 3-piece, single-focus silicone IOL has the longest history as a foldable IOL. The mechanical properties of this foldable lens are reported to provide excellent centration, and the rigid haptics resist pressure due to capsular shrinkage. This type of silicone IOL is used routinely in our hospital and has produced acceptable results following implantation.

The causes of postoperative IOL rotation and decentration are eye-dependent factors (such as capsular size and asymmetric capsular shrinkage) and IOL-dependent factors (such as the material, shape, and design of the lens’ optics and haptics). There is a report that the capsular size after lens extraction measures about 10 mm in diameter, but there is no report on the horizontal and vertical diameter of the lens capsule. A certain combination of capsular size and IOL design may affect postoperative rotation, tilt, and decentration. Any postoperative long-term change in the IOL rotation, tilt, and decentration is possibly related to the IOL fixation bag.

Stability of a three-piece silicone intraocular lens implanted in the capsular bag

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Purpose: To assess the postoperative stability of a 3-piece silicone intraocular lens (IOL) implanted in cataract patients, and to determine whether the lens can be a platform toric intraocular lens for the correction of pre-existing astigmatism.

Methods: The cases included 47 eyes of 42 patients (11 eyes of 10 males, 36 eyes of 32 females; mean age: 70.2 ± 7.3 years). Postoperative IOL axis rotation was evaluated by anterior ocular segment photographs, and IOL tilt and decentration were assessed with Scheimpflug images.

Results: At 3 months after surgery, the mean rotation of the IOL was 2.5 ± 2.3 degrees (range: -7.9−8.5 degrees), mean tilt was 3.13 ± 1.56 degrees (range: 1.29−7.09 degrees), and mean decentration was 0.31 ± 0.15 mm (range: 0.03−0.72 mm). There was no significant difference in the rotation, tilt or decentration between cases undergoing IOL fixation at the vertical meridian (from 6 to 12 o’clock) and those at the horizontal meridian (from 3 to 9 o’clock).

Conclusions: The 3-piece silicone IOL was safely implanted with continued stable fixation during a long-term follow-up. This IOL may potentially provide a platform lens design for the toric IOL.

Key words: three-piece silicone intraocular lens, rotation, tilt, decentration, toric intraocular lens
position. The STAAR toric IOL was approved by the U.S. Food and Drug Administration (FDA) in November 1998, it was silicone, plate-haptics, toric IOL. There was a report that the single-piece acrylic toric IOL had better rotational stability than the silicone, plate-haptics toric IOL, but there were no reports for the 3-piece silicone IOL. In this study, we measured postoperative rotation, decentration, and tilt of the three-piece silicone IOL with reference to the stability of the lens in the bag. The subjects were divided into two groups according to the direction of fixation. In this way, we determined whether or not the 3-piece silicone lens provides a superior platform design for the toric IOL.

Materials and Methods

Of patients who underwent cataract surgery in Kitasato University Hospital between March and December of 2008, 47 eyes of 42 patients (11 eyes of 10 males, 36 eyes of 32 females; mean age: 70.2 ± 7.3 years) were retrospectively selected for this study. The selected patients had regular follow-up examinations, in which the haptics and optics of the implanted lenses could be visualized after a full pupillary dilation. The preoperative mean refractive errors were 0.90 D ± 3.04 D, mean corneal refraction was 44.55 ± 1.75 D, and mean astigmatism was 0.83 ± 0.54 D.

Surgery consisted of a 2.65-mm temporal corneal incision and implantation of a 3-piece, single-focus silicone IOL (AQ-110NV; STAAR Surgical), and follow-up examinations were performed at 1 day, 1 week, 1 month, and 3 months after the procedure. Anterior ocular segment photographs were taken to evaluate IOL rotation. Scheimpflug photographs were taken using a Nidek EAS-1000 instrument (Nidek, Japan) to assess tilt and decentering of the IOL.

To evaluate postoperative rotational stability of the implanted IOL, the anterior ocular photographs were reviewed to measure IOL rotation angle. Two straight lines were drawn on a photograph, one from an anatomic landmark of a prominent episcleral vessel to the IOL center and the other from the haptics to the IOL center; the angle between the two straight lines was then calculated (Figure 1). Sequential changes of postoperative IOL rotation were measured in reference to the baseline value at postoperative Day 1, and the mean angle of rotation was calculated from values at 1 week, 1 month, and 3 months after surgery, with clockwise rotation being expressed as positive value and counterclockwise rotation as negative value. We measured the angle of 20 eyes in two different examiners to evaluate precision of the method for measurement of the lens rotation, we used Brand-Altman plots to evaluate the stability between examiners.

To determine postoperative IOL tilt and decentration, the Scheimpflug images were analyzed to determine corneal anterior curvature with plotting anterior and posterior corneal surface, corneal anterior surface and the IOL anterior and posterior surface.

Referring to the position of the IOL haptics fixation by quadrants, the subjects were divided into 2 groups: a vertical fixation group, in which the IOL haptics were positioned in the vertical quadrants at the 12 o’clock and 6 o’clock positions (25 eyes of 24 patients; mean age: 70.9 ± 7.8 years, range: 58–82 years); and a horizontal fixation group, in which the IOL haptics were positioned in the horizontal quadrants at the 3 o’clock and 9 o’clock positions (22 eyes of 18 patients; mean age: 68.3 ± 6.7 years, range: 58–78 years) (Figure 2).

Results

Lens rotation

Mean absolute rotation of the implanted IOL was 1.7 ± 1.4 degrees (-7.1–4.8 degrees) at 1 week after surgery (Figure 3), 2.1 ± 1.6 degrees (-7.7–5.5 degrees) at 1 month after surgery (Figure 4) and 2.5 ± 2.3 degrees (-7.9–8.5 degrees) at 3 months after surgery (Figure 5), demonstrating no significant differences in sequential rotations (P = 0.13, analysis of variance [ANOVA]).

Bland-Altman plots indicate that mean difference between 2 examiners (95% limits of agreement; LoA) was 0.2 ± 0.7 degree (-0.6–0.7 degrees) (Figure 6).

Figure 1. Two straight lines were drawn on the photograph, one from an anatomic landmark of a prominent episcleral vessel to the IOL center and the other from the haptics to the IOL center. The angle between the two straight lines was then calculated. The angle of the postoperative Day 1 was determined as the baseline.
Figure 2. Patients were divided into 2 groups, a vertical fixation group in which the IOL haptics were positioned in the vertical quadrants at the 12 o’clock and 6 o’clock positions and a horizontal fixation group in which the IOL haptics were positioned in the horizontal quadrants at the 3 o’clock and 9 o’clock positions.

Figure 3. The rotation of the implanted IOL at 1 week after surgery. The mean absolute rotation of the implanted IOL was 1.7 ± 1.4 degrees (-7.1 − 4.8 degrees).

Figure 4. The rotation of the implanted IOL at 1 month after surgery. The mean absolute rotation of the implanted IOL was 2.1 ± 1.6 degrees (-7.7 − 5.5 degrees).
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**Figure 5.** The rotation of the implanted IOL at 3 months after surgery. The mean absolute rotation of the implanted IOL was $2.5 \pm 2.3$ degrees ($-7.9 - 8.5$ degrees).

**Figure 6.** Bland-Altman plots represent the conformity between examiners. The solid lines represent the mean differences between the 2 examiners, the upper and lower borders of the 95% limit of agreement (mean difference $\pm$ 1.96 standard deviation of the mean difference).

**Figure 7.** The IOL tilt over time
**Lens tilt (Figure 7)**
Mean IOL tilt was $2.66 \pm 1.26$ degrees ($0.42 - 5.53$ degrees) at 1 day after surgery, $2.59 \pm 1.47$ degrees ($0.63 - 6.24$ degrees) at 1 week after surgery, $3.11 \pm 1.26$ degrees ($0.79 - 5.99$ degrees) at 1 month after surgery and $3.13 \pm 1.56$ degrees ($1.29 - 7.09$ degrees) at 3 months after surgery, indicating no significant differences in sequential change of IOL tilt ($P = 0.61$, ANOVA).

**Lens decentration (Figure 8)**
Mean IOL decentration was $0.27 \pm 0.15$ mm ($0.12 - 0.68$ mm) at 1 day after surgery, $0.28 \pm 0.16$ mm ($0.05 - 0.80$ mm) at 1 week after surgery, $0.28 \pm 0.13$ mm ($0.10 - 0.58$ mm) at 1 month after surgery and $0.31 \pm 0.15$ mm ($0.03 - 0.72$ mm) at 3 months after surgery, showing no significant difference in sequential decentration of IOL ($P = 0.25$, ANOVA).

**Comparison between vertical and horizontal IOL fixation group (Table 1)**
Mean IOL rotation at 3 months after surgery was $1.8 \pm 1.6$ degrees ($-6.8 - 3.4$ degrees) in the vertical fixation group and $3.4 \pm 2.6$ degrees ($-7.9 - 8.5$ degrees) in the horizontal fixation group, indicating no significant difference between quadrants ($P = 0.10$, Mann-Whitney U test).

Mean IOL tilt at 3 months after surgery was $3.26 \pm 1.48$ degrees ($1.29 - 7.08$ degrees) in the vertical fixation group and $3.00 \pm 1.66$ degrees ($0.41 - 6.48$ degrees) in the horizontal fixation group, demonstrating no significant difference between quadrants ($P = 0.73$, Mann-Whitney U test).

Mean IOL decentration at 3 months after surgery was $0.31 \pm 0.15$ mm ($0.02 - 0.51$ mm) in the vertical fixation group and $0.30 \pm 0.16$ mm ($0.03 - 0.72$ mm) in the horizontal fixation group, indicating no significant difference between quadrants ($P = 0.81$, Mann-Whitney U test).

At 3 months after surgery, there was no statistically significant difference between the vertical and horizontal fixation groups for IOL rotation, tilt, and decentration.

**Table 1.** Comparison between vertical and horizontal IOL fixation group at 3 months after surgery

<table>
<thead>
<tr>
<th></th>
<th>Vertical fixation</th>
<th>Horizontal fixation</th>
<th>Mann-Whitney U test</th>
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<tbody>
<tr>
<td><strong>Rotation</strong></td>
<td>$1.8 \pm 1.6$</td>
<td>$3.4 \pm 2.6$</td>
<td>$P = 0.10$</td>
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<tr>
<td></td>
<td>(-6.8 - 3.4 degrees)</td>
<td>(-7.9 - 8.5 degrees)</td>
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<tr>
<td><strong>Tilt</strong></td>
<td>$3.26 \pm 1.48$</td>
<td>$3.00 \pm 1.66$</td>
<td>$P = 0.73$</td>
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<td></td>
<td>(1.29 - 7.09 degrees)</td>
<td>(0.41 - 6.48 degrees)</td>
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<tr>
<td><strong>Decentration</strong></td>
<td>$0.31 \pm 0.15$</td>
<td>$0.30 \pm 0.16$</td>
<td>$P = 0.81$</td>
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<td>(0.02 - 0.51 mm)</td>
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significant difference between the groups when evaluating IOL rotation, tilt or decentration. 96% of the IOLs with vertical fixation and 81% of those with horizontal fixation had axis rotations within 5 degrees, with the largest rotation being 8.5 degrees.

**Discussion**

Recent advances in cataract surgery have focused on requests for greater improvement in postoperative quality of vision. There are reports that 15% to 29% of cataract patients have preexisting astigmatism of more than 1.5 D.7,8 In our hospital, 15.4% of the 12,428 eyes of 7,187 patients have preexisting astigmatism of more than 1.5 D.9 Toric IOLs, now believed to provide an excellent tool for the correction of preexisting astigmatism during cataract surgery, were first introduced in the 1990s by Shimizu et al. as an option for astigmatism correction in cataract patients.1 The polymethylmethacrylate lens with polypropylene loop haptics used at that time was so rigid that it required a large corneal incision, sometimes inducing considerable astigmatism and lens rotation due to capsular shrinkage.2 Development of foldable lenses effectively reduced the corneal incision size needed for insertion. In the case of a temporal corneal incision, the incision length that is “astigmatism neutral” is reported to be about 2.64 mm.10 It is, therefore, conceivable that astigmatism was not likely induced in the present study due to the 2.65 mm temporal corneal incision used in our procedure.

It is evident that toric IOL axis rotation of 1-degree decreases the efficacy of astigmatic correction by about 3.3% and that lens rotation as large as 30 degrees results in failure of astigmatic correction.11 In the present study, 96% of the IOLs with vertical fixation and 81% of those with horizontal fixation had axis rotations within 5 degrees, with the largest rotation being 8.5 degrees. There is a report of a case that showed toric IOL rotation of 10.3 degrees after cataract surgery. Although no specific cause was identified for this large deviation, the patient did not require secondary repositioning of the lens because of satisfaction with visual acuity.12 It is likely that the AQ-110NV lens used in the present study may provide a superior toric IOL platform and a resultant favorable visual outcome.

Because 2 examiners measured the rotary angle manually, there was a question as to the reproducibility and stability of the measurement. However, as shown in Figure 6, Bland-Altman plots indicate that the mean difference between 2 examiners (95% LoA) was 0.2 ± 0.7 degrees (-0.6—0.7 degrees). Although a small test-retest variability may not necessarily mean high accuracy, it is related to the reproducibility of the measurements for elucidating the applicability of the data.

Decentration and tilt of IOLs degrade optical quality in pseudophakic eyes.13 The acceptable decentration and tilt of IOLs that does not affect the quality of vision are reported to be 1 mm of decentration and 5 degrees of tilt.14 It is remarkable in the present study that our cases with both vertical and horizontal IOL fixation showed decentration of approximately 0.3 mm and tilt of approximately 3 degrees.

In the present study, there was no statistically significant difference in the amount of postoperative IOL axis rotation between vertical and horizontal fixation at 3 months after surgery, but the mean rotation was 1.8 ± 1.6 degrees in the vertical fixation group and 3.4 ± 2.6 degrees in the horizontal fixation group, demonstrating that IOL fixation in the vertical quadrant may tend to induce a smaller rotation. The ciliary sulcus-to-sulcus (STS) diameter measured in four axes (at 0, 45, 90, and 135 degrees) using 35-MHz ultrasound biomicroscopy revealed that the mean 0-degree STS was 12.19 ± 0.47 mm and the mean 90-degree STS was 12.51 ± 0.43 mm, with the ciliary sulcus being vertically oval with the shortest diameter in the 0-degree STS and the longest in the 90-degree STS.15 These findings suggest that the lens capsule is not round but vertically oval, and that the fixation direction-dependent small difference in IOL axis rotation can be attributed to the quadrant-dependent difference in the lens capsular bag size.

The AQ-110NV lens is a 5.5-mm optics polymer silicone IOL with polymide haptics. The polymide has high shape memory which is advantageous for IOL haptics.16 A comparison of the mechanical properties of the IOL haptics examined in vitro showed that the lens is the largest in rotation among the polymide group. Therefore, rotation does not depend only on the haptics material. The relatively infrequent rotation of the AQ-110NV may be related to the unique shape of the haptics junction, as well as to a good combination of haptics material and design.4 The single-piece acrylic toric IOL, AcrySof IQ (Alcon Surgical) most frequently used sometimes shows a large rotation when applied in eyes of long axial length. Chang17 reported a series of 3 patient cases with axial lengths of 27.10 mm, 26.56 mm, and 25.84 mm, who underwent repositioning after implantation of an AcrySof IQ toric IOL and suggested...
that it is more likely to occur in larger myopic eyes that have what subjectively appear to be large-diameter capsular bags. In the present study, there were 3 eyes having axial lengths of more than 26 mm, but none of them developed large rotation or displacement. The 3-piece silicone toric IOL in this study differs in mechanical properties from the classic single-piece toric IOL, and use of the AQ-110NV IOL in eyes of long axial length may show a different long-term rotational stability.

In conclusion, it can be safely stated from the present study, as well as previous in vitro studies, that the AQ-110NV IOL shows excellent postoperative long-term rotational stability. Along with advancements in cataract surgical technique and refinement of IOL design, the toric IOL is expected to prevent surgery-induced astigmatism. The important remaining safety and efficacy issues for the toric IOL involve postoperative stability in the capsular bag. The AQ-110NV lens is definitely a superior toric IOL platform.

References