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Incidence and Outcomes of Repositioning Surgery to Correct Misalignment of Toric Intraocular Lenses

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Purpose: To analyze the incidence and appropriate timing of repositioning surgery to correct misalignment of acrylic foldable toric intraocular lenses (IOLs).

Design: Retrospective, multicenter case series.

Participants: Patients who had undergone phacoemulsification and implantation of toric IOL at 8 surgical sites.

Methods: Patient charts were reviewed to collect data on repositioning surgery of toric IOLs.

Main Outcome Measures: Incidence, timing, and outcomes of repositioning surgery.

Results: Among 6431 eyes implanted with toric IOLs, 42 eyes (0.653%) of 42 patients underwent repositioning surgery at an average of 9.9±7.5 days (range, 0–30 days) after IOL implantation. The repositioning surgery significantly reduced misalignment from 32.9°±15.7° to 8.8°±9.7° ($P < 0.001$), which was measured at 7.6±5.0 weeks postoperatively. Refractive cylinder was significantly reduced from 2.4±1.1 diopters (D) to 1.1±0.8 D ($P < 0.001$). There was a significant negative correlation between the interval from cataract surgery to repositioning procedure and the degree of residual misalignment ($r = -0.439$, $P < 0.001$). The residual misalignment was 13.1°±13.5° when the repositioning surgery was performed within 6 days after cataract surgery, whereas the residual misalignment was 6.3°±5.9° when the IOL was repositioned 7 days or later ($P < 0.001$). In 2 eyes that were treated within 24 hours after cataract surgery, the IOL re-rotated significantly, and additional surgical intervention was required.

Conclusions: Toric IOLs were repositioned in 0.653% of cases. A relationship was found between the timing of repositioning surgery and surgical outcome. These data suggest that repositioning surgery should be performed 1 week after IOL implantation. *Ophthalmology 2017;■:1–5 © 2017 by the American Academy of Ophthalmology*

With the advent of toric intraocular lens (IOL) technology, an increasing number of surgeons attempt to correct preexisting corneal astigmatism at the time of cataract surgery to enhance the postoperative unaided vision of patients. Evidence has been mounting that toric IOLs provide better uncorrected distance visual acuity, greater spectacle independence, and lower degrees of residual astigmatism than nontoric IOLs.[1,2] Crucial to the efficacy of toric IOLs is the precise positioning of the lens in relation to the intended alignment axis.[1] Toric IOL misalignment less than 10° changes the eye's refraction by less than 0.50 diopters (D), and thus is not a problem for satisfactory astigmatism correction.[3] However, large axis misalignment will eliminate the corrective effect of toric IOLs,[4] and surgical interventions are sometimes required to realign the IOL.

A previous study reported 3 cases of surgical repositioning of AcrySof toric IOL (Alcon Laboratories, Inc., Fort Worth, TX) due to a misalignment of more than 15° off axis, with an overall rate of 1.1% (3/263 eyes).[5] A multicenter, 1-year study showed that among 256 eyes implanted with AcrySof toric IOLs, reorientation of the lens axis was needed in 1 eye.[6] Other studies reported that the incidence of repositioning surgery after AcrySof toric IOL implantation was 2 of 111 eyes,[7] 4 of 122 eyes,[8] 1 of 82 eyes,[9] and 7 of 378 eyes.[10] Of 172 eyes implanted with TECNIS toric IOLs (Abbott Medical Optics, Inc., Santa Ana, CA), realignment surgery was performed in 4 eyes (2.3%) during a 6-month clinical trial.[11] TECNIS toric IOLs have been repositioned in 4 of 174 eyes[12] and 2 of 27 eyes.[13] In a prospective multicenter clinical trial that included 93 eyes that were implanted with a hydrophobic acrylic toric IOL (TC2, HOYA, Tokyo, Japan), 3 lenses were repositioned.[14] Except for these small case reports, however, there has been no large-scale clinical investigation on the rate and outcomes of toric IOL repositioning surgery. We conducted the present study to assess the incidence and proper timing of repositioning surgery to correct misalignment of acrylic foldable toric IOLs of several manufacturers.

Methods

We retrospectively collected the data of patients who had undergone toric IOL repositioning surgery from May 2013 to April 2016

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at 8 surgical sites in Japan. By reviewing the medical files, records were analyzed on preoperative keratometry, axial length, model of toric IOLs, power of IOLs, target toric axis, degree of axis misalignment, direction of axis misalignment (clockwise or counterclockwise), timing of repositioning surgery, and outcomes of repositioning surgery including final axis orientation and degree of residual misalignment.

Because this was a retrospective study, surgical procedures, examination methods, and indication of repositioning surgery were not standardized before surgery. In general, the following procedures were used. At the time of initial cataract surgery, the reference and alignment axes were manually marked on the eye. The marking techniques were not identical among the surgeons with different spatulas or markers used, but otherwise there were substantial similarities. Before surgery, with the patients in an upright seated position to avoid cyclotorsion errors, the corneal limbus of each eye was marked along the principal meridians at the slit lamp. At the beginning of surgery, the steepest meridian of the corneal limbus was identified and marked with a toric IOL marker. After phacoemulsification and removal of cortical materials, a toric IOL was implanted in the capsular bag using an injector. The IOL was rotated to its final position by aligning the reference marks on the IOL with the limbal axis marks. The incision was not sutured. Limbal relaxing incision or astigmatic keratotomy was not performed.

After surgery, IOL alignment was assessed at each postoperative visit. The misalignment was defined as the difference between the preoperatively calculated IOL axis and real IOL axis after surgery. Postoperative orientation of the toric IOL was measured on slit-lamp digital retroillumination photographs taken with the eyes fully dilated. Repositioning surgery was indicated when the surgeons judged that visual function of the patients would be improved by correcting IOL axis misalignment and the patients consented to the secondary surgical intervention. In the repositioning surgery, we attempted to realign the toric IOL axis to the orientation planned at the time of cataract surgery. Capsular tension ring was not used in any cases.

The study protocol was reviewed and approved by the Institutional Review Board or the Ethical Review Committee of participating institutions. This study was conducted in accordance with the Declaration of Helsinki, the Ministerial Ordinance Regarding Good Clinical Practice Principles for Medical Devices (2005, Ministry of Health, Labour and Welfare Ordinance No. 36). All patients provided written informed consent.

Paired variables, such as data before and after repositioning surgery, were statistically compared using the Student t test. Unpaired data were compared using the unpaired t test, and the relation between continuous variables was assessed by means of the Pearson's correlation coefficient. For assessment of data among 3 or more groups, such as among different IOL models, the multiple comparison test was used, that is, 1-way analysis of variance. The incidence of repositioning surgery among different IOL groups was compared with the Kruskal–Wallis test, and the ratio of clockwise and counterclockwise rotation was compared using the chi-square test. All statistical tests were 2 sided, and a P value of less than 0.05 was considered significant. The numeric data are presented as the mean ± standard deviation unless otherwise noted. Statistical analysis was performed using SPSS software version 22 (IBM Corp, Armonk, NY).

Results

Among 6431 eyes implanted with toric IOLs at the 8 surgical sites, 42 eyes (0.653%) of 42 patients underwent repositioning surgery. The basic characteristics of these 42 patients are summarized in Table 1, and a histogram of axial length is shown in Figure 1. The average axial length was 24.3±1.9 mm (range, 22.0–30.3 mm), and the axial length was longer than 25.0 mm in 11 eyes (26.2%). The average degree of misalignment was 32.9°±15.7° (range, 10°–74°), including 11 eyes with clockwise rotation (misalignment = 30.7°±19.3°; range, 10°–69°) and 31 eyes with counterclockwise rotation (misalignment = 33.6°±14.5°; range, 13°–74°). Refractive cylinder was 2.4±1.1 diopters (D) (range, 0.5–6.5 D).

Table 1. Patient Characteristics

Age, yrs	
Mean (SD)	69.6 (10.4)
Range	35–86
Male/female	18/24
Axial length (mm)	
Mean (SD)	24.3 (1.9)
Range	22.0–30.3
IOL power (D)	
Mean (SD)	19.1 (4.9)
Range	6.0–24.5
Preoperative corneal cylinder (D)	
Mean (SD)	2.17 (0.73)
Range	1.0–4.2
WTR/ATR/oblique	12/24/6

ATR = against-the-rule astigmatism (steep corneal cylinder axis was between 0° and 30° or 150° and 180°); oblique = oblique astigmatism (steep corneal cylinder axis was between 30° and 60° or 120° and 150°); D = diopters; IOL = intraocular lens; SD = standard deviation; WTR = with-the-rule astigmatism (steep corneal cylinder axis was between 60° and 120°).

The repositioning surgery was performed at an average of 9.9±7.5 days (range, 0–30 days) after the primary cataract surgery. There were no complications during and after the repositioning surgery. The final measurement of alignment after repositioning was obtained at 7.6±5.0 weeks postoperatively. Misalignment was reduced by 24.1°±16.5° (range, −2°–72°) to 8.8°±9.7° (range, 0°–40°) ($P < 0.001$). Refractive cylinder was significantly reduced to 1.1±0.8 D (range, 0–3.25 D) ($P < 0.001$). There was a significant negative correlation between the interval from cataract surgery to repositioning procedure and the degree of residual misalignment (Fig 2) (Pearson $r = -0.439$, $P < 0.001$). The degree of residual misalignment was 13.1°±13.5° when the repositioning surgery was done within 6 days after cataract surgery; a misalignment of 6.3°±5.9° remained when the IOL was repositioned 7 or more days after cataract surgery (Fig 3) ($P < 0.001$). The degree of misalignment before the repositioning surgery was 34.1°±15.4° and 32.2°±16.1° in eyes that underwent repositioning surgery within 6 days and 7 or more days after the cataract surgery, respectively. In 2 eyes that were treated within 24 hours after cataract surgery, the IOL re-rotated significantly, and additional surgical intervention was required to correct misalignment.

Discussion

The present study represents the largest case series of patients who underwent surgical repositioning to correct misalignment of toric IOLs. The overall incidence of

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