

ORIGINAL ARTICLE

Results of cataract surgery with Z-flex hydrophilic acrylic toric IOL

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PURPOSE. To report the outcome of cataract surgery with implantation of the Z-flex 690TA hydrophilic acrylic toric intraocular lens (IOL).

METHODS. We enrolled consecutive patients who had 1.75 D or more of preexisting corneal astigmatism. Patients had cataract extraction surgery with implantation of a Z-flex 690TA toric IOL (Medicontur, Hungary). Refractive outcomes, keratometry, correction ratio (CR), and error of magnitude (EM) were evaluated.

RESULTS. Nineteen eyes of 13 patients were evaluated. Mean follow-up time was 4.3 ± 2.3 months. Mean preoperative keratometric astigmatism was 3.05 ± 0.74 D. Mean postoperative deviation from the anticipated spherical equivalent was $+0.23 \pm 0.39$ D, with 100% of eyes achieving a spherical equivalent within ± 1.00 D of the target refraction. Mean deviation from the anticipated refractive cylinder was 0.46 ± 0.47 D. Mean IOL misalignment was 5.67 ± 6.45 degrees. Mean CR was 1.02 ± 0.22 , and the mean EM was -0.09 ± 0.55 D.

CONCLUSION. The Z-flex 690TA hydrophilic acrylic toric IOL implantation was safe, effective, and predictable in correcting corneal astigmatism during cataract surgery.

KEY WORDS. Cataract surgery, Hydrophilic, Medicontur, Toric intraocular lens

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INTRODUCTION

Corneal astigmatism of 1.25 D or more exists in approximately 30% of eyes that undergo cataract surgery (1-3). Toric intraocular lenses (IOLs) provide a precise and stable way to correct this refractive problem and thus achieve the best uncorrected vision and spectacle independence in patients with concomitant cataract and corneal astigmatism (4-15), and are therefore increasingly being used during cataract surgery. Crucial to the efficacy of all toric IOLs is the ultimate position of the IOL with regard to the intended alignment axis because each degree of misalignment leads to increasing residual astigmatism (16, 17). There are many reports in the literature regarding hydrophobic toric IOLs (5-11), but there are few studies that deal with hydrophilic toric IOLs (18).

The aim of this prospective single-arm study was to report the outcomes of cataract surgery with implantation of the Z-flex 690TA hydrophilic acrylic toric IOL (Medicontur, Hungary).

PATIENTS AND METHODS

Enrolled in this prospective nonrandomized clinical study were patients who were scheduled for cataract surgery with implantation of a toric IOL. The study was performed at the Assaf Harofeh Medical Center, Israel, and followed the tenets of the Declaration of Helsinki. Patients provided informed consent after they received an explanation of the nature and possible consequences of the study. Inclusion criteria were age over 21 years, decreased visual acuity due to cataract, and preoperative corneal astigmatism of 1.75 D

or more. Exclusion criteria were irregular astigmatism or signs of Fuchs endothelial dystrophy.

Preoperatively, all patients had a full ophthalmic examination consisting of uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), funduscopy, Goldmann applanation tonometry, corneal topography (TMS4, Tomey), and partial coherence interferometry optical biometry (IOLMaster, Carl Zeiss Meditec AG).

Intraocular lenses

A Z-flex 690TA hydrophilic acrylic toric aspheric 1-piece IOL (Medicontur, Hungary) was used in all patients (Fig. 1). The IOL has a 6.0 mm optic diameter, and is available in spherical powers ranging from 0.00 to 30.00 D and astigmatic power of 1.5-9.0 D. The IOL has an A-constant of 118.2 with a toric posterior surface and an anterior spherical surface. It has open-loop modified L-haptics with no angulation; the haptics are of the same acrylic material as the optic.

In all patients, the spherical power was calculated using axial length and keratometry (K) values obtained with the IOLMaster using the SRK/T formula. The IOL cylinder power and alignment axis were calculated using a Web-based toric IOL calculator software (<http://medicontur.hu/toric-iol-calculator>). We assumed a 0.5 D surgically induced astigmatic effect for the corneal incision in all cases.

Surgical technique

Preoperative marking of the eye was done in 2 steps. First, at the slit lamp, the surgeon placed reference marks at the 3, 6, 9, and 12-o'clock meridians at the limbus with the patient sitting upright to avoid the effect of cyclorotation when the patient moves to a supine position for the cataract procedure. Then, in the supine position just prior to surgery, a Mendez-type degree gauge was placed using the above markings, and the alignment axis obtained from the toric calculator program was then marked.

The surgeon's standard phacoemulsification technique was performed through limbal corneal incision using either 2.2-mm or 2.5-mm knife. After insertion of the foldable toric IOL, the IOL was rotated to its final position such that there was exact alignment of the reference marks on the toric IOL with the implantation axis marks. As we routinely use an anterior chamber maintainer, the IOL was inserted without the use of viscoelastic material. All patients were operated by the senior author (D.Z.).



Fig. 1 - A Z-Flex 690TA hydrophilic acrylic toric aspheric 1-piece intraocular lens (Medicontur, Hungary).

Postoperative examinations

All patients were examined on postoperative day 1, after 1 week, and after 1 or more months. The examinations were performed by the same investigator and included UDVA, CDVA, subjective refraction, and slit-lamp evaluation; during the final examination, we also obtained corneal topography, and a retroillumination image of the toric IOL, in which the axis marks were visible. The exact location of the toric IOL was determined using the Goniotrans program (<http://www.facoelche.com/utilidades/goniotrans-en>).

Statistical analysis

All data were collected and analyzed in an Excel database (Microsoft Office 2003, Microsoft Corp., Redmond, Washington, USA). For normally distributed variables, the arithmetic mean and standard deviation (SD) were used. Otherwise, the median and range were used. Statistical analysis and graphical visualization were performed using Excel software and MATLAB software (MathWorks, Natick, Massachusetts, USA).

TABLE I - PREOPERATIVE DATA^a

| Characteristics | Mean ± SD | Range |
|---|--------------|----------------|
| Age, y | 73.63 ± 7.25 | 61 to 89 |
| Axial length, mm | 23.99 ± 1.18 | 22.38 to 26.48 |
| Corneal astigmatism, optical biometer, D | 3.05 ± 0.74 | 1.75 to 4.44 |
| Corneal astigmatism, corneal topographer, D | 3.13 ± 0.73 | 1.84 to 4.58 |
| Labeled SE IOL power, D | 18.42 ± 4.03 | 9.5 to 24 |
| Labeled IOL cylinder, D | 3.33 ± 1.04 | 1.5 to 5.5 |
| Expected SE, D | -0.59 ± 0.18 | -0.93 to -0.21 |
| Expected residual cylinder, D | 0.25 ± 0.15 | 0.03 to 0.48 |

IOL = intraocular lens.
^aTotal n = 19 eyes.

The following values were calculated for each patient as described previously (19). Surgically induced refractive correction (SIRC), intended refractive correction (IRC) and correction ratio (CR) = |SIRC|/|IRC|, where CR = 1 is ideal, CR<1 implies undercorrection and CR>1 implies overcorrection. The mean spherical equivalent prediction error is the difference between achieved and attempted refraction. The error of magnitude (EM) is the arithmetic difference of the magnitudes between SIRC and IRC (|IRC|-|SIRC|). Error of magnitude of 0 is the ideal. If EM <0, then the axis effectively rotates 90° (overcorrection).

RESULTS

We enrolled 19 eyes of 13 consecutive patients. The mean follow-up time was 4.3 ± 2.3 months. Table I shows the preoperative demographic, biometric, and refractive data of all patients. One eye had been known to be amblyopic, and in one eye there was a history of retinal detachment for which pars plana vitrectomy had been

TABLE II - POSTOPERATIVE DATA^a

| Characteristics | Mean ± SD | Median | Range |
|--|--------------|--------|---------------|
| Refractive sphere, D | -0.01 ± 0.41 | 0 | -0.75 to 1.00 |
| Refractive cylinder, D | 0.71 ± 0.47 | 0.75 | 0 to 2.00 |
| Achieved SE, D | -0.37 ± 0.36 | -0.375 | -1.13 to 0.13 |
| Corneal astigmatism, optical biometer, D ^b | 2.89 ± 0.87 | 2.83 | 0.35 to 4.3 |
| Corneal astigmatism, corneal topographer, D ^c | 2.96 ± 0.79 | 3.09 | 1.21 to 4.55 |
| UDVA (decimal) (n = 17) | 0.76 ± 0.12 | 0.67 | 0.33 to 1 |
| CDVA (decimal) (n = 17) | 0.85 ± 0.17 | 0.8 | 0.4 to 1.00 |

CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity.
^aTotal n = 19 eyes.
^bPreoperative vs postoperative: p = 0.17.
^cPreoperative vs postoperative: p = 0.65.

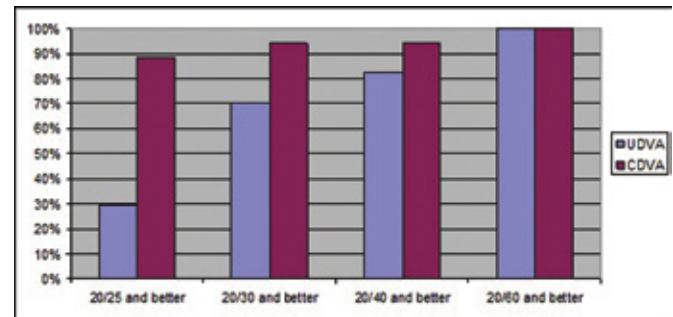


Fig. 2 - Cumulative postoperative uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) results.

done. These 2 eyes were not included in the analysis of visual outcome.

Table II summarizes in detail the postoperative visual acuity and refraction outcomes. Figure 2 shows cumulative postoperative UDVA and CDVA results. There was a 1-line difference between the mean UDVA and the mean CDVA postoperatively, indicating a good refractive result.

Table III shows comparison of preoperative and postoperative refractive parameters. There was no statistically

TABLE III - COMPARISON OF PREOPERATIVE AND POSTOPERATIVE REFRACTIVE PARAMETERS

| | Preoperative, expected, mean ± SD (range) | Postoperative, achieved, mean ± SD (range) | Deviation, mean ± SD | p Value |
|---|---|--|----------------------|---------|
| Corneal astigmatism (optical biometer), D | 3.05 ± 0.74 (1.75 to 4.44) | 2.89 ± 0.87 (0.35 to 4.3) | 0.16 ± 0.51 | 0.17 |
| Corneal astigmatism (corneal topographer), D | 3.13 ± 0.73 (1.84 to 4.58) | 2.96 ± 0.79 (0.35 to 4.3) | 0.17 ± 0.52 | 0.65 |
| Spherical equivalent, expected vs achieved, D | -0.59 ± 0.18 (-0.93 to -0.21) | -0.37 ± 0.36 (-1.13 to 0.13) | 0.22 ± 0.39 | 0.021 |
| Residual subjective cylinder, expected vs achieved, D | 0.25 ± 0.15 (0.03 to 0.48) | 0.71 ± 0.47 (0 to 2) | 0.46 ± 0.47 | 0.0004 |

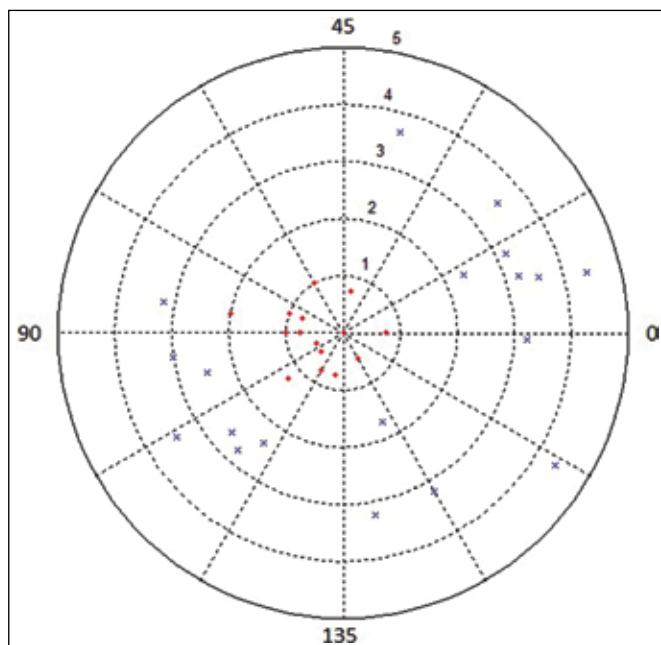


Fig. 3 - Double-angle scatterplot of corneal cylinder preoperatively, which was measured by the IOLMaster (blue x) and subjective cylinder postoperatively (red rhombus).

significant difference between the preoperative and postoperative corneal astigmatism measurements with the optical biometer (IOLMaster) and corneal topography ($p > 0.17$). The mean SE prediction error was 0.22 ± 0.39 D. All patients were within ± 1.00 D from the anticipated SE. The mean deviation from the anticipated refractive cylinder was 0.46 ± 0.47 . The mean CR was 1.02 ± 0.22 (CR = 1 is ideal). Overcorrection of astigmatism (CR > 1) was seen in 12 patients. The mean EM was -0.09 ± 0.55 D (0 is ideal). Figure 3 shows a double-angle scatterplot of corneal cylinder preoperatively and postoperatively. Eighty-nine percent of eyes had postoperative residual refractive astigmatism of 1.00 D or less.

The mean misalignment (absolute difference in IOL axis between intended placement at time of surgery and measured IOL axis at the last follow-up visit) was 5.67 degrees (range 0-26 degrees). There were 2 patients with exceptionally high misalignment of 16 and 26 degrees, both of whom declined to undergo IOL repositioning. When these 2 cases are excluded from analysis, the mean misalignment is 3.75 degrees. The alignment was within 5 degrees of the intended axis in 11 eyes (57.9%), and between 6 degrees and 10 degrees in 6 eyes (31.6%). No minor or major intraoperative or postoperative complications occurred.

DISCUSSION

In the current study, we evaluated the visual and refractive outcomes after implantation of the Z-flex 690TA hydrophilic acrylic toric IOL in patients with corneal astigmatism over 1.75 D. This is the first published study reporting results of this IOL. Our results show good UDVA for most patients: 82.5% of eyes achieved 20/40 or better UDVA. This is similar to results in previous studies using hydrophobic toric IOLs (8-11). Almost 90% of eyes had residual refractive astigmatism of 1.00 D or less. The mean deviation from the anticipated refractive cylinder was 0.46 ± 0.47 . There was a 1-line difference between the mean UDVA and the mean CDVA postoperatively, indicating a good refractive result. These results indicate that the correction of preexisting corneal astigmatism can be effectively achieved with this hydrophilic toric IOL. In our study, 29.4% of eyes achieved a UDVA of 20/25 or better, whereas in some studies evaluating hydrophobic toric IOLs, higher rates have been reported, such as 41% to 60% (5, 8, 9, 12). A total of 88.2% of eyes in our study achieved CDVA of 20/25 or better.

Undercorrection of astigmatism (correction ratio < 1) was seen in 7 patients and overcorrection in 12 patients. Nevertheless, the average correction ratio was 1.02, indicating good accuracy of the hydrophilic IOL (CR = 1 is ideal). However, there are factors that might influence the calculation of the corneal astigmatism and are not considered by the toric IOL formula, like the posterior surface of the cornea. Cheng et al (20) showed that neglecting the posterior corneal surface measurement may lead to significant deviation in the corneal SIA estimation after phacoemulsification.

The effectiveness of a toric IOL depends on its position, as for every 1 degree of off-axis rotation, 3.3% of the lens cylinder power is lost (16). Misalignment of the IOL can be caused by 2 factors: inaccurate placement of the IOL during surgery or postoperative rotation of the IOL. The surgical placement of the toric IOL should be as accurate as possible. Currently there is still no easy, reproducible, and precise technique to ensure placement of the toric IOL on the desired axis. Corneal marking using specifically designed instruments relies on an accurate location of the horizontal meridian of the eye in the sitting position and then the placement of an accurate axis marking on the cornea at the time of surgery. Irrespective of how well the surgeon can place the markings in relation to the gauge used, the width of the marking may limit how accurately the axis

can be determined. Postoperative rotational stability and rotation within the lens capsule used to be significant limitations with older silicone toric IOL models, which were reported to rotate more than 10 degrees in 10%-25% of eyes or even more (21, 22). However, with the hydrophobic acrylic IOLs, the rotational stability is better. Zuberbuhler et al (23) reported that the postoperative rotation of the AcrySof toric IOLs was within 5 degrees in 95% of cases and within 2 degrees in 68% of eyes 3 months postoperatively. Mendicute et al (10) demonstrated a mean toric IOL axis rotation of 3.6 degrees, with rotation less than 10 degrees in 96.7% of eyes using the AcrySof toric IOL. During the early postoperative period, IOLs may rotate within the capsular bag until they form an adhesive bond with the posterior capsule. Most IOL rotation happens in the early postoperative period. Once the anterior and posterior capsules fuse, IOL rotation is likely physically limited. Possible factors influencing the capsule fusion and resultant IOL stability include capsulorhexis size and IOL design and material. Ruhswurm et al (14) found IOL rotation to be associated with increasing capsular bag diameter as well as with longer axial length. To evaluate multiple possible factors on IOL rotation, further prospective comparative study is warranted. In our study, we did not measure the rotation but we did measure the misalignment (i.e., the absolute difference in IOL axis between intended and postoperatively measured IOL axis). Previous studies of AcrySof toric

IOLs reported mean misalignments less than 4 degrees (5, 8-10). The mean misalignment in our study was somewhat higher, 5.67 degrees. However, excluding 2 subjects with extreme misalignment who declined to undergo repositioning, the calculated misalignment was 3.75 degrees.

The alignment in our study was within 5 degrees of the intended axis in 57.9% of eyes. Since we did not use viscoelastic material during implantation, we cannot attribute potential postoperative rotation to its removal, or lack thereof. Ensuring more accurate placement of the toric IOL during surgery and minimizing postoperative rotation should enhance its efficacy. This is especially important when implanting IOLs with a high cylinder power.

In conclusion, implantation of the Z-flex hydrophilic acrylic toric IOL was safe, effective, and predictable in correcting corneal astigmatism during cataract surgery. Further research is needed to directly compare postoperative stability to that of hydrophobic IOLs.

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