·Clinical Research·

Distance vision after bilateral implantation of AcrySof toric intraocular lenses: a randomized, controlled, prospective trial

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Abstract

• AIM: To evaluate the distance vision of Chinese patients with cataracts and corneal astigmatism after implantation of bilateral AcrySof toric intraocular lens (IOL) versus bilateral AcrySof spherical IOL.

• METHODS: This study randomized 60 patients into equal groups to receive toric IOL or spherical IOL. IOL powers targeting emmetropia were selected for 93% of toric IOL patients and for 90% of spherical IOL patients. Assessments included monocular and binocular distance vision, with and without best correction. Patients also completed surveys about their distance vision.

• RESULTS: Preoperatively, the two study groups were similar in age, in distance visual acuity, and in the magnitude of corneal astigmatism. At 6 months postoperative, binocular uncorrected distance vision was 0.06± 0.14 logMAR in the AcrySof toric IOL group, significantly better than the 0.14± 0.11 logMAR in the spherical IOL group (P<0.05). For eyes with emmetropia as a target, the equivalent of 20/20 uncorrected vision was more likely (P<0.001) in the toric IOL group (36% of eyes) than in the spherical IOL group (4% of eyes). No patients in the emmetropia/toric IOL group used distance glasses, as compared to 52% of patients in the emmetropia/spherical IOL group. All patients were satisfied or highly satisfied. Quality of distance vision was rated higher by toric IOL patients than by spherical IOL patients (P<0.05).

• CONCLUSION: Bilateral AcrySof toric IOL is superior to bilateral spherical IOL in providing uncorrected distance vision to cataract patients with corneal astigmatism.

• KEYWORDS: astigmatism; cataract extraction; lenses, intraocular; pseudophakia

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INTRODUCTION

In the United States, toric intraocular lense (IOL) is now an established option for the correction of corneal astigmatism at the time of cataract surgery [1,2]. One available model is the AcrySof toric IOL (Alcon Laboratories, Inc). The clinical trials demonstrated that 94% of astigmatic eyes that received these IOLs had postoperative uncorrected distance vision of 20/40 or better, and 66% of eyes had 20/25 vision or better [3]. Those trials compared patients who received unilateral toric IOLs to patients who received unilateral spherical IOLs. Even though toric patients had only one eye corrected for astigmatism, spectacle independence for distance vision was provided to more toric IOL patients (60%) than to spherical IOL patients (38%)[3]. The original trials of unilateral AcrySof toric IOL implants were followed by studies that included bilaterally implanted patients in the Netherlands [4], Spain [5], and the United Kingdom [6]. However, no studies yet have reported English-language results for Chinese patients with AcrySof toric IOL. Demographic data suggest that Chinese patients might especially benefit from these lenses. A study in Taiwan of 1361 Chinese adults aged 65 years or older found that 50% had presence or history of cataracts [7]. Of the 490 subjects with untreated cataracts, 76% had astigmatism >0.5D[7]. This prevalence appears even greater than the comorbidity observed in 7500 American cataract eyes, 60% of which had astigmatism >0.5D [8]. Moreover, in a study of 4493 Chinese adults in Beijing, astigmatic refractive error increased significantly with the degree of nuclear cataract and with the degree of cortical cataract [9]. Thus, the need for astigmatic correction may be widely prevalent in Chinese cataract patients, but the benefit of AcrySof toric lenses has not yet been established in a Chinese population. Therefore, this study randomized Chinese cataract patients to receive either bilateral AcrySof toric IOL or bilateral AcrySof spherical control IOL, and then evaluated objective and subjective distance vision outcomes.

MATERIALS AND METHODS

Patients To be eligible for the study, patients were required to have a diagnosis of bilateral age-related cataracts. All patients had preoperative regular corneal astigmatism of ≥0.5D and ≤3D in both eyes. Patients were excluded if either eye had any condition that might affect vision outcomes, such as glaucoma, keratopathy, or ocular fundus diseases. All patients gave consent in accordance with the Declaration of Helsinki. The 60 patients were randomized into two equal open-label groups for bilateral implantation of AcrySof toric IOL or spherical AcrySof Natural IOL. Baseline examinations included monocular and binocular logMAR distance visual acuity with and without correction, fundus examination, intraocular pressure measurement, manual keratometry, and biometry by IOL Master (Carl Zeiss Meditech AG).

Methods At the preoperative and postoperative visits, each patient completed a structured questionnaire about their distance vision. One question asked patients to select a single choice that best described what type of vision correction they used. The response options were as follows: distance glasses, reading glasses, both reading and distance glasses (as separate pairs of glasses), bifocals, trifocals, progressive lens glasses, contact lenses, both contact lenses and glasses, none, or other. Another question asked the patients to rate the quality of their distance vision without glasses or contact lenses, on a scale of 0 to 6 (0=worst, 6=best). Patients also were asked about their satisfaction with their distance vision without glasses or contact lenses, with a 5-point Likert scale of response options (very dissatisfied, dissatisfied, neither satisfied nor dissatisfied, satisfied, or very satisfied).

For the patients in the spherical AcrySof Natural group, all IOL were model SN60AT, with appropriate spherical power as determined by biometry. For patients in the AcrySof toric group, IOL models could be SN60T3, SN60T4, or SN60T5. The SN60T3 has 1.5D of cylinder power at the IOL plane, yielding 1.03D of cylinder at the corneal plane, which is indicated for the correction of corneal astigmatism between 0.75D and 1.5D [3]. At the discretion of the investigators, the SN60T3 lens also was used to correct levels of cylinder that were lower than indicated in the directions for use. The SN60T4 has 2.25D of cylinder power at the IOL plane, yielding 1.55D of cylinder at the corneal plane, for the correction of corneal astigmatism between 1.5D and 2.0D[3]. The SN60T5 has 3.0D of cylinder power at the IOL plane, yielding 2.1D of cylinder power at the corneal plane, for eyes with ≥2.0D of corneal astigmatism [3]. To determine which toric lens model should be used, and to determine lens alignment, each patient's keratometry measurements and IOL spherical power were entered into the AcrySof Toric Calculator (www.acrysoftoriccalculator.com). The default value for surgically induced astigmatism (0.5D) was used for all cases. Incision site was temporal for all cases.

Before each surgery, while patients were sitting up at a slit lamp, the cornea was marked at 0°, 90°, and 180°, using a Cionni Toric Kit (Duckworth & Kent, Hertfordshire, UK). After topical anesthesia, 3.0-mm clear corneal incisions were made. Torsional phacoemulsification was performed using the Infiniti Vision System with the OZil handpiece, a 45-degree Kelman miniflared tip, and DuoVisc viscoelastic (all from Alcon). The IOL was injected using a MonarchII Delivery System with the C cartridge (Alcon). For each patient, the felloweye surgery was performed 1 to 4 weeks after the first eye implant. Postoperative assessments were conducted at 1, 3, and 6 months. Postoperative examinations included monocular and binocular logMAR distance visual acuity with and without correction. Patients also completed the questionnaires about distance vision.

Statistical Analysis All results of these assessments are presented as average ±standard deviation unless otherwise specified.Student's *t*-test was applied to parametric variables and a Chi-square test was applied to categorical variables, with statistical significance set to $P<0.05$.

Table 1 Preoperative characteristics

	Toric IOL	Spherical IOL
Corneal astigmatism, D	1.33 ± 0.50*	1.26 ± 0.46*
Age/y	67 ± 10	65 ± 12
bUCDVA, logMAR	0.9 ± 0.3	0.8 ± 0.3
bBCDVA, logMAR	0.8 ± 0.3	0.8 ± 0.4
Direction of astigmatism		
With the rule, % of eyes	31.7%	31.7%
Against the rule, % of eyes	61.7%	63.3%
Oblique, % of eyes**	6.7%	5.0%

IOL=intraocular lens; bUCDVA = binocular uncorrected distance visual acuity;
bBCDVA=binocular best-corrected distance visual acuity
*Extended below the range recommended in the directions for use[3]
**Steep axis >30º but ≤60º or >120º but ≤150º

RESULTS

Preoperatively, the two study groups were similar in age, in distance visual acuity, and in the magnitude and direction of corneal astigmatism, as shown in Table 1. In both groups, baseline distance vision averaged 0.8 to 0.9 logMAR and was not generally improved with spectacles (Table 1). The two study groups also were similar in their preoperative responses to the questionnaires (data not shown). In the toric IOL group, 43% of eyes were implanted with the SN60T3 IOL model, 42% of eyes were implanted with the SN60T4 IOL model, and 15% of eyes were implanted with the SN60T5 model. IOL powers targeting emmetropia were selected for 93% of patients in the toric IOL group and for

90% of patients in the spherical IOL control group. Bilateral residual myopia of 1D to 3D was targeted for 2 patients in the toric IOL group and for 3 patients in the spherical IOL group. Results for these patients are excluded where noted.

Binocular uncorrected distance visual acuity (UCDVA) at 6 months postoperative was significantly better in the AcrySof toric IOL group than in the spherical control group (Figure 1). Average binocular UCDVA was (0.06±0.14)logMAR for the 30 AcrySof toric IOL patients and (0.14±0.11)logMAR for the 30 spherical IOL patients. The difference between groups was significant (P<0.05). Both groups were similar in percentage of patients at the equivalent of Snellen 20/40 or better for binocular UCDVA (93% of toric patients, 97% of spherical patients). However, Snellen equivalent of at least 20/20 was statistically more likely (P=0.001) in the toric IOL group (50% of patients) than in the control IOL group (10% of patients). Binocular best-corrected distance visual acuity (BCDVA) was statistically similar between groups, at (-0.02±0.07)logMAR in the toric IOL group and (-0.01 ±0.06)logMAR in the spherical IOL group. Average binocular UCDVA was improved slightly but not significantly in both study groups when patients with myopic targets were excluded, as shown in Figure 1. The difference between the toric IOL patients and the spherical IOL patients was still statistically significant for these emmetropia-targeted subgroups (P<0.05). In the emmetropia-targeted subgroups, all patients had vision equivalent to 20/40 or better, but the percentage of patients at 20/20 or better was still significantly different between groups (54% of toric IOL patients versus 11% of spherical IOL patients, P=0.001).

For eyes with emmetropia as a target, monocular UCDVA at 6 months postoperative was (0.08±0.10)logMAR in the toric IOL group (n=56 eyes) and (0.16±0.09)logMAR in the spherical IOL group (n=54 eyes). The difference was statistically significant between groups (P<0.05). The equivalent of at least 20/40 monocular vision was equally likely in either group (100% of toric IOL eyes, 96% of spherical IOL eyes). However, the equivalent of 20/20 vision was more likely in the toric IOL group (36% of eyes) than in the spherical IOL group (4% of eyes); this difference was statistically significant at P<0.001. Monocular BCDVA was statistically similar between groups, at (0.02±0.15)logMAR in the toric IOL group and (0.02 ±0.07)logMAR in the spherical IOL group.

At 6 months after the operation, the questionnaire results indicated that all patients in both IOL groups were satisfied or very satisfied with their distance vision. These satisfaction ratings were statistically similar between groups. In contrast, the quality of uncorrected distance vision was rated 5.6±0.7 out of 6 by the toric IOL group, which was significantly

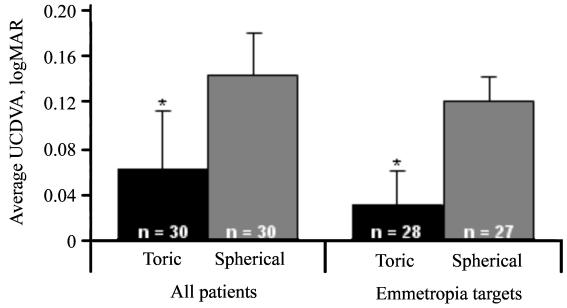

Figure 1 Average binocular uncorrected distance visual acuity (UCDVA) at 6 months after the operation Asterisks mark P<0.05 and error bars represent 95% confidence intervals (shown unidirectional for clarity)

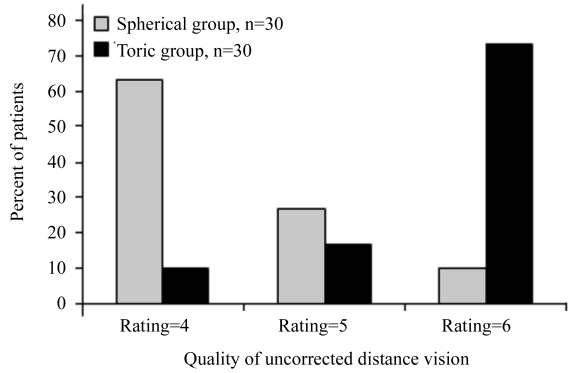

Figure 2 Postoperative patient ratings for quality of uncorrected distance vision Rating scale ranged from 0 to 6 (0=worst, 6=best). No patients rated their vision at 3 or less

better than the 4.5 ±0.7 rating given by the spherical IOL group (P<0.05). The distribution of those ratings is shown in Figure 2. Among patients with emmetropia as a target, 52% of spherical IOL patients (n=14 patients) used only distance glasses, but none of the toric IOL patients used only distance glasses. Similarly, 15% of spherical IOL patients (n=4 patients) with emmetropia as a target reported using separate pairs of spectacles for both distance and near vision, while none of the toric IOL patients did. The remainder of the emmetropia-targeted patients in both IOL groups either used glasses for near vision or did not use glasses at all. Complete spectacle independence (no glasses for either near vision or for distance vision) was equally likely between IOL groups, with 14% of toric IOL patients (n=4 patients) never using glasses and 11% of spherical IOL patients (n=3 patients) never using glasses.

DISCUSSION

The patients in this study had baseline distance vision that was very poor-even worse than the vision of patients enrolled in similar studies. Preoperative BCDVA was 0.8 logMAR in both of our study groups (standard deviations 0.3 to 0.4 units). Similar studies of patients receiving AcrySof toric IOLs reported baseline BCDVA values of (0.4 ±0.1)

logMAR[5], (0.3±0.2)logMAR[6], and the equivalent of about (0.3±0.1)logMAR[4] (converted from Snellen for comparison). For both of our study groups, the majority of eyes had against-the-rule astigmatism (62% to 63% of eyes). In contrast, a surgical center in the US assessed 806 cataract astigmatic eyes, with patient races and ages unspecified, and reported that 25% of eyes had against-the-rule astigmatism[10]. In a study of 1045 citizens of Iceland, subjects aged 60 to 80 years old (similar to our patients, aged about 70±10 years) had a prevalence of against-the-rule astigmatism ranging from <15% of eyes (aged 60 to 64 years) to 35% of eyes (age 74 to 79 years) [11]. Overall, the direction of the astigmatism of the Chinese eyes in this study seemed to be different from eyes of other ethnicities.

Despite poor preoperative vision and possibly unusual direction of corneal astigmatism, the postoperative uncorrected distance vision in the toric IOL group was very good, with monocular UCDVA for the 56 emmetropia-targeted eyes at (0.08±0.10)logMAR. This result is similar to a recent literature report of (0.11±0.15)logMAR for 20 eyes that received AcrySof toric IOL [12]. Binocular UCDVA of our 30 bilateral toric IOL patients was (0.06 ±0.14) logMAR, which compares favorably against the results of a recent study of bilateral AcrySof toric IOLs in 15 patients, who had (0.16 ±0.18)logMAR vision at 3 months postoperatively[5].

For our patients, uncorrected distance vision was significantly better in the toric IOL group than in the spherical IOL group. When targeting emmetropia, the Snellen equivalent of at least 20/20 distance vision was provided to 36% of eyes in the toric IOL group, but only 4% of eyes in the spherical IOL group. This difference is even larger than in the clinical trials, in which 38% of eyes in the toric group had 20/20 vision, compared to only 19% of eyes in the spherical IOL group [3]. Eyes in either of our study groups were equally likely to have at least 20/40 monocular distance vision (100% of toric IOL eyes, 96% of spherical IOL eyes), unlike the clinical trials, which reported 20/40 vision for 94% of toric IOL and 77% of spherical IOL patients [3]. The difference between groups in uncorrected distance vision was not only statistically significant, but also had an impact on the lifestyles of our patients. For patients with emmetropia as a target, 52% of spherical IOL patients used distance glasses, while none of the toric IOL patients did. Moreover, the patients in the toric IOL group were significantly more satisfied with the quality of their uncorrected distance vision.

From these results, we conclude that bilateral AcrySof toric IOL are a better choice than bilateral spherical IOL for the correction of aphakia secondary to the removal of cataracts in patients with corneal astigmatism.

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