

Comparative clinical outcomes of Tecnis toric IOL implantation in femtosecond laser-assisted cataract surgery and conventional phacoemulsification surgery

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Abstract

• **AIM:** To compare the short-term visual outcomes, residual refractive cylinder, and rotation stability after Tecnis toric intraocular lens (IOL) implantation during femtosecond laser-assisted cataract surgery (Femto phaco) and conventional phacoemulsification surgery (Conventional phaco).

• **METHODS:** In a prospective cohort study, Conventional phaco and Femto phaco (anterior capsulotomy and lens fragmentation by a femtosecond laser) with Tecnis toric IOL implantation were performed in 40 eyes from 36 patients and 37 eyes from 33 patients, respectively. The uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and manifest refraction were assessed during 1d, 1wk, and 1mo follow-ups. The orientation of the Tecnis Toric IOL was evaluated during 1wk and 1mo follow-ups.

• **RESULTS:** There were no significant differences in UDVA or CDVA between two groups at 1mo postoperatively, though relatively more subjects had UDVA values of 20/25 or better in Femto phaco group than in the Conventional group ($P>0.05$). A lower but not significantly lower rate of having more than 5° of IOL rotation was observed in Femto phaco group at the 1-month follow-up, while a significant lower rate of residual astigmatism of ≤ 1 D was observed in Femto phaco group.

• **CONCLUSION:** The Femto phaco group has significantly more subjects with the residual astigmatism of ≤ 1 D, but there are no significant differences in rotation stability and visual outcomes as compared with the Conventional phaco group after the application of the Tecnis toric IOL in this cohort.

• **KEYWORDS:** toric intraocular lens; femtosecond laser-assisted cataract surgery; visual outcomes; rotation stability

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INTRODUCTION

Cataract surgery has evolved into a period of refractive procedure. Advances in cataract surgery have improved patients' outcomes and expectations. Corneal astigmatism is one of the major refractive errors that decreases postoperative visual acuity and visual quality. In a study of 4540 cataractous eyes, corneal astigmatism was found to be between 0.25 and 1.25 diopters (D) in 64.4% of eyes and 1.50 D or higher in 22.2% of eyes^[1]. In a study of 4831 cataractous eyes in South China, the mean corneal astigmatism was 1.01 D; 67.7% of eyes had astigmatism of 0.25 to 1.25 D, and 27.5% had astigmatism of 1.25 D or higher^[2]. In another study in China, 29.7% had astigmatism of 1.25 D or higher^[3].

In recent years, toric intraocular lenses (IOLs) have been widely used for correcting corneal astigmatism. Numerous studies have demonstrated effective and safe clinical outcomes on the part of various toric IOL models, including the Acrysof toric IOL (Alcon Laboratories, Inc., Fort Worth, TX, USA) and the Tecnis toric IOL (Abbott Medical Optics, Inc., Santa Ana, CA, USA)^[4-7]. The main concern regarding toric IOL implantation is postoperative IOL rotation. Each degree of rotational deviation from its intended axis can result in an approximately 3.3% reduction in cylindrical power^[8]. A deviation of 30 degrees negates all potential astigmatism correction. Thus, the rotation stability of toric IOLs is critical to clinical use. An intact and well-centered capsulorhexis with a 360-degree overlap with the IOL optics helps ensure optimal centration and good stability^[9-10].

Femtosecond laser-assisted cataract surgery (Femto phaco) has increased in the past few years, and has been reported as an effective and safe technique for the surgical management

of cataract^[11]. Recent studies have demonstrated reduced ultrasound energy, reduced corneal endothelial cell loss, higher capsulorrhexis precision^[12-14], and better IOL decentration with Femto phaco as compared to Conventional phaco^[15]. In the present research project, we conducted a prospective study to investigate the effect of Femto phaco on short-term visual outcomes, residual refractive cylinder, and rotation stability after Tecnis toric IOL implantation as compared with Conventional phaco.

SUBJECTS AND METHODS

Ethical Approval After obtaining approval from the Institutional Review Board, this prospective study was conducted at the Eye Center, the Second Affiliated Hospital, School of Medicine, Zhejiang University, and it adhered to the tenets of the Declaration of Helsinki. It was registered at <http://www.clinicaltrials.gov> (identification number ChiCTR-OPS-14005285). Thirty-seven eyes from 33 patients (Femto phaco group) and 40 eyes from 36 patients (Conventional phaco group) with the implantation of the Tecnis Toric IOL were enrolled in the present study. Written informed consent was obtained from all patients after a full explanation of the study was provided.

The inclusion criteria were age >18y, decreased visual acuity due to cataract, and preoperative corneal astigmatism greater than 0.75 D. The exclusion criteria were irregular corneal astigmatism, corneal abnormality, previous corneal surgery, pupil abnormality (small pupil, fixed pupil or irregular pupil shape), pseudoexfoliation syndrome, uncontrolled glaucoma, history of uveitis, history of retinal detachment, or another ocular disease that may affect postoperative visual acuity (e.g., macular degeneration, cystoid macular edema, diabetes retinopathy, or optic atrophy). Subjects were also excluded based on intraoperative findings or complications, including zonular damage, capsulorrhexis tear, capsular rupture, vitreous loss, anterior chamber hyphema, and uncontrollable intraocular pressure.

Before cataract surgery, eligible patients were interviewed regarding their medical histories and underwent a full preoperative ophthalmic evaluation, including uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) measurements, slit-lamp examination, applanation tonometry, corneal endothelial cell count, dilated funduscopy, and ultrasonic pachymetry and biometry according to a standardized protocol. Corneal astigmatism was measured with an optical biometer (IOLmaster, Carl Zeiss, Jena, Germany) and corneal topography (Pentacam, Oculus, Rochester, NY, USA).

Surgical Techniques All surgeries were performed by the same surgeon (Yao K). According to our standard protocol, a topical non-steroid anti-inflammatory drug (NSAID,

pranoprofen, Senju Pharmaceutical Co., Osaka, Japan) was applied to patients in Femto phaco group four times one day preoperatively to maintain intraoperative pupil dilation. Pupillary dilation was achieved *via* the application of one drop of tropicamide every 15min three times before surgery.

Before pupillary dilation, horizontal markings (0° and 180°) were made under the slit lamp, with the subject seated upright to prevent cyclotorsion while in the supine position. The axis of the incisions and the axis for the placement of the IOL were marked with an angular ring. All the preoperative markings were performed by the same assistant (Lai KR).

The Femto phaco procedures involved anterior capsulotomy and lens fragmentation using a LenSx Laser System (Alcon Inc., Aliso Viejo, CA, USA). The anterior capsulotomy diameter was 5.0 mm. Manual capsulorrhexis was performed using the continuous curvilinear capsulorrhexis technique with an intended diameter of 5.0 mm. All other aspects of the surgery were standard, including phacoemulsification and lens extraction. Standard phacoemulsification was performed *via* a Stellaris system (Bausch+Lomb, Rochester, NY, USA). The widths of the primary and secondary clear corneal incisions (CCIs) were 2.0 mm and 0.8 mm, respectively.

Measurements Subjects were evaluated one day, one week, and one month postoperatively. The assessments included UDVA, CDVA, manifest refraction, and slit-lamp examination. The orientation of the Tecnis Toric IOL was evaluated at one week and one month after surgery *via* slit-lamp (Haag-Streit BQ900, Zug, Switzerland) examination with a reticle of 5-degree markings by viewing the cylinder axis of the IOL after pupillary dilation. The corneal topography was analyzed using a Pentacam (Oculus) at one month postoperatively.

Statistical Analysis Statistical analyses were performed with SPSS Version 16.0 (SPSS, Inc., Chicago, IL, USA). Differences between the groups were tested with a *t*-test or Chi-square test when appropriate. A *P*-value of less than 0.05 was considered statistically significant.

RESULTS

The results exclude subjects who discontinued treatment or were lost to follow-up (Femto phaco group, *n*=4; Conventional group, *n*=4). A total of 37 eyes from 33 patients and 40 eyes from 36 patients were included in Femto phaco and Conventional phaco groups, respectively. Patient demographics and baseline characteristics were shown in Table 1. All the subjects were Han Chinese. The mean age was 73.5±12.2y (range: 41 to 89y) in Femto phaco group and 71.2±14.0y (range: 42 to 90y) in Conventional phaco group (*P*=0.437). The proportion of female subjects was 45.9% (17/37) in Femto phaco group and 50.0% (20/40) in Conventional phaco group (*P*=0.722). Average preoperative corneal astigmatism was 1.57±0.58 D and 1.50±0.85 D in Femto phaco and

Table 1 Patient demographics and baseline characteristics

Parameter	Femto phaco group (n=37)	Conventional phaco group (n=40)	P
Age (y)	73.5±12.2	71.2±14.0	0.437
Female	45.9%	50%	0.722
Corneal astigmatism (D)	1.57±0.58	1.50±0.85	0.667
Predicted postop. residual astigmatism (D)	0.23±0.20	0.19±0.23	0.418

SD: Standard deviation; D: Diopters; Femto phaco: Femtosecond laser-assisted cataract surgery; Conventional phaco: Conventional phacoemulsification surgery.

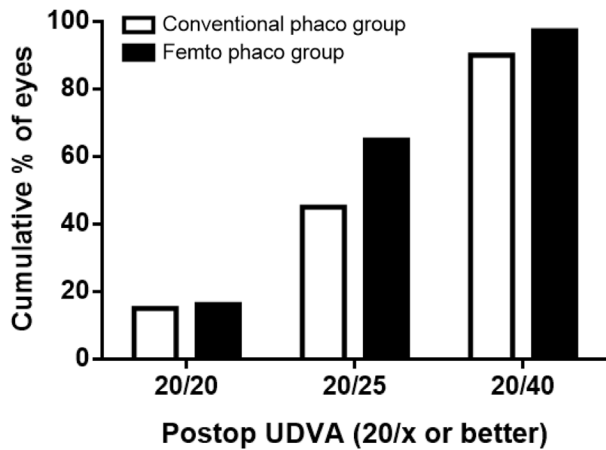


Figure 1 UDVA in both groups at 1mo postoperatively.

Conventional phaco groups, respectively ($P=0.667$). The predicted postoperative residual astigmatism was 0.23 ± 0.20 D and 0.19 ± 0.23 D in Femto and Conventional phaco groups, respectively ($P=0.418$).

There were no significant differences in UDCA and CDVA between the two groups at 1mo postoperatively. In Femto phaco group, 16.2%, 64.9%, and 97.3% of patients had UDVA values of 20/20, 20/25, and 20/40 or better, as compared with 15.0%, 45%, and 90% in Conventional phaco group, respectively ($\chi^2=0.022, 3.059, \text{ and } 1.686, P=0.883, 0.080, \text{ and } 0.194$; Figure 1). In Femto phaco group, 54.1%, 89.2%, and 100% of eyes had postoperative CDVA values of 20/20, 20/25, and 20/40 or better, as compared with 47.5%, 75%, and 95%, in Conventional phaco group, respectively ($\chi^2=0.33, 2.601, \text{ and } 1.899, P=0.566, 0.107, \text{ and } 0.168$; Figure 2).

Three eyes (8.1%) had an IOL rotation of more than 5° in Femto phaco group, as compared with six eyes (15%) in Conventional phaco group one month after surgery. However, there was no significant difference between two groups in this regard ($\chi^2=0.884, P=0.347$; Figure 3). With regard to the residual astigmatism, 23 eyes (62.2%) and 20 eyes (50%) had astigmatism of 0.50 D or less at 1mo postoperatively in Femto phaco and Conventional phaco groups, respectively ($\chi^2=1.153, P=0.283$; Figure 4). There was a significant difference between the groups regarding residual astigmatism values of 1.0 D or less [35 eyes (94.6%) in Femto phaco group vs 30 eyes (75%) in Conventional phaco group, $\chi^2=5.61, P=0.018$; Figure 4].

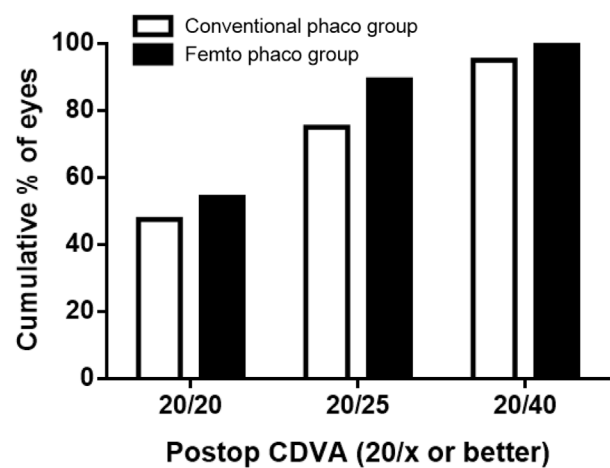


Figure 2 CDVA in both groups at 1mo postoperatively.

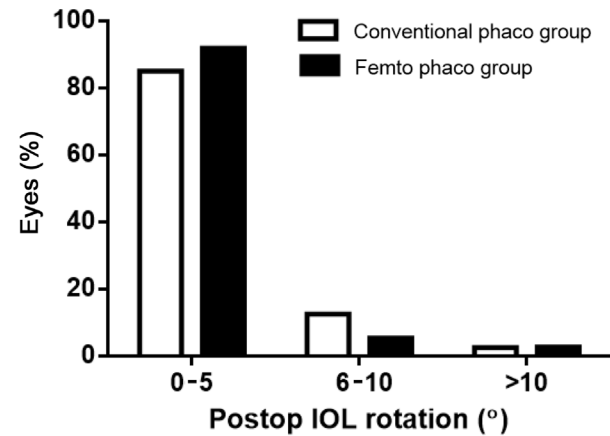


Figure 3 IOL rotation in both groups at 1mo postoperatively.

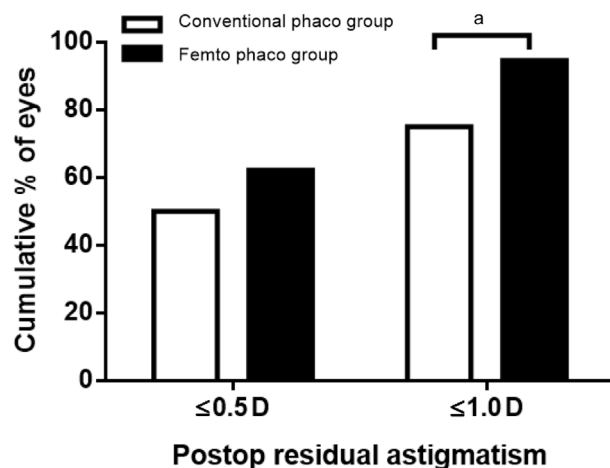


Figure 4 Residual astigmatism in both groups at 1mo postoperatively ^a $P<0.05$.

DISCUSSION

The rotation stability of the IOL in the capsule is one of the most important factors in toric IOL implantation. The misalignment of a toric IOL may increase residual astigmatism and reduce the likelihood of spectacle independence. Some earlier toric studies showed IOL rotations of more than 10° in 50% of cases and more than 30° in 20% of cases^[16]. Many advances have been made in terms of both IOL designs and surgical techniques that promote stability. After implantation, the fusion of the anterior and posterior capsules around the IOL haptics and optic border plays an important role in preventing IOL rotation. Thus, it is beneficial for the capsulorhexis to be well-centered and smaller than the diameter of the lens optic to provide 360° of overlap. The diameter of the Tecnis Toric IOL optic is 6 mm, so the intended diameter of the capsulorhexis was set to 5.0 mm. The use of a femtosecond laser can facilitate precise, well-centered circular repeatable capsulotomy^[17-18]. Manual capsulorhexis, in the hands of an experienced surgeon, provided similar results. Therefore, our study found similar rotation stability and visual outcomes in both groups. Only a significantly lower rate of residual astigmatism of more than 1 D was observed in Femto phaco group.

A previous study has shown that IOL rotation is more likely to occur in larger myopic eyes that have what subjectively appear to be large-diameter capsular bags^[19]. Therefore, in the present study, patients with very high levels of myopia were not enrolled. There were only five and four eyes with IOL spherical power values of less than 16 D, with values ranging between 10 and 13 as well as 12.5 and 15, respectively, in Femto phaco and Conventional phaco groups.

The surgically induced astigmatism (SIA) is also an important factor in the implantation of a toric IOL. The amount of SIA depends on several factors, including the size, shape, architecture, and location of the incision. Although a femtosecond laser is theoretically expected to induce lower and more stable SIA values because of the precise architecture and the resulting three-planar self-sealing incision, the clinical outcomes of previous studies have been controversial. Our team reported that the use of femtosecond laser CCIs for cataract surgery resulted in higher SIA values, and manual CCI is recommended in femtosecond laser-assisted cataract surgery^[20]. Thus, we performed manual CCIs in both groups to control this variable in the present study.

Posterior corneal astigmatism also makes some contribution to the total cornea astigmatism. Koch *et al*^[21] reported that the mean magnitude of posterior corneal astigmatism was -0.30 D and that about 9% of eyes had >0.5 D of posterior corneal astigmatism. In a study of Chinese patients, the mean posterior corneal astigmatism was 0.28 ± 0.16 D and 87.04% of eyes had <0.5 D of posterior corneal astigmatism^[22]. Most of the

posterior corneal astigmatism was against-the-rule. Posterior corneal astigmatism had a limited effect on the results in most cases, and methods of measuring it are not well-established, but the estimation of corneal astigmatism *via* Scheimpflug imaging may help in the accurate measurement of total corneal astigmatism.

The present study mainly focused on early clinical outcomes, and end point of the 1-month follow-up was selected. A previous study has shown that IOL rotations occurred within 10d postoperatively, and there were no significant IOL rotations in any cases after 1mo postoperatively^[23]. Chang reported that there were no cases in which the IOL rotated by as much as 5 degrees between the 1-day and 1-month postoperative visits^[19]. In our study, the mean rotation between the 1-week and 1-month postoperative visits was 1.33 ± 1.66 and 1.08 ± 2.34 degrees in Femto phaco and Conventional phaco groups, respectively. Furthermore, the corneal astigmatism of the 2.2 mm or 2.6 mm incision was already stabilized at 30d postoperatively^[24]. In a previous study performed by our group, we found no significant difference in SIA at 1-month and 3-month postoperative visits among patients who received a 2.0 mm manual incision (0.58 ± 0.38 vs 0.45 ± 0.35 D)^[20].

All the cases in the present study were performed by the same experienced surgeon in one medical center. Therefore, a multi-center study with surgeons having different levels of experience should be performed later. In conclusion, Femto phaco group had significantly more subjects with the residual astigmatism of ≤ 1 D but no significant differences in rotation stability and visual outcomes as compared with Conventional phaco group after the application of the Tecnis toric IOL in this cohort.

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