Original Article

One-year long-term clinical outcomes following diffractive trifocal toric intraocular lens implantation: retrospective observational case series study

Young-Sik Yoo[1,2], Dong Won Paik[1,3], Dong Hui Lim[1,4], Tae-Young Chung[1]

[1]Department of Ophthalmology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; [2]Department of Ophthalmology, College of Medicine, Uijeongbu St. Mary's Hospital, The Catholic University of Korea, Seoul, South Korea; [3]Eyeonce Eye Clinic, Seoul, South Korea; [4]Department of Medical Device Management and Research, Samsung Advanced Institute for Health Sciences and Technology, Sungkyunkwan University, Seoul, South Korea

Contributions: (I) Conception and design: DH Lim, TY Chung; (II) Administrative support: DH Lim, TY Chung; (III) Provision of study materials or patients: TY Chung; (IV) Collection and assembly of data: DW Paik; (V) Data analysis and interpretation: DW Paik; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Tae-Young Chung, MD, PhD; Dong Hui Lim, MD, PhD. Department of Ophthalmology, Samsung Medical Center, Sungkyunkwan University School of Medicine, #81 Irwon-ro, Gangnam-gu, Seoul 06351, South Korea. Email: tychung@skku.edu; donghui.lim@samsung.com.

Background: Trifocal intraocular lens (IOL) provides three foci for the external light to the eye. The reduction of corneal astigmatism makes three foci to clearly focus on the fovea. This study aimed to evaluate one-year clinical outcomes for near, intermediate, and far distance visual acuity and satisfaction in patients implanted with diffractive trifocal toric IOLs.

Methods: This retrospective observational case series study was based on the medical records of patients who undergone uncomplicated cataract surgery with implantation of a trifocal toric IOL (POD AY 26P F-T FineVision Toric; PhysIOL SA, Liège, Belgium). Eyes with corneal astigmatism greater than 1.00 diopters were included. Postoperative evaluations included uncorrected near, intermediate, and distance and corrected distance visual acuity; defocus curves; and contrast sensitivity measured at both three months and one-year postoperatively. Subjective satisfaction was evaluated based on three kinds of questionnaires for spectacle dependence, quality of vision, and overall satisfaction.

Results: Postoperative uncorrected distance visual acuity and that at 33, 43, 50, 60, and 80 cm at one-year were 0.07±0.08, 0.22±0.11, 0.17±0.11, 0.14±0.10, 0.14±0.10, and 0.15±0.10 logarithm of the minimal angle of resolution (logMAR), respectively. A smooth range of good visual acuity was found on defocus curve. Subjective scores for spectacle dependence, quality of vision, and subjective satisfaction showed no significant differences between three months and one-year postoperatively. The mean amount of IOL axis rotation was 2.14±1.72° (range: 0.2–5.1°) at one-year postoperatively.

Conclusions: Implantation of a diffractive trifocal toric IOL for cataract, presbyopia, and astigmatism correction provided good refractive and visual outcomes, relatively smooth range of intermediate vision, and high levels of visual quality and patient satisfaction until one-year after surgery.

Keywords: Multifocal intraocular lens; cataract; intraocular lens implantation

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Introduction

Multifocal intraocular lens (IOL) is becoming more commonly used as patients increasingly long for spectacle independence after cataract surgery across all ages due in part to the growing use of smartphones and tablets and the desire for convenience during outdoor activities (1,2). Among multifocal IOLs, trifocal IOLs aim to provide a broad range of spectacle independence relative to bifocal IOLs, especially at intermediate distances. Trifocal IOLs provide three foci to improve the intermediate visual acuity after cataract surgery. However, if astigmatism remains after cataract surgery with the implantation of diffractive multifocal IOLs, such could prevent visual improvement after surgery (3). This probable residual astigmatism after cataract surgery is primarily due to the presence of pre-existing corneal astigmatism (4).

Corneal astigmatism greater than 1.00 diopters (D) in eyes implanted with a diffractive multifocal IOL has been shown to impair corrected distance vision and distance-corrected near vision. (5). Therefore, to attain visual improvement after implanting multifocal IOLs, the correction of pre-existing corneal astigmatism is important for postoperative visual outcomes. Several surgical methods and considerations have been used to reduce pre-existing corneal astigmatism during cataract surgery, such as toric IOL implantation, selective positioning of the main incision, length of the main incision, limbal-relaxing incisions (LRI), and peripheral corneal-relaxing incisions (6,7). Further, the reduction of corneal astigmatism during cataract surgery can improve postoperative both visual acuity and quality of vision, especially in multifocal IOLs.

Toric IOL is a reliable way to effectively correct pre-existing corneal astigmatism in patients who need cataract surgery, providing better postoperative visual outcomes (8,9). This was the reason that led to the development of various multifocal toric IOLs. In addition, implantation of multifocal toric IOL has proven effective for good visual outcomes at near, intermediate, and far distance (10,11). However, the long-term prognosis, such as rotational stability for toric IOLs, should be evaluated for each toric IOL. Toric IOLs have the specific design of haptic, material, and surface, which are related to the rotational stability, postoperatively (12-18). Therefore, clinical studies of longer-term rotational stability of each toric IOL is needed to inform to clinician for better visual outcomes after the cataract surgery with toric IOL.

Recently, the most commonly used type of IOL for astigmatism correction has been the diffractive trifocal toric IOL, with clinical outcomes of various types of IOLs belonging to this category reported to date. Among them, we planned to analyze the FineVision Toric (POD AY 26P F-T; PhysIOL SA, Liège, Belgium), which is still difficult to find long-term clinical results related to vision or patient satisfaction on relative to other types of IOLs. Most of the papers published so far have reported clinical results up to three months after surgery and there is one paper that has commented on the progress over one-year, which focused on confirming rotation stability (19,20).

The purpose of the present study was to evaluate the one-year long-term clinical outcomes in terms of visual acuity, refraction, contrast sensitivity, visual quality, and satisfaction in patients who underwent cataract surgery with a diffractive trifocal toric IOL. We present the following article in accordance with the STROBE reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-1007/rc).

Methods

Subjects

This retrospective observational case series study was based on the medical records of patients who undergone uncomplicated cataract surgery with implantation of a diffractive trifocal toric IOL (POD AY 26P F-T FineVision Toric; PhysIOL SA, Liège, Belgium). The inclusion criteria were patients with senile cataract with corneal astigmatism of more than 1.0 D with the potential for surgically induced astigmatism (SIA) (0.5 D with temporal incision) and the desire to take off glasses at all distances. Exclusion criteria were age younger than 21 years old, previous history of ocular surgery, trauma, and pre-existing ocular disease other than cataract. This study was approved by the institutional review board of Samsung Medical Center (IRB#2016-11-106) and followed the tenets of the Declaration of Helsinki (as revised in 2013). The individual consent for this retrospective study was waived.

The implanted IOLs were all diffractive trifocal toric IOLs (POD AY 26P F-T; PhysIOL SA, Liège, Belgium). This device makes use of the same multifocal principles as the diffractive trifocal IOL (PhysIOL®; FineVision, PhysIOL, Liège, Belgium) and the same toric principles as the Ankoris IOL (PhysIOL, Liège, Belgium). The FineVision Toric IOL is a diffractive trifocal IOL that provides a combination of near vision at 3.5 D and

intermediate vision at 1.75 D. It is a hydrophilic aspheric toric IOL that uses double-C loop quadripode haptics for stabilization and has an unpolished surface and diffractive rings on its anterior surface. Toric IOL calculations were performed using the standard calculation for the PhysIOL lenses (https://www.physioltoric.eu).

The intraocular lens power closest to emmetropia was selected from SRK/T, Haigis, or Hoffer Q formulas based on axial length, corneal curvature, and anterior chamber depth as measured by IOL Master version 5.4 (Carl Zeiss Meditec, Jena, Germany).

Surgical technique

All surgical procedures were performed using a standardized, suture-free phacoemulsification technique, with a 2.75 mm clear corneal incision in the temporal region under topical anesthesia by one experienced surgeon (TYC). Postoperative gatifloxacin eye drops (Gatiflo®; Handok, Seoul, Korea) and fluorometholone 0.1% eye drops (Flumetholon®; Santen, Seoul, Korea) were administered four times per day for one month.

Patient evaluation

Prior to surgery, all patients underwent ocular examinations including slit-lamp microscopy, corrected and uncorrected visual acuity, manifest refraction, and retina assessment. The patients were evaluated postoperatively after one day, one week, one month, three months, and one-year. At three months and one-year after the surgery, the corrected and uncorrected visual acuity, manifest refraction, defocus curve, and subjective satisfaction were determined. Contrast sensitivity was evaluated at one-year postoperatively.

All patients underwent measurements of corrected and uncorrected distance visual acuity (CDVA and UDVA) at 5 m. Uncorrected intermediate visual acuity was measured at 60 and 80 cm, while uncorrected near visual acuity was measured at 33, 43, and 50 cm using the Snellen chart. Defocus curves were plotted by measuring the visual acuity under photopic conditions at 5 m and when adding lenses in 0.5-D increments from –4.0 to +2.0 D.

Contrast sensitivity was measured at 3, 6, 12, and 18 cycles per degree using a CSV-1000 chart (Vector Vision, Greenville, OH, USA) under photopic (85 cd/m^2) and mesopic (~3 cd/m^2) conditions at one-year after surgery. The results were converted to logarithmic units for statistical analysis using a specific table designed for the CSV-1000 (21).

For the evaluation of the five visual artifacts (i.e., glare, halos, starburst, hazy vision, and blurred vision), at three months and one-year after the surgery, patients were shown images and asked to rate the frequency, degree, and discomfort associated with the visual artifacts as 0= none, 1= minimal, 2= moderate, or 3= severe. From this, the mean score for the five visual artifacts were calculated, respectively. Artifact images and a questionnaire modified from the Quality of Vision questionnaire were adopted in the present study (22). Satisfaction with near, intermediate, and distance vision and spectacle dependence were evaluated using a questionnaire. The satisfaction with vision for each distance was rated on one of five scales (very satisfied, satisfied, neither satisfied nor unsatisfied, unsatisfied, or very unsatisfied).

Images of the IOL were captured through a maximally dilated pupil immediately after surgery and after three months and one-year using a digital slit-lamp biomicroscope. The axis of the toric IOL was calculated with the ImageJ software (National Institutes of Health, Bethesda, MD, USA). The slit lamp images were opened using the ImageJ software and the rotation degree was measured using the marks with the features in the application.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences version 18.0 (IBM Corp., Armonk, NY, USA) with the level of statistical significance set at $P<0.05$ which was two-sided. Shapiro-Wilk test was performed to assess the normality of variables. Most data were analyzed with descriptive statistics and presented as means ± standard deviations. The measured decimal visual acuities were converted to logarithm of the minimal angle of resolution (logMAR) for statistical analysis. When parametric analysis was possible, Student's t-test of paired data were performed for all parameter comparisons between pre- and post-operative examinations. If the variables did not follow a normal distribution, the Wilcoxon rank-sum test was applied to assess the significance of differences between preoperative and postoperative examinations.

Results

Those patients who finished the one-year long-term follow-up were included in the analysis (32 eyes of 32 patients).

Table 1 Preoperative patient demographics

Demographics	Mean ± SD	Range
Patients [eyes]	32 [32]	
Age (years)	57.63±7.57	42–73
Sex (M:F)	8:24	
Refractive Sph (D)	−1.91±3.67	−10.50–3.00
Refractive Cyl (D)	−0.87±0.63	−2.50–0.00
Spherical equivalent (D)	−2.35±3.67	−11.00–2.50
Corneal astigmatism (D)	1.16±0.38	0.56–1.91
Corneal astigmatism + SIA (D)	1.45±0.41	0.62–2.23
UCVA (logMAR)	0.62±0.49	0.00–2.00
BCVA (logMAR)	0.23±0.26	0.00–1.30
Anterior chamber depth (mm)	3.32±0.37	2.53–3.71
Axial length (mm)	24.56±1.75	22.34–26.41

SD, standard deviation; Sph, sphere diopter; Cyl, cylinder diopter; D, diopter; SIA, surgical-induced astigmatism; UCVA, uncorrected visual acuity; BCVA, best-corrected visual acuity; logMAR, logarithm of the minimal angle of resolution.

The mean age of the patients at the time of surgery was 57.63±7.57 years and there were eight males and 24 females (*Table 1*).

Postoperative refractive outcomes including sphere D (Sph), cylinder D (Cyl), and spherical equivalent (SE) all improved significantly at both three months and one-year. Postoperative visual acuities at distance, intermediate, and near also improved significantly at both three months and one-year. Although the findings were not statistically significant, visual acuities showed better vision results over time at near and intermediate (*Figure 1*).

Figure 2 presents the cumulative distribution of the postoperative refractive cylinder. At three months after surgery, 86.84% of eyes showed residual refractive cylinder of 0.50 D or less, while 87.50% of eyes showed the same at one-year (*Figure 2*). While not shown, the mean residual refractive cylinder values at three months

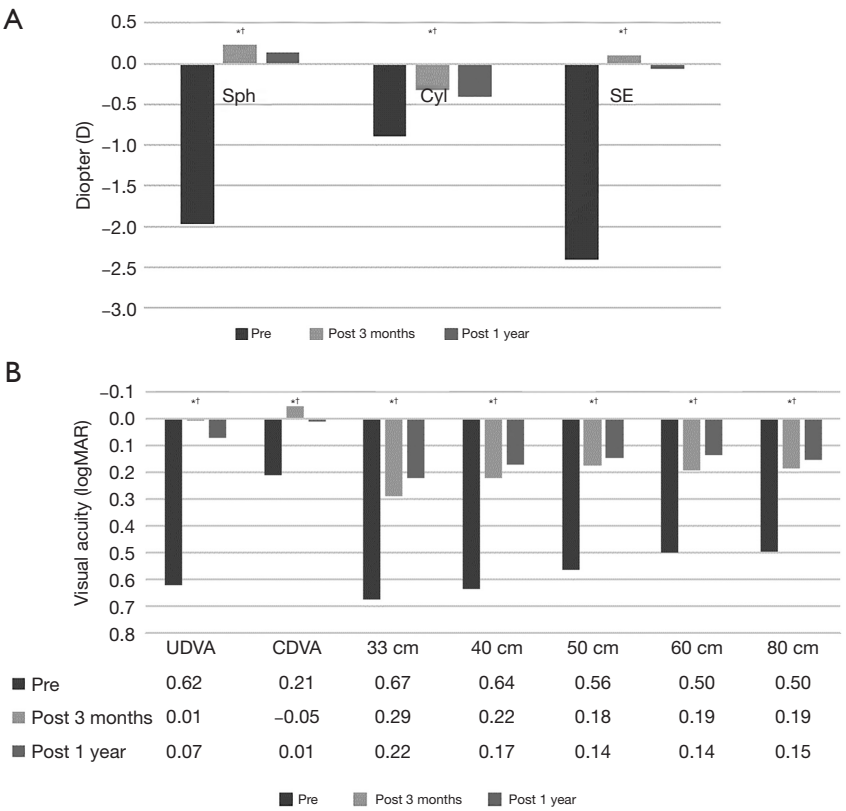

Figure 1 Refractive outcomes (A) and visual acuities (B) at three months and one-year postoperatively. *, pre-operation *vs.* three months post-operation; †, pre-operation *vs.* one-year post-operation. Sph, sphere diopter; cyl, cylinder diopter; pre, preoperative; post, postoperative; SE, spherical equivalent; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; logMAR, logarithm of the minimal angle of resolution.

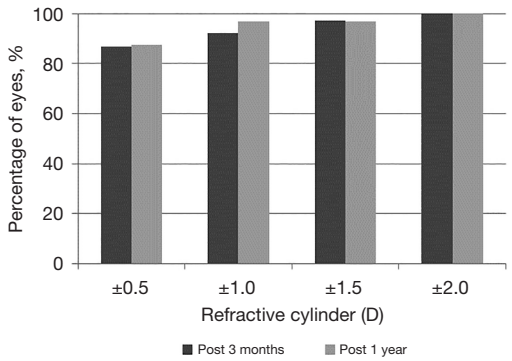

Figure 2 Distribution of postoperative refractive cylinder. D, diopters; post, postoperative.

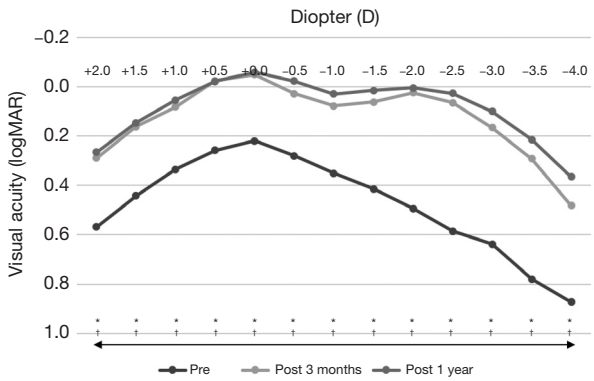

Figure 3 Monocular defocus curve at three months and one-year postoperatively. *, pre-operation *vs.* three months post-operation; †, pre-operation *vs.* one-year post-operation; ↔, postoperative improvement was statistically significant across the whole range (+2.0 to −4.0 D) of the defocus curve. Pre, preoperative; post, postoperative; logMAR, logarithm of the minimal angle of resolution.

and one-year were −0.32±0.42 D and −0.41±0.44 D, respectively (P=0.39).

In the defocus curve tests, the postoperative defocus curve was improved significantly at both three months and one-year across the whole range (+2.0 to −4.0 D). The trend demonstrated slightly improved results at one-year relative to three months (*Figure 3*).

Most of the results presented normal values under the photopic and mesopic conditions during the contrast sensitivity test at one-year. Also, postoperative one-year values showed relatively better outcomes regarding contrast sensitivity than the preoperative values recorded under photopic conditions, especially at the spatial frequency of 12 and 18 cycles per degree (cpd) (P=0.008 and P=0.006), while there were no differences under the mesopic conditions (*Figure 4*).

Evaluation of spectacle dependence, quality of vision (visual artifacts), and subjective satisfaction using the questionnaire revealed that there were no significant differences in any questionnaire results between three months and one-year postoperatively. However, the trend showed mostly better results at one-year relative to three months (*Figure 5*).

The mean amounts of IOL axis rotation measured by the ImageJ software at three months and one-year were 1.01±1.15° and 2.14±1.72°. The mean difference between one-year and three months was 1.17±1.04° (range: 0.1–3.0°).

Discussion

Diffractive trifocal toric intraocular lens implantation for the correction of cataract, presbyopia and astigmatism

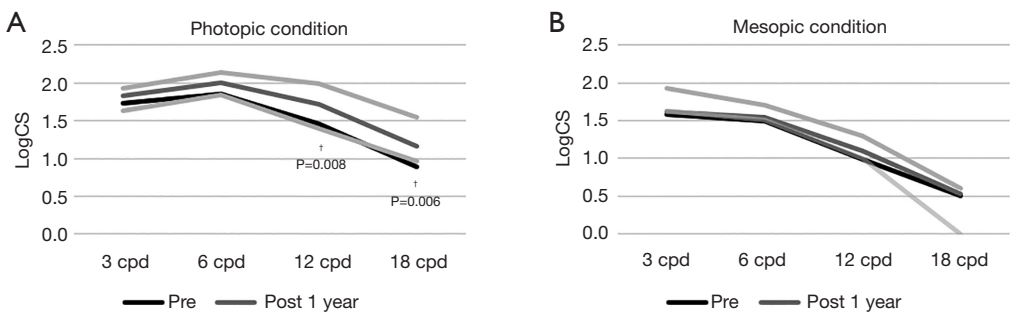

Figure 4 Contrast sensitivity on (A) photopic and (B) mesopic condition at one-year postoperatively. †, pre-operation *vs.* one-year post-operation. The lightest gray lines above and below represent the normal value range. CS, contrast sensitivity; cpd, cycles per degree; pre, preoperative; post, postoperative.

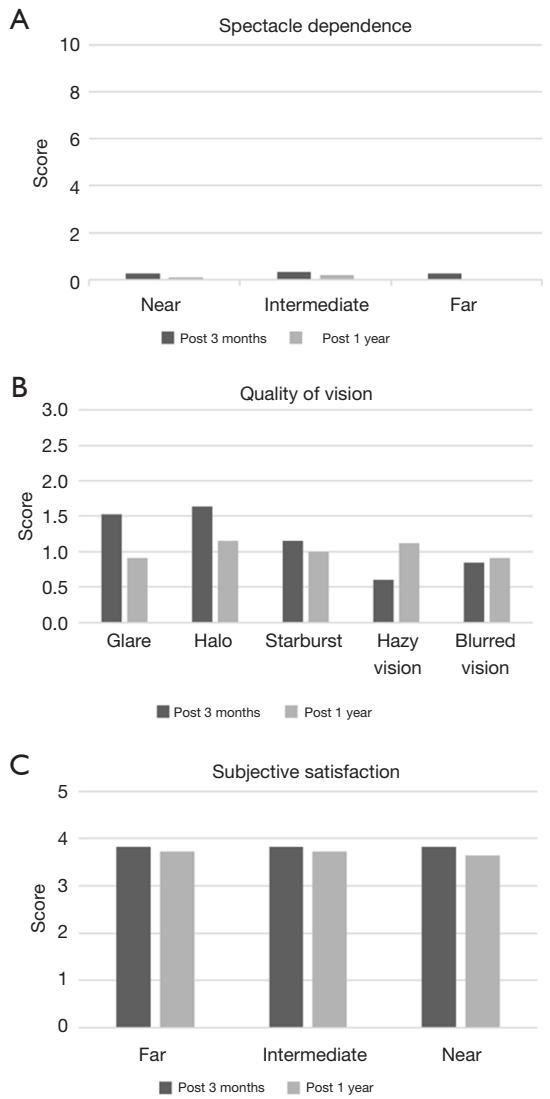

Figure 5 Postoperative questionnaire for (A) spectacle dependence, (B) quality of vision, and (C) subjective satisfaction at three months and one-year. Spectacle dependence score scale: 0–10 points (0= none; N = N out of 10; 10= always). Quality of vision score scale: 0–3 points (0= none; 1= mild; 2= moderate; 3= severe). Subjective satisfaction score scale: 1–5 points (1= very unsatisfied; 2= unsatisfied; 3= neither satisfied nor dissatisfied; 4= satisfied; 5= very satisfied). Post, postoperative.

showed good visual outcomes including relatively smooth range of intermediate visual acuity, and subjective satisfaction for up to one-year postoperatively in the present study.

Previously published studies have evaluated visual outcomes after the implantation of the same IOL as used in our study at three months, reporting a mean postoperative monocular UDVA of 0.05±0.08 logMAR and mean monocular CDVA of 0.02±0.03 logMAR. Meanwhile, monocular visual acuity at 80 cm, 63 cm, and 40 cm were 0.12±0.09, 0.08±0.14, and 0.17±0.09 logMAR (19). Elsewhere, Gundersen *et al.* reported a mean postoperative UDVA of 0.03±–0.10 logMAR and CDVA of –0.01±–0.06 logMAR at three months postoperatively (23). These findings are similar to those in our study at three months, which revealed a mean UDVA of 0.01±0.14 logMAR and CDVA of –0.05±0.11 logMAR. As mentioned above, Poyales *et al.* reported similar UDVA and CDVA outcomes as compared with our results but better intermediate and near visual acuities than our findings at three months (19). The differences in test methods and language characteristics may contribute to variance in results (24,25).

To our knowledge, this is the first study to evaluate the one-year long-term clinical outcomes and quality of vision outcomes of the new diffractive trifocal toric IOL. Most of the recently published papers evaluated the period only up to three months after surgery (19,23) and one paper that assessed the progress over one-year focused mainly on confirming rotation stability. In this prior paper, regarding visual outcomes, only the postoperative UDVA and refractive cylinder were reported (20). The authors reported a UDVA of 0.13±0.09 logMAR at one-year after implantation and this was similar to our result of 0.07±0.08 logMAR at one-year. However, in our study, visual outcomes were further subdivided and analyzed, and stable visual acuity was shown in relation to near, intermediate, and distance results up to the first year. Also, looking at the results of the first year, it was noted that the visual outcome and defocus curve findings were all improved and maintained better than at the third month. In addition, both the contrast sensitivity test and the patient satisfaction survey, which were analyzed to check the quality of life outcomes, showed a steady improvement until the first year and remained stable.

Compared with other type of multifocal diffractive toric IOLs, the visual outcomes were similar or better than those reported in other studies (26-28). A 12-month prospective multicenter study by Piovella *et al.* following implantation of the AT LISA tri toric 939MP IOL (Carl Zeiss Meditec, Jena, Germany) reported almost similar results for near, intermediate, and distance visual acuities as compared with ours. Also, the shape of the defocus curve seems similar between our study and theirs as well; however, our contrast sensitivity test results were slightly better (29).

In our study, postoperative IOL rotation was 1.01±1.15° after three months and 2.14±1.72° after one-year. This was better than the 12-month rotational stability result (2.55±2.62°) reported by Kristof.20 Kristof also reported that 64.9% of patients achieved a refractive cylinder of 0.50 D or less at 12 months, while 81.1% did so at six months. There were no big differences in comparison with our results, where 86.84% of patients achieved a refractive cylinder of 0.50 D or below at three months and 87.50% did so at one-year. Maybe the small difference in the first-year results is that, unlike in our study, this prior investigation included eyes with comorbidities such as pseudoexfoliation syndrome. It is believed that the persistence of the stable results of our IOL is due to the double-C loop quadripode haptics of the IOLs and their unpolished surface with anterior diffractive rings. So, the structural characteristics of these lenses might have had a positive effect on IOL centration and rotation stability and are thought to be the source of the stable long-term visual acuity and patient satisfaction.

In conclusion, this is the study to evaluate visual outcomes and patient satisfaction for diffractive trifocal toric IOL implantation during a long-term period. The clinical outcomes at one-year were mostly improved relative to at three months, including considering near, intermediate, and distance visual acuity; defocus curve; spectacle dependence; and visual quality as assessed by questionnaire. Although our results showed that patients' satisfaction slightly decreased over time, all other clinical outcomes presented stable and improving results until one-year. Around one-year after cataract surgery, vision can sometimes be lost due to complications such as posterior capsule opacity, IOL decentration, and macula edema. However, no special issues occurred during the observation period of about one-year in this study. The results of this study and the one-year follow-up period do not reflect all possibilities, but we do not doubt the effectiveness of this IOL. So, in clinical practice, the choice of this diffractive trifocal toric IOL in multifocal IOL surgery with astigmatism is expected to be a very safe one in the long run, even when compared with other IOLs.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-1007/rc

Data Sharing Statement: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-1007/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-1007/coif). TYC reports that this work was supported by a grant from a National Research Foundation of Korea funded by the Ministry of Education, Republic of Korea (NRF-2020R1A2C2014139; Seoul, Korea), which had no role in this study. DHL reports that this work was supported by a grant from the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI) funded by the Ministry of Health & Welfare, Republic of Korea (HC19C0142), which had no role in this study. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy of integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional board of Human Studies at Samsung Medical Center (IRB #2016-11-106) and individual consent for the retrospective analysis was waived.

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