

Visual Function After Implantation of Trifocal and Trifocal Toric Intraocular Lenses Using Intraoperative Aberrometry

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Purpose: To evaluate patient outcomes and visual function following trifocal and trifocal toric intraocular lens (IOL) implantation using intraoperative aberrometry at a single site in the US.

Methods: This prospective, single arm study included 21 subjects that completed 3 month follow-up. Inclusion criteria were visually significant cataract and potential post-operative visual acuity of 20/25 or better. Endpoints included postoperative prediction error, refractive outcomes, uncorrected visual acuities at distance (UDVA), intermediate (UIVA), and near (UNVA), contrast sensitivity, and subject responses on the modified Visual Function Quality of Life Questionnaire (VF-14 QOL).

Results: Binocular UDVA, UIVA, and UNVA were 20/25 or better in 100% (21/21), 100% (21/21), 90% (19/21) of subjects. The absolute prediction error was 0.50 D or less in 79% (33/42) of eyes, and 81% (34/42) and 86% (36/42) of eyes achieved ≤ 0.5 D of residual astigmatism and manifest refraction spherical equivalent, respectively. On the modified VF-14 QOL, driving at night, reading small print, and reading a newspaper or book were the tasks that had the lowest percentages of subjects reporting no difficulty or a little difficulty.

Conclusion: Implantation with trifocal and trifocal toric IOLs using intraoperative aberrometry can provide high refractive precision, leading to excellent visual performance and low visual task difficulty at all ranges (distance, intermediate, and near).

Plain Language Summary: An intraocular lens (IOL) is a clear artificial lens that can be used to replace the natural lens in the eye when the natural lens becomes opaque (develops a cataract). Monofocal IOLs are designed to provide good vision to see distant objects; however, spectacles may still be needed to see objects clearly up close (such as reading a book or using a digital device). Trifocal IOLs are designed to provide good vision to see objects at distance and up close, however, the power of the IOL must be accurately determined for the best visual outcomes.

Devices called biometers are used by cataract surgeons to measure the eye and determine the most appropriate lens power to implant. Most biometers are used prior to surgery, however one type, intraoperative aberrometry (IA), can be used during surgery to measure the eye and determine the most appropriate lens power. The purpose of this study was to evaluate patient outcomes and visual function following trifocal IOL implantation using IA. The results of this study suggest that implantation with trifocal IOLs using IA can provide high refractive accuracy and excellent visual outcomes.

Keywords: trifocal IOL, PanOptix, cataract surgery, intraoperative aberrometry

Introduction

Cataract surgery patients—and surgeons—have high expectation of good clinical outcomes following intraocular lens (IOL) implantation. Postoperative visual outcomes are heavily reliant on achieving the postoperative target refraction especially for trifocal and other advanced technology lenses. Recent studies estimate that 73–80% of eyes are within 0.5 D of target refraction following cataract surgery with modern day biometry and formulas.^{1,2}

Trifocal IOLs are designed to split incoming light and redirect the light into 3 distinct foci, to achieve good visual outcomes at distance intermediate, and near. The first trifocal IOL that was approved by the US FDA was the AcrySof PanOptix IOL (Alcon Vision, LLC). With the PanOptix lens, 50% of incoming light is distributed for distance vision, 25% intermediate, and 25% for near vision.³ The PanOptix lens has been reported to provide good visual outcomes.⁴⁻⁶ However, as with other multifocal or presbyopia correcting IOLs, visual disturbances have been reported.⁷⁻¹⁰

As lens technology advances, so do patient expectations for excellent refractive outcomes after cataract surgery. The goal of the modern day surgeon is to improve the percentage of eyes within targeted refraction and thereby improve patient satisfaction and decreased dependence on glasses and contact lenses after surgery. Biometry with advanced lens formulas have proven effective at improving our lens calculations, however refractive surprises still exist, especially for more complex eyes like extremes of axial length. It is especially crucial for optimal performance of trifocal lenses to achieve the postoperative target refraction due to their complex optics. Missing the refractive target may significantly impact patient postoperative visual function and satisfaction. Intraoperative aberrometry (IA) is a tool that allows precise measurements of aphakic and pseudophakic eyes during cataract surgery. Using IA in aphakic eyes can allow for IOL power determination.¹¹ Using IA in pseudophakic eyes can assist in determining if any adjustments to the lens position are needed and is especially helpful in toric IOLs.¹⁰ The only currently approved IA device is the ORA system (Alcon Vision, LLC). The use of ORA has been reported to improve refractive outcomes compared to preoperative calculations alone.¹²⁻¹⁵ Though there have been reports of no differences in prediction error between ORA and preoperative planning.^{16,17}

Many reports of outcomes with IA have focused on toric IOLs.^{13,18,19} With the increasing popularity of multifocal IOLs, it is important to understand the predictive accuracy and refractive outcomes with IA in this patient cohort. There have been a few reports on refractive outcomes with intraoperative aberrometry and trifocal IOLs outside the US,^{12,20,21} however, there is little data regarding outcomes within the US. In addition, many of the published OUS studies were retrospective. The purpose of this study is to prospectively evaluate patient outcomes and visual function following trifocal IOL implantation using intraoperative aberrometry at a single site in the US.

Methods

This was a single arm, prospective study of visual function following bilateral cataract surgery and implantation with a trifocal IOL. This study was reviewed and approved by an institutional review board (IRB, Weill Cornell Medicine). Subjects gave written informed consent before participation in the study. This study was conducted in compliance with Good Clinical Practice (GCP), International Harmonization (ICH) guidelines, and the tenets of the Declaration of Helsinki. This study was registered on clinicaltrials.gov (NCT04196569). Data are not available for sharing.

Subjects were included if they had visually significant cataract and potential post-operative visual acuity of 20/25 or better. Exclusion criteria were irregular astigmatism, prior corneal refractive surgery, or ocular pathology contraindicated for trifocal IOLs (including but not limited to diabetic retinopathy, age-related macular degeneration or other macular pathology, cornea guttata, corneal scarring, corneal ectasia, glaucoma with visual field loss).

Preoperative biometry measurements were obtained using Veracity and IOL Master 700 (Carl Zeiss Medica) with Barrett Total Keratometry Formula to determine IOL power. One experienced surgeon performed all surgeries (AB). The dispersive viscoelastic was removed from the eye, and cohesive viscoelastic was instilled in a uniform manner. Intraocular pressure was measured with the Ocular Kasaby Barraquer Tonometer to validate fill. All patients were offered options for Femtosecond Laser Assisted Cataract Surgery (FLACS) and manual cataract surgery. If they opted for FLACS, capsulotomy, lens fragmentation, and limbal relaxing incision (if required) were performed using a LenSx femtosecond laser (Alcon Vision, LLC). The VERION System was used for image-guided digital tracking. The ORA System with Verifeye+ (Alcon Vision, LLC) was used intraoperatively to determine IOL power, cylinder power, and final axis of placement. Where the powers suggested by preoperative biometry and intraoperative aberrometry differed, the power suggested by intraoperative aberrometry was selected. AcrySof IQ PanOptix non-toric and toric IOL models, were implanted (TFAT00, TFAT30, TFAT40; Alcon Vision, LLC). The postoperative regimen was the surgeon's preferred standard of care.

Study endpoints included the distribution of residual refractive error at 3 months postoperative, uncorrected visual acuities at distance (UDVA; 4m), intermediate (UIVA; 60cm), and near (UNVA; 40cm) at 1 and 3 months postoperative,

contrast sensitivity testing at 1 and 3 months postoperative, and subject responses on the modified Visual Function Quality of Life Questionnaire (VF-14 QOL) at 1 and 3 months postoperative.²² Contrast sensitivity was measured using a scale from 100% to 0.8% with 100% being highest contrast and 0.8% being lowest contrast. Subjects were shown 2 letters at the 20/100 line for each contrast level and worked down the scale until they reached the lowest contrast that they could see.

This study was intended to be descriptive, thus there was no a priori sample size calculation. However, it is worth noting that sample sizes of 20 to 30 have been successfully used to characterize the performance of trifocal IOLs.^{4,20} The target sample size for this study was 25 subjects. Statistical analyses were performed using the software program R (version 4.2.2; The R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 25 subjects (50 eyes) were enrolled in this study. Three patients did not complete study due to COVID restrictions at the time. One subject did not complete the Month 3 visit as they were lost to follow up. The preoperative and patient demographics are summarized in Table 1. There were no adverse events related to the IOL or surgery.

The postoperative refractive outcomes are summarized in Table 2. Refractive outcomes were excellent, with 81% (34/42) and 86% (36/42) of eyes achieving ≤ 0.5 D of residual astigmatism and manifest refraction spherical equivalent, respectively. In addition, 79% (33/42) of eyes had ≤ 0.5 D of absolute prediction error using IA. The powers suggested by IA and preoperative planning were different in 24% (10/42) of eyes. All suggested power differences were within 0.5 D. Mean axial length in the cases where the powers differed was 25.61 ± 1.12 mm compared to 24.60 ± 1.92 mm in the cases where the suggested powers were the same. The differences in mean axial lengths between these cases was statistically significant using the Welch two sample *t*-test ($p = 0.048$).

Table 1 Preoperative Patient Demographics

Parameter	Outcomes*
Number of eyes (patients)	44 (22)
Sex	
Female (n)	16 (73)
Male (n)	6 (27)
Age	65.5 ± 9.6 (39 to 83)
Axial Length (mm)	24.84 ± 1.80 (22.16 to 28.83)
Sphere (D)	-3.04 ± 5.21 (-13.25 to +5.25)
Cylinder (D)	-1.08 ± 0.74 (-2.75 to 0.00)
MRSE (D)	-3.58 ± 5.23 (-13.88 to +5.25)
Lens Model (n)	
TFAT00	32 (73)
TFAT30	9 (20)
TFAT40	3 (7)

Note: *Presented as Mean \pm SD (Range) or n (%).

Abbreviations: D, diopters; MRSE, manifest refraction spherical equivalent; SD, standard deviation.

Table 2 Postoperative Refractive Outcomes (n = 42 Eyes)

Parameter	Mean \pm SD (Range)	% Eyes ≤ 0.5 D
MRSE (D)	0.10 ± 0.32 (-0.62 to 1.12)	85.7
Residual Astigmatism (D)	0.32 ± 0.36 (0.00 to 1.25)	81.0
Absolute Prediction Error for IA (D)	0.28 ± 0.27 (0.00 to 1.23)	78.6

Abbreviations: D, diopters; IA, intraoperative aberrometry; MRSE, manifest refraction spherical equivalent; SD, standard deviation.

Monocular and binocular visual acuities are summarized in Table 3 and Figure 1. Monocular visual acuities at postoperative month 3 were generally higher than at postoperative month 1, with 93% (39/42), 100% (42/42), 98% (41/42) of eyes 20/32 or better at distance, intermediate, and near. Binocular visual acuities at postoperative month 3 were also generally higher than at postoperative month 1, with 100% (21/21), 100% (21/21), 90% (19/21) of patients 20/25 or better at distance, intermediate, and near.

Table 4 summarizes the percentage of subjects reporting “No Difficulty” or “A Little Difficulty” on the Visual Function Quality of Life Questionnaire. Visual tasks are grouped by distance, intermediate, and near in Table 4. Difficulty for distance visual tasks was low, with greater than 80% of subjects reporting none or little difficulty at postoperative months 1 and 3 for all tasks, with the exception of the task Driving at night. Difficulty for intermediate visual tasks was also low, with greater than 85% of subjects reporting none or little difficulty at postoperative months 1 and 3 for all tasks. Difficulty was higher for near tasks, compared to intermediate and distance tasks. However, difficulty was still acceptable with 75% or more subjects reporting none or little difficulty at postoperative month 3 for all tasks.

Table 5 summarizes the postoperative month 1 and 3 monocular and binocular contrast sensitivity. Contrast sensitivity was good, with all patients able to see at 4% contrast. As expected, binocular contrast sensitivity was higher than monocular contrast sensitivity. The differences between postoperative months 1 and 3 were minor.

Discussion

Good refractive outcomes following cataract surgery and IOL implantation are crucial for good visual outcomes. In this study, we evaluated the refractive outcomes, visual outcomes, and visual function of subjects who had IA performed intraoperatively and received a trifocal IOL bilaterally. In general, the results of our study suggest that clinical outcomes are excellent using IA and trifocal IOLs.

The prediction error with IA and trifocal implantation was good, with 79% of eyes within ± 0.5 D of the predicted refraction. Ma et al²⁰ observed similar results to ours, with 82% of eyes within ± 0.5 D of the predicted refraction using IA with trifocal implantation. Blaylock and Hall¹² reported $APE \leq 0.5$ D in 88% of eyes using IA with trifocal

Table 3 Postoperative Visual Outcomes

Monocular			
Visual Acuity	Month	n	Mean \pm SD (Range) logMAR
UDVA	1	44	0.06 \pm 0.11 Range (-0.10 to 0.40)
	3	42	0.04 \pm 0.08 Range (-0.16 to 0.22)
UIVA	1	44	0.04 \pm 0.06 Range (0.00 to 0.18)
	3	42	0.03 \pm 0.05 Range (0.00 to 0.18)
UNVA	1	44	0.02 \pm 0.05 Range (0.00 to 0.26)
	3	42	0.01 \pm 0.02 Range (0.00 to 0.14)
Binocular			
Visual Acuity	Month	n	Mean \pm SD (Range) logMAR
UDVA	1	14	0.02 \pm 0.05 Range (-0.10 to 0.10)
	3	21	0.01 \pm 0.06 Range (-0.12 to 0.10)
UIVA	1	14	0.01 \pm 0.03 Range (0.00 to 0.10)
	3	21	0.01 \pm 0.02 Range (0.00 to 0.00)
UNVA	1	14	0.00 \pm 0.00 Range (0.00 to 0.00)
	3	21	0.04 \pm 0.12 Range (0.00 to 0.40)

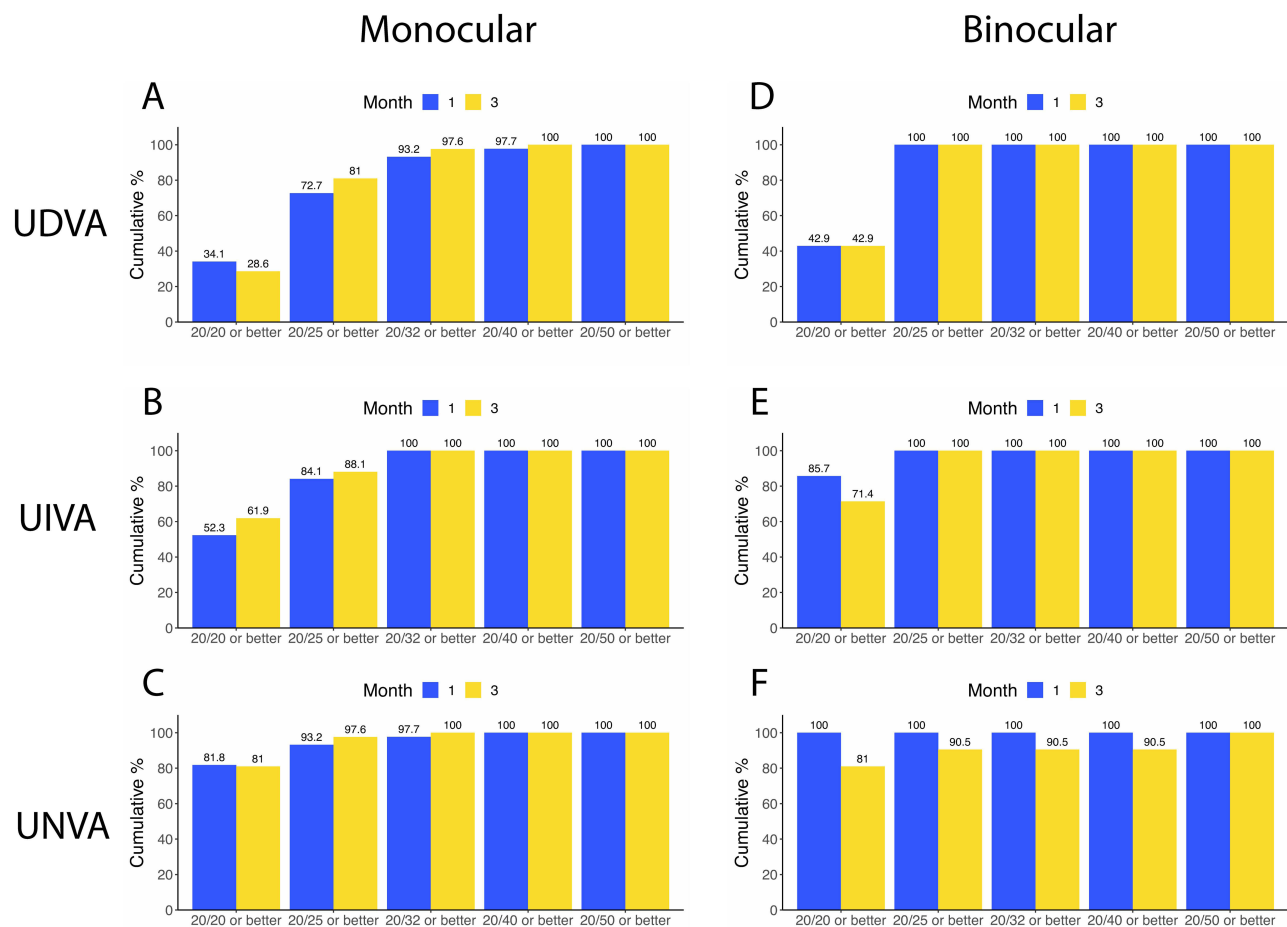


Figure 1 Monocular uncorrected visual acuities at (A) Distance, (B) Intermediate, and (C) Near and binocular uncorrected visual acuities at (D) Distance, (E) Intermediate, and (F) Near.

implantation, higher than our study. In addition, Watanabe²¹ observed ≤ 0.5 D in 93% of eyes (after optimization) using IA with trifocal implantation. Differences between our study and previous reports of IA with trifocals^{12,20,21} may be explained by the lower sample size in our study, the retrospective design of the other studies, or patient populations.

The manifest refraction spherical equivalent (MRSE) ≤ 0.5 D was achieved in 86% of study eyes. This is a similar result to the United States Food and Drug Administration trial,²³ which reported MRSE ≤ 0.5 D was achieved in 84% of study eyes with the PanOptix (non-toric only). Scheepers et al²⁴ observed that MRSE ≤ 0.5 D was achieved in 84% of study eyes with the PanOptix. In a retrospective study, Carreno et al²⁵ reported MRSE ≤ 0.5 D in 96% of study eyes using the PanOptix. In another retrospective study, Lawless et al²⁶ observed MRSE ≤ 0.5 D in 100% of study eyes with the PanOptix. Differences between our study and previous reports of the PanOptix may be explained by the lower sample size in our study or patient populations. Based on the results of our study and previous reports, it appears that implantation of a trifocal using IA can result in excellent refractive outcomes.

Visual outcomes were excellent in our study, with binocular UDVA, UIVA, and UNVA 20/25 or better in 100%, 100%, 90% of patients. Kohnen et al,⁵ reported on the visual outcomes from 547 bilaterally implanted patients with the TFNT00 IOL, with binocular UDVA, UIVA, and UNVA 20/25 or better in 92%, 87%, 88% of patients, similar to our study. Other studies have also reported good visual outcomes with the PanOptix trifocal IOL at distance, intermediate and near.^{4,6,10,12,23,24} The results of our study and other suggest that the PanOptix trifocal IOL using IA can provide good visual outcomes.

Visual function and quality of life were evaluated using a questionnaire. We used the modified VF-14 QOL questionnaire reported by Akman et al.²² In their study, the authors observed generally low patient report difficulty

Table 4 Postoperative Task “No Difficulty” or “A Little Difficulty” (Percentage of Subjects)

	Month 1 (n=20)	Month 3 (n=21)
Distance Visual Task		
Seeing steps, stairs, or curbs	94.4	85.7
Reading traffic, street, or store signs	90.0	90.5
Taking part in sports like bowling, handball, tennis, golf	100.0	85.7
Watching television	100.0	90.5
Driving during the day	92.3	85.7
Driving at night	66.7	66.7
Recognizing people from a distance	95.0	85.7
Difficulty in going out to see movies, theater, plays, sports events	87.5	83.3
Intermediate Visual Task		
Reading a large-print book or numbers on a telephone	100.0	95.2
Recognizing people when they are close to you	100.0	100.0
Playing games such as bingo, dominos, card games, mahjong	100.0	87.5
Cooking	100.0	100.0
Using a personal computer	90.0	90.5
Shaving, styling hair, or putting on makeup	95.0	85.7
Near Visual Task		
Reading small print	55.0	71.4
Reading newspaper/book	73.7	75.0
Doing fine handwork like sewing	75.0	84.6
Writing checks or filling out forms	100.0	90.5

Table 5 Postoperative Monocular (n = 42 Eyes) and Binocular (n = 19 Subjects) Contrast Sensitivity

Parameter	Month 1 Mean ± SD (Range)	Month 3 Mean ± SD (Range)
Monocular Contrast Sensitivity (%)	3.52 ± 1.56 (1.00 to 10.00)	3.54 ± 1.26 (1.25 to 6.00)
Binocular Contrast Sensitivity (%)	2.46 ± 0.93 (1.00 to 4.00)	2.35 ± 1.04 (1.00 to 5.00)

with performing tasks, though driving at night, reading small print, and doing fine hand work were the tasks with the highest patient reported difficulty. The results from our study are similar, with driving at night, reading small print, and reading a newspaper or book the tasks that had the lowest percentages of subjects reporting no difficulty or a little difficulty. It should be noted that in our study we are reporting the results of each question on the questionnaire as percentages of respondents, as we assume that the questionnaire scales are ordinal not interval.²⁷

A limitation of this study was the relatively short follow up period. Three months postoperative is a typical time frame to characterize clinical outcomes; however, we are not able to draw any conclusions about the long-term clinical outcomes. Another limitation was the relatively small sample size as the first few patients were enrolled right before the COVID-19

pandemic and were subsequently lost to follow up due to New York State's strict regulations for elective surgery at the time. However, a final sample size of 22 subject has shown to be sufficient to describe the performance of IA and the trifocal IOL.

In conclusion, the results of this study suggest that implantation with trifocal and trifocal toric IOLs using intraoperative aberrometry can provide high refractive precision, leading to excellent visual performance and low visual task difficulty at all ranges (distance, intermediate, and near).

Data Sharing Statement

Data are not available for sharing.

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Disclosure

Dr Brissette is a consultant for Alcon and Carl Zeiss Medica. Brad Hall reports that he has received consulting fees from Ace Vision Group outside the submitted work. The authors report no other conflict of interest for this work.

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