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ORIGINAL RESEARCH

Outcomes After Implantation of a Trifocal Toric Intraocular Lens Using Intraoperative Aberrometry, Digital Image Tracking, and Femtosecond Laser

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Purpose: To evaluate the refractive and visual acuity outcomes when using trifocal toric intraocular lenses (IOLs), femtosecond laser assisted cataract surgery (FLACS), swept-source optical coherence tomography (SS-OCT) biometry, digital image tracking (DT) and intraoperative aberrometry (IA).

Methods: This prospective, single-arm, observational study of refractive and visual outcomes included 40 eyes of 34 subjects. Preoperative biometry was performed with the Argos, FLACS and digital marking with LenSx, and IA and DT with ORA. Eyes were implanted with the Clareon PanOptix toric IOL. Study outcome measures included absolute prediction error, residual refractive astigmatism, and monocular uncorrected and distance corrected visual acuity at distance (UDVA, CDVA), intermediate (UIVA, DCIVA; 60cm), and near (UNVA, DCNVA; 40cm).

Results: Mean absolute prediction error (spherical equivalent) was 0.43 ± 0.36 D, and the percentage of eyes with absolute prediction error ≤ 0.5 D was 72.5% (29/40 eyes). Mean residual astigmatism was 0.36 ± 0.65 D, and the percentage of eyes with residual astigmatism ≤ 0.5 D was 80% (32/40 eyes). Monocular UDVA, UIVA, and UNVA was 20/25 or better in 75%, 64%, and 87% of eyes respectively. Monocular CDVA, DCIVA, and DCNVA was 20/25 or better in 95%, 64%, and 87% of eyes respectively.

Conclusion: The results of this study suggest that trifocal toric implantation with SS-OCT, FLACS, DT, and IA can provide excellent refractive and visual outcomes.

Plain Language Summary: When the natural lens inside the eye becomes opaque (develops a cataract), it can be surgically replaced with a clear artificial intraocular lens (IOL). There are many different technologies available to the cataract surgeon in order to maximize postoperative visual outcomes with implanted IOLs. These include, modern biometers, femtosecond laser-assisted cataract surgery (FLACS), trifocal IOLs, toric IOLs, image-guided digital tracking (DT), and intraoperative aberrometry (IA). Individually, good refractive outcomes have been reported with these technologies. However, there is minimal data on outcomes using a combination of all of them. The purpose of this study was to determine the refractive and visual acuity outcomes when using modern biometers, toric IOLs, FLACS, DT, IA, and trifocal IOLs. The results of this study suggest that trifocal toric implantation with modern biometry, FLACS, DT, and IA can provide excellent refractive and visual outcomes.

Keywords: Clareon PanOptix, Argos, intraoperative aberrometry, FLACS

Introduction

One of the primary goals of cataract surgery is achieving excellent refractive outcomes for patients. A large part of hitting the refractive target is reducing the amount of postoperative residual astigmatism (PRA). It has been estimated that for every diopter of PRA, distance visual acuity could be reduced by up to 1.5 lines.[1] There are a variety of technologies

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available to surgeons to help optimize refractive outcomes, including PRA. Preoperatively, modern biometers in combination with the latest generation IOL power formulas can result in great refractive outcomes.[2–4] In addition, femtosecond laser-assisted cataract surgery (FLACS) may increase the precision and accuracy of capsulotomy size compared to conventional phacoemulsification.[5] Moreover, toric intraocular lenses (IOLs) are effective for correcting astigmatism, and may offer better visual outcomes over relaxing incisions.[6] Image-guided digital tracking (DT) can be used to aid in aligning toric IOLs along the target axis, and may offer better accuracy compared to manual marking.[7] Finally, using intraoperative aberrometry (IA) during cataract surgery on aphakic and pseudophakic eyes can enable predictions of spherical and cylinder IOL power and adjustments to IOL implantation to maximize refractive outcomes.[8]

Another important goal of cataract surgery is spectacle independence for patients. The most commonly implanted IOL type is a monofocal. These lenses provide excellent visual outcomes at far distances. Some patients may still need spectacles for good visual outcomes at intermediate and near. Trifocal IOLs expand the range of clear vision to intermediate and near distances by splitting incoming light in 3 distinct foci. However, splitting the incoming light may lead to visual disturbances, as reported with other multifocal or presbyopia correcting IOLs.[9–12]

Individually, good refractive outcomes have been reported with modern biometers, toric IOLs, FLACS, DT, IA, and trifocal IOLs. However, there is minimal data on outcomes using a combination of all these technologies. The purpose of this study was to determine the refractive outcomes and visual acuity outcomes when using modern biometers, toric IOLs, FLACS, DT, IA, and trifocal IOLs.

Methods

This was a prospective, single surgeon, observational study of refractive and visual outcomes in subjects implanted with a trifocal toric IOL. An independent institutional review board (IRB) was used as this study was conducted at a private practice. The independent IRB (Salus IRB) reviewed and approved the study (IRB00013544). Written informed consent was obtained from all subjects. The study was also conducted in accordance with Good Clinical Practice (GCP), International Harmonization (ICH) guidelines, and the tenets of the Declaration of Helsinki.

Inclusion criteria were adults (≥ 50 years) presenting with bilateral cataracts, clear intraocular media other than cataract, monocular corrected distance visual acuity (CDVA) predicted to be logMAR 0.10 (20/25) or better after cataract removal and IOL implantation, and a candidate for trifocal toric IOL implantation. Exclusion criteria were significant corneal abnormalities, dystrophies, or degenerations (other than regular refractive astigmatism), previous ocular surgery, any conditions that may affect or prolong cataract removal, history of retinal detachment or glaucoma, diagnosed degenerative visual disorders, and any acute or chronic disease or illness that would confound the results of this investigation.

Data were collected at the preoperative visit, intraoperatively, and at one month postoperatively. The primary endpoint was absolute prediction error for spherical equivalent. Absolute prediction error was calculated as the absolute difference between the predicted spherical equivalent and the actual spherical equivalent from manifest refraction. Other endpoints included residual astigmatism, absolute prediction error for residual astigmatism (calculated as the absolute difference between the predicted astigmatism and the actual astigmatism from manifest refraction), and monocular uncorrected and distance corrected visual acuities at distance (UDVA, CDVA), intermediate (UIVA, DCIVA; 60cm), and near (UNVA, DCNVA; 40cm).

The Alcon Vision Suite (Alcon Vision, LLC) was used for all eyes, and included a swept-source optical coherence tomography biometer (SS-OCT; Argos), FLACS (LenSx), and DT and IA (ORA). Preoperative biometry, including keratometry, was performed with the Argos. Preoperative planning was done using the Barrett Universal II and the Barrett Toric calculator targeting 0.00 to first minus. One experienced surgeon (RM) performed all cataract surgeries. A femtosecond laser (LenSx) was used to create the capsular rhexis and for lens fragmentation, with a continuous curvilinear capsulorhexis diameter of 5.1 mm. Limbal relaxing incisions were also created using the LenSx in cases where astigmatism could not be corrected with a toric IOL. The VERION System (Alcon Vision, LLC) was used for image-guided digital tracking. Intraoperative aberrometry (ORA System with Verifeye) was used to determine the final IOL power, cylinder power, and axis of placement. Clareon trifocal toric models were implanted (CCWTT3, CCWTT4, CCWTT5, CCWTT6). The postoperative regimen was the surgeon's usual standard of care.

It was estimated that 40 eyes would provide sufficient data to characterize the refractive and visual outcomes. The statistical analyses were performed using R (version 4.3.1; The R Foundation for Statistical Computing, Vienna, Austria). Standard graphs were created using mEYEstro software (version 1.0; Total Cornea Lasik Inc, Montreal, Canada).[13]

Results

A total of 40 eyes of 34 subjects completed the study; 6 eyes were not included as the subjects dropped out before attending the postoperative visit, and were excluded from the analysis. Patient demographic and preoperative data are summarized in Table 1. No adverse events were reported during the study.

Table 2 summarizes the prediction error for spherical equivalent and astigmatism. Mean absolute prediction error for MRSE was 0.43 ± 0.36, and 72.5% of eyes had absolute prediction error ≤ 0.5 D. Mean absolute prediction error for residual astigmatism was 0.46 ± 0.48, and 75% of eyes had absolute prediction error ≤ 0.5 D.

Table 1 Preoperative and Patient Demographic Data

Parameter	Outcomes*
Eyes	40
Patients	34
Age (years)	65.1 ± 7.5 (50 to 76)
Sex	
Female Eyes	32 (65)
Male Eyes	17 (35)
Model	
CCWTT3	17 (42)
CCWTT4	8 (20)
CCWTT5	9 (22)
CCWTT6	6 (15)
Sphere (D)	−2.49 ± 4.03 (−14.00 to 3.25)
Cylinder (D)	1.74 ± 1.21 (0.00 to 4.50)
MRSE (D)	−1.62 ± 3.96 (−12.38 to 4.38)
ACD (mm)	3.30 ± 0.39 (2.43 to 4.02)
Axial Length (mm)	24.56 ± 1.53 (21.58 to 28.23)
Degree of Cataract	
1	6 (15)
2	9 (23)
3	20 (50)
4	5 (12)

Notes: *Presented as Mean ± SD (Range) or n (%).
Abbreviations: ACD, anterior chamber depth; D, diopters; MRSE, manifest refraction spherical equivalent.

Table 2 Absolute Prediction Error

Absolute Prediction Error	Mean ± SD (Range)	Percentage of Eyes			
		≤0.25D	≤0.50D	≤0.75D	≤1.00D
MRSE	0.43 ± 0.36 (0.00 to 1.29)	37.5	72.5	82.5	92.5
PRA	0.46 ± 0.48 (0.00 to 2.28)	45.0	75.0	82.5	92.5

Abbreviations: D, diopters; MRSE, manifest refraction spherical equivalent; PRA, postoperative residual astigmatism.

Standard plots are shown in Figure 1. Postoperatively, 78% of eyes had MRSE ≤ 0.5 D. In addition, 80% of eyes had PRA ≤ 0.5 D. Distance visual acuity was excellent with 75% and 95% of eyes 20/25 or better for UDVA and CDVA, respectively. Mean UDVA and CDVA were 0.10 ± 0.16 logMAR and 0.00 ± 0.08 logMAR, respectively.

Figure 2 summarizes the postoperative uncorrected intermediate and near visual acuities. Intermediate visual acuity was functional with 77% and 77% of eyes 20/32 or better for UIVA and DCIVA, respectively. Mean UIVA and DCIVA were 0.18 ± 0.18 and 0.18 ± 0.18, respectively. Near visual acuity was excellent with 87% and 87% of eyes 20/25 or better for UNVA and DCNVA, respectively. Mean UNVA and DCNVA were 0.07 ± 0.17 and 0.07 ± 0.17, respectively.

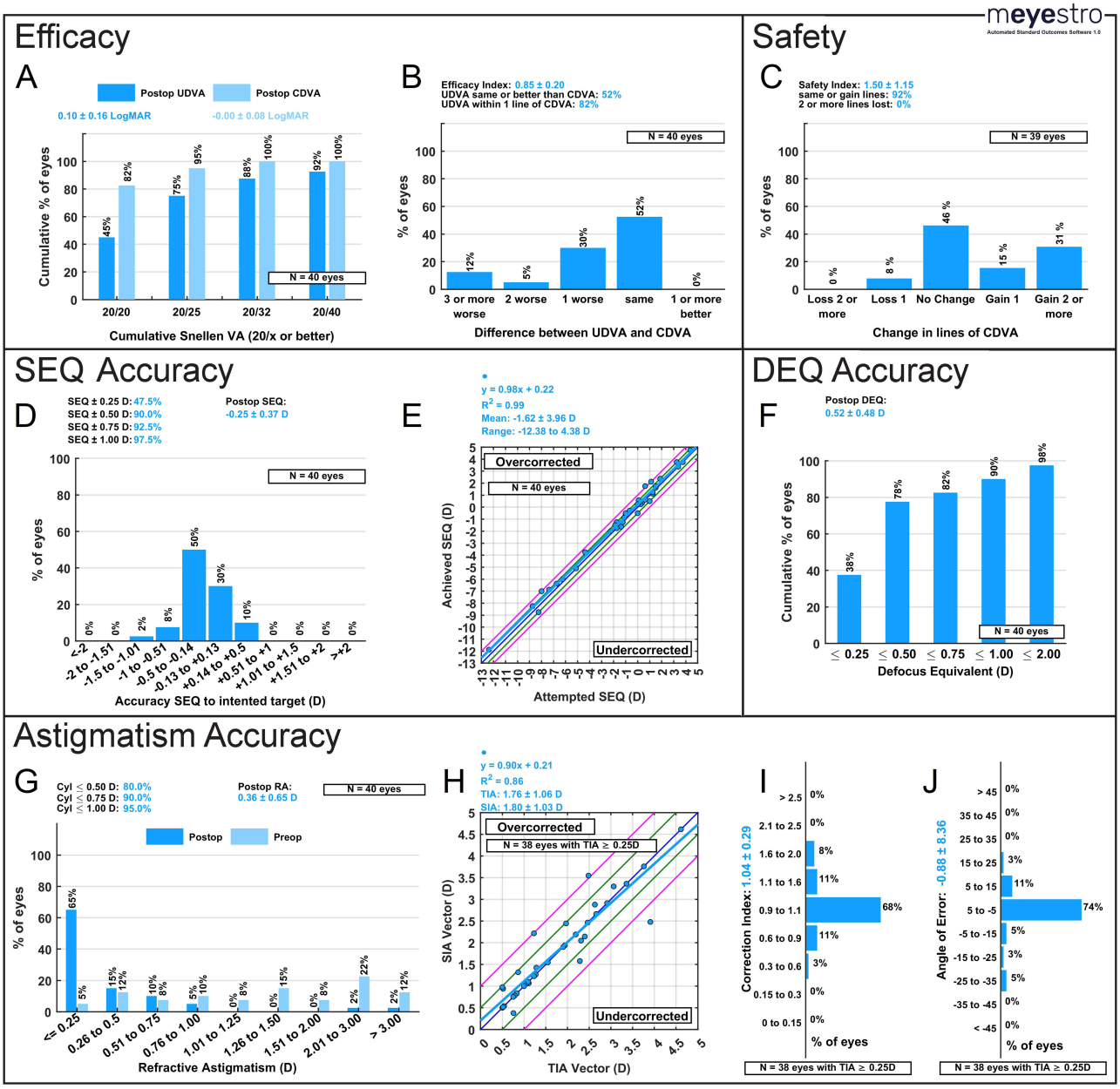

Figure 1 Standard plots for IOL implantation. (**A**) Cumulative Snellen visual acuity; (**B**) Difference between UDVA and CDVA; (**C**) Change in lines of CDVA; (**D**) SEQ accuracy; (**E**) Attempted versus achieved SEQ; (**F**) DEQ accuracy; (**G**) Distribution of astigmatism; (**H**) TIA versus SIA; (**I**) Correction index; (**J**) Angle of error.
Abbreviations: CDVA, corrected distance visual acuity; D, diopters; DEQ, defocus equivalent; SEQ, spherical equivalent; SIA, surgically induced astigmatism; TIA, target induced astigmatism; UDVA, uncorrected distance visual acuity.

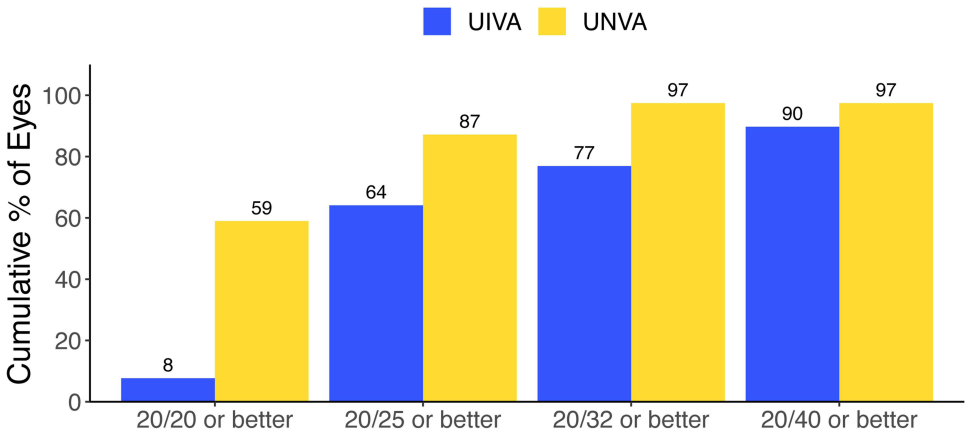

Figure 2 Cumulative uncorrected visual acuities at intermediate (UIVA) and near (UNVA).

Discussion

Excellent refractive outcomes following cataract surgery are key to achieving happy patients (and happy surgeons). However, spherical equivalent within 0.5 D of target may only occur in 73% of eyes.[14] In this study, we evaluated the refractive outcomes in eyes following trifocal toric implantation using SS-OCT, FLACS, and IA.

The prediction error with SS-OCT, FLACS, and IA and Clareon PanOptix toric implantation was acceptable in our study, with 72.5% of eyes within ± 0.5 D of the predicted MRSE. Blaylock and Hall[15] reported an absolute prediction error 0.5 D or less in eyes that received the FLACS, IA, and the AcrySof PanOptix toric IOL, higher (90.5%) than that reported in our study. Our outcome is also lower than that reported by Watanabe,[16] who observed an absolute prediction error 0.5 D or less in approximately 92% eyes that AcrySof PanOptix toric (57/180 eyes) and non-toric (123/180 eyes) implanted using FLACS and IA. In addition, Ma et al,[17] observed an absolute prediction error 0.5 D or less in approximately 82% eyes that received IA and a AcrySof PanOptix IOL. Differences between our study and previous reports may be explained by the lower sample size in our study, given that our study was a prospective study and the other studies were retrospective. The outcomes in our study are higher than the benchmark standards released by the UK National Health Service (NHS) in 2009, which are that 55% of patients to be within 0.5 D of predicted refraction.[18] It is also worthwhile to note that 90% and 80% of eyes were within 0.5 D of the intended MRSE and PRA targets.

Any PRA can affect visual outcomes. In our study, 80% of eyes had PRA ≤ 0.5 D. Blaylock and Hall[15] reported PRA ≤ 0.5 D in 97.8% of eyes that received the FLACS, IA, and the AcrySof PanOptix toric IOL. Carreño et al[19] reported PRA ≤ 0.5 D in 94% of eyes implanted with AcrySof PanOptix toric IOLs using LenSx in 53% of cases and ORA in all cases. Kohnen et al[20] observed that 96% of eyes implanted with AcrySof PanOptix toric IOLs using LenSx had PRA ≤ 0.5 D. Mean preoperative astigmatism was higher in our study (1.74 D) compared to the other studies (1.01 to 1.37 D),[15,19,20] which may explain why the percentage of eyes with PRA ≤ 0.5 D was lower in our study.

The refractive outcomes in this study translated to good visual outcomes. Postoperative mean monocular UDVA, UIVA, and UNVA were 0.10 logMAR, 0.18 logMAR, and 0.07 logMAR, respectively. These are similar to other published reports with the AcrySof PanOptix.[15,16,20]

The primary limitation of this study was the single arm design. The intention of the study was to describe the refractive and visual outcomes after implantation with a trifocal toric using SS-OCT, FLACS, DT, and IA. However, a comparator group would have enabled conclusions to be drawn about the differences between, for example, using IA and not using IA. Another limitation was the lack of a sub-analysis for different axial lengths, given that our study included long, medium, and short eyes. It can be challenging to achieve good refractive outcomes in eyes with long (≥ 24.5 mm) or short (≤ 22.5 mm) axial lengths, and can be a good evaluation of prediction accuracy.

In conclusion, the results of this study suggest that trifocal toric implantation with SS-OCT, FLACS, DT, and IA can provide excellent refractive and visual outcomes.

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Disclosure

Robert F. Melendez reports that he is a consultant for Alcon Laboratories. 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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