

# Visual and Refractive Outcomes After Bilateral Implantation of a New Toric Intraocular Lens

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**Purpose:** To evaluate the clinical outcomes of a new FDA approved toric aspheric hydrophobic acrylic intraocular lens.

**Patients and Methods:** This is a single surgeon, single-arm, on-label, non-randomized, prospective observational study. Thirty patients underwent bilateral cataract surgery (60 eyes) with placement of a Clareon™ Toric IOL in each eye. The Barrett Universal II formula and Barrett toric calculator were used to determine the IOL power and toric axis. Endpoints included binocular and monocular best corrected distance visual acuity (BCDVA), binocular and monocular best uncorrected distance visual acuity (UCDVA), binocular uncorrected intermediate visual acuity (UCIVA), manifest refraction and patient Satisfaction Survey (IOLSAT) results over a 3 month follow-up.

**Results:** The postoperative mean LogMAR visual acuity for binocular BCDVA and UCDVA were each 0.01±0.05. The monocular BCDVA and UCDVA were 0.04±0.06 and 0.08±0.08 respectively. The mean refractive cylinder improved from 1.87±1.12D to 0.43±0.25D with 78.3% within 0.50D. The mean refractive spherical equivalent (MRSE) was 0.008 ± 0.30 D (range -0.75 to +0.63, 93.3% results within ± 0.5D). Patient surveys showed 96.7% gained distance spectacle independence and 96.7% would recommend this lens to friends or family members.

**Conclusion:** The Clareon Monofocal Toric IOL is effective in astigmatism correction and significantly improved uncorrected distance visual acuity. High spectacle independence for distance vision and high overall satisfaction were achieved.

**Keywords:** toric, intraocular lens, IOL, cataract, astigmatism

## Introduction

Astigmatism is a common refractive finding in which the curve of the cornea is not uniform causing blurry or distorted vision without spectacle correction. Uncorrected distance vision is affected by the degree and axis of astigmatism.<sup>1,2</sup> The prevalence of astigmatism has been reported as 64.4% with corneal astigmatism between 0.25 and 1.25 diopters (D) and 22.2% with corneal astigmatism of 1.50 D or higher.<sup>3</sup> Another review article calculated the pooled prevalence of various studies and was estimated at 40% in adults across World Health Organization regions.<sup>4</sup> Astigmatism can be corrected with laser vision correction, incisional keratotomy or toric intraocular lens (IOL) implantation. Correcting astigmatism with toric IOLs have been used for more than 30 years and effectively reduces preexisting corneal astigmatism during cataract surgery.

The ability to achieve predictable refractive results with toric IOLs relies on each element of the surgical process. Determination of the power and axis of the IOL depends on the precision of biometry and topography as well as accurate IOL power formulas for all eyes. Consistent surgical execution and placement of the IOL are also important to ensure accurate results. Finally, the clarity and predictability of the toric IOL itself is critical in achieving excellent outcomes.

The FDA approved Clareon™ Toric IOL (Alcon Laboratories Inc.) is a new aspheric hydrophobic acrylic intraocular lens. It utilizes the same optic and haptic design as the AcrySof IQ monofocal toric IOL and its toric component aims to correct preexisting corneal astigmatism. Previous studies on the monofocal IOLs have shown that the new Clareon IOL provides stable post-operative refractive outcomes and increased optic clarity, including low surface haze, subsurface

glistening and glistening.<sup>5,6</sup> This study evaluates the Clareon™ Toric IOL's visual, refractive and patient satisfaction outcomes.

While the primary goal of cataract surgery is to remove the cataractous lens and replace it with a clear artificial intraocular lens (IOL), it is also an opportunity and an expectation to improve spherical and astigmatic refractive errors. Toric IOLs are an excellent option to achieve decreased astigmatism and minimize reliance on glasses. This study is a prospective observational study looking at the visual and refractive outcomes of the Clareon™ monofocal toric intraocular lens (model CNW0T) with real-world clinical data.

## Material and Methods

In this single-arm, on-label, non-randomized, prospective observational study, thirty patients underwent cataract surgery with implantation of the Clareon™ Monofocal Toric IOL in each eye. All surgeries were completed by a single surgeon (MS) at a single surgery center to reduce variability. Informed consent was obtained from the subjects after explanation of the nature and possible consequences of the study. HIPAA regulations were followed. This study conformed to the ethical code based on the tenets of the Declaration of Helsinki and was approved by the Milkie-Shammas Surgery Center Institutional Review Board (Lynwood, CA).

## About the IOL

The Clareon™ Monofocal Toric IOL developed by Alcon Vision LLC utilizes a new hydrophobic acrylic material made from an acrylate–methacrylate copolymer.<sup>5,6</sup> This lens has a water content of 1.5% at 35°C, refractive index of 1.55, and glass transition temperature of 9.1°C.<sup>5,6</sup> It is a foldable, single piece IOL with power ranging from +6.0 to +30.0 diopters (D) in 0.5 D increments and +31.0 to 34.0 D in 1.0 D increments. The optic design is aspheric biconvex with a diameter of 6.0mm. The IOL has an overall length of 13.0mm and the haptics are configured with STABLEFORCE Modified L Haptics.<sup>5,6</sup> In this study we used all UV blocking and blue light filtering lenses with an A-constant of 119.1, models CNW0T3 to CNW0T6.

## Statistical Considerations

This is a prospective observational (descriptive), single arm, single surgeon, single site study. A review of the literature shows the typical number of patients enrolled is 25–35 patients. The primary endpoint is binocular best corrected distance visual acuity (BCDVA) in LogMAR units with standard deviation. Additional endpoints of the study include binocular and monocular uncorrected distance visual acuity (UCDVA), monocular BCDVA, binocular uncorrected intermediate visual acuity (UCIVA), postoperative refractive error (residual astigmatism and spherical equivalent), and patient satisfaction (measured by a standard survey, IOLSAT). The astigmatic data was analyzed using the ASCRS Astigmatism Double Angle Plot tool and the AstigMATIC software for vectorial analysis utilizing Alpin's method.<sup>7–9</sup>

## Clinical Protocol

Prior to surgery, LogMAR monocular and binocular distance visual acuities were measured without correction (UCDVA). Manifest refraction was completed to determine LogMAR best corrected visual acuity (BCDVA). The binocular uncorrected intermediate vision was measured at 66cm with a near card. Additional preoperative assessments included a complete biomicroscopy and retinal exam, biometry (Argos Biometer, Movu), corneal topography (Pentacam, OCULUS) and OCT of the macula and optic nerve (OCT Spectralis, Heidelberg Engineering, Inc). The Barrett Universal II and Barrett toric calculator embedded within the biometer were used to determine optimal IOL power and axis of placement, targeting emmetropia. Surgically induced astigmatism was set at 0.1 D with a temporal incision. Preoperative astigmatism was recorded as the cylinder at the corneal plane and as the cylinder at the spectacle plane. Cylinder at the corneal plane was determined by the corneal power from the biometer. The cylinder at the spectacle plane was recorded from the results of the preoperative manifest refraction.

Each patient underwent surgery in each eye at different visits. On the surgery day, the RoboMarker® system was used to mark the axis of placement with the patient sitting upright. Clear cornea cataract surgery was performed with the

placement of the Clareon™ Toric IOL and aligning it to the predetermined axis. Patients had visits one day after each surgery, one week after each surgery, one month after their second surgery and three months after their second surgery.

At the three-month visit, the patient had final measurements of monocular and binocular UCDVA, monocular and binocular BCDVA, binocular UCIVA and manifest refraction. All visual acuities were recorded in LogMAR units. The actual postoperative refractive astigmatism was taken from the cylinder and axis at the postoperative manifest refraction. The predicted postoperative refractive astigmatism was determined by the predicted result from the Barrett toric calculator. The postoperative astigmatism prediction error is the vector difference between the actual and the predicted postoperative refractive astigmatism and was calculated utilizing the ASCRS Astigmatism Double Angle Plot tool and Alpin's Method.<sup>7,8,9</sup>

Patients also completed a standardized patient survey called the IOLSAT at the 3-month postoperative visit. The IOLSAT survey includes 23 questions regarding patient reported spectacle independence and satisfaction levels under specific conditions.

## Patient Selection

Patients at least 50 years of age diagnosed with visually significant cataracts and having planned cataract surgery with implantation of Clareon™ Toric IOL in each eye were included. Planned toric power ranged from T3 to T6 with no more than 60% of IOLs implanted having power of T3. The predicted corrected monocular visual acuity is expected to be logMAR 0.10 (20/25) or better after cataract removal and IOL implantation.

Exclusion from the study occurred if the patient had any ocular condition that would limit best monocular corrected visual acuity such as corneal abnormalities, dystrophies or degeneration; strabismus with or without amblyopia; previous ocular surgery of any kind; history of retinal detachment; macular degeneration; or cloudy ocular media other than the cataract. Additionally, patients with acute or chronic diseases that may confound the results of the study were excluded from the study.

## Results

Sixty eyes of thirty patients underwent cataract surgery with a toric IOL implant. Of the 30 patients, 15 (50%) were men and 15 (50%) were female. The average age was  $70.8 \pm 6.7$  years ranging from 60–88 with a median of 70 years. The distribution of the IOL cylindrical power used includes T3 (38.3%), T4 (41.7%), T5 (13.3%) and T6 (6.7%). The average spherical power IOL used was  $21.58 \pm 3.3$  diopters (D) with a median of 22.0 D and a range of 12–29 D. No adverse events were experienced during the study.

## Visual Acuity Results

Visual acuity results expressed in LogMar units are summarized in [Table 1](#) including binocular and monocular, corrected and uncorrected distance and intermediate distances. Average binocular best corrected distance visual acuity (BCDVA) improved from  $0.35 \pm 0.11$  to  $0.01 \pm 0.05$ . Average monocular BCDVA improved from  $0.49 \pm 0.37$  to  $0.04 \pm 0.06$ . Average binocular uncorrected distance visual acuity (UCDVA) improved from  $0.65 \pm 0.34$  to  $0.01 \pm 0.05$ . Average monocular UCDVA improved from  $0.80 \pm 0.48$  to  $0.08 \pm 0.08$ . Average binocular uncorrected intermediate visual acuity

**Table 1** Preoperative and 3 Month Postoperative Mean LogMAR Visual Acuities

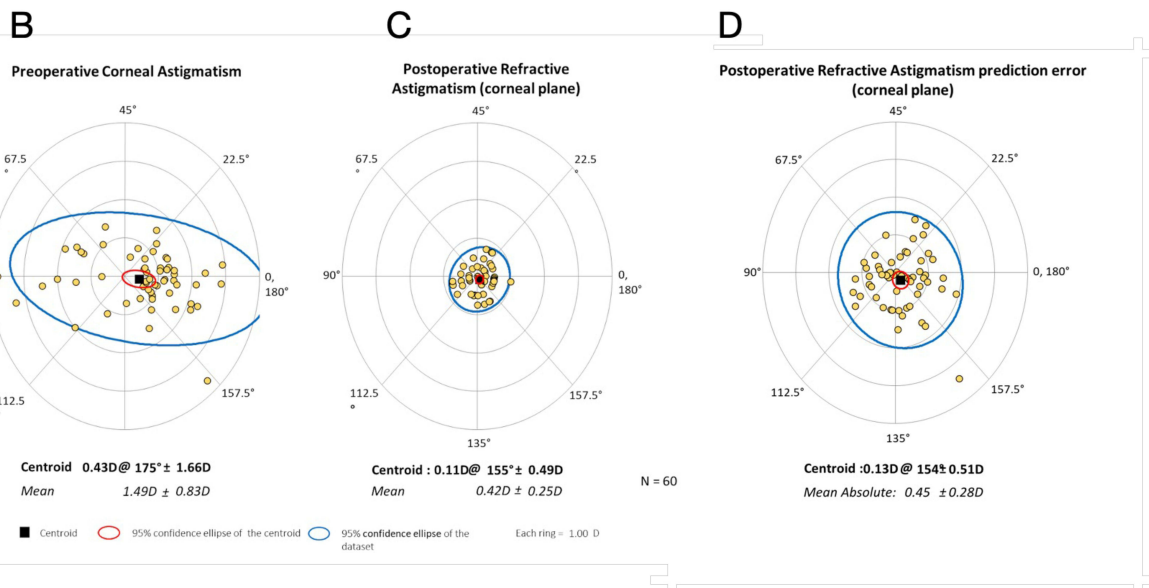
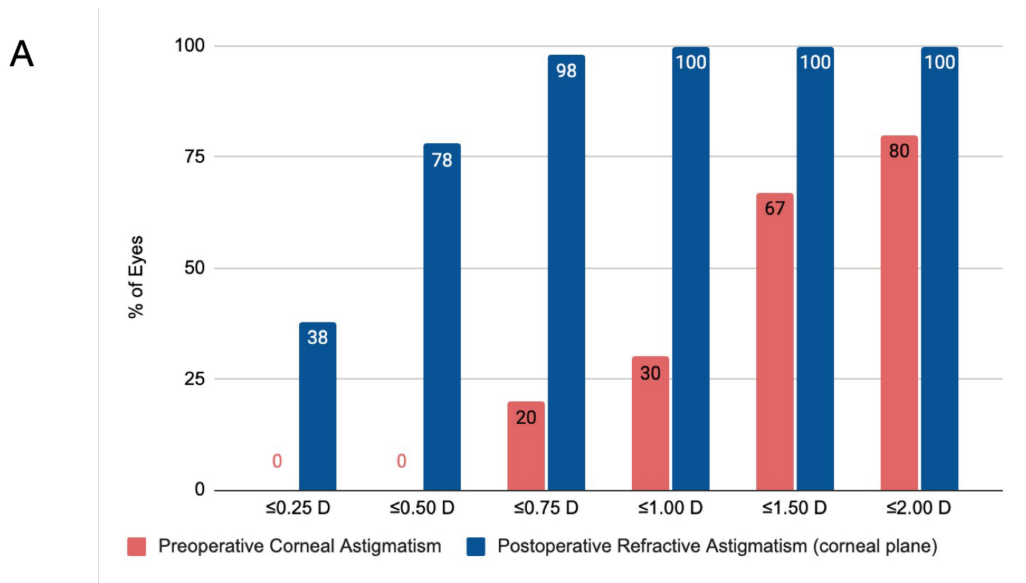
		Preoperative	Postoperative
<b>BCDVA</b>	<b>Binocular</b>	$0.35 \pm 0.11$	$0.01 \pm 0.05$
	<b>Monocular</b>	$0.49 \pm 0.37$	$0.04 \pm 0.06$
<b>UCDVA</b>	<b>Binocular</b>	$0.65 \pm 0.34$	$0.01 \pm 0.05$
	<b>Monocular</b>	$0.80 \pm 0.48$	$0.08 \pm 0.08$
<b>UCIVA</b>	<b>Binocular</b>	$0.46 \pm 0.42$	$0.05 \pm 0.08$

**Abbreviations:** BCDVA, best corrected distance visual acuity; UCDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity.

(UCIVA) improved from  $0.46 \pm 0.42$  to  $0.05 \pm 0.08$ . The postoperative spherical equivalent was determined from the postoperative refraction. The mean refractive spherical equivalent (MRSE) was  $0.008 \pm 0.30$  D (range  $-0.75$  to  $+0.63$ , 93.3% results within  $\pm 0.5$ D).

### Astigmatism Correction

Prior to surgery, astigmatism was measured by the difference in corneal powers at the steep and flat meridians (cylinder at the corneal plane) and via the cylinder in the preoperative refraction (cylinder at the spectacle plane). The average preoperative astigmatism at the corneal plane was  $1.49 \pm 0.84$  D and the average preoperative astigmatism at the spectacle plane was  $1.88 \pm 1.1$  D. For simplicity, further analysis looked only at the preoperative astigmatism at the corneal plane since that is what is used for IOL power planning. Postoperative evaluation of astigmatism relies on the postoperative manifest refraction. The mean postoperative refractive astigmatism decreased to  $0.43 \pm 0.26$ . **Figure 1A**



**Figure 1** (A) Cumulative histogram of the magnitude of the preoperative corneal and postoperative refractive cylinder, vertex to the corneal plane (n=60). (B) Double-angle plots of the preoperative corneal (n=60). (C) Double-angle plots of the postoperative refractive astigmatism (n=60). (D) Double-angle plots of the postoperative refractive astigmatism prediction errors (n=60) of the Barrett Toric Calculator.

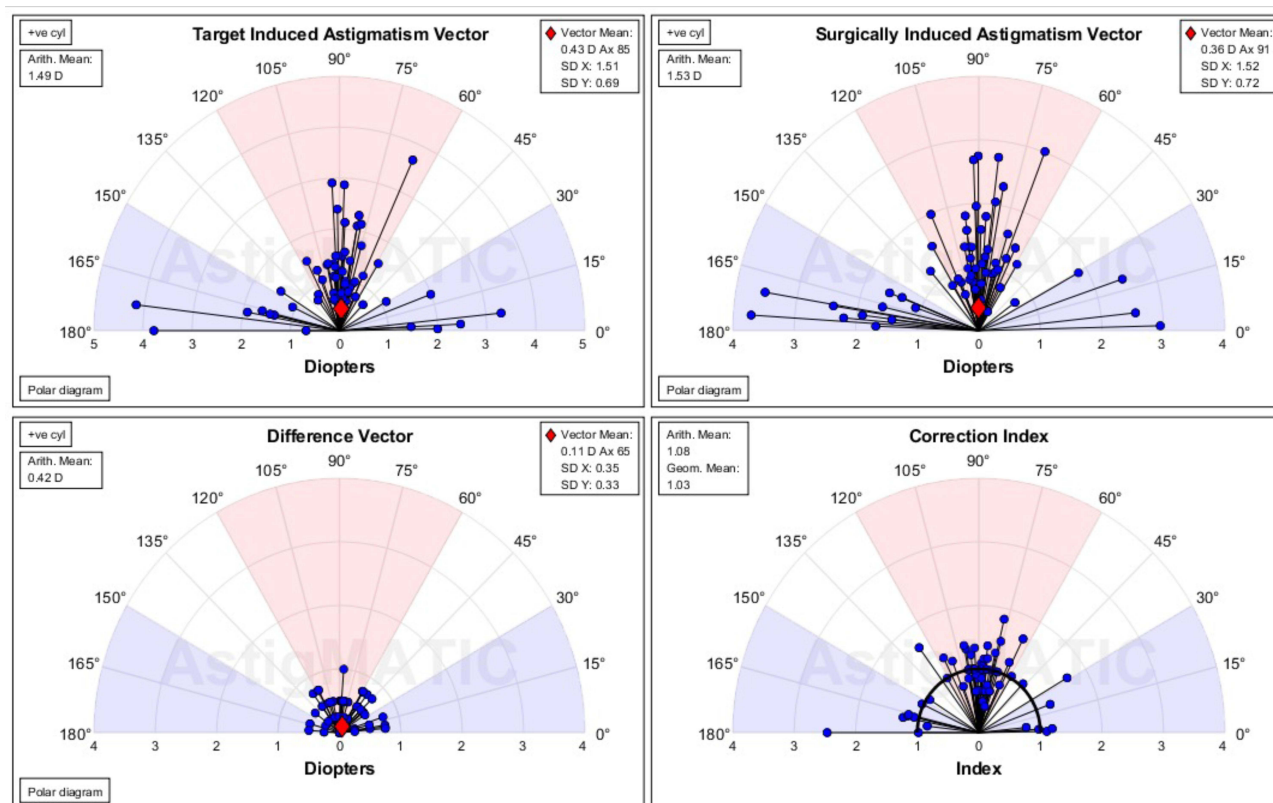
depicts the magnitude of the preoperative corneal and postoperative refractive astigmatism. The percentage of eyes with a residual cylinder of 0.50 D or less is 78.3%.

Utilizing the ASCRS Astigmatism Double Angle Plot tool, Figure 1B and C depicts the magnitude and axis of the preoperative and postoperative astigmatism respectively.<sup>7</sup> The centroid decreased from 0.43D @ 175 degrees  $\pm$  1.66D preoperatively to 0.11D @ 155 degrees  $\pm$  0.49D postoperatively. The 95% confidence ellipses change can be easily compared on the graph. To better understand how the toric IOL calculation formula performed on this toric IOL, double-angle plots of the postoperative refractive astigmatism prediction errors were done (Figure 1D).<sup>7</sup> The centroid was 0.13D @ 154 degrees  $\pm$  0.51D.

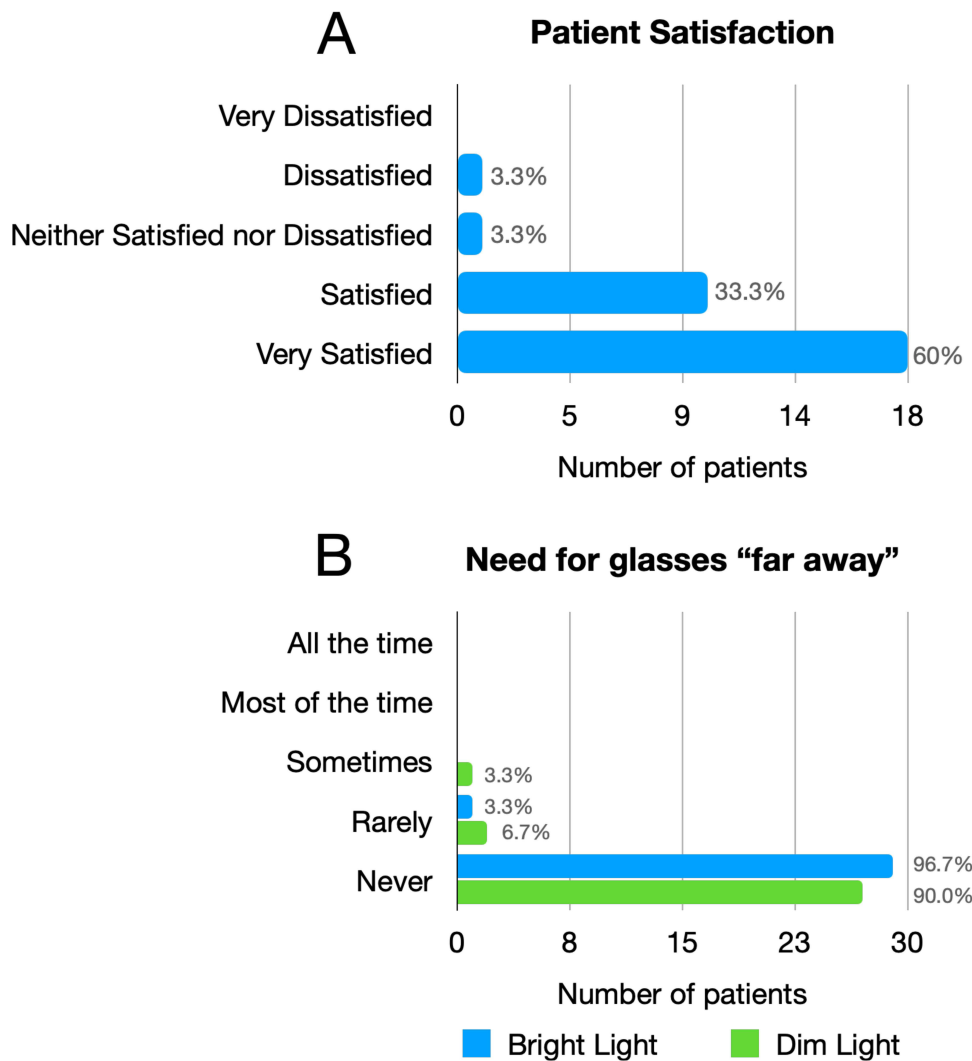
Vectoral analysis by Alpins Method was performed via the AstigMATIC software to better understand the refractive outcome.<sup>8,9</sup> Figure 2 shows four standard graphs including target-induced astigmatism (TIA) vector, surgically induced astigmatism (SIA) vector, difference vector (DV) and correction index (CI). The TIA, a reflection of the intended amount of astigmatism to correct, had a vector mean of 0.43 D x 85 with standard deviation (SD) of 1.51 at X and 0.69 at Y. The SIA is a measure of astigmatism corrected with the surgery, and the vector mean measured 0.36 D x 91 with SD 1.52 at X and 0.72 at Y. The DV maps the remaining astigmatism after correction and this study resulted in a vector mean of 0.11 D x 65 with SD 0.35 at X and 0.33 at Y. Finally, the CI is calculated by dividing the SIA by the TIA to show over or under correction where “1” would be an ideal surgical result.<sup>9</sup> This study had a geometric mean CI of 1.03 showing slight over correction.

## Patient Satisfaction

All patients completed the IOLSAT survey at the 3-month postoperative visit with results shown in Figure 3A and B. One series of questions focused on seeing objects “far away” in bright and dim light. In the bright light 96.7% never needed glasses; 96.7% felt their vision was “good” or “very good”. In the dim light 90% never needed glasses; 96.7% felt their vision was “good” or “very good”. No patient needed glasses most or all the time. With respect to seeing objects “at



**Figure 2** (A) Target induced astigmatism vector. (B) Surgically induced astigmatism vector. (C) Difference vector. (D) Correction index.



**Figure 3 (A)** Glasses dependence at distance. **(B)** Patient Satisfaction.

arm’s length”, in the bright light 66.7% never needed glasses; 70% felt their vision was “good” or “very good”. In the dim light 63.3% never needed glasses; 73.3% felt their vision was “good” or “very good”. With respect to seeing objects “up close”, in bright light 43.3% needed glasses sometime, rarely or never; 56.7% needed glasses most or all the time. In dim light: 33.3% needed glasses sometimes, rarely or never, while 66.7% of patients needed glasses most or all the time.

When asked about overall satisfaction, 93.3% were either satisfied or very satisfied and 93.3% would have the same lens implanted again. Additional space is provided for comments. One patient noted that they would have chosen a multifocal if they were able to do it again to get a better range of vision. When asked if they would recommend this implant to a friend or family member, 96.7% would recommend this lens.

### Discussion

Placement of toric IOLs during cataract surgery remains an excellent option to decrease refractive astigmatism and decrease spectacle dependence. There are many available toric IOL options, and this study looked at a newer model, the Clareon™ Toric IOL. Outcomes of toric IOLs aim at evaluating best potential vision, uncorrected distance visual acuity, astigmatism reduction and patient reported spectacle independence and satisfaction.

The primary endpoint of the study was best corrected distance visual acuity (BCDVA) to better understand the best achievable vision with this IOL. The mean LogMAR binocular BCVA was 0.01 ± 0.05, which is a Snellen equivalent of

20/20 minus 0.5 letter. The mean LogMAR monocular BCDVA was  $0.04 \pm 0.06$ , which is a Snellen equivalent of 20/20 minus 2 letters. This shows that the optical properties of the Clareon™ Toric IOL allow for excellent potential vision.

Postoperative uncorrected visual acuity at distance depends on the residual spherical and astigmatic refractive error. A recent review evaluated 21 published toric studies reporting LogMAR mean postoperative UCDVA 0.28 (SN6AT), 0.27 (ZCT) and 0.11 (MX6OE).<sup>10</sup> In this study the mean LogMAR UCDVA was  $0.01 \pm 0.05$  (binocular) and  $0.08 \pm 0.08$  (monocular). That same review article showed that 90–100% of eyes had vision of 20/40 in all the articles.<sup>10</sup> In this study 98.3% had monocular UCVA of 20/40 or better on par with previous studies on other toric models. Reliable outcomes are achievable with the Clareon™ Toric IOL.

Residual astigmatism is minimized postoperatively with toric IOLs, but achieving perfection in all patients is not possible for multiple reasons. In general, reducing the overall refractive astigmatism to 0.5D or less is acceptable. The postoperative refractive astigmatism reported in other studies had a range of 0.21–0.81 D.<sup>10</sup> The mean for SN6AT and SN60T IOLs was 0.42 D and the mean for ZCT and ZCU IOLs was 0.44 D.<sup>10</sup> The mean in this study was  $0.43 \pm 0.26$  D within the range seen with other toric IOLs.

Overall satisfaction was high with most patients experiencing spectacle independence at distance, satisfied with their decision and would have recommended the same IOL to a friend or family member. One patient was dissatisfied, explaining that they would have chosen a multifocal if they could choose again for spectacle independence at near. Overall, the Clareon™ Monofocal Toric IOL provides an effective option to reduce astigmatism during cataract surgery.

## Conclusion

The Clareon Monofocal Toric IOL is effective in astigmatism correction and significantly improved uncorrected distance visual acuity. High spectacle independence for distance vision and high overall satisfaction were achieved.

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## Disclosure

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