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Project Title: Correlating the Precision of Toric Intraocular Lens Alignment in Cataract Surgery with Post-Operative Best Corrected Visual Acuity and Refraction

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SUMMARY: (no more than 250 words single spaced)

The purpose of this project will be to determine the precision of the intraocular lens (IOL) alignment with postoperative aberrometry. After insertion of the toric IOL, eyes will undergo corneal topography and aberrometry testing. The iTrace will allow the determination of the IOL astigmatic axis vs. the corneal topographic axis, and provide an exact number, and degrees needed to rotate the IOL to the proper position.

We will address the question of how significant is the precision of toric IOL placement and stability, by comparing degrees of rotation and alignment to post-operative cylinder and CDVA.

Student Signature **Supervisor Signature**

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Introduction and Background

The toric intraocular lens (IOL) was first manufactured in 1998. The first Toric lens was the AA4203 TF, a 1-piece silicone Staar Toric IOL (Chan, 2012). Unfortunately, this lens had fairly high rates of rotational instability and often required surgical correction (Chang, 2008). This led to the creation of the AA4203 TL (Staar Surgical), a somewhat longer IOL of 11.2mm compared to the 10.8mm TF model (Chang, 2008). The increased length of the TL model did indeed result in improved rotational stability, and in a study by Chang (2003), none of the TL cases required a second surgery for further toric rotation.

Over the past several years, a variety of toric lenses have been introduced to the North American market. The initial Acrysof lens was designed correct astigmatism of up to only 3.0D. Newer models were gradually introduced that allowed for correction of up to 6.0D of cylinder (Visser et al, 2011). A study looking at the efficacy of Acysof toric IOLs in eyes with greater than 2.25D of cylinder showed excellent alignment, with a mean IOL misalignment of 3.2+/-0.28 degrees (Visser et al, 2011). The Acri.Comfort Toric (Carl Zeiss Meditec AG) was also introduced, which can correct up to 12D of astigmatism, as was the T-flex (Rayner Intraocular Lenses Ltd), which can correct up to 11D of astigmatism (Visser, 2011). The Acri.Comfort has been shown to result in a post-operative residual cylinder of -0.45+/-0.63 (Alio et al, 2010), while the T-Flex has been associated with a post-operative residual cylinder of -0.95 +/-0.66 (Entabi et al, 2011).

Many studies have looked at the effects of toric misalignment and rotation on long-term post-operative astigmatism. In this era of increasing precision in cataract and refractive surgeries, patient expectations are continuously increasing, and one of the ophthalmologist's goal in cataract surgery is often to obviate the need for glasses or contact lenses post-operatively. The formulae for calculating the proper toric IOL cylinder and axis placement are increasingly detailed and specific. It is important to understand to what degree the precision of toric IOL placement actually translates into post-operative CDVA (corrected distance visual acuity) and astigmatism. For example, if there is one degree of toric misalignment from the intended axis, will this actually have clinically significant consequences for the patient?

The goal in toric IOL placement is to coincide the IOL's most negative meridian with the most positive meridian of the rest of the eye (Ma et al, 2008). The toric IOL is customized for each surgical case based on an online calculator that takes into account axial length, keratometry, astigmatism meridians, and surgically induced astigmatism (Chan, 2012; Visser et al, 2011). Preoperatively, axis marks are delineated over the patient's limbus. Intraoperatively, the hash marks on the actual IOL are matched with these limbal markings such that the toric IOL is placed in the appropriate axis to counter the eye's natural cylinder (Chan, 2012). Studies have shown that just one degree of toric misalignment at the time of surgery can result in 3.49% of residual cylinder (Ma et al, 2008). If the IOL is misaligned by thirty degrees or greater from the intended axis, then there is actually an increase in astigmatism compared to the pre-operative astigmatism (Chang, 2008). A study of a series of Acrysof toric insertions showed that the average IOL misalignment was 3.2 +/-0.28 degrees. This translates to 11% of the pre-op astigmatism, or in other words, an 89% reduction in astigmatism. This correlated with a post-operative UDVA (uncorrected distance visual acuity) of 0.61 +/-0.26D and CDVA of 0.81+/-0.21, and 81% of eyes having a post-operative cylinder of less than 1.0D.

Toric misalignment alters post-operative refraction in three ways. Firstly and most obviously, any error in alignment decreases the intended astigmatic correction. Other ways in which refraction is altered, however, include hyperopic spherical change, as well as astigmatic rotation. This was both theoretically postulated and clinically proven by a study by Jin et al (2010).

There are several methods of assessing the accuracy of toric IOL alignment and rotation. Slit-lamp examination is used in the office to see how well the hash marks have lined up with the intended axis. More accurate measures rely on the use of conventional slide photography and digital photography (Watanabe et al, 2012). It is the use of an aberrometer, however, that is the gold standard for assessing the toric IOL position. Standard keratometry values report on the corneal astigmatic component, and the degree of the lenticular astigmatism is inferred by a comparison of the keratometry values and the cylinder on refraction. Aberrometers, however, go one step further and give information on the internal astigmatic component of the eye, which is essentially the position of the toric IOL.

The I-Trace is a combination corneal topographer and optical aberrometer. In the present study, the I-Trace will be utilized to correlate toric IOL axis with CDVA and post-operative astigmtism, in order to determine what amount of toric misalignment becomes clinically significant for patients' vision.

Purpose

After insertion of the toric IOL, eyes will undergo corneal topography and aberrometry testing. The iTrace will allow the determination of the IOL astigmatic axis vs. the corneal topographic axis, and provide an exact number, and degrees needed to rotate the IOL to the proper position.

We will address the question of how significant is the precision of toric IOL placement and stability, by comparing degrees of rotation and alignment to post-operative cylinder and CDVA.

Materials and Methods

Participants

Retrospective data collection for 18 eyes undergoing cataract surgery after toric IOL insertion that have been planned by the iTrace machine.

Inclusion Criteria

More than or equal to 1.00 D of corneal astigmatism as determined by Sim K readings on the iTrace machine.

Study Groups

1. Controls: Eyes with more than or equal to 1.00 D of corneal astigmatism, who elected to get the regular, non-toric IOL.
2. Acrysof (Alcon) Toric
3. Light adjustable lens
4. ReStor Toric
5. Rayner Toric
6. Rayner Toric Multifocal

7. Tecnis Toric

iTrace

- Uses ray tracing technology to analyze aberrations, total refractive power, and thus visual function of the entire eye.
- Projects 256 beams of light through the pupil and detects where the light rays land on the retina. The iTrace measures the optical aberrations through the analysis of the retinal spot pattern and visual function.
- There are several functions of the iTrace which include:
  - Wavefront aberometer
  - Corneal topographer
  - Auto-refractor
  - Auto-keratometer
  - Pupillometer

- Helps decide which aspheric IOL best matches the patient. Helps with toric IOL planning by using a calculator to determine lens power and axis placement.
- Helps to determine the origin of the aberrations (cornea vs. lens). In our case, we are interested in the corneal aberrations.
- Helps determine incision location and calculates the surgically induced astigmatism
- Preoperatively, the iTrace plans and determines the exact location (axis) of placement of the toric IOL in the eye.
- After surgery, the iTrace determines the actual placement of the toric lens and its axis. If the toric lens is not at the exact axis that was planned, it provides us the exact amount of degrees the toric IOL needs to be rotated in order to achieve the planned axis.

<u>Example</u>

- Patient has an MR (manifest refraction) reading of -2.00 +3.00 x90.
- Astigmatism of the cornea exists, the +3.00 cylinder in this prescription.
- If the patient is to have their astigmatism neutralized upon cataract surgery, a toric lens is required.
- **Toric lens**
  - Available in different diopter corrections (1,2,3,4,5, etc.)
- In this case, a lens that will correct the astigmatism for 3 diopters at 90 degrees is required.
- A lens with 20 diopters is required to neutralize the sphere. If a spherical lens is used, the patient's vision will be pl. +3.00 x 90.
- If a toric lens is used that is 20 diopters and 3 diopters of astigmatism, this will correct the vision.
- The lens is finally aligned to neutralize the astigmatism.

<u>Alignment</u>

- Preoperatively, the iTrace is used to determine the alignment of the toric IOL and it tells us it needs to be inserted at an axis of alignment of 90 degrees.
- Upon completion of the surgery the iTrace is used to check the location of the lens and the result is 95 degrees.
- There is a difference of 5 degrees as originally planned.

- Questions that need to be addressed:
  - How accurate are the alignment strategies?
  - How much does the lens need to be rotated?
  - Is this clinically significant?
    - How does the planned and resultant lens placement affect the CDVA or astigmatism postoperatively?

Preoperative Assessment

1. The uncorrected distance visual acuity (UDVA) and corrected distance visual acuity were (CDVA) measured using logMAR charts.
2. Manifest refraction was measured using a phoropter and the values for sphere, cylinder and axis were recorded.
3. Keratometry was measured using the auto-keratometer functionality of the iTrace.
4. Using the preoperative keratometry data, specifically the flat and steep values and their axis', these values were inputted into the toric IOL calculator.
5. The toric online calculator is used to determine the exact axis of placement of the toric IOL by inputting the keratometry data. The IOL Master by Zeiss is used to calculate IOL lens power. The calculator also takes into consideration the surgically induced astigmatism due to the incision size and location and allows the surgeon (Dr. Rocha) to minimize the residual cylinder.

   <u>Main outcome measures (pre-operatively):</u>

   UDVA
   MR
   CDVA
   Topographic cylinder and axis

Surgery

1. Marking the location of the axis was done exclusively by Dr. Rocha prior to surgery.
2. Markings were made while the patient was sitting up to avoid cyclorotation.

Postoperative Assessment

1. Each patient was assessed after his or her IOL implantation. The time for each assessment varied patient-to-patient.
2. At every postoperative assessment, toric IOL orientation was determined by slit lamp and iTrace, noting the IOL axis.
3. UDVA, CDVA, MR were all reassessed.

<u>Main outcome measures (post-operatively)</u>

UDVA
MR
CDVA
Topographic cylinder and axis
Measurements of iTrace alignment and need to rotate

Results

There were a total of 13 patients enrolled in the study (18 eyes). Of these patients, 7 were female and 8 were male and the mean age was 63.8 +/- 12.2 years. The mean preoperative corneal astigmatism was 2.42 +/- 1.27 D.

Figure 2 shows the postoperative residual astigmatism and figure 1 shows the preoperative corneal astigmatism in the 18 eyes. Postoperatively 89% of the patients had 1.00 D or less of refractive astigmatism and 78% of patients had less than 0.5 D of astigmatism. The mean residual astigmatism was 0.31 +/- 0.52 D, which was statistically significantly lower than preoperative corneal values (P<0.001, paired t-test).

Preoperatively, the mean binocular UDVA was 0.70 +/- 0.42 logMAR and the mean binocular CDVA, 0.27 +/- 0.22 logMAR. Postoperatively, the mean binocular UDVA was 0.17 +/- 0.21. After surgery, 83% of patients had a binocular UDVA of 20/40 or better and 33% had a UDVA of 20/20 or better. The improvement in UDVA from preoperatively to postoperatively was statistically significant (P<.001).

Preoperatively, the mean binocular CDVA was 0.27 +/- 0.22 logMAR. Postoperatively, the mean binocular CDVA was -0.01 +/- 0.09 logMAR. The improvement in CDVA from preoperatively to postoperatively was statistically significant (P<.001).

Table 1 shows the rotational stability of the toric IOLs. Of the 18 IOLs, 67% of the IOLs were within 6 degrees of the operative axis. There were 3 IOLs that required greater than 12 degrees of rotation. The correlation coefficient between the degrees of rotation required to achieve the preoperative planned axis and the postoperative astigmatism was R= 0.22 (figure 3). The correlation coefficient between the degrees of rotation required to achieve the preoperative planned axis and the postoperative CDVA was R=0.22 (figure 4).

Discussion

In this study of 18 eyes with a mean preoperative corneal astigmatism of 2.42 +/- 1.27 D, apparent astigmatism was reduced to 0.31 +/- 0.52 D postoperatively. The mean preoperative astigmatism was slightly higher in similar studies (Chang, 2008) and the mean post operative astigmatism was slightly lower than other studies (Ahmed et al., 2009).

In our study, the mean postoperative binocular UDVA was 0.17 +/- 0.21 with 83% of patients had a binocular UDVA of 20/40 or better and 33% had a UDVA of 20/20 or better. These results are slightly higher than the study by Ahmed et al., which was 0.05 +/- 0.11 logMAR.

The mean binocular CDVA was -0.01 +/- 0.09 logMAR. This improvement was statistically significant and indicates that the toric IOL implantation and placement provided excellent binocular CDVA.

When comparing the degrees of rotation required of the toric IOL to achieve the target axis and post-operative astigmatism, the resultant correlation was 0.22. This implies a weak correlation between these two parameters and indicates that patients were able to minimize their astigmatism even though the toric IOL was not accurately placed. Similarly, when comparing degrees of rotation of the toric IOL to the target axis and post-operative CDVA, the resultant correlation was 0.22. This weak correlation also indicates that even though there were cases where the iTrace calculated a significant required rotation, 16 of 18 patient's CDVA were excellent.

Postoperative assessment may be improved in future studies by examining the patients at regular time intervals. This would include one month, three months, and six months postoperatively. This would ensure accuracy or the toric IOL placement and take into account any shifting of the lens during the months following surgery. When marking the eye with the limbal marker, the tool does not have exact accuracy and may affect the lens placement by 2-3 degrees. Normal cyclorotation may also affect the accuracy of toric IOL placement as the eye rotates when the patient is moved from a position of sitting to supine.

In conclusion, the use of the iTrace in planning for cataract surgery and toric IOL insertion produced excellent binocular CDVA and UDVA and also greatly improved astigmatism in the eye. The iTrace had a low correlation between the required rotation of the toric lens to postoperative CDVA and astigmatism.

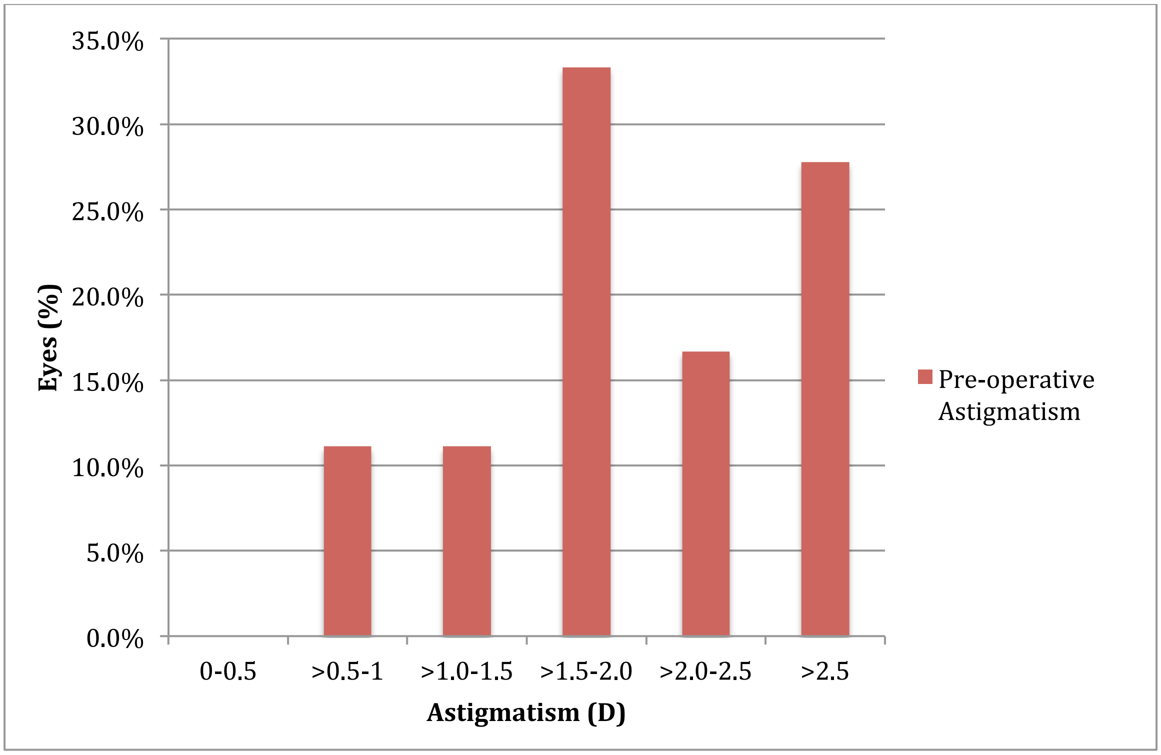

Figure 1. Pre-operative astigmatisms prior to toric IOL insertion.

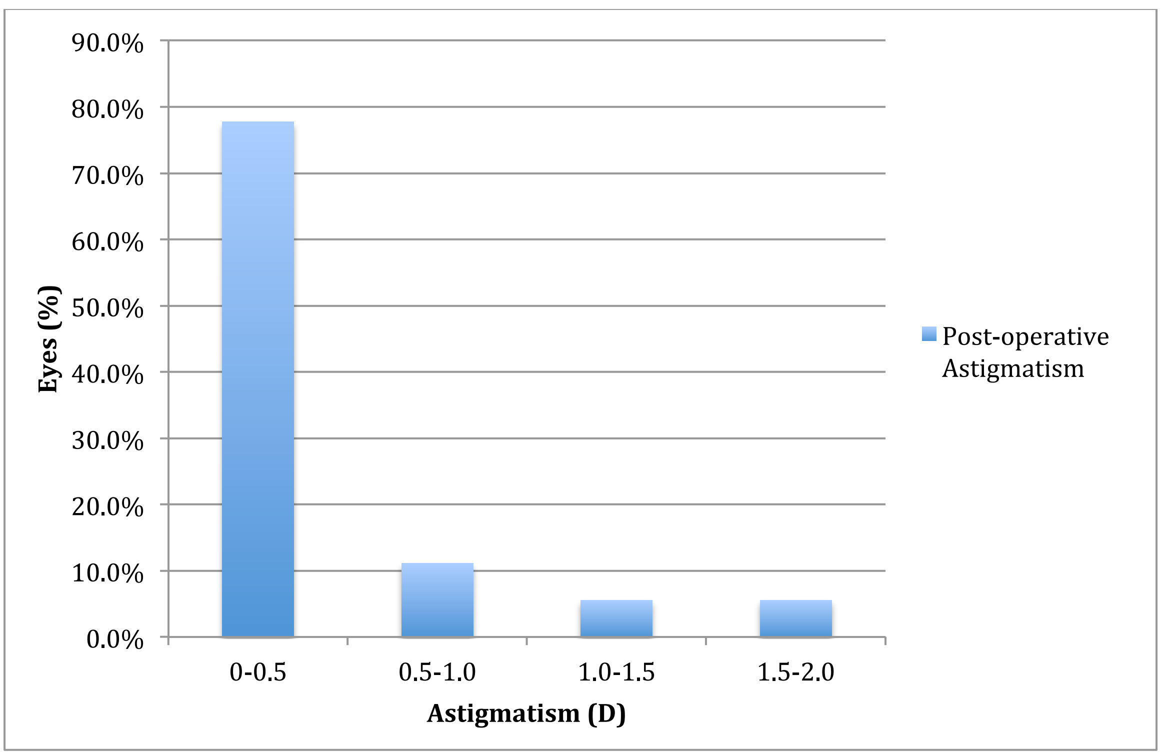

Figure 2. Post-operative astigmatisms following toric IOL insertion.

	Postoperative assessment
Mean Degrees from operative axis	**6 +/- 4**

Table 1. Rotational stability of the Toric IOLs

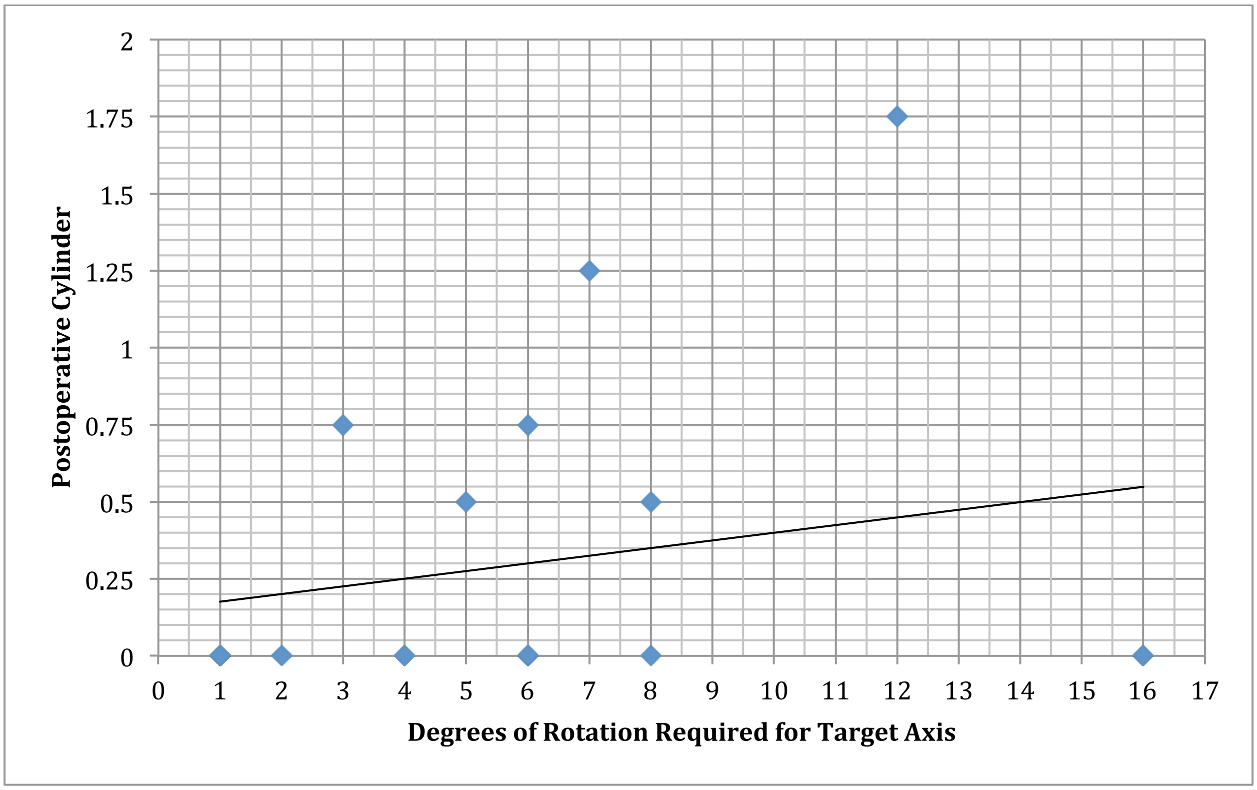

Figure 3. Precision of toric IOL lens placement postoperatively as compared to postoperative astigmatism

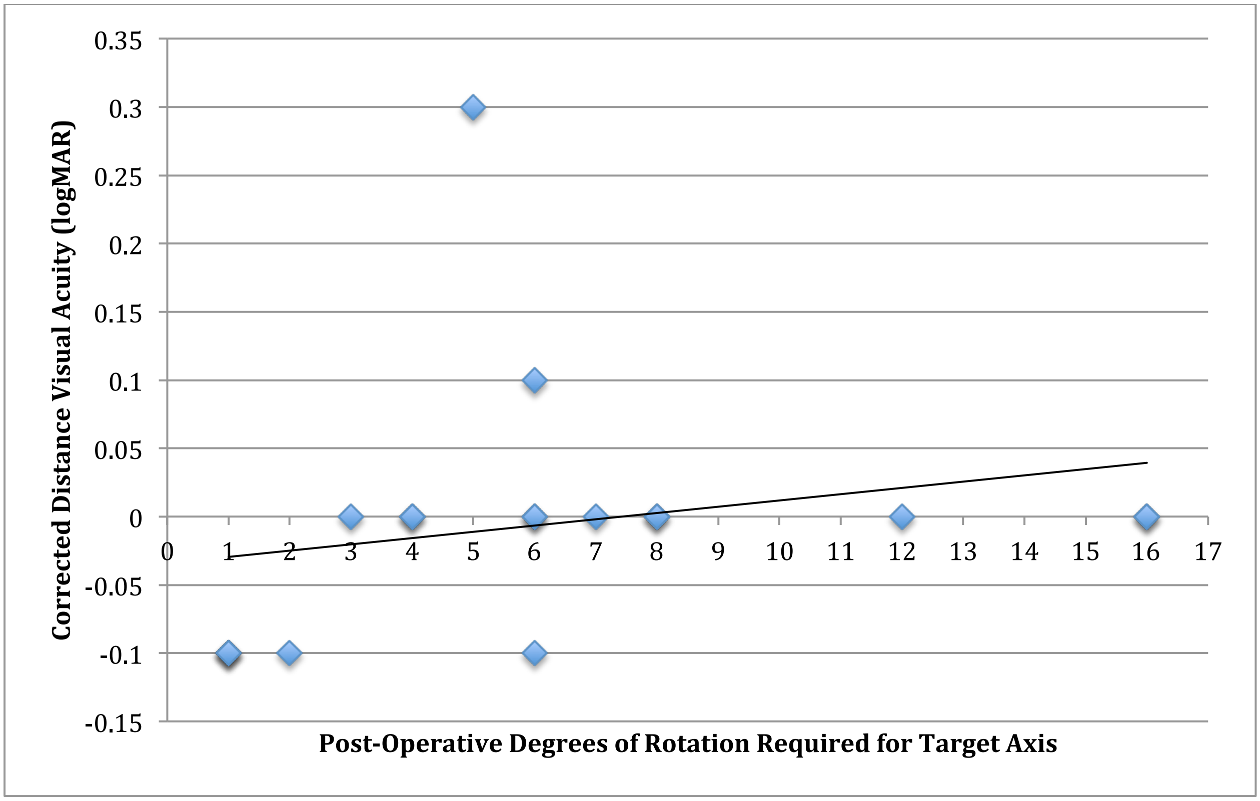

Figure 4. Precision of toric IOL lens placement postoperatively as compared to postoperative CDVA (Corrected Distance Visual Acuity)

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