Rotation Stability of the Cachet Angle-Supported Phakic Intraocular Lens

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ABSTRACT

PURPOSE: To evaluate the rotational stability of an acrylic angle-supported phakic intraocular lens (PIOL) 12 months after implantation in myopic eyes.

METHODS: Patients with a history of moderate to high myopia underwent unilateral or bilateral implantation of an acrylic angle-supported PIOL (AcrySof Cachet; Alcon Laboratories, Inc., Fort Worth, TX). All were followed up for 12 months. IOL rotation was assessed using digital overlay of ocular photographs captured within 2 weeks of implantation and at postoperative month 12. The secondary outcomes of refractive power (spherical equivalent, refractive sphere, and cylinder) and uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were assessed preoperatively and again at 3 months after implantation.

RESULTS: Fifty eyes of 28 patients with a mean age of 32 years were included in this retrospective cohort study. All underwent successful IOL implantation and follow-up. A mean 12-month rotation of 11° was observed (standard deviation: 15.1°, range: 0 to 60°). All preoperative measures (mean) of refractive power improved by 3 months postoperatively (**AQ1**spherical equivalent = -0.35 ± 0.79 diopters [D], spherical refraction = 0.04 ± 0.82 D, cylindrical refraction = -0.77 ± 0.91 D). Two percent of eyes requiring additional laser adjustment by postoperative month 12, primarily due to corneal astigmatism.

CONCLUSION: The study findings suggest that AcrySof Cachet angle-supported PIOLs offer moderate 1-year rotational stability. Because this type of IOL also corrects myopia effectively, it appears to be a good treatment option for myopic eyes. However, the rotation that occurs makes it unsuitable for cylinder corrections.

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Implantation of an angle-fixated phakic intraocular lens (PIOL) in the eye's anterior chamber is a recognized treatment for myopia. However, the use of this type of IOL remains limited because its ocular location increases the risk of tissue damage and complications.[1] Such concerns have triggered the withdrawal of several PIOL models, including the Vivarte and NewLife IOLs (Carl Zeiss Meditec, Jena, Germany).[2] Studies have shown that endothelial interaction, pupil ovalization, and other complications associated with angle-fixated PIOL implantation arise from inflexible lens materials or oversized IOLs.[3] A new acrylic angle-fixated PIOL (AcrySof Cachet; Alcon Laboratories, Inc., Fort Worth, TX) was developed to overcome the known limitations of these lenses.[1] In theory, the design of this angle-fixated lens with a 6-mm optic and two haptics increases optic and footplate flexibility and accommodates minor IOL sizing errors without compromising stability and positioning.[3]

To date, studies remain focused on the visual outcomes achievable with the AcrySof Cachet IOL. In a study by Kohnen et al.[3] that involved 190 individuals with moderate to high myopia, implantation of the AcrySof Cachet IOL produced high levels of refractive correction and predictability of manifest refraction spherical equivalent. Toso and Morselli[4] reported significantly improved quality of vision (determined by negative spherical aberration and point spread function measurement) following angle-supported PIOL implantation in 35 highly myopic eyes. Mastropasqua et al.[5] found that both quality of vision and refraction improved following angle-supported PIOL implantation in eyes with moderate to high myopia.

The rotational stability of implanted angle-supported PIOLs has not previously been frequently studied. This study

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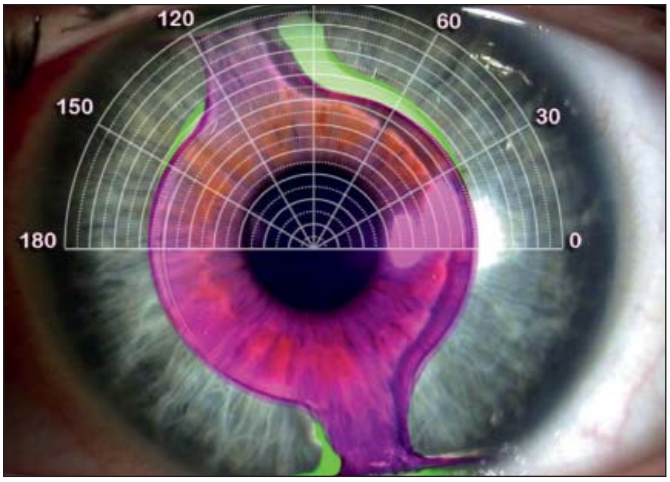

Figure 1. Median intraocular lens rotation (11.5°).

therefore aimed to evaluate the level of rotational stability offered by the AcrySof Cachet IOL over a 12-month period following implantation in myopic eyes.

PATIENTS AND METHODS

This retrospective analysis comprised eyes with moderate to high myopia, defined as a spherical equivalent refraction of -5.25 to -19.63 diopters (D). All eyes had a clear crystalline lens before surgery. All eyes were implanted with the AcrySof Cachet IOL, with implantation performed by two surgeons (OK, GG) from 2009 to 2011. All patients provided written informed consent before examination and surgery. Surgeries were performed at the Augenklinik am Neumarkt in Cologne, Germany. The study adhered to the tenets of the Declaration of Helsinki.

The inclusion criteria for patient selection were as follows: anterior chamber depth of 2.8 mm or more, stable refraction past 12 months, no chamber angle dysgenesia or significant pigment dispersion, otherwise healthy eyes, endothelial cell count of minimum 2.000°C/cm^2, informed consent about risk–benefit ratio and alternative treatment options, mesopic pupil diameter no larger than 7.0 mm, and eligibility for laser corneal refractive surgery in the event of corneal astigmatism.

We performed a complete ophthalmologic examination of all eyes at least 2 weeks before surgery to confirm the absence of anterior segment and retinal abnormalities. All patients were followed up for 12 months after IOL implantation. IOL rotation was assessed using digital overlay of ocular photographs taken at 0 and 12 months postoperatively (**Figure 1**) using image processing software (Photoshop; Adobe Systems Inc., Cupertino, CA). Refractive power (spherical equivalent, refractive sphere, and cylinder), uncorrected distance visual acuity (UDVA), and corrected distance visual acuity (CDVA) were assessed preoperatively and at 3 months postoperatively. Refractive power was measured using phoropter-based best spectacle correction. UDVA and CDVA were assessed with a Snellen chart.

SURGICAL TECHNIQUE

We implanted an AcrySof Cachet angle-supported PIOL in the anterior chamber of each eye. For each eye, the most appropriate of four available IOL sizes (12.5, 13.0, 13.5, and 14.0 mm) was determined using the white-to-white measurement of the IOLMaster 500 (Carl Zeiss Meditec). In keeping with a nomogram provided by Alcon Laboratories, Inc., an additional 0.5 mm was added to the measurement obtained with the IOLMaster to determine the final IOL size to be implanted. The appropriate IOL power was identified with Alcon Laboratories, Inc.'s online calculation form (http://www.acrysofcachetcalculator.com) and the van der Heyde formula.[6] Variables used in the calculation were K-readings, spherical and cylindrical correction, and anterior chamber depth.

The IOL was implanted under topical anesthesia. Before IOL insertion, the anterior chamber was filled with a high-viscosity viscoelastic material. The IOL was introduced into the anterior chamber using the Alcon P cartridge, through a 2.7-mm single-plane clear corneal incision made at the 12-o'clock position in all cases. The intended IOL position was at the 6- and 12-o'clock positions in all cases except eyes with a nasally centered pupil, for which IOLs were positioned in an oblique primary position (10- and 4-o'clock positions). The viscoelastic material was then aspirated, but no iridectomy was performed. No sutures were required to close the clear corneal incision, which was self-sealing.

STATISTICAL ANALYSIS

Statistical analysis was performed using Datagraph Med (Ingenieurbuero Pieger GmbH, Wendelstein, Germany) for refraction and visual acuities and Excel (Microsoft, Redmond, WA) software. Quantitative variables were expressed as the mean. Pearson's test of correlation was used to compare different parameters (rotation, anterior chamber depth, and endothelial cell count). A *P* value of less than .05 was used to define statistical significance.

RESULTS

The study included 50 eyes (26 left and 24 right) of 18 women and 10 men. The mean age of the cohort was 32 years (range: 18 to 55 years). No patients were lost to follow-up.

A mean IOL rotation of 11.4° ± 15.1° (standard deviation: 15.1°, range: 0 to 60°) (when direction of rotation

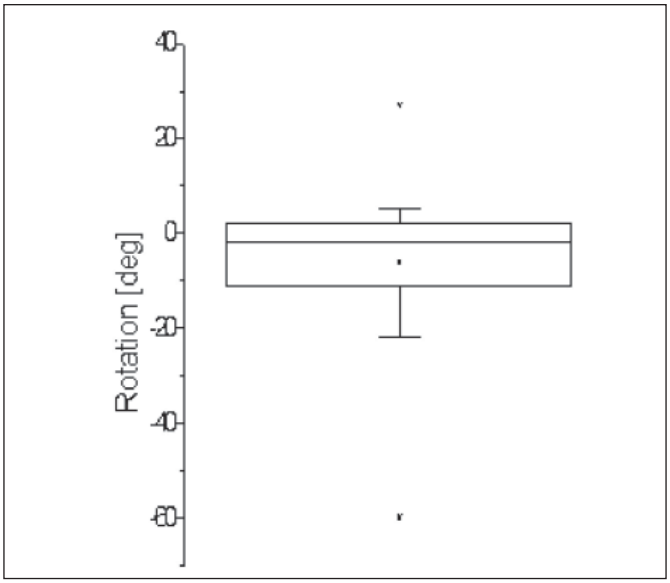

Figure 2. Intraocular lens rotation within the first year. The bottom and top of the box are the first and third quartiles, the band inside the box is the second quartile (median), and the ends of the whisker plots represent one standard deviation above and below the mean of the data. The rotational direction (clockwise/counter-clockwise) has been taken into account.

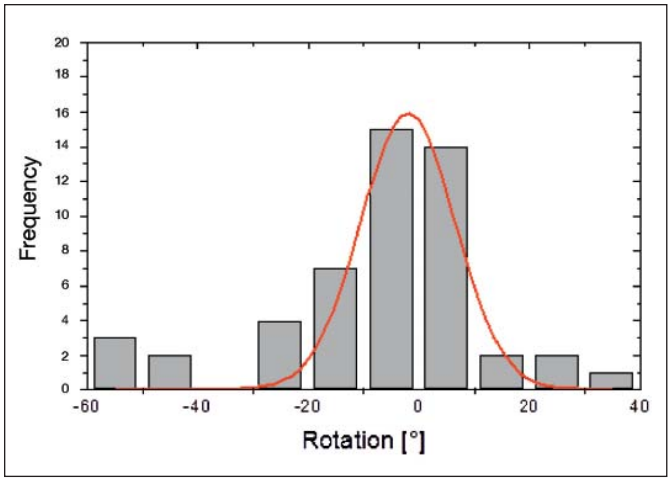

Figure 3. Histogram and Gaussian fit of intraocular lens (IOL) rotational distribution within the first year. Most of the IOLs lie within ±10°.

was not taken into account) was observed at postoperative month 12 compared with month 0. The median IOL rotation that occurred during this follow-up period was 4.5°. Minimum and maximum rotations of 0° and 60°, respectively, were observed among the cohort (**Figures 2** and **3**).

AQ2 The mean preoperative spherical equivalent was -9.71 ± 3.07 D (range: -19.63 to -5.25 D). This value decreased to -0.35 ± 0.79 D (range: -3.00 to 0.75 D) at postoperative month 3. Mean spherical refraction was -9.08 ± 2.95 D (range: -19.25 to -5.25 D) preoperatively and improved to 0.04 ± 0.82 D (range: -3.00 to 1.25 D) at postoperative month 3. Mean cylindrical refraction also improved from -1.28 ± 1.28 D (range: -7.75 to 0.00 D) preoperatively to -0.77 ± 0.91 D (range: -5.50 to 0.00 D) 3 months postoperatively.

By postoperative month 3, no eyes had lost any Snellen chart lines for CDVA. Forty-four percent of eyes gained no lines, 36% gained one line, 10% gained two lines, and 10% gained more than two lines. A total of 69% had UDVA (only IOL treatment taken into account; no additional corneal refractive enhancement) of 20/20 or better, 18% had 20/25 or better, and 8% had 20/30 or better.

Laser re-treatment was needed for 2% of eyes by 12 months after IOL implantation. A total of 84% of eyes achieved postoperative refractive correction within 0.5 D of the target refractive correction calculated preoperatively.

Pupil ovalization or block did not occur. Mean endothelial cell count decreased from 2,650 ± 500 (standard deviation [SD]) to 2,500 ± 410 cells/mm^2 over the first 3 months, after which time the endothelial cell count remained fairly stable until postoperative month 12. No significant correlation was observed between cell loss and IOL rotation ($r = -0.183$; $r^2 = 0.033$). PIOL rotation showed no significant correlation with white-to-white diameter ($r = 0.164$; $r^2 = 0.027$), anterior chamber depth ($r = 0.325$; $r^2 = 0.105$), patient age ($r = 0.042$; $r^2 = 0.002$), or IOL sizing ($r = 0.215$; $r^2 = 0.046$).

DISCUSSION

Previous studies have shown that angle-supported PIOLs can provide effective long-term correction of moderate to high myopia while avoiding the loss of accommodative power seen with refractive lens exchange and the corneal weakening associated with corneal surgery.[3-7] In contrast, the short- and long-term rotational stability of angle-supported PIOLs has been less extensively studied.[8] In the current study, myopic eyes implanted with an angle-supported PIOL exhibited variable but significant IOL rotation over the first 12 postoperative months. No significant correlation was seen between IOL rotation and endothelial cell loss. Lens rotation was not associated with endothelial cell loss. However, because IOL rotation as small as 15° can decrease cylindrical correction by up to 50%, the small level of rotation that occurs with the AcrySof Cachet IOL makes it unsuitable for cylinder corrections.[9]

Our finding of IOL rotation following angle-supported PIOL implantation is consistent with that of a 2012 study by Mesa et al.,[10] in which 1-year postoperative IOL rotation determined by slit-lamp examination was assessed among 42 eyes implanted with the AcrySof Cachet IOL. The results obtained showed a

mean IOL rotation of 3.97° (range: 0° to 10°), with most eyes (76%) experiencing IOL rotation of no more than 5°. Our study showed a larger overall range of rotation than that of Mesa et al.,[10] but this may be due to differences in the level of precision used to assess IOL rotation in both studies. We used digital overlay of images of the implanted IOL captured immediately and 1 year after implantation. The Mesa et al.[10] study provides no detailed explanation of how rotation was assessed, other than it was performed during slit-lamp examination. This leaves the possibility that rotation was left to the subjective interpretation of a study investigator. Such a technique leaves a greater margin of error than the method used in our study.

It has been suggested by the manufacturer of the AcrySof Cachet IOL that a slightly oversized IOL diameter encourages stronger haptic compression, thus leading to better fixation without risking an anterior shift of the PIOL's optic. In the current study, we assessed only the relationship between rotation amount and IOL sizing, and observed no significant correlation between these two factors. This suggests that compression forces do not influence IOL rotational stability.

Highly predictable refractive results were also observed and only one eye (2%) needed an additional laser refractive surgery to achieve target refraction. No complications occurred among the study cohort. These secondary findings are similar to those produced from a 2009 study by Kohnen et al., in which AcrySof Cachet IOL implantation produced highly predictable refractive outcomes, no pupil ovalization, and minimal endothelial cell loss.[3]

Previous research has suggested that pupil movement may trigger positional changing of other (non-angle-supported) PIOLs implanted in the anterior chamber.[11-14] Data from a 2007 study by Gerl et al.[15] indicated that the anterior chamber is not circular in shape. This incongruity between IOL shape and anterior chamber shape may provide an opportunity for an anterior chamber PIOL to continue to move after implantation until it settles into a stable position at which optimal balance between IOL compressive forces and chamber angle stability is achieved.[15] Long-term follow-up of the current study is required to determine whether the AcrySof Cachet IOL continues to move in this manner after implantation and the length of time taken for positional stabilization to occur.

Literature has also suggested that accommodation may be the driving force of anterior chamber PIOL rotation after implantation. The Helmholtz theory states that accommodation is achieved through the triad of convergent eye movement, pupil constriction, and ciliary muscle contraction. Both pupil constriction and ciliary muscle contraction directly interfere with the appearance and width of the anterior chamber angle.[16] Research has also shown that anterior chamber angle width increases during accommodation and decreases during non-accommodation.[17,18] Because the Acrysof Cachet IOL is fixated only by the compressive forces of the four footplates, the dynamics of accommodation on the anterior chamber angle width may drive the rotation of the PIOL after implantation. Further long-term study evaluating IOL rotation rates among individuals with higher accommodation activities may shed some light on this theory.

The main limitation of the current study is the small number of eyes included in the cohort. As a study investigating outcomes infrequently assessed by previous research, it is difficult to draw definite conclusions from a cohort of only 50 eyes. An additional limitation of the current study is that it offers little information about the longevity of the rotational stability exhibited by the AcrySof Cachet IOL and also about the rotational stability of the IOL during the first 3 postoperative months. Because eyes were followed up for a period of 12 months, no firm conclusions can be made about the long-term rotational stability of the AcrySof Cachet IOL.

Studies have shown that ultrasound biomicroscopy improves the accuracy of PIOL sizing, which in turn increases long-term IOL stability.[19] Further study into the rotational stability of the Acrysof Cachet IOL may benefit from the use of immersion ultrasound biomicroscopy among eyes that exhibit the greatest levels of IOL rotation. This may help to determine whether IOL sizing errors underlie cases where larger degrees of rotation occur with this IOL.

As a retrospective study, some degree of selection bias is likely to have occurred during cohort compilation. Patients included in the cohort were not chosen at random; instead, selection was based on the availability of relevant patient data.

Anterior chamber implantation of the AcrySof Cachet angle-supported PIOL appears to be a safe and effective treatment option for moderate-to-severe myopia. The specific design of the AcrySof Cachet IOL offers only moderate 1-year rotational stability, making this design unsuitable for toric correction.

AUTHOR CONTRIBUTIONS

Study concept and design (OK, UO); data collection (GG, OK); analysis and interpretation of data (OK, UO); drafting of the manuscript (OK, UO); critical revision of the manuscript (GG, OK, UW); statistical expertise (UO)

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AUTHOR QUERIES

AQ1 Please verify the data added to Results of the Abstract are correct.

AQ2 Per the editor, please list the *P* values for each comparison here (see page 2, left column, 2nd paragraph).