Rotational stability and posterior capsule opacification of a plate-haptic and an open-loop-haptic intraocular lens

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PURPOSE: To compare the rotational stability and posterior capsule opacification (PCO) rate in eyes with a 1-piece or 3-piece acrylic intraocular lens (IOL).

SETTING: Department of Ophthalmology, Medical University of Vienna, Vienna, Austria.

DESIGN: Prospective randomized masked clinical trial.

METHODS: Patients with age-related cataract received a plate-haptic acrylic IOL (Acri.Smart 46S) in 1 eye and a 3-piece loop-haptic acrylic IOL (Acri.Lyc 53N) in the other eye. Retroillumination images were taken 1 hour, 1 week, and 1, 6, and 12 months postoperatively. Intraocular lens rotation was measured using standard software (Adobe Photoshop). The amount of PCO was assessed subjectively at the slitlamp and objectively using an automated image-analysis software (AQUA).

RESULTS: The study enrolled 80 eyes of 40 patients. The IOL rotation measurements showed excellent reproducibility, with a deviation of less than 0.8 degrees. Both IOLs had comparable and good rotational stability; rotation was less than 4 degrees in 71% of eyes 1 year postoperatively. The mean absolute rotation was 2.6 degrees ± 1.9 (SD) in the plate-haptic IOL group and 3.1 ± 2.4 degrees in the loop-haptic IOL group. The mean AQUA PCO score (scale 0 to 10) was 0.4 in both IOL groups (P = .7).

CONCLUSION: The 2 IOL models had comparable, excellent rotational stability and low PCO intensity 1 year postoperatively. Thus, the plate-haptic IOL may be a good platform for a toric model.

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In the past few years, refinements in surgical technique and modifications in intraocular lens (IOL) design and material have led to a decreased incidence of posterior capsule opacification (PCO). Moreover, much effort has gone into developing advanced phaco machines and foldable IOLs for microincision cataract surgery (MICS), which can be performed through a corneal incision smaller than 1.5 mm. This improvement has several advantages, including rapid visual restoration with minimum postoperative inflammation, less iatrogenic corneal damage, and lower surgically induced corneal astigmatism.1,2

Recently, several new IOL designs, including toric IOLs, have become available for implantation through microincisions. Because of the astigmatically neutral aspect of the corneal microincisions, implantation of a toric IOL may yield emmetropia in patients with manifest astigmatism (about 20% of all cataract patients) if the IOL does not rotate postoperatively.3 Stability of an IOL may be defined as rotation of less
than 5 degrees between visits 3 months apart in 90% of the eyes.

It is well known that the IOL haptic design is crucial for maintaining axial and rotational stability of the IOL. The current MICS-compatible IOL models have a plate-haptic design, similar to the first foldable silicone IOLs in the 1980s, while the most frequently used IOL designs have 1-piece or 3-piece open-loop haptics. Previous studies4,5 found that 3-piece IOLs have excellent rotational stability in the capsular bag. Moreover, the incidence of PCO remains low for a longer period in eyes with this IOL design.6,7 Because current MICS IOLs tend to deviate from the 3-piece open-loop design, it is unclear whether the 1-piece plate-haptic design compromises the clinical performance of these IOLs and if so, to what degree.

The aim of this study was to compare the clinical performance of a plate-haptic IOL and a standard 3-piece open-loop-haptic IOL made of the same acrylic material. Outcome measures were rotational stability of the IOL in the capsular bag and development of PCO over a long-term follow-up.

PATIENTS AND METHODS

This prospective randomized patient- and examiner-masked clinical trial with intraindividual comparison was performed at the Department of Ophthalmology, Vienna General Hospital, Medical University of Vienna, Austria. The patients were recruited in a continuous cohort. The inclusion criterion was bilateral age-related cataract. Exclusion criteria were a history of other ocular disease or intraocular surgery, laser treatment, glaucoma, retinal pathology, and diabetes requiring medical treatment. The study was performed according to the guidelines of the Declaration of Helsinki, and ethics committee approval was obtained.

Intraocular Lens Assignment

Each patient received, according to a randomization list, an Acri.Smart 46S IOL (Carl Zeiss Meditec AG) in 1 eye (plate-haptic group) and an Acri.Lyc 53N IOL (Carl Zeiss Meditec AG) in the contralateral eye (loop-haptic group) to allow intraindividual comparison. The 2 models are of the same foldable acrylic material with a 25% water content and hydrophobic surfaces. The 1-piece IOL has a biconvex square-edged 6.0 mm optic, an overall diameter of 11.0 mm, and supporting plate haptics with no haptic angulation. The IOL was designed for MICS and can be injected through a 1.5 mm incision. For the purpose of this study, the 1-piece plate-haptic IOLs were specially manufactured with 2 additional optic marks to allow accurate measurement of rotational stability in the capsular bag. The 3-piece loop-haptic IOL has a biconvex 6.0 mm optic and a total diameter of 13.0 mm. The C-loop haptics are poly(methyl methacrylate) and have an angulation of 5 degrees.

Surgical Technique

Surgery was performed between August 2006 and September 2007 by 1 of 2 experienced surgeons (M.G., R.M.) using a standardized small-incision phacoemulsification technique. The same surgeon operated on both eyes of a patient. A 3.0 mm temporal, single-plane, self-sealing, limbal–corneal incision was created. The anterior chamber was filled with sodium hyaluronate 1.0% (Healon), and a continuous curvilinear capsulorhexis (CCC) with a diameter between 5.0 mm and 5.5 mm was created to attain symmetrical 360-degree CCC–IOL overlap. After hydrodissection and phacoemulsification, the surgeon was unmasked to the IOL type and implanted the IOL using an injector. No additional procedures to reduce PCO, such as capsular bag polishing, were applied during surgery. After implantation, each IOL was rotated approximately 90 to 180 degrees to imitate the alignment manipulation usually performed with a toric IOL. Postoperative treatment consisted of topical gentamicin–dexamethasone eyedrops (Dexagent-POS) and ketorolac eyedrops (Acular) 3 times a day for 4 weeks.

Follow-up Examination and Image Acquisition

Postoperative examinations were performed at 1 hour, 1 week, 1 and 6 months, and 1 year. On each occasion, patients received phenylephrine 2.5% and tropicamide 0.5% drops at least 30 minutes before they were examined at the slitlamp. Using a standardized evaluation form, the following parameters were assessed subjectively: IOL centration, CCC–IOL overlap, amount and type of anterior capsule opacification (ACO) (score range 0 to 3), amount and type of posterior fibrosis (score range 0 to 3), and amount of regenerative PCO (score range 0 to 10). The corrected distance visual acuity (CDVA) was assessed using Snellen charts at the 1-month, 6-month, and 1-year follow-up examinations. Finally, the need for a neodymium:YAG (Nd:YAG) laser capsulotomy was noted.

At each examination, digital retroillumination images of the posterior capsule were obtained with a digital camera (Nikon/Kodak/DCS 720x). The camera was mounted on a modified Zeiss 30 slitlamp (Carl Zeiss Meditec AG) with an external flashlight source, which provides coaxial illumination from the flash pack through a fiberoptic cable to the camera. This system provides even illumination over the entire image with relatively small flash artifacts and has high reproducibility.8 It is similar to the system described by Pande et al.9 In this study, the system was used to document the position of the IOL in the capsular bag and to evaluate regenerative PCO. All digital images were transferred to a personal computer.

Data and Image Analysis

To measure the IOL position in the capsular bag, retroillumination images of each examination were imported into standard software (Adobe Photoshop 7.0). Accurate IOL position was defined as an angle between the reference and comparison axis and was quantified in degrees. The software automatically ascertained the horizontal reference axis in each image. The comparison axis was determined using an image-editing feature of the software that allows the examiner to connect 2 critical details of an IOL, such as optic marks and haptic insertions. Accordingly, the software calculates the angle of the comparison axis with reference to the horizontal. For this purpose, at each follow-up examination, it was necessary to obtain images with sufficient mydriasis to enable identification of critical details of the IOL.

The intraobserver repeatability of determining IOL position was tested in 10 patients for each IOL design. For this
purpose, 2 retroillumination images were taken per eye. Between the first and second images, the patients were instructed to take their chin off the chin rest, blink, and then return to the examination position. The position of the photographic device was readjusted before the second image was taken in standardized fashion.

For slitlamp evaluation, a subjective scale of 0 to 3 (0 = clear capsule; 3 = severe fibrotic PCO) was used for fibrotic PCO and a scale of 0 to 10 (0 = clear capsule; 10 = severe regeneratory PCO) was used for regeneratory PCO. Regeneratory PCO was also objectively assessed using automated image-analysis software (AQUA), which was developed at the Department of Ophthalmology, Medical University of Vienna, in cooperation with the Technical University of Graz, Austria. For each patient, digital retroillumination images at the 1-year follow-up examination were imported into the program and the region within the CCC was evaluated. The program detects the CCC edge semiautomatically (computer aided). The software measures the inhomogeneity using a statistical texture analysis. To calculate the inhomogeneity of the image, a gray-level co-occurrence matrix (GLCM) of the bit map of the image is built. The GLCM belongs to 2nd-order statistics; it is a square matrix with a side length corresponding to the number of gray levels of a bit map. The grading is performed using GLCM entropy, which is a measure of inhomogeneity. This value is converted into a score between 0 and 10 (0 = clear capsule; 10 = severe PCO). This fully automated system provides a scoring process without interactive or subjective steps and has been shown to correlate well with subjective scoring of PCO at the slitlamp.10

To assess the possible influence of initial IOL axial position on rotational stability, the rotational movement of each IOL type in the near-to-vertical position (between 45 degrees and 135 degrees) was compared with the rotational movement in the near-to-horizontal position (between 0 degrees and 45 degrees and between 135 degrees and 180 degrees).

Statistical Analysis

Statistical analysis was performed using the Excel program (Microsoft Corp.) and SPSS for Windows software (version 14.0, SPSS, Inc.). The results are presented as the mean, standard deviation (SD), 95% confidence interval (CI), and range (ie, minimum and maximum). The statistical significance was calculated using the paired t test and chi-square test. Correlations were determined using linear regression. A P value less than 0.05 was considered statistically significant.

RESULTS

Forty patients (80 eyes) were enrolled in the study. The mean age of the patients was 74.0 ± 9.2 years. The plate-haptic IOL was implanted in the right eye in 19 cases and in the left eye in 21 cases. No surgical complication led to patient exclusion.

Sixty eyes of 30 patients were available for examinations until the 1-month follow-up visit; 2 patients died shortly after surgery, 4 patients could not come because of severe illness, and 4 patients did not appear due to noncompliance. Mydriasis was sufficient to depict the critical IOL details accurately in 46 eyes, 26 with a plate-haptic IOL and 20 with a loop-haptic IOL. At the 1-year follow-up, 23 patients were available for examination (unable to reach 7 patients); rotational movement was analyzed in all 23 eyes with a plate-haptic IOL and in 19 eyes with a loop-haptic IOL (insufficient mydriasis in 4 eyes).

Intracocular Lens Rotational Stability

All IOLs were implanted in the bag with 360-degree CCC–IOL overlap. On slitlamp examination, no IOL was significantly decentered (> 0.5 mm of the visual axis and causing visual symptoms) or tilted 1 year after surgery.

Regarding intraexaminer reproducibility of the IOL rotation measurement, there was a high correlation with both IOL types, with a difference of less than 0.8 degrees between the 2 repeated measurements on different images within patients (r = 0.99, P < .01). The mean absolute difference and 95% CI in the test-retest analysis was 0.41 ± 0.22 degrees (95% CI, 0.25-0.57) for the plate-haptic IOL and 0.35 ± 0.20 degrees (95% CI, 0.21-0.49 degrees) for the loop-haptic IOL.

At the 1-year follow-up examination, the mean absolute IOL rotation was 2.6 ± 1.9 degrees (range 0.4 to 5.7 degrees) in the plate-haptic group and 3.1 ± 2.4 degrees (range 0.1 to 7.1 degrees) in the loop-haptic group. Absolute rotational movement was less than 4 degrees in 71% of eyes and less than 2 degrees in 29% of eyes in both groups (P = .18). Figure 1 shows the mean absolute rotation at each follow-up in chronological sequence. There was no significant difference between the 2 IOL types in rotational movement at any time point (P > .3). Early rotation (within the first week postoperatively) was clockwise in 19 (73%) of 26 eyes in the plate-haptic group and in 14 (70%) of 20 eyes in the loop-haptic group. Late rotation (within 1 year postoperatively) was clockwise in 15 (71%) of 21 eyes and in 20 (95%) of 21 eyes, respectively.

In the plate-haptic IOL group, the mean absolute early rotation was 2.4 ± 2.6 degrees (range 0.5 to 9 degrees) in a vertical IOL position and 1.1 ± 1.0 degrees (range 0.2 to 3.3 degrees) in a horizontal IOL position (P = .13). In the loop-haptic IOL group, the mean absolute early rotation was 1.7 ± 1.1 degrees (range 0.1 to 3 degrees) in a vertical IOL position and 2.3 ± 1.4 degrees (range 0.3 to 4.1 degrees) in a horizontal IOL position (P = .3). There was no correlation between clockwise or counterclockwise rotation and PCO in either group (r = 0.07, plate-haptic IOL; r = 0.05, loop-haptic IOL).

Figure 2 shows follow-up images of a representative case from the image data set. Post hoc power analysis for the observed SD of 23 patients (42 eyes) showed
clinically that relevant rotational movement of 3 degrees (ie, 10% loss in compensatory anti-astigmatic effect) could be calculated with a 99% power at an α level of 5%.

### Posterior Capsule Opacification

The mean objective PCO score (scale 0 to 10) was 0.4 ± 0.7 in the plate-haptic group and 0.4 ± 0.9 in the loop-haptic group (P = .7). Intraindividual comparison showed the same PCO score in 50% of patients (Figure 3). Post hoc power analysis for the observed SD of 23 patients (46 eyes) showed that a clinically relevant difference in the PCO score of 1 (ie, 10%) could be calculated with a 99% power at an α level of 5%.

Similar to the results in the objective PCO image analysis, the mean subjective PCO score assessed by the slitlamp examination (scale 0 to 10) was 0.9 ± 1.0 in the plate-haptic group and 0.7 ± 0.8 in the loop-haptic group (P = .4). The mean ACO score (scale 0 to 3) was 1.58 ± 0.5 and 1.59 ± 0.5, respectively; the difference between the 2 groups was not statistically significant (P = .98). There was also no significant difference between the groups in fibrotic PCO (scale 0 to 3) (mean 0.52 ± 0.7 and 0.62 ± 0.8, respectively; P = .43) or in number of capsule folds (cases 1 year postoperatively: 2 and 1, respectively; P = .55).

There was no significant difference between the 2 IOL groups in visual acuity 1 year after surgery (P = .86). The mean CDVA was 0.84 ± 0.17 (range 0.5 to 1.0) in the plate-haptic group and 0.83 ± 0.16 (range 0.5 to 1.0) in the loop-haptic group. One patient required Nd:YAG laser capsulotomy treatment 6 months postoperatively.
postoperatively (performed elsewhere) because of disturbing visual sensations caused by capsule folds in the eye with a loop-haptic IOL. Another patient had the same treatment in both eyes because of decreased visual acuity after the 1-year follow-up examination; the PCO score was 2.01 in the eye with the loop-haptic IOL and 1.04 in the eye with the plate-haptic IOL).

**DISCUSSION**

Microincision cataract surgery can lead to less surgically induced corneal astigmatism than surgery in which a larger corneal incision is created. Implantation of a toric IOL through these small incisions has the potential to provide more predictable treatment for patients with cataract and preexisting corneal astigmatism. However, IOL stability and lack of rotation are still essential for effectiveness with every toric IOL design. Every degree of off-axis rotation results in a loss of 3.3% of lens cylinder power; at a rotation of 30 degrees, the cylinder power is absent.\(^\text{11}\)

Most IOL rotation occurs in the early postoperative period, and its extent is mainly influenced by capsular bag size, capsulorhexis size, and the capsule-fusion process.\(^\text{12}\) Once the anterior and posterior capsules fuse, IOL rotation occurs less often. The most frequent cause of late IOL rotation is capsular bag shrinkage, which mainly occurs within the first 3 months postoperatively.\(^\text{13}\) Because it has become clear that IOL design plays an important role in improving rotational stability, much effort has been expended to develop several types of haptic designs. However, it is unclear which IOL design allows better stability and centration and is therefore more suitable for toric IOL design.

The first published results of a toric nonfoldable 3-piece loop-haptic IOL\(^\text{12}\) found a significant amount of rotation in 21% of cases 3 months after surgery. The authors suggested that this high level if IOL instability was related to the 3-piece design and that a 1-piece IOL would rotate less. In fact, early plate-haptic foldable IOL models were associated with less instability and, possibly, less need for early IOL repositioning.\(^\text{14}\)

In a study that compared the rotational stability of plate and loop multifocal IOLs, Patel et al.\(^\text{15}\) found that plate-haptic IOLs had a tendency to be less stable than 3-piece loop-haptic IOLs in the early postoperative period, whereas in the late postoperative period, the plate-haptic IOLs had greater rotational stability (mean late rotation \(< 8\) for loop-haptic IOL and \(< 2\) degrees for plate-haptic IOL). Similar to these results, our study found that the greatest rotation occurred within the first week postoperatively with both IOL types, whereas the loop-haptic IOL tended to rotate slightly less than the plate-haptic IOL (Figure 1). However, contrary to the results of Patel et al., we found very good rotational stability (\(< 3\) degrees for plate-haptic IOLs and \(< 4\) degrees for loop-haptic IOLs) within 1 year postoperatively, with no significant difference between the 2 IOL models. Furthermore, our results on the direction of rotational movement were different from those of Patel et al. In their study, the rotation at 6 months was predominantly counterclockwise in 89% of eyes with a loop-haptic IOL and with 52% of eyes with a plate-haptic IOL. We found that the rotation at 1 year was predominantly clockwise in 95% of eyes with a loop-haptic IOL and 71% of eyes with a plate-haptic IOL. One explanation for this discrepancy in the rotational behavior of the loop-haptic IOLs might be that there was a reduction in the capsular bag circumference that was compressing the haptics, which induced torque on the optic in a clockwise direction. Thus, the counterclockwise rotation observed by Patel et al. likely represents rotation of the haptic into the areas of the open capsular bag.

In addition, several studies report that the initial axial positioning of the IOL affects rotational stability during the first weeks postoperatively. Ruhswurm et al.\(^\text{16}\) found that a plate-haptic IOL tended to rotate significantly more with a vertical axis, and Till et al.\(^\text{17}\) observed that the oblique axis was the most unstable. Similar to the results of Ruhswurm et al., we found that the plate-haptic IOL tended to rotate more with a vertical axis, although the difference between groups was not statistically significant.

Weinand et al.\(^\text{5}\) evaluated the rotation of the spherical AcrySof SA60AT IOL (Alcon, Inc.) using a high-precision method that reduces assessment bias caused by the cyclorotation of the eye. They found a mean rotation of less than 2 degrees 6 months postoperatively; in 59% of the eyes, the IOL rotation did not exceed 1 degree. Thus, the authors recommend that this IOL...
design could be incorporated into a toric model. The toric version of this IOL is now commercially available and is approved by the U.S. Food and Drug Administration. However, recent studies of clinical performance of the toric IOL showed some degree of rotation (range 3 to 4 degrees) consistently and that the IOL was not as stable as the older monofocal version.18–20

Although high-quality photographs are crucial for correct evaluation of IOL rotation, the accuracy of measuring IOL rotation must be questioned because possible limitations may arise from bias in the photographic assessment process caused by head inclination and cyclorotation of the eye and in image evaluation caused by drawing the connecting lines between IOL markers.21 Even though our method does not eliminate the possibility of cyclorotation of the eye, we found excellent rotation stability (rotation <2 degrees) in 79% of 19 eyes with a plate-haptic IOL and 67% of 15 eyes with a loop-haptic IOL; there was no case of late rotation greater than 7 degrees in either group. We believe this is because the images were obtained in a standardized manner using a highly reproducible image-acquisition technique that we used in previous studies to precisely observe morphology changes caused by regeneratory PCO over a long-term follow-up. Thus, given our results without outliers and a high reproducibility of repeated measurements, we believe our method is close to optimal.

Although we used the same images for assessment of rotation as well as PCO, there was no relationship between rotation or rotational direction and the incidence or amount of PCO. Furthermore, the PCO intensity was low in both the plate-haptic group and the loop-haptic group, with no significant between-group differences. A possible explanation for this is that IOL haptic design does not play a significant role in PCO prevention if the IOL has a sharp optic edge. Another possible explanation is that a plate-haptic design allows the same strong fibronectin reaction to optic and haptics, which leads to an enhanced capsule bend and thus a decreased PCO rate.23

In contrast, a plate-haptic design has been associated with a higher incidence of PCO under the assumption that the bulky haptics may leave a section of the optic circumference without a sharp edge, resulting in loss of anterior and posterior capsule fusion at that point. To our knowledge, Abhilakh Missier et al.24 are the only authors to have published a comparison of the PCO rate between a plate-haptic IOL and a 3-piece open-loop-haptic IOL. They found a significantly higher PCO incidence with the plate-haptic silicone IOL that was the result of incomplete formation of a capsular bend along the junction. However, they compared 2 IOLs that differed in optic material, optic edge design, and haptic design. In contrast, our study used an objective PCO quantification system and varied in only a single parameter (haptic design). A potential drawback of our study may be the high dropout rate of patients. However, the power analysis showed enough power for statistical conclusions on rotational stability and PCO intensity.

In conclusion, our study found that the plate-haptic IOL remained rotationally stable over a period of 1 year without differences in clinical outcome and PCO intensity compared with a 3-piece standard IOL. Accordingly, this IOL design based on microincision surgery technology may be a good platform for a toric IOL product. Further follow-up will show whether the incidence of PCO will be higher with the plate-haptic IOL style over a longer follow-up.

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