ARTICLE

Impact of intraocular lens haptic design and orientation on decentration and tilt

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PURPOSE: To assess the effect of intraocular lens (IOL) orientation (vertical versus horizontal) and haptic design (1-piece versus 3-piece) on centration and tilt using a Purkinje meter.

SETTING: Moorfields Eye Hospital NHS Foundation Trust, London, United Kingdom.

DESIGN: Randomized pilot study with intrapatient comparison.

METHODS: In part 1 of this study, patients received plate-haptic IOLs (Akreos Adapt) in both eyes that were positioned vertically in 1 eye and horizontally in the other eye. In part 2, patients received a 1-piece IOL (Acrysof SA60AT) in 1 eye and a 3-piece IOL (Acrysof MA60AC) in the contralateral eye. Decentration and tilt were measured 1 month and 3 months postoperatively with a new Purkinje meter.

RESULTS: In part 1 (n = 15), the mean decentration of plate-haptic IOLs was 0.4 mm \pm 0.2 (SD) with vertical orientation and 0.4 \pm 0.2 mm with horizontal orientation and the mean tilt, 1.5 \pm 1.1 degrees and 2.9 \pm 0.9 degrees, respectively. In part 2 (n = 15), the mean decentration was 0.4 \pm 0.3 mm with 1-piece IOLs and 0.6 \pm 0.8 mm with 3-piece IOLs and the mean tilt, 2.2 \pm 7.2 degrees and 5.3 \pm 2.4 degrees, respectively.

CONCLUSIONS: Three-piece IOLs had a greater tendency toward more decentration than 1-piece IOLs, perhaps because of slight deformation of 1 or both haptics during implantation or inaccuracies in production when the haptics are manually placed into the optic. The IOL orientation for plate-haptic IOLs appeared to have no effect on IOL position. The Purkinje meter was useful in assessing the capsule bag performance of the IOLs.

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With recent advances in intraocular lens (IOL) technology, cataract surgery has transitioned from being solely a treatment for visual rehabilitation to also being a refractive procedure with the aim of gaining visual function comparable to that of the noncataractous elderly eye. Examples are aspheric IOLs to compensate for the spherical aberration of the cornea and increase contrast sensitivity, multifocal IOLs to decrease spectacle dependence, and toric IOLs to correct corneal astigmatism and enhance uncorrected distance vision. Intentionally, these IOL designs should increase visual function and ultimately the patient's quality of life. The performance of these new IOL designs is highly dependent on the position of the IOL in the optical system of the eye. Theoretical simulations by Holladay et al. 1 showed that aspheric IOLs should be decentered less than 0.4 mm and tilted less then 7 degrees to

exceed the optical performance of conventional spherical IOLs. Another theoretical study by Piers et al.² showed slightly more tolerance for decentration and tilt. The authors report 0.8 mm as the critical decentration point and 10 degrees as the critical tilt point for these IOLs. For multifocal IOL designs, decentration of the optic may alter the light distribution between the distance focus and near focus, resulting in poorer performance of the IOLs. For toric IOLs, orientation and centration in the bag are important because misalignments can result in a shift of the axis and possibly in decreased visual quality. Even though an IOL may appear centered at the end of surgery, capsule collapse and contraction resulting from capsule opacification can induce decentration, tilt, or both.

There are several ways of assessing decentration and tilt of an IOL. These include slitlamp assessment,

Table 1. Mean decentration and tilt 1 month and 3 months postoperatively for the vertical and horizontal axis position of plate-haptic IOLs. Negative values indicate inferior or temporal movement.

IOL Axis/Follow-up	Mean \pm SD				
	Decentration (mm)		Tilt (Degrees)		
	X	Y	X	Y	
Vertical					
1 month	0.09 ± 0.26	0.21 ± 0.25	0.4 ± 1.2	-0.4 ± 1.4	
3 months	0.07 ± 0.28	0.23 ± 0.27	-1.5 ± 1.1	-1.6 ± 1.2	
Horizontal					
1 month	0.06 ± 0.19	0.30 ± 0.19	0.6 ± 1.0	-0.4 ± 1.5	
3 months	0.11 ± 0.13	0.34 ± 0.15	2.9 ± 0.9	-1.9 ± 1.4	

retroillumination photography,³ Scheimpflug imaging,⁴ and measurements using Purkinje reflections.^{5–12} The most commonly used is the slitlamp method, which is entirely subjective, can vary between examiners, and is more qualitative than quantitative. Furthermore, because slitlamp grading of IOL decentration and tilt can only be performed with a dilated pupil, the assessment may be difficult to relate to the pupil center or fixation axis. Also, because there is no fixation target for the patient, a slight change in the direction of gaze during slitlamp examination, which might not be spotted by the examiner, will result in the wrong impression of a decentered and tilted IOL.

Rotating Scheimpflug imaging requires sufficient pupil dilation to visualize the optic edge and the posterior IOL surface; in addition, it requires the cooperation of the patient to fixate steadily during the 1.5 seconds of scanning without moving. Also, Scheimpflug images are not corrected for optical distortion by the cornea. Additional problems may be the identification of the anatomic structures of the eye that are used as reference points. The observation

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of Purkinje reflexes dates back to the 19th century, when candles were used to generate ocular reflections. The use of lasers and light-emitting diodes (LEDs) was proposed by Guyton et al., ¹⁴ who used a simple hand light to illuminate the eye and look for the alignment point of the Purkinje III and IV reflexes. Their experiments provided qualitative information about IOL alignment. Newer methods allow calculation from Purkinje images. It was shown that the method using Purkinje images was more accurate than Scheimpflug imaging. ¹³ The Purkinje meter used in the present study ¹⁵ allows simple and quick acquisition of images in pseudophakic eyes. The method was shown to be highly reliable and repeatable in measuring tilt and decentration of IOLs. ⁸

This pilot study compared the effect of IOL haptic orientation and of haptic-loop design on IOL centration and tilt using a Purkinje meter.

PATIENTS AND METHODS

This prospective randomized study with intraindividual comparison comprised patients with age-related cataract. It adhered to the tenets of the Declaration of Helsinki and was reviewed by the local ethics committee. After receiving an explanation of the study, all patients signed a consent form.

Exclusion criteria were age younger than 21 years, pseudoexfoliation syndrome, pigment dispersion syndrome, and history of ocular trauma or other ocular comorbidity that could affect position of the IOL in the eye after implantation.

The study consisted of 2 parts. In part 1, decentration and tilt between the horizontal orientation and vertical orientation of a plate-style IOL (Akreos Adapt, Bausch & Lomb) were compared. In part 2, decentration and tilt between a hydrophobic acrylic 1-piece IOL (Acrysof SA60AT, Alcon Laboratories, Inc.) and a 3-piece IOL (Acrysof MA60AC, Alcon Laboratories, Inc.) with the same optic material were compared. Both IOLs have an optic diameter of 6.0 mm and an overall length of 13.0 mm. The 1-piece IOL is not angulated, and the haptic material is the same as the optic material.

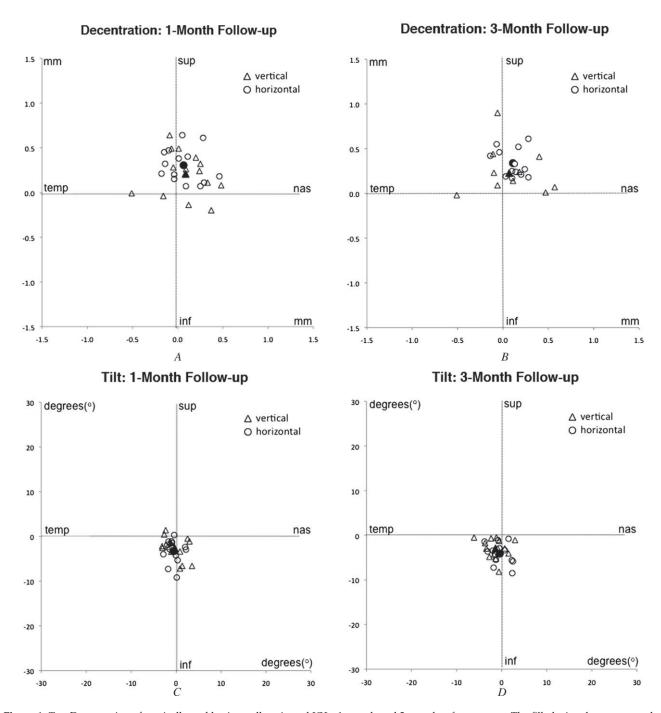


Figure 1. *Top*: Decentration of vertically and horizontally oriented IOLs 1 month and 3 months after surgery. The filled triangles represent the mean decentration of the vertically oriented IOLs. The filled circles represent the mean decentration of the horizontally oriented IOLs. *Bottom*: Tilt of vertically and horizontally oriented IOLs 1 month and 3 months after surgery. The filled triangles represent the mean tilt of the vertically oriented IOLs. The filled circles represent the mean tilt of the horizontally oriented IOLs.

The 3-piece IOL has 10-degree angulated haptics made of poly(methyl methacrylate) (PMMA) filaments.

Patients were randomized using a sealed-envelope technique derived and supplied by the clinical trials unit. The surgeons were masked to group allocation until the time of IOL implantation. After randomization, all patients had standardized sutureless cataract surgery by an experienced surgeon. The technique included a 3.2 mm temporal corneal

incision, capsulorhexis, hydrodissection, phacoemulsification, irrigation/aspiration of cortical remnants, IOL implantation in the capsular bag, intracameral injection of an antibiotic agent, and hydration of the incisions.

In part 1 of the study, the plate-style IOL was oriented with its haptic axis along the vertical or horizontal meridian according to the randomization. The contralateral eye received the alternate orientation of the IOL. In part 2, a 1-piece

Table 2. Mean decentration and tilt 1 month and 3 months postoperatively for 1-piece and 3-piece IOLs. Negative values indicate inferior or temporal movement.

IOL Haptic/Follow-up	Mean ± SD				
	Decentration (mm)		Tilt (Degrees)		
	X	Y	X	Y	
1 piece					
1 month	0.05 ± 0.23	0.11 ± 0.24	1.0 ± 1.4	2.0 ± 1.0	
3 month	0.08 ± 0.30	0.19 ± 0.20	2.2 ± 7.2	1.9 ± 0.3	
3 piece					
1 month	0.11 ± 0.43	0.23 ± 0.24	1.7 ± 1.2	2.1 ± 1.6	
3 month	-0.08 ± 0.57	0.32 ± 0.48	5.3 ± 2.4	2.6 ± 4.1	

open-loop or a 3-piece open-loop IOL was implanted according to the randomization. The contralateral eye received the alternate IOL haptic design. All IOLs in part 2 were vertically oriented. The 3-piece IOLs were folded longitudinally using a dedicated holding and folding forceps. Care was taken to avoid deforming the haptics during the implantation procedure. In cases of higher IOL power, the incision was extended to a width of approximately 3.4 mm. The 1-piece IOL design was implanted using a B-cartridge and Monarch II injector (both Alcon). In both parts of the study, the IOLs were centered on the pupil.

Follow-up examinations were performed 1 month and 3 months postoperatively. Visual acuity was assessed with a Snellen chart, and images were taken with the Purkinje meter after pupil dilation with phenylephrine 2.5% and tropicamide 0.5% eyedrops. The patient fixated the eye being measured on a fixation light, and a photograph of the reflections of the semicircular array of LEDs was taken. Three Purkinje reflexes are seen on the photographs. The first and second Purkinje reflexes are superimposed, and the third and fourth are from the anterior and posterior IOL surface, respectively. The Purkinje reflexes and the pupil margin were manually marked, and the dedicated software calculated the position of the IOL and the angle κ. Intraocular lens decentration and tilt were calculated relative to the center of the pupil, and tilt was defined relative to the pupillary axis. The technical details of the Purkinje meter system used in the study have been described. 8,15–17 The technique is noncontact without the use of a flash. At 3 months, an additional slitlamp examination was performed to ensure complete in-the-bag IOL fixation.

The paired t test was used for statistical analysis with the Bonferroni correction when needed.

RESULTS

Thirty patients were recruited into the study. The mean age of the 15 patients in part 1 was 75 years (range 55 to 85 years) and the mean age of the 15 patients in part 2, 77 years (range 59 to 85 years). The mean IOL power was 21.5 diopters (D) (range 18.0 to 30.0 D) in part 1 and 21.6 D (range 18.5 to 24.5 D) in part 2.

At the 3-month follow-up, nasal decentration was measured in 8 (57%) vertically oriented IOLs and in 11 (77%) horizontally oriented IOLs. Upward decentration was measured in 12 (79%) vertically oriented IOLs and in all horizontally oriented IOLs. Temporal tilt was measured in 12 (79%) vertically oriented IOLs and in 9 (62%) horizontally oriented IOLs. The rest of the IOLs were tilted nasally. All IOLs were tilted downward (Table 1 and Figure 1).

At the 3-month follow-up, nasal decentration was measured in 10 (67%) 1-piece IOLs and in 10 (67%) 3-piece IOLs. Upward decentration was measured in most IOLs in both groups; 2 IOLs in each group decentered downward. Temporal tilt was measured in 7 (45%) 1-piece IOLs and in 8 (57%) 3-piece IOLs. Again, most IOLs were tilted downward; 1 IOL in the 1-piece group and 3 IOLs in the 3-piece group were tilted upward (Table 2 and Figure 2). None of the differences in decentration and tilt between the 2 groups of IOLs in part 1 and part 2 of the study was statistically significant.

A post hoc statistical power analysis using the standard deviation in both parts of the study was performed to calculate the difference that would have been able to be detected with the given sample size. In part 1, a between-group difference of 0.19 mm in decentration and of 0.95 degrees in tilt could have been detected. In part 2, a between-group difference of 0.57 mm in decentration and of 5.05 degrees in tilt could have been detected.

DISCUSSION

To our knowledge, this is the first study to compare IOL axis orientation and to use a Purkinje meter to assess the effect of IOL haptic design on optic decentration and tilt. This pilot study used a randomized clinical controlled design with intrapatient comparison; however,

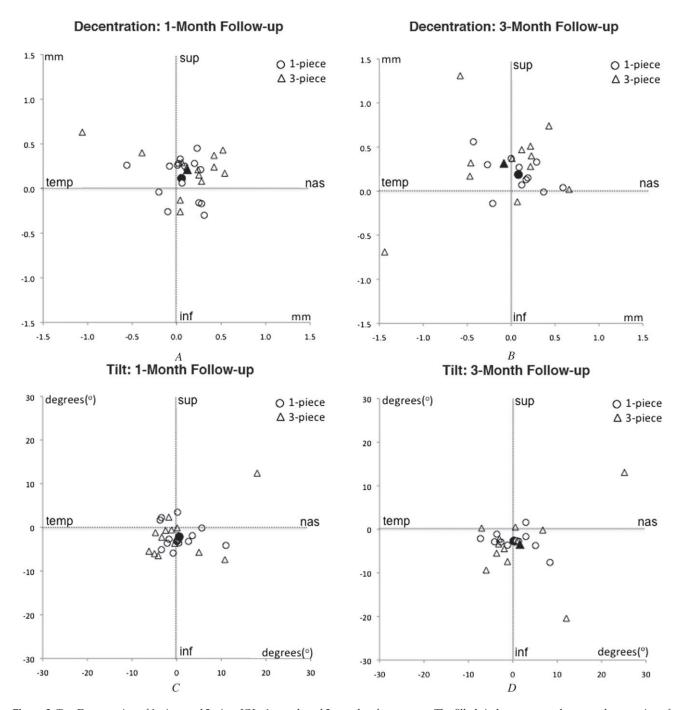


Figure 2. *Top*: Decentration of 1-piece and 3-piece IOLs 1 month and 3 months after surgery. The filled circles represent the mean decentration of the 1-piece IOLs. The filled triangles represent the mean decentration of the 3-piece IOLs. *Bottom*: Tilt of 1-piece and 3-piece IOLs 1 month and 3 months after surgery. The filled circles represent the mean tilt of the 1-piece IOLs. The filled triangles represent the mean tilt of the 3-piece IOLs.

the patient numbers may have been too small to detect the effect of small, maybe clinically less relevant, differences between the groups.

In part 1 of the study, which assessed the effect of IOL orientation, both groups showed a tendency toward nasal and upward decentration. There was a tendency for the horizontally oriented IOL to decenter more upward, especially at the 3-month follow-up.

These findings led to the decision to implant the IOLs vertically in part 2 of the study, which compared decentration and tilt of 1-piece IOLs and 3-piece IOLs. Most IOLs in both groups were tilted downward and slightly nasally. Downward tilt was more pronounced after 3 months.

A study by de Castro et al.¹³ compared Purkinje and Scheimpflug imaging methods to measure

decentration and tilt of IOLs (not defined). It also found mostly nasal and upward decentration of the IOLs, with most IOLs tilted nasally. Mester et al.⁵ compared decentration and tilt of 1-piece hydrophobic acrylic IOLs (Tecnis ZCB00, Abbott Medical Optics) and the crystalline lens. The IOLs showed nasal decentration and almost no vertical displacement. In contrast, the crystalline lenses were displaced temporally and downward. Both were tilted significantly up and temporally. A study by Schaeffel¹⁸ of phakic IOLs measured with the same apparatus as in the study by Mester et al.5 found temporal and inferior decentration and significant upward and temporal tilt. To our knowledge, the latter 2 trials used the same Purkinje meter setup, which works slightly differently than ours in terms of image acquisition and possibly the image-analysis algorithm used to obtain quantitative decentration and tilt data.

Measurements in part 2 of our study, which assessed the effect of haptic design, showed a tendency for open-loop 1-piece and 3-piece IOLs to decenter nasally and upward. Three-piece IOLs were decentered slightly more with more outliers, especially after 3 months. However, the difference was not statistically significant. Most IOLs were tilted downward. Again, the 3-piece IOLs were tilted more and the difference was not statistically significant. Taketani et al. 19 did not find differences in decentration between 1-piece and 3-piece hydrophobic acrylic IOLs. However, Scheimpflug imaging showed a statistically significant difference in tilt between the 2 groups, with 3-piece IOLs tilted more. Hayashi et al.²⁰ also did not find any differences between decentration and tilt of 1-piece and 3-piece PMMA IOLs using an anterior eye segment analysis system (EAS-1000, Nidek Co. Ltd.). None of these studies defined the direction of decentration and tilt. The Scheimpflug methods may not be sensitive enough to measure the slight decentration and tilt found with modern cataract surgery and IOL

Three-piece IOLs had a tendency to decenter and tilt more than 1-piece IOLs. The reason for this trend could be related to the production process of 3-piece IOLs, during which the PMMA haptics are placed into the optic by hand with a lower precision than would be expected with machine placement. Second, the haptics are PMMA, which is known to lose its memory within a few days under compression. Third, the haptics may be deformed during the implantation procedure, causing slight kinking of the haptics that is not visible during unfolding in the eye. In our study, care was taken to minimize mechanical stress on the haptics during implantation by enlarging the wound in cases of high-powered IOLs with greater optic thickness and by not maneuvering the IOL inside the eye by

touching or grasping the haptic with the forceps. The IOLs were positioned in the bag by pushing on the optic. Also, the optic-haptic junction is more friable than with the thicker hydrophobic acrylic haptics of the 1-piece IOLs. Obviously, capsule contraction in the first months after surgery is less likely to alter the position of the 1-piece IOLs because the hydrophobic acrylic haptic material has higher memory than PMMA. However, the number of patients in this study was limited. If a decentration value of less than 0.6 mm is of clinical relevance, a study with a larger number of patients would be needed.

In conclusion, axis orientation of a plate-haptic IOL in the bag seemed to have no clinical impact because we did not find differences in decentration or tilt in this pilot study. Single-piece IOLs may be more predictable than multipiece IOLs in terms of tilt and decentration. This must be confirmed in a larger trial with sufficient statistical power. Also, it may be of interest to assess the effect of vertical and horizontal orientation with open-loop IOLs.

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