Stability and Visual Outcomes of the Capsulotomy-Fixated FEMTIS-IOL After Automated Femtosecond Laser–Assisted Anterior Capsulotomy

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• PURPOSE: To evaluate stability and performance of a new monofocal anterior capsulotomy–fixated intraocular lens (IOL) (FEMTIS; Teleon Surgical B.V., Spankeren, Netherlands) after femtosecond laser–assisted cataract surgery (FLACS).

• DESIGN: Prospective, multicenter, interventional, noncomparative case series.

• METHODS: FLACS with FEMTIS IOL was performed in 336 eyes of 183 cataract patients with fixation of the IOL to the anterior capsulotomy followed up for 12 months. Examination included uncorrected distance visual acuity (UDVA), best-corrected visual acuity (CDVA), subjective refraction, IOL centration, posterior capsule opacification (PCO), and investigators' satisfaction questionnaire.

• RESULTS: At 12 months, mean IOL rotation was 1.50 ± 1.76 degrees and decentration 0.14 ± 0.14 mm from baseline (day of surgery). Mean horizontal IOL tilt was 0.70 ± 0.60 degrees and vertical 1.15 ± 1.06 degrees relative to the baseline (crystalline lens). Mean distance between IOL and iris was 0.32 mm to 0.36 mm for all measured meridians. Mean UDVA was 0.12 ± 0.14 logMAR (range -0.20 to 0.54 logMAR), mean CDVA -0.01 ± 0.09 logMAR (range -0.30 to 0.20 logMAR). Mean spherical equivalent was 0.35 ± 0.53 diopter (D) and 98% of eyes (n = 235) were within ±1.0 D. Median PCO score was 1 with an Nd:YAG laser rate of 3.1% after 12 months. Most surgeons were very satisfied (median score: 1) with surgery and implanted IOL.

• CONCLUSIONS: Implantation of FEMTIS IOL provided excellent visual and stable refractive outcomes. IOL decentration was very low compared to other published studies and showed an exceptional high in-the-bag stability over a 12-month period. This lens benefits from femtosecond laser capsulotomies. It can be positioned very predictably and offers an optimal platform for toric and multifocal IOL optics. (Am J Ophthalmol 2021;225:27–37. © 2020 Published by Elsevier Inc.)

THERE IS A GROWING DEMAND FOR EXCELLENCE IN postoperative vision following cataract surgery. This has led to the development of more sophisticated surgical techniques and novel intraocular lens (IOL) designs. In addition to correcting the spherical refractive error by implanting an accurately calculated IOL, it is now even possible to adapt IOL designs to control higher-order aberrations in a pseudophakic eye. Advances in modern IOLs, such as aspheric, multifocal, or toric IOLs, have made the need for accurate postoperative alignment and stability even more important to achieve the optimal postoperative results that are being sought after by the patients.

There are multiple factors that influence postoperative tilt, decentration, or rotation of traditional in-the-bag IOLs after uneventful cataract surgery; these include capsular bag shrinkage and fibrosis, the lens characteristics (material, size, and design), IOL fixation site (position of the haptics), and capsulorrhexis type and integrity.[1] It has also been shown that a severely malformed capsulorrhexis can lead to IOL decentration and hence it is likely that small variations in the capsulorrhexis will have some effect on IOL position.[2] This malposition can significantly affect the optical performance of IOLs and thus the optical quality of the visual system.[3–5]

With the introduction of femtosecond laser–assisted cataract surgery (FLACS), it is now possible to create a completely reproducible capsulotomy with a predictable diameter and precise centering. The new Femtis IOL

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(Teleon Surgical B.V., Spankeren, The Netherlands) is one of the first examples of how FLACS has influenced modern lens designs and concepts. The Femtis IOL has 4 additional anteriorly placed haptics, especially designed to fit in front of the capsulotomy created by the femtosecond laser in order to reduce postoperative IOL misalignment.

The aim of this study was to evaluate the stability of the lens position and the visual and refractive outcomes after FLACS capsulotomy and Femtis IOL implantation.

METHODS

THIS WAS A PROSPECTIVE INTERNATIONAL MULTICENTER study. The study adhered to the tenets of the Declaration of Helsinki and informed consent was obtained from all patients. The study was registered under the German Clinical Trials Register number DRKS00023914. Institutional Review Board approval was obtained from the Ethics Committee of the University of Heidelberg.

In total, 366 eyes of 183 patients were recruited from 7 study sites in Germany, the United Kingdom, and Spain between May 2015 and June 2018. The inclusion criteria were as follows: senile cataract, patient age ≤ 90 years, expected postoperative refractive astigmatism ≤ 1.0 diopters (D), and required IOL power from 15.0 to 27.0 D. The exclusion criteria were patients with strabismus, previous refractive or glaucoma surgery, previous keratoplasty, corneal scars, ocular disorders other than cataracts that may cause postoperative visual acuity loss, and relevant concomitant ophthalmic diseases that could affect capsular bag stability.

• **EXAMINATION PROTOCOL:** Before surgery, a complete ophthalmologic examination had been performed, including manifest refraction, monocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity, tonometry, slit-lamp examination, corneal topography with Scheimpflug imaging, optical biometry, and funduscopy. Preoperative keratometry (K), anterior chamber depth (ACD), and axial length (AL) were measured using an IOLMaster 700 (Carl Zeiss Meditec, Jena, Germany). The IOL power was calculated using the Haigis formula for all patients. The A-constant of the IOL was a0 = 0.515, a1 = 0.4, and a2 = 0.1. Immediately before surgery, the cornea was marked in seated position of the patients with 2 small horizontal reference marks and directly after surgery a photograph of the anterior sector of the eye was taken using the surgical microscope.

Immediately after surgery, capsulotomy size, incision size, and surgery time were documented and the surgeons were asked to complete a short questionnaire to subjectively assess their satisfaction regarding intraoperative IOL handling and performance on a scale from 1 (very satisfied/very easy) to 5 (very dissatisfied/very difficult). The questionnaire consisted of these 7 questions: (1) How satisfied are you with the performance of the femtosecond laser? (2) How satisfied are you with the injection of the Femtis IOL? (3) How satisfied are you with the aspiration of viscoelastic solution from the back surface of the Femtis IOL? (4) How easy was the positioning of the 2 large clip haptics in front of the capsulotomy? (5) How easy was the positioning of the 2 small clip haptics in front of the capsulotomy? (6) How was the behavior of capsulotomy stretching during haptic positioning? (7) How was the experienced stability performance of the Femtis IOL after complete positioning?

Patients were examined at 1-7 days (hereinafter indicated as 1 day), 6-8 weeks (hereinafter indicated as 6 weeks), 6 months, and 12 months after surgery. In addition to all preoperative assessments, slit-lamp images from the anterior segment of the eye and Scheimpflug images, as baseline for the evaluation of IOL tilt, were taken after dilating the pupils. To evaluate postoperative rotational stability and centration behavior of the implanted IOL, anterior ocular images were captured (intraoperative via surgical microscope and postoperative via slit lamp under mydriasis), reviewed, and marked with reference points by the Reading Center of the Department of Ophthalmology (University of Heidelberg).

For the evaluation of IOL decentration, the IOL optic and the pupil were detected, digitized, and subsequently analyzed by the Department of Applied Mathematics (University of Heidelberg) with an validated C++ software,[6] which automatically visualized the best-fitted circles based on the set marks to indicate the IOL optic (yellow) and pupil (green), as shown in Figure 1. The software automatically analyzed and calculated the difference of both circle midpoints (Figure 1, red arrow) to evaluate the decentration length and angle β by correlation with the known real IOL optic size of 5.7 mm.

To evaluate IOL rotation, the 2 optic gravures and, for all intraoperative captured images, the horizontal corneal marks are highlighted with reference points by the Reading Center, as shown in Figure 1. The angle α between the connecting line of the 2 optic gravures and the horizontal plane was automatically analyzed by the C++ software. Sequential changes of postoperative IOL rotation and decentration were evaluated in reference to the baseline value (intraoperative measurement) and between each postoperative follow-up visit.

The assessment of IOL tilt and the distance between the iris and the IOL was performed using 2 Scheimpflug 2D images representing a horizontal segment at 0 degrees (180 degrees) and a vertical segment at 90 degrees (270 degrees). For IOL tilt, 2 reference lines were automatically analyzed by the C++ software: a blue line on the Scheimpflug image to represent the plane of the iridocorneal angle and a red line to represent the plane of the visible crystalline lens (preoperative) or the implanted IOL (postoperative) based on the previously set reference points of the Reading

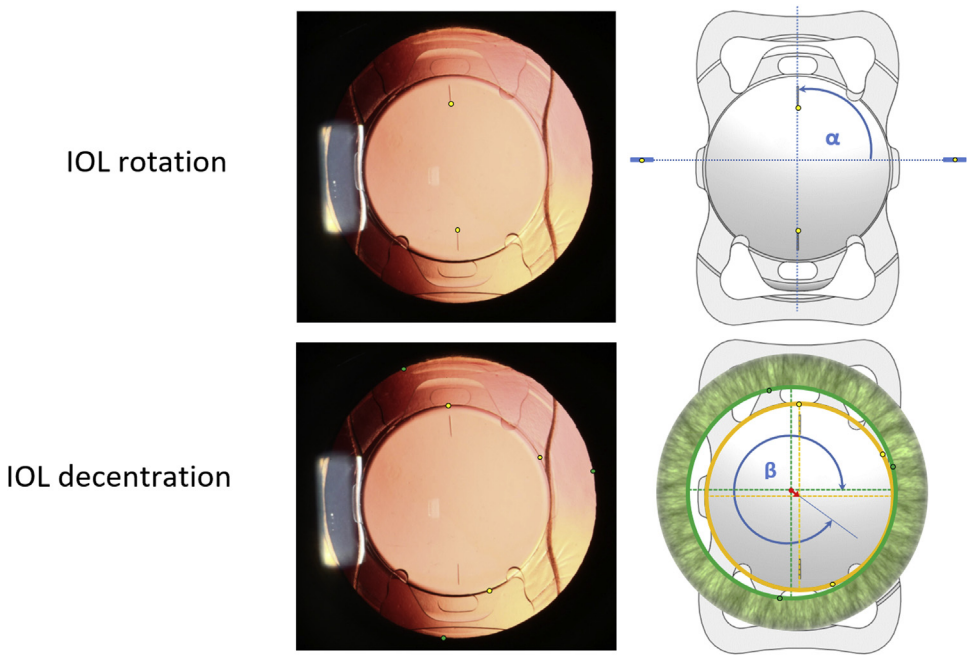

FIGURE 1. Measurement of intraocular lens (IOL) rotation and decentration using the C++ software.

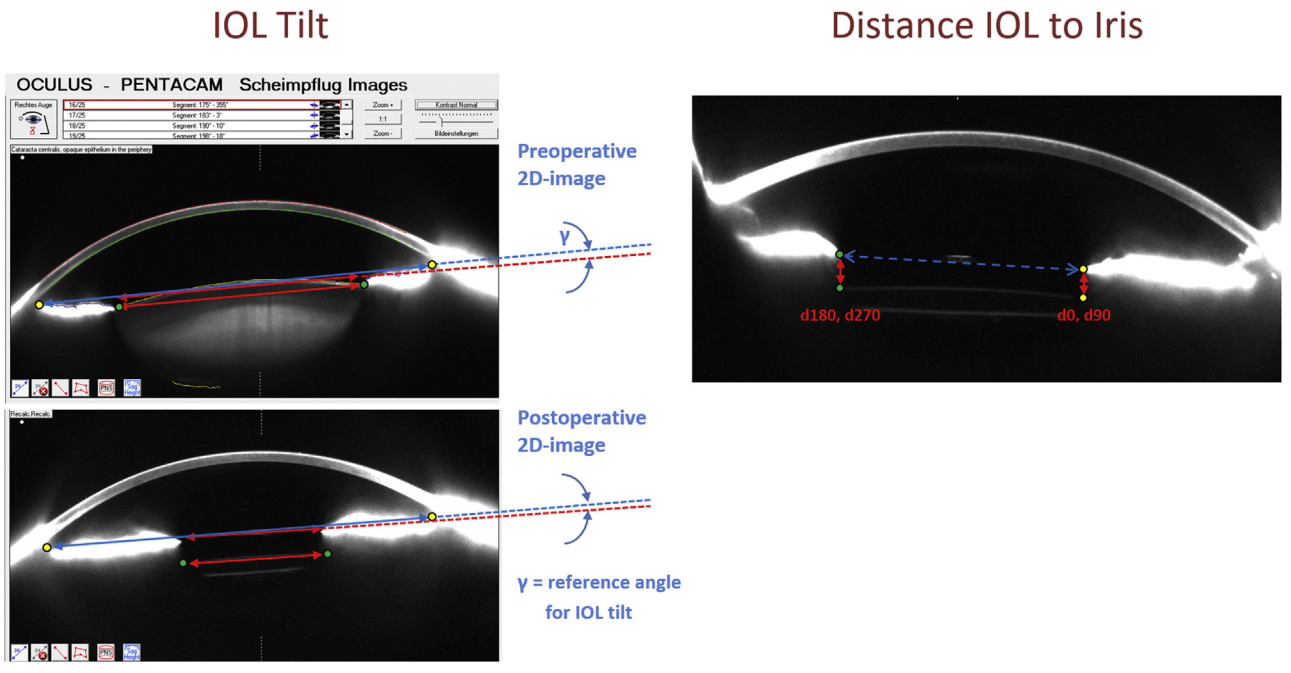

FIGURE 2. Measurement of intraocular lens (IOL) tilt and IOL-iris distance using the C++ software.

Center. The angle γ between both reference lines represents the lens position at the time of measurement. IOL tilt was evaluated by calculating the differences between the pre- and postoperative lens positions (Figure 2).

To calculate the distance between the iris and the IOL, the C++ software automatically analyzed the distances between the set reference points by the Reading Center, which indicate the visible iris edges and the anterior IOL optic (horizontal at 0 degrees and 180 degrees position as well as vertical at 90 degrees and 270 degrees position). The calculated distance values were correlated on the basis of the measured pupil size of the Scheimpflug image (blue

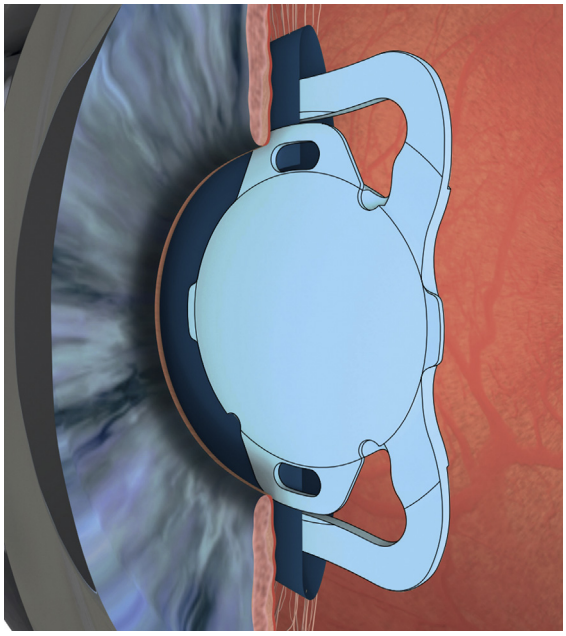

FIGURE 3. The capsulotomy-fixated Femtis FB-313 intraocular lens with 4 additional clip haptics.

line) to evaluate the effective distances between the iris and IOL (Figure 2).

Subjective refraction was determined with trial lenses and the cross-cylinder method, and visual acuity measurements were performed using the Early Treatment Diabetic Retinopathy Study (ETDRS) charts (Precision Vision, Woodstock, Illinois, USA) at 4 m.

The degree of posterior capsule opacification (PCO) was subjectively classified at slit-lamp examinations, using a score from 0 to 4 (0: none; 1: visible but not reaching the IOL optic edge; 2: slightly covering the IOL optic edge; 3: covering the IOL optic but clear visual axis; 4: covering the visual axis).

• **THE FEMTIS INTRAOCULAR LENS:** The Femtis FB-313 IOL (Teleon Surgical B.V., Spankeren, The Netherlands) is a monofocal 1-piece hydrophilic acrylic posterior chamber lens with an aspherical posterior surface and is aberration neutral. It is intended for fixation in an automated-created circular capsulotomy created by the femtosecond laser (Figure 3). The IOL optic size is 5.7 mm and the overall diameter is 10.5 mm. In addition to 2 standard plate haptics, the Femtis lens design is characterized by 4 additional haptics that are enclaved in front of the capsulotomy. For the purposes of the study to assess axis, markings (gravures) were applied to the IOL (Figure 1) in the manner that would be on a toric IOL, although this IOL did not correct corneal astigmatism.

• **SURGERY:** Preoperatively limbal markings at 0 degrees and 180 degrees were created with the patient sitting upright and focusing at a distant target. Sutureless cataract surgery was performed using a femtosecond laser. After pupil dilation, the Lensar Laser System (LENSAR, Inc, Orlando, Florida, USA) was used to create a capsulotomy with a diameter of 4.7-5.0 mm; it was also used for lens fragmentation. A manual or laser-assisted corneal incision of about 2.2 mm was prepared for lens implantation. The lens was inserted using the Viscoject Bio 2.2 injector (Medicel AG, Altenrhein, Switzerland). Once the FEMTIS IOL was fully positioned in the bag, the ophthalmic viscosurgical devices behind the lens was aspirated. The additional 2 large longitudinal haptics, followed by the 2 small lateral haptics of the lens, were finally enclaved in front of the capsulotomy.

• **STATISTICAL ANALYSIS:** The G*Power tool (version 3.1.9.2; University of Dusseldorf, Dusseldorf, Germany) was used for sample size calculation. For a 1-sided *t* test and a statistical power of 80%, an alpha of 0.05 and an expected standard deviation of 1.75 in the level of decentration a sample size of 305 was necessary for detecting a change of 0.25 mm in decentration over time. As the deviation from baseline was used as an absolute value, a 1-sided test was applied. In total, 366 eyes were recruited to secure a sufficient number of evaluable cases calculated with an expected average of 15%-20% dropout rate.

Statistical evaluations were performed with SAS 9.1 (SAS Institute Inc, Cary, North Carolina, USA) and Microsoft Office Excel 7.0 (Microsoft, Redmond, Washington, USA). Descriptive data are shown as mean ± standard deviation and range values. For missing data, observations were excluded from analysis.

One-way repeated measures ANOVA was performed to test whether there were statistically significant differences in study outcomes over the follow-up period. In all cases, a *P* value of less than .05 was considered as statistically significant ($P < .05$).

RESULTS

THE PATIENTS' PREOPERATIVE CHARACTERISTICS ARE shown in Table 1. Of the 366 recruited eyes, 336 eyes (183 patients) met the inclusion and exclusion criteria. Two patients (n = 2 eyes) did not proceed with surgery on 1 eye. Eleven eyes were retrospectively excluded from the study because the study IOL was not implanted owing to posterior capsule rupture (n = 4 eyes), anterior radial tear (n = 1 eye), extremely loose zonule fibers (n = 1 eye), technical problems with the surgical camera system (n = 1 eye), high pupil decentration (n = 1 eye) evaluated preoperatively, arcus senilis (n = 2 eyes), and 1 nervous patient who moved too much (n = 1 eye).

Overall, 323 lens implantations were analyzed. The mean IOL power was 20.32 ± 2.33 D (range, 15.0-27.0 D). The mean capsulotomy size was 4.95 ± 0.08 mm,

TABLE 1. Preoperative Patient Demographics

Patients (n)	183
Eyes (n)	336
Age (y)	
Mean (SD)	72.02 (7.64)
Median (range)	73 (49 to 89)
Sex, n (%)	
Male	81 (44.3)
Female	102 (55.7)
AL (mm)	
Mean (SD)	23.31 (0.98)
Median (range)	23.32 (20.72 to 26.43)
ACD (mm)	
Mean (SD)	3.06 (0.39)
Median (range)	3.06 (1.94 to 4.39)
K1 (mm)	
Mean (SD)	7.77 (0.26)
Median (range)	7.77 (7.11 to 8.61)
K2 (mm)	
Mean (SD)	7.66 (0.25)
Median (range)	7.66 (6.97 to 8.46)

ACD = anterior chamber depth; AL = axial length; K = keratometry; SD = standard deviation.

mean incision size was 2.45 ± 0.34 mm, and the average surgery time was 12.58 ± 6.88 minutes. A total of 321 eyes (1 day), 306 eyes (6 weeks), 269 eyes (6 months), and 240 eyes (12 months) completed the follow-up examinations.

• **VISUAL ACUITY AND REFRACTIVE OUTCOMES:** Outcomes for monocular UDVA and CDVA are summarized in Table 2. At 6 and 12 months postoperatively, mean CDVA was 0.00 ± 0.08 logMAR and -0.01 ± 0.09 logMAR, respectively. After 12 months postoperatively, 85.8% and 97.5% of the included patient eyes achieved CDVA of 0.0 logMAR and 0.1 logMAR, respectively (Figure 4). There was no statistically significant change in UDVA and CDVA over the follow-up period ($P > .05$).

Mean pre- and postoperative subjective refraction is shown in Table 2. After 6 months postoperatively, spherical equivalent (SE) was within ±0.50 D in 77% of eyes (n = 206) and within ±1.0 D in 97% of eyes (n = 262). At the 12-month visit, SE was within ±0.50 D in 79% of eyes (n = 190) and within ±1.0 D in 98% of eyes (n = 235). Between 6 weeks and 6 months as well as 6 months and 12 months postoperatively the mean SE shift was +0.12 D and 0.00 D, respectively.

• **INTRAOCULAR LENS CENTRATION AND STABILITY:** Postoperative IOL decentration, tilt, and rotation are summarized in Table 3 and Figure 5 (A-C). Between surgery and 1 day, 6 weeks, 6 months, and 12 months postoperatively, the mean decentration change from the pupillary center was 0.10 ± 0.10 mm, 0.08 ± 0.08 mm, 0.09 ± 0.08 mm, and 0.07 ± 0.08 mm, respectively (Figure 5, A).

The IOL tilt assessment between preoperative and 6 weeks, 6 months, and 12 months postoperatively showed a mean vertical tilt of 1.09 ± 0.98 degrees, 1.18 ± 1.36 degrees, and 0.99 ± 0.86 degrees and mean horizontal tilt of 0.73 ± 0.61 degrees, 0.66 ± 0.65 degrees, and 0.69 ± 0.72 degrees, respectively (Figure 5, B). There was no statistically significant difference in horizontal and vertical tilt over the follow-up period ($P > .05$).

The mean IOL rotation between surgery and 1 day, 6 weeks, 6 months, and 12 months postoperatively was 1.49 ± 1.54 degrees, 1.05 ± 0.80 degrees, 0.92 ± 0.75 degrees, and 0.74 ± 0.72 degrees, respectively (Figure 5, C).

• **DISTANCE BETWEEN IRIS AND INTRAOCULAR LENS:** The horizontal and vertical distances between the Femtis IOL and the iris were comparable over the follow-up period (Table 4), with no statistically significant differences from visit 2 (6 weeks) to visit 4 (12 months). At 12 months, the mean horizontal distance was 0.33 ± 0.12 mm at the 0-degree position and 0.35 ± 0.12 mm at the 180-degree position. At the vertical meridian, the mean distance was 0.35 ± 0.15 mm at the 90-degree position and 0.36 ± 0.14 mm at the 270-degree position (Table 4).

• **INVESTIGATOR QUESTIONNAIRE:** Most surgeons were very satisfied with the surgery and the implanted IOL (Figure 6). The median satisfaction score was 1 for questions regarding femtosecond laser performance, Femtis injection, and IOL stability. The median score was 2 for questions on ophthalmic viscosurgical devices aspiration, positioning of the 2 small and large haptics, and capsulotomy stretching during haptic positioning.

• **POSTERIOR CAPSULE OPACIFICATION:** At 6 and 12 months, the median PCO score was 0 and 1 (range, 0-4), respectively. Most eyes were rated with PCO not visible at all, visible but not reaching IOL optic edge, or slightly over the IOL optic edge, indicated by a score from 0 to 2 with 87% at 6 months and 69% at 12 months, respectively (Figure 7). Overall, Nd:YAG laser posterior capsulotomy was performed in 10 eyes (3.1%): in 2 eyes (0.6%) before the 6-month visit, in 1 eye (0.3%) before the 12-month visit, and in 7 eyes (2.2%) after the 12-month examination (range, 12-16 months).

• **COMPLICATIONS:** Intraoperatively, implantation of a capsular tension ring was performed in 2 eyes (0.6%) and the Femtis IOL could not be fixated in the capsulotomy of another 2 eyes (0.6%). In 1 case (n = 1 eye; 0.3%) the lens was implanted upside-down, subsequently turned without complications. Afterward, the IOL showed a small nasal haptic defect, but the IOL could finally still be well centered. Owing to haptic luxation, secondary intervention with IOL repositioning was

TABLE 2. Pre- and Postoperative Monocular Visual Acuity and Refraction

Variable	Preoperative	Visit 1 1-7 Days	Visit 2 6-8 Weeks	Visit 3 6 Months	Visit 4 12 Months	*P* Values[a]
UDVA (logMAR)	0.57 (0.28)	0.17 (0.18)	0.12 (0.15)	0.13 (0.14)	0.12 (0.14)	.382
	0.50 (0.00 to 1.20)	0.10 (−0.16 to 0.90)	0.10 (−0.20 to 1.00)	0.10 (−0.10 to 0.70)	0.10 (−0.20 to 0.54)	
SE (D)	0.30 (2.25)	-	0.23 (0.52)	0.35 (0.54)	0.35 (0.53)	<.001
	0.50 (−10.00 to 6.13)		0.25 (−2.88 to 1.88)	0.38 (−2.25 to 1.75)	0.38 (−2.25 to 1.88)	
Cylinder (D)	−0.71 (0.53)	-	−0.56 (0.51)	−0.56 (0.46)	−0.59 (0.47)	.711
	−0.75 (−2.75 to 0.00)		−0.50 (−2.50 to 0.00)	−0.50 (−2.00 to 0.00)	−0.50 (−2.00 to 0.00)	
Sphere (D)	0.66 (2.24)	-	0.51 (0.61)	0.63 (0.58)	0.64 (0.59)	<.001
	1.00 (−9.75 to 6.50)		0.50 (−2.50 to 2.50)	0.75 (−1.75 to 2.00)	0.75 (−1.75 to 2.50)	
CDVA (logMAR)	0.25 (0.18)	-	0.00 (0.09)	0.00 (0.08)	−0.01 (0.09)	.852
	0.20 (−0.10 to 0.80)		0.00 (−0.20 to 0.32)	0.00 (−0.26 to 0.30)	0.00 (−0.30 to 0.20)	

CDVA = corrected distance visual acuity; D = diopters; SE = spherical equivalent; UDVA = uncorrected distance visual acuity.
Values reported as mean (SD), median (range).
[a]ANOVA repeated measures (visit 2 to visit 4).

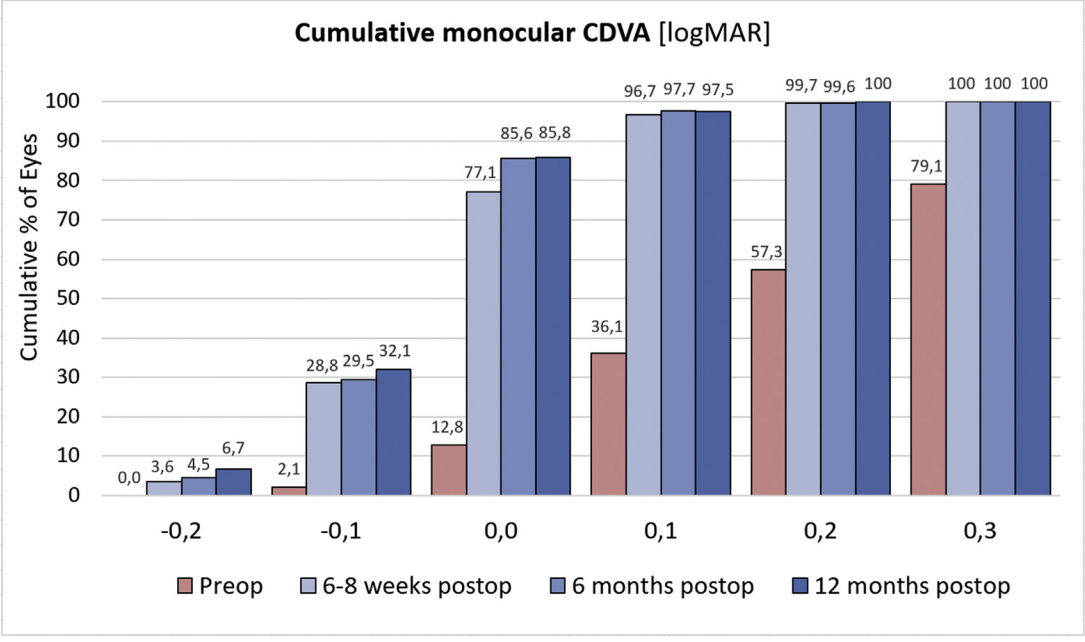

FIGURE 4. Cumulative monocular corrected distance visual acuity (CDVA), pre- and postoperatively over the follow-up period.

necessary in 2 eyes (0.6%). No other postoperative complications occurred.

DISCUSSION

THE USE OF FEMTOSECOND LASERS FOR VARIOUS STEPS IN cataract surgery is increasing worldwide and in addition to the well-known advantages, such as the reduction of the effective phaco time and the possibility to correct corneal astigmatism with incisions in the same procedure, the accurate sizing and forming of the capsulotomy is another major advantage of this technology. However, it has proved difficult (when implanting standard in-the-bag IOLs) to confirm the benefits of femtosecond vs conventional surgery. The femtosecond laser can, however, contribute to the optimization of the IOL position and opens new possibilities.[11,12] A recently published article assessed differences in effective lens position based on the lens design.[12] IOLs with plate-haptic, c-loop haptic, and a rhexis-fixated lens were compared. Effective lens position for rhexis-fixated IOL was shortest (4.29 ± 0.24 mm),

TABLE 3. Postoperative Femtis FB-313 Intraocular Lens Rotation, Decentration, and Tilt Between Different Examinations

Variable	Surgery to 1 Day	Preop to 6 Weeks	1 Day to 6 Weeks	6 Weeks to 6 Months	6 Months to 12 Months	Surgery to 12 Months	Preop to 12 Months	*P* Values[a]
Rotation (degrees)	1.49 (1.54)	-	1.05 (0.80)	0.92 (0.75)	0.74 (0.72)	1.50 (1.76)	-	<.001
	1.11 (0.00 to 10.12)		0.89 (0.00 to 4.18)	0.78 (0.01 to 3.91)	0.60 (0.00 to 4.62)	0.77 (0.01 to 10.23)		
Decentration (mm)	0.10 (0.10)	-	0.08 (0.08)	0.09 (0.08)	0.07 (0.08)	0.14 (0.14)	-	.001
	0.07 (0.00 to 0.56)		0.05 (0.00 to 0.48)	0.07 (0.00 to 0.43)	0.05 (0.00 to 0.46)	0.10 (0.00 to 0.62)		
Horizontal tilt (degrees)	-	0.73 (0.61)	-	0.66 (0.65)	0.69 (0.72)	-	0.70 (0.60)	.516
		0.54 (0.00 to 3.40)		0.49 (0.00 to 3.89)	0.49 (0.00 to 4.12)		0.56 (0.00 to 2.95)	
Vertical tilt (degrees)	-	1.09 (0.98)	-	1.18 (1.36)	0.99 (0.86)	-	1.15 (1.06)	.135
		0.85 (0.00 to 6.83)		0.87 (0.00 to 15.27)	0.71 (0.00 to 4.63)		0.85 (0.00 to 9.07)	

Preop = preoperative.
Values reported as mean (SD), median (range).
[a]ANOVA repeated measures (surgery/preoperative to 12 months).

followed by c-loop haptic (4.41 ± 0.42 mm) and plate-haptic (4.51 ± 0.26 mm) IOL. The difference in IOL fixation and its resulting position in the capsular bag had a significant effect on the effective lens position and consequently a significant effect on the prediction of postoperative refraction.[12]

Theoretically, coma increases with increasing IOL tilt and decentration.[13,14] The effects of this misalignment depend on the IOL design, and aberration-correcting lenses appear to be very sensitive to decentration and tilt.[15] Theoretical simulations by Holladay and associates[16] showed that aspheric IOLs should have less than 0.4 mm decentration and less than 7 degrees tilted to exceed the optical performance of conventional spherical IOLs. Another theoretical study, by Piers and associates,[17] showed slightly more tolerance, with a critical decentration of 0.8 mm and critical tilting of 10 degrees for these IOLs. Decentration is especially critical for multifocal IOLs, for obvious reasons. Laboratory analysis show that monofocal lenses are least negatively affected by decentration, with a mean optical quality reduction of less than 10% for 1 mm decentration at physiological pupil sizes. For diffractive bifocal and trifocal lenses, optical quality at all distances is significantly reduced if decentration exceeds 0.75 mm, with intermediate focus showing the least reduction.[18]

According to a review of published studies,[1] more than 10 degrees of IOL tilt are reported even with modern cataract surgery in about 10% of the pseudophakic population. The author summarized that on average, excluding some reports of extreme malpositioning, 2-3 degrees of IOL tilt is common following surgically uneventful implantation of posterior chamber IOLs.[1] In our study, the average tilt movement between preoperative and 12 months postoperative was 0.70 degrees at horizontal and 1.15 degrees at vertical directions. These results are much lower than those reported in previous studies.

The aim of a prospective study by Mester and associates[8] was to compare IOL tilt and decentration of a single-piece aspheric IOL (Tecnis ZCB00; Johnson & Johnson Vision, Santa Ana, California, USA) and the position of the natural crystalline lens in young individuals. All lenses were tilted upward (IOL: mean 2.5 degrees) and to the temporal side (IOL: mean 3.1 degrees).[8] Comparable results were reported by another study by Baumeister and associates,[19] with a mean optic tilt of 2.89 ± 1.46 degrees for the spherical IOL and 2.85 ± 1.36 degrees for the aspheric IOL 4 months after implantation. In this study we found that IOL tilt behavior with the Femtis lens is very low compared to the position of the natural lens and also stable during the postoperative period for 12 months follow-up.

Our results show that mean IOL decentration from the intraoperative position was 0.10 ± 0.10 mm 1 day postoperatively with a minimal change to the 6-week result of 0.08 ± 0.08 mm. These values are much lower than in a comparative trial that assessed the effect of a capsular tension ring (CTR) on IOL tilt and decentration after cataract

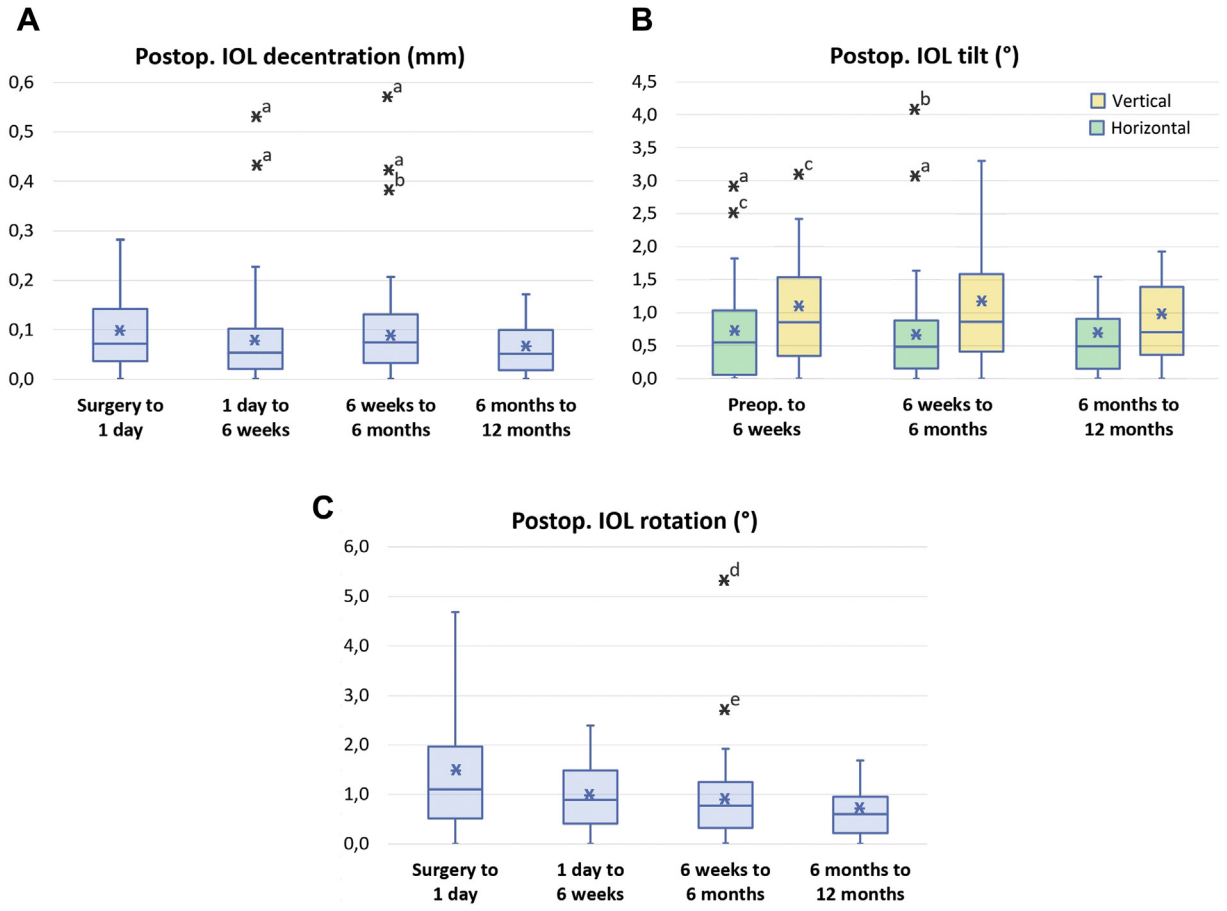

FIGURE 5. Postoperative intraocular lens (IOL) decentration (A), vertical and horizontal IOL tilt (B), and IOL rotation (C). [a]Comparative study results by Lee et al.[7] [b]Comparative study results by Findl et al.[2] [c]Comparative study results by Mester et al.[8] [d]Comparative study results by Becker et al.[9] [e]Comparative study results by Tsinopoulos et al.[10]

TABLE 4. Distance Between the Iris and the Femtis FB-313 Lens Over the Postoperative Period

Meridian	Visit 2 6 to 8 Weeks	Visit 3 6 Months	Visit 4 12 Months	*P* Values[a]
Horizontal 0 degrees (mm)	0.32 (0.12) 0.31 (0.08 to 0.72)	0.34 (0.12) 0.32 (0.09 to 0.66)	0.33 (0.12) 0.33 (0.08 to 0.70)	.124
Horizontal 180 degrees (mm)	0.34 (0.12) 0.33 (0.08 to 0.68)	0.35 (0.12) 0.35 (0.09 to 0.81)	0.35 (0.12) 0.33 (0.10 to 0.71)	.304
Vertical 90 degrees (mm)	0.33 (0.13) 0.32 (0.06 to 1.11)	0.34 (0.13) 0.33 (0.08 to 0.73)	0.35 (0.15) 0.34 (0.07 to 1.20)	.525
Vertical 270 degrees (mm)	0.34 (0.14) 0.33 (0.06 to 1.39)	0.35 (0.13) 0.34 (0.07 to 0.78)	0.36 (0.14) 0.35 (0.10 to 1.05)	.585

Values reported as mean (SD), median (range).
[a]ANOVA repeated measures.

surgery and implantation of AcrySof MA60BM (Alcon) lenses.[7] The extent of IOL decentration was statistically significantly less in eyes with both an IOL and CTR compared to the IOL-only group. Mean decentration in the CTR group was 0.38 ± 0.16 mm at 7 days, 0.43 ± 0.15 mm at 30 days, and 0.42 ± 0.17 mm at 60 days. Mean values in the IOL-only group were 0.49 ± 0.11 mm, 0.53 ± 0.14 mm, and 0.57 ± 0.16 mm,

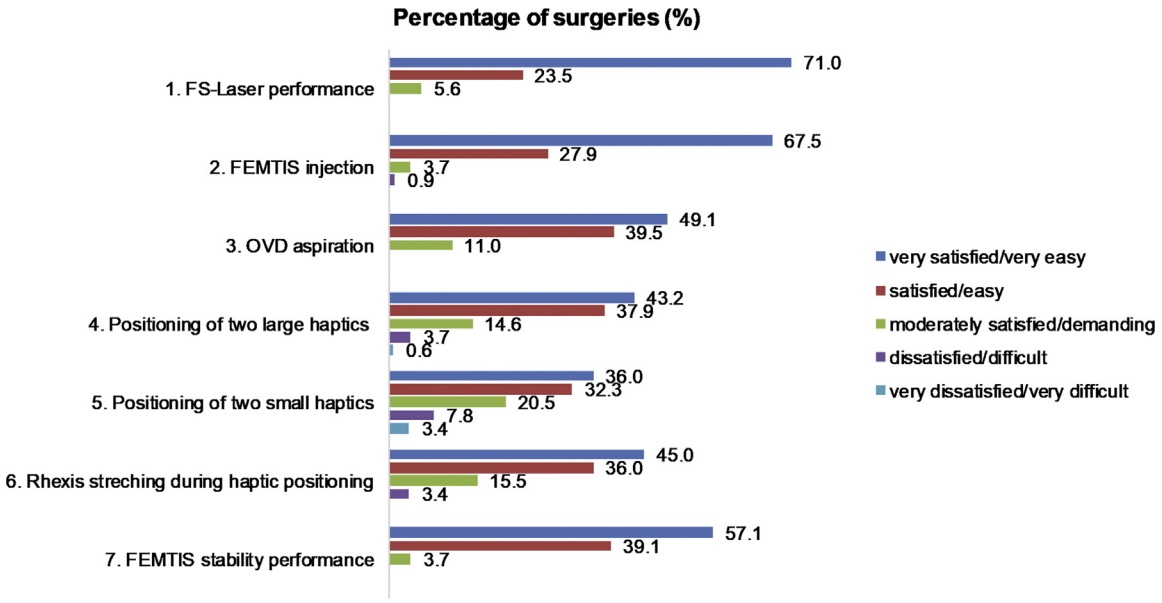

FIGURE 6. Outcomes of the investigator questionnaire regarding satisfaction with the procedure and the Femtis FB-313 intraocular lens.

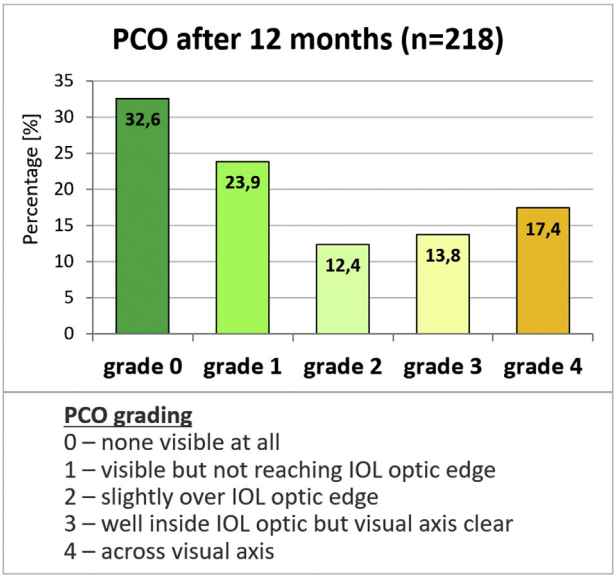

FIGURE 7. Posterior capsule opacification (PCO) rate after 12 months postoperatively.

respectively.[7] The low values of decentration in our study might be explained by the enclavation into the capsulorrhexis, which seems to show better stability and less decentration compared to the usual implantation into the capsular bag. Higher decentration values might be caused by the shrinking of the capsular bag with or without CTR. At 6 and 12 months postoperatively, the mean decentration change from the pupillary center stayed on a very low level of 0.09 ± 0.08 mm and 0.07 ±0.08 mm. This finding is also very low compared to other published studies. In a large prospective case series with 255 eyes, Findl and associates[2] evaluated the influence of a manual capsulorrhexis size, shape, and position on postoperative IOL stability. Patients were implanted with different acrylic IOL models (hydrophilic 1-piece, hydrophobic 1-piece, hydrophobic 3-piece) and postoperatively divided into 3 groups: control group (symmetrical capsulorrhexis between 4.5 mm and 5.5 mm), small group (capsulorrhexis smaller than 4.5 mm), and eccentric group (all other capsulorrhexis). Mean decentration in the control group, eccentric capsulorrhexis group, and small capsulorrhexis group was 0.38 ± 0.23 mm (range, 0.05-1.14 mm), 0.40 ± 0.21 mm (range, 0.04-1.02 mm), and 0.17 ± 0.08 mm (range, 0.06-0.27 mm), respectively.[2] The authors concluded that capsulorrhexis size and shape had little effect on the capsular bag performance of modern IOLs and that only eyes with a severely malformed capsulorrhexis showed a slightly decentered IOL.[2]

Another study[20] compared the outcomes of Scheimpflug and Purkinje imaging systems at least 6 months after implantation of 21 aspherical lenses and reported a mean absolute horizontal decentration of 0.34 ± 0.19 mm (Purkinje) and 0.23 ± 0.19 mm (Scheimpflug), and a mean absolute vertical decentration of 0.17 ± 0.23 mm (Purkinje) and 0.19 ± 0.20 mm (Scheimpflug).

The rotational stability of the Femtis IOL was extremely high, averaging 1.50 ± 1.76 degrees 12 months after implantation. The greatest IOL rotation occurred between the time immediately after surgery and the first postoperative day (mean: 1.49 ± 1.54 degrees). Between all the other follow-up examinations, mean IOL rotation was always

below 1.05 degrees. Becker and associates[9] measured the in-the-bag stability of a hydrophilic acrylic IOL and reported an average IOL rotation of 5.3 ± 1.4 degrees after 6 months compared to the position directly after implantation. Another study, by Tsinopoulos and associates,[10] evaluated the rotational stability after in-the-bag implantation of AcrySof toric lenses (Alcon, Fort Worth, Texas, USA) and found a mean IOL axis rotation of 2.7 ± 1.5 degrees with a range from 0.9 to 8.4degrees. Comparable outcomes were reported by Draschl and associates[21] in 2017. They evaluated the rotational stability of a non-toric IOL of the same design and different materials (hydrophilic and hydrophobic). Three months postoperatively mean IOL rotation was 2.4 ± 1.85 degrees (range, 0.3-7.1 degrees) in the hydrophilic IOL group and 1.6 ± 1.61 degrees (range, 0.1-6.1 degrees) in the hydrophobic IOL group.[21]

Visual outcomes after Femtis IOL implantation were also very promising. There was stable visual acuity immediately after surgery and throughout the postoperative evaluation period. Mean UCVA changed from 0.17 logMAR at 1 day to 0.12 logMAR at 6 weeks, 0.13 logMAR at 6 months, and 0.12 logMAR at 12 months postoperatively. Mean CDVA showed constant values, with 0.00 logMAR after 6 weeks, 0.00 logMAR after 6 months, and -0.01 logMAR after 12 months postoperatively.

Owing to haptic luxation, secondary intervention with Femtis IOL repositioning was necessary in 2 eyes (0.6%) during the course of our study. No other serious postoperative complications occurred that were related to the lens. The mean distance between the iris and the IOL was between 0.33 and 0.36 mm 12 months postoperatively, so the risk of iris chafing was minimal.

At 12 months, 33% of eyes showed no signs of PCO, 36% of eyes showed mild PCO (grade 1-2), 14% of eyes showed moderate PCO (grade 3), and 17% of eyes showed significant PCO (grade 4). The relatively high incidence of grade 4 PCO at 1 year might be attributable to reduced stretch or pressure by the IOL on the posterior capsule owing to the anterior position of the IOL. Overall, Nd:YAG laser posterior capsulotomy was only performed in 3.1% of eyes. Surprisingly, the visual acuity was not restricted, even for most of the eyes with PCO grade 4; possible reasons should be evaluated with future studies. However, a limitation of our study was that a PCO analysis after 12 months is rather early.

This study shows a significantly improved IOL stability behavior for the new capsulotomy-fixated FEMTIS IOL compared to conventional IOL positioned in the capsular bag, with regard to decentration, rotation, and tilt, resulting in high consistent visual performance. The option for a more stable and predictable IOL position, for example in the visual axis, might establish the FEMTIS IOL as a suitable platform for future toric, extended-depth-of-focus, or multifocal lens designs. Perfect centration and rotational stability could help to achieve even better results in terms of the correction of astigmatism and presbyopia.

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REFERENCES

1. Ale JB. Intraocular lens tilt and decentration: a concern for contemporary IOL designs. *Nepal J Ophthalmol* 2011;3(1):68–77.
2. Findl O, Hirnschall N, Draschl P, Wiesinger J. Effect of manual capsulorhexis size and position on intraocular lens tilt, centration, and axial position. *J Cataract Refract Surg* 2017;43(7):902–908.
3. Barbero S, Marcos S, Jiménez-Alfaro I. Optical aberrations of intraocular lenses measured in vivo and in vitro. *J Opt Soc Am A Opt Image Sci Vis* 2003;20(10):1841–1851.
4. Taketani F, Matuura T, Yukawa E, Hara Y. Influence of intraocular lens tilt and decentration on wavefront aberrations. *J Cataract Refract Surg* 2004;30(10):2158–2162.
5. Korynta J, Bok J, Cendelin J, Michalova K. Computer modeling of visual impairment caused by intraocular lens misalignment. *J Cataract Refract Surg* 1999;25(1):100–105.
6. Friedmann E, Dörsam S, Kuppel L, et al. Computer programs for the detection of the IOL-stiffness and -stability in cataract surgery. *Invest Ophthalmol Vis Sci* 2018;59(9):2210.
7. Lee D-H, Shin S-C, Joo C-K. Effect of a capsular tension ring on intraocular lens decentration and tilting after cataract surgery. *J Cataract Refract Surg* 2002;28(5):843–846.
8. Mester U, Sauer T, Kaymak H. Decentration and tilt of a single-piece aspheric intraocular lens compared with the lens position in young phakic eyes. *J Cataract Refract Surg* 2009;35(3):485–490.
9. Becker KA, Auffarth GU, Völcker HE. Messmethode zur Bestimmung der Rotation und der Dezentrierung von Intraokularlinsen. *Ophthalmologe* 2004;101(6):600–603.
10. Tsinopoulos IT, Tsaousis KT, Tsakpinis D, Ziakas NG, Dimitrakos SA. Acrylic toric intraocular lens implantation: a single center experience concerning clinical outcomes and postoperative rotation. *Clin Ophthalmol* 2010;4:137–142.
11. Darian-Smith E, Versace P. Visual performance and positional stability of a capsulorhexis-fixated extended depth-of-focus intraocular lens. *J Cataract Refract Surg* 2020;46(2):179–187.
12. Shajari M, Sonntag R, Niermann T, et al. Determining and comparing the effective lens position and refractive outcome of a novel rhexis-fixated lens to established lens designs. *Am J Ophthalmol* 2020;213:62–68.
13. Eppig T, Scholz K, Löffler A, Messner A, Langenbucher A. Effect of decentration and tilt on the image quality of aspheric intraocular lens designs in a model eye. *J Cataract Refract Surg* 2009;35(6):1091–1100.
14. Pieh S, Fiala W, Malz A, Stork W. In vitro strehl ratios with spherical, aberration-free, average, and customized spherical aberration-correcting intraocular lenses. *Invest Ophthalmol Vis Sci* 2009;50(3):1264–1270.
15. McKelvie J, McArdle B, McGhee C. The influence of tilt, decentration, and pupil size on the higher-order aberration profile of aspheric intraocular lenses. *Ophthalmology* 2011;118(9):1724–1731.
16. Holladay JT, Piers PA, Koranyi G, van der Mooren M, Norrby NES. A new intraocular lens design to reduce spherical aberration of pseudophakic eyes. *J Refract Surg* 2002;18(6):683–691.
17. Piers PA, Weeber HA, Artal P, Norrby S. Theoretical comparison of aberration-correcting customized and aspheric intraocular lenses. *J Refract Surg* 2007;23(4):374–384.
18. Tandogan T, Son HS, Choi CY, Knorz MC, Auffarth GU, Khoramnia R. Laboratory evaluation of the influence of decentration and pupil size on the optical performance of a monofocal, bifocal, and trifocal intraocular lens. *J Refract Surg* 2017;33(12):808–812.
19. Baumeister M, Bühren J, Kohnen T. Tilt and decentration of spherical and aspheric intraocular lenses: effect on higher-order aberrations. *J Cataract Refract Surg* 2009;35(6):1006–1012.
20. Castro A de, Rosales P, Marcos S. Tilt and decentration of intraocular lenses in vivo from Purkinje and Scheimpflug imaging. Validation study. *J Cataract Refract Surg* 2007;33(3):418–429.
21. Draschl P, Hirnschall N, Luft N, et al. Rotational stability of 2 intraocular lenses with an identical design and different materials. *J Cataract Refract Surg* 2017;43(2):234–238.