Journal Pre-proof

Stability and visual outcomes of the capsulotomy-fixated FEMTIS-IOL after automated femtosecond laser-assisted anterior capsulotomy.

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PII: S0002-9394(20)30683-8

DOI: https://doi.org/10.1016/j.ajo.2020.12.025

Reference: AJOPHT 11677

To appear in: *American Journal of Ophthalmology*

Received Date: 3 October 2020

Revised Date: 22 December 2020

Accepted Date: 22 December 2020

Abstract

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, non-comparative 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 (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° and decentration 0.14±0.14 mm from baseline (day of surgery). Mean horizontal IOL tilt was 0.70±0.60° and vertical 1.15±1.06° 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 (SE) was 0.35±0.53 D and 98% (n=235) of eyes were within ±1.0 D. Median PCO score was 1 with a 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.

Stability and visual outcomes of the capsulotomy-fixated FEMTIS-IOL after automated femtosecond laser-assisted anterior capsulotomy.

Short title: Stability and visual results of the FEMTIS-IOL after FLACS

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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 capsulorhexis type and integrity.[1] It has also been shown that a severely malformed capsulorhexis can lead to IOL decentration and hence it is likely that small variations in the capsulorhexis 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 (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.

Patients and 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, UK, 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 which may cause postoperative visual acuity loss and relevant concomitant ophthalmic diseases that could affect capsular bag stability.

Examination protocol

Before surgery, a complete ophthalmological examination had been performed, including manifest refraction, monocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity, tonometry, slit-lamp examination, corneal topography with Scheimflug imaging, optical biometry and fundoscopy. 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 photo of the anterior sector of the eye was taken using the surgical microscope.

Immediately after surgery capsulotomy size, incision size and surgery time was 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 FS-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 two large clip haptics in front of the capsulotomy? (5) How easy was the positioning of the two 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 to 7 days (hereinafter indicated as 1 day), 6 to 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° (180°) and a vertical segment at 90° (270°). 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 center. The angle γ between both reference lines represent 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° and 180° position as well as vertical at 90° and 270° position). The calculated distance values were correlated on basis of the measured pupil size of the Scheimpflug image (blue 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; 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 IOL

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 two 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° and 180° 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., Florida, USA) was used to create a capsulotomy with a diameter of 4.7 to 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 OVD behind the lens was aspirated. The additional two large longitudinal haptics, followed by the two 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, Germany) was used for sample size calculation. For a one-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 one-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 to 20% dropout rate.

Statistical evaluations were performed with SAS 9.1 (SAS Institute Inc, Cary, NC) and Microsoft Office Excel 7.0 (Microsoft, Redmond, Wash). Descriptive data are shown as mean ± SD 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-values of less than 0.05 were considered as statistically significant ($p<0.05$).

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 one eye. Eleven eyes were retrospectively excluded from the study because the study IOL was not be implanted due 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 one 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 to 27.0 D). The mean capsulotomy size was 4.95±0.08 mm, 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 ($p>0.05$).

Mean pre- and post-operative subjective refraction is shown in Table 2. After 6 months postoperatively, SE was within ±0.50 D in 77% (n=206) of eyes and within ±1.0 D in 97% (n=262) of eyes. At the 12-month visit, SE was within ±0.50 D in 79% (n=190) of eyes and within ±1.0 D in 98% (n=235) of eyes. 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.

IOL centration and stability

Postoperative IOL decentration, tilt, and rotation are summarized in Table 3 and Figure 5 (A, B, C). Between surgery, 1 day, 6 weeks, 6 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, 6 weeks, 6 and 12 months postoperatively showed a mean vertical tilt of 1.09±0.98°, 1.18±1.36° and 0.99±0.86 and mean horizontal tilt of 0.73±0.61°, 0.66±0.65° and 0.69±0.72°, respectively (Figure 5 B). There was no statistically significant difference in horizontal and vertical tilt over the follow-up period ($p>0.05$).

The mean IOL rotation between surgery, 1 day, 6 weeks, 6 and 12 months postoperatively was 1.49±1.54°, 1.05±0.80°, 0.92±0. 75° and 0.74±0.72°, respectively (Figure 5 C).

Distance between iris and IOL

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° position and 0.35±0.12 mm at the 180° position. At the vertical meridian, the mean distance was 0.35±0.15 mm at the 90° position and 0.36±0.14 mm at 270° positions (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 FS-laser performance, Femtis injection and IOL stability. The median score was 2 for questions on OVD aspiration, positioning of the two 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 to 4), respectively. Most eyes were rated with PCO none 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-months visit, in 1 eye (0.3%) before the 12-month visit, and in 7 eyes (2.2%) after the 12-month examination (range 12 to 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 one case (n=1 eye; 0.3%) the lens was implanted upside down, subsequently turned without complications. Afterwards, the IOL showed a small nasal haptic defect, but the IOL could finally still be well centered. Due to haptic luxation, secondary intervention with IOL repositioning was 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 world-wide 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 versus conventional surgery. The femtosecond laser can however contribute to the optimization of the IOL position and opens new possibilities.[7,8] A recently published article assessed differences in effective lens position (ELP) based on the lens design.[8] Intraocular lenses (IOLs) with plate-haptic, c-loop haptic, and a rhexis-fixated lens were compared. ELP for rhexis-fixated IOL was shortest (4.29 ± 0.24 mm), 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.[8]

Theoretically, coma increases with increasing IOL tilt and decentration.[9,10] The effects of this misalignment depend on the IOL design, and aberration-correcting lenses appear to be very sensitive to decentration and tilt.[11] Theoretical simulations by Holladay et al[12] 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 et al[13] 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.[14]

According to a review of published studies[1] more than 10° 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 to 3° 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-month postoperative was 0.70º at horizontal and 1.15º at vertical directions. These results are much lower than those reported in previous studies.

The aim of a prospective study by Mester et al[15] was to compare IOL tilt and decentration of a single-piece aspheric IOL (Tecnis ZCB00, Johnson & Johnson Vision, Santa Ana, CA, USA) and the position of the natural crystalline lens in young individuals. All lenses were tilted upward (IOL: mean 2.5°) and to the temporal side (IOL: mean 3.1°).[15] Comparable results were reported by another study by Baumeister et al[16] with a mean optic tilt of 2.89±1.46° for the spherical IOL and 2.85±1.36° 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 which assessed the effect of a capsular tension ring (CTR) on IOL tilt and decentration after cataract surgery and implantation of Acrysof MA60BM (Alcon) lenses.[17] 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, respectively.[17] The low values of decentation in our study might to be explained by the enclavation into the capsulorhexis 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 colleagues[2] evaluated the influence of a manual capsulorhexis 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 capsulorhexis between 4.5 mm and 5.5 mm); small group (capsulorhexis smaller than 4.5 mm); and eccentric group (all other capsulorhexis). Mean decentration in the control group, eccentric capsulorhexis group, and small capsulorhexis group was 0.38±0.23 mm (range 0.05 to 1.14 mm), 0.40±0.21 mm (range 0.04 to 1.02 mm), and 0.17±0.08 mm (range 0.06 to 0.27 mm), respectively.[2] The authors concluded that capsulorhexis size and shape had little effect on the capsular bag performance of modern IOLs and that only eyes with a severely malformed capsulorhexis showed a slightly decentered IOL.[2]

Another study[18] 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° 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°). Between all the other follow-up examinations, mean IOL rotation was always below 1.05°. Becker et al[19] measured the in-the-bag stability of a hydrophilic acrylic IOL and reported an average IOL rotation of 5.3±1.4° after 6 months compared to the position directly after implantation. Another study by Tsinopoulos et al[20] evaluated the rotational stability after in-the-bag implantation of Acrysof toric lenses (Alcon, Fort Worth, TX, USA) and found a mean IOL axis rotation of 2.7±1.5° with a range from 0.9 to 8.4°. Comparable outcomes were reported by Draschl et al[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° (range 0.3 to 7.1°) in the hydrophilic IOL group and 1.6±1.61° (range 0.1 to 6.1°) 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.

Due 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 chaffing was minimal.

At 12 months, 33% of eyes showed no signs of PCO, 36% of eyes showed mild PCO (grade 1 to 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 one year might be due to reduced stretch or pressure by the IOL on the posterior capsule due 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, EDOF 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.

FIGURE LEGEND

Figure 1. Measurement of IOL rotation and decentration using the C++ software.

Figure 2. Measurement of IOL tilt and IOL-iris distance using the C++ software.

Figure 3. The capsulotomy-fixated Femtis FB-313 IOL with 4 additional clip haptics.

Figure 4. Cumulative monocular corrected distance visual acuity, pre- and postoperatively over the follow up period.

Figure 5 A-C. Postoperative IOL decentration (A), vertical and horizontal IOL tilt (B) and IOL rotation (C). [a] Comparative study results by Lee DH et al. Effect of a capsular tension ring on intraocular lens decentration and tilting after cataract surgery. *J Cataract Refract Surg. 2002* ([17]). [b] Comparative study results by Findl O et al. Effect of manual capsulorhexis size and position on intraocular lens tilt, centration, and axial position. *J Cataract Refract Surg. 2017* ([2]). [c] Comparative study results by Mester U et al. Decentration and tilt of a single-piece aspheric intraocular lens compared with the lens position in young phakic eyes. *J Cataract Refract Surg. 2009* ([15]). [d] Comparative study results by Becker KA et al. Measurement method for the determination of rotation and decentration of intraocular lenses. *Ophthalmologe. 2004* ([19]). [e] Comparative study results by Tsinopoulos IT et al. Acrylic toric intraocular lens implantation: a single center experience concerning clinical outcomes and postoperative rotation. *Clin Ophthalmol. 2010* ([20]).

Figure 6. Outcomes of the investigator questionnaire regarding satisfaction with the procedure and the Femtis FB-313 IOL.

Figure 7. Posterior capsule opacification rate after 12 months postoperatively.

Acknowledgments/Financial Disclosure

A - Funding Support:

The implanted intraocular lenses (Femtis) for 334 eyes of 181 patients were provided free of charge by Teleon Surgical B.V. (Spankeren, The Netherlands) for this study.

B - Financial Disclosures:

Gerd Uwe Auffarth: reports grants, personal fees and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands); grants and non-financial support from Klaus Tschira Foundation (Heidelberg, Germany); grants, personal fees and non-financial support from Alcon Laboratories, Inc. (Fort Worth, TX, USA) ; grants, personal fees and non-financial support from J&J Vision (Abbott Medical Optics, Inc. [Santa Ana, CA, USA]); grants, personal fees and non-financial support from Hoya Surgical Optics GmbH (Frankfurt, Germany) ; grants and non-financial support from Kowa Company, Ltd. (Nagoya, Aichi, Japan); personal fees from Ophtec B.V. (Groningen, The Netherlands); grants and non-financial support from Physiol s.a.(Liège, Belgium); grants and non-financial support from Acufocus, Inc. (Irvine, CA USA); grants, personal fees and non-financial support from Rayner Intraocular Lenses Ltd. (Worthing, West Sussex, UK); grants from Sifi S.p.A (Catania, Italy); grants, personal fees and non-financial support from Santen Pharmaceutical Co., Ltd. (Osaka, Japan).

Elfriede Friedmann reports grants from Klaus Tschira Foundation (Heidelberg, Germany).

Detlef Breyer reports grants and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands).

Hakan Kaymak reports grants and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands).

Detlef Holland reports grants and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands).

Burkhard Dick reports grants and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands); non-financial support from Acufocus, Inc. (Irvine, CA USA); other from J&J Vision (Abbott Medical Optics, Inc. [Santa Ana, CA, USA]); other from Bausch & Inc. (Bridgewater, NJ, USA); other from Implandata Ophthalmic Products GmbH (Hannover, Germany); other from Healthe Inc. (Melbourne, FL, USA); other from Orasis Pharmaceuticals Ltd. (Herzliya, Israel); other from RxSight Inc. (Aliso Viejo, CA, Columbia); other from Stroma Medical Corporation (Irvine, CA, US); other from TearClear Corp. (Boston, USA); other from EXCEL-Lens Inc. (Livermore, CA, USA); other from Vivior AG (Zürich, Switzerland); other from Percept Corporation (Palo Alto, CA, USA); other from Atia Medical Inc. (Campbell, CA, USA); other from Avellino Lab. Inc. (Menlo Park, CA, USA); other from Avedro Inc. (Waltham, MA, USA).

Alexander Petzold reports grants and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands).

Sunil Shah reports grants and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands).

Luis Salva Ladaria reports grants and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands).

Scott Anderson Garcia reports grants and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands).

Ramin Khoramnia reports grants, personal fees and non-financial support from Teleon Surgical B.V. (Spankeren, The Netherlands); grants and non-financial support from Klaus Tschira Foundation (Heidelberg, Germany); grants, personal fees and non-financial support from Alcon Laboratories, Inc. (Fort Worth, TX, USA) ; grants, personal fees and non-financial support from J&J Vision (Abbott Medical Optics, Inc. [Santa Ana, CA, USA]); grants, personal

fees and non-financial support from Hoya Surgical Optics GmbH (Frankfurt, Germany) ; grants and non-financial support from Kowa Company, Ltd. (Nagoya, Aichi, Japan); personal fees from Ophtec B.V. (Groningen, The Netherlands); grants and non-financial support from Physiol s.a.(Liège, Belgium); grants and non-financial support from Acufocus, Inc. (Irvine, CA USA); grants, personal fees and non-financial support from Rayner Intraocular Lenses Ltd. (Worthing, West Sussex, UK); grants from Sifi S.p.A (Catania, Italy); grants, personal fees and non-financial support from Santen Pharmaceutical Co., Ltd. (Osaka, Japan).

All authors attest that they meet the current ICMJE criteria for authorship. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

C – Other Acknowledgments:

Raquel Gil Cazorla (Aston University, Birmingham), Tina Kipioti (Midland Eye, Solihull), Ramesh Sivraj (Midland Eye, Solihull), Jill Goodman (Midland Eye, Solihull), Ankur Barua (Midland Eye, Solihull), Simon Dörsam (Interdisciplinary Center for Scientific Computing, Modeling and Simulation in Ophthalmology, Faculty of Mathematics and Informatics, Heidelberg University), Alexander Drobny (Interdisciplinary Center for Scientific Computing, Modeling and Simulation in Ophthalmology, Faculty of Mathematics and Informatics, Heidelberg University) provided additional support in evaluation of study data or preparation of this manuscript.

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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)
Gender, 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)

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

Table 2 – Pre- and postoperative monocular visual acuity and refraction[a]

Variable	Preoperative	Visit 1 1 to 7 days	Visit 2 6 to 8 weeks	Visit 3 6 months	Visit 4 12 months	P-Values†
UDVA (logMAR)	0.57 (0.28) 0.50 (0.00 to 1.20)	0.17 (0.18) 0.10 (-0.16 to 0.90)	0.12 (0.15) 0.10 (-0.20 to 1.00)	0.13 (0.14) 0.10 (-0.10 to 0.70)	0.12 (0.14) 0.10 (-0.20 to 0.54)	0.382
SE (D)	0.30 (2.25) 0.50 (-10.00 to 6.13)	-	0.23 (0.52) 0.25 (-2.88 to 1.88)	0.35 (0.54) 0.38 (-2.25 to 1.75)	0.35 (0.53) 0.38 (-2.25 to 1.88)	<0.001
Cylinder (D)	-0.71 (0.53) -0.75 (-2.75 to 0.00)	-	-0.56 (0.51) -0.50 (-2.50 to 0.00)	-0.56 (0.46) -0.50 (-2.00 to 0.00)	-0.59 (0.47) -0.50 (-2.00 to 0.00)	0.711
Sphere (D)	0.66 (2.24) 1.00 (-9.75 to 6.50)	-	0.51 (0.61) 0.50 (-2.50 to 2.50)	0.63 (0.58) 0.75 (-1.75 to 2.00)	0.64 (0.59) 0.75 (-1.75 to 2.50)	<0.001
CDVA (logMAR)	0.25 (0.18) 0.20 (-0.10 to 0.80)	-	0.00 (0.09) 0.00 (-0.20 to 0.32)	0.00 (0.08) 0.00 (-0.26 to 0.30)	-0.01 (0.09) 0.00 (-0.30 to 0.20)	0.852

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

Table 3 – Postoperative Femtis FB-313 IOL rotation, decentration and tilt between different examinations[a]

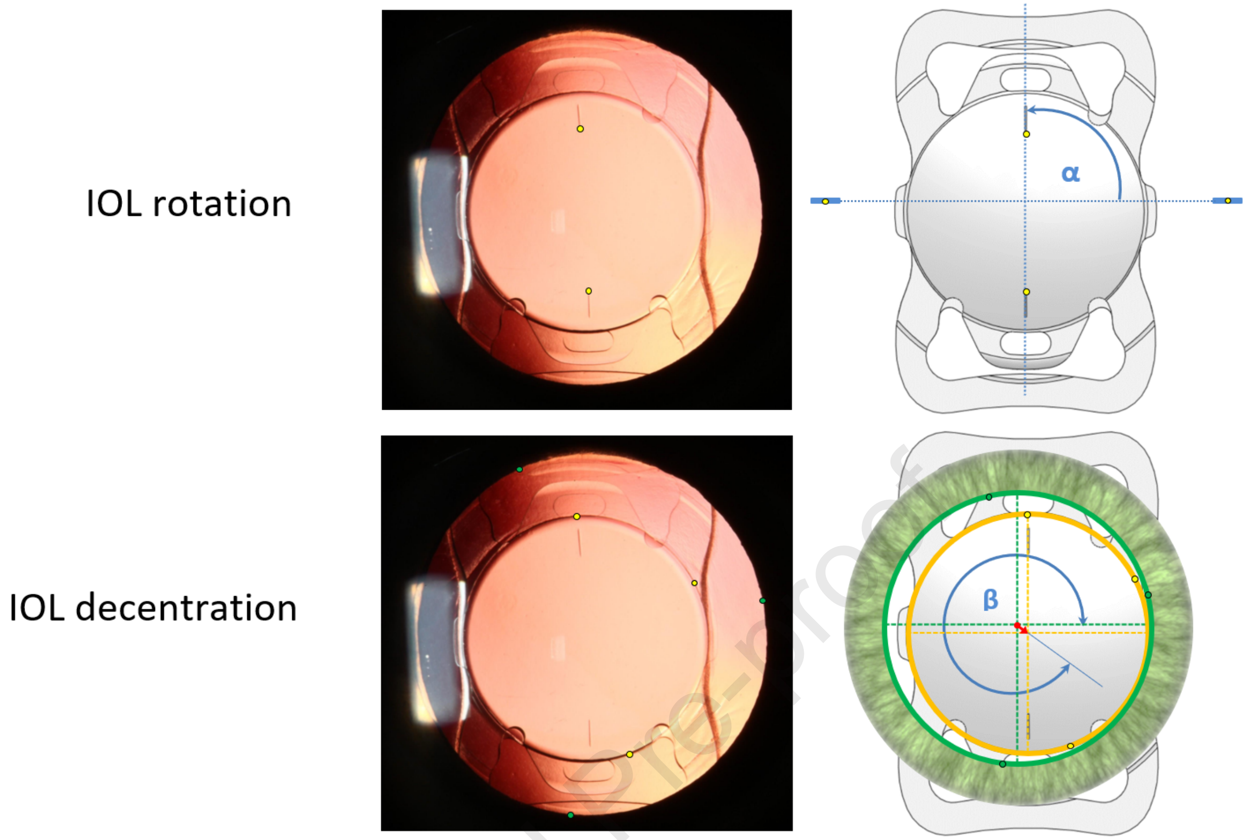
Variable	Surgery to 1 day	Preop to 6 weeks	1 day to 6 weeks	6 weeks to 6 months	6 months to 12 months	Surgery to 12 months	Preop to 12 months	P-Values[†]
Rotation (°)	1.49 (1.54) 1.11 (0.00 to 10.12)	-	1.05 (0.80) 0.89 (0.00 to 4.18)	0.92 (0.75) 0.78 (0.01 to 3.91)	0.74 (0.72) 0.60 (0.00 to 4.62)	1.50 (1.76) 0.77 (0.01 to 10.23)	-	<0.001
Decentration (mm)	0.10 (0.10) 0.07 (0.00 to 0.56)	-	0.08 (0.08) 0.05 (0.00 to 0.48)	0.09 (0.08) 0.07 (0.00 to 0.43)	0.07 (0.08) 0.05 (0.00 to 0.46)	0.14 (0.14) 0.10 (0.00 to 0.62)	-	0.001
Horizontal tilt (°)	-	0.73 (0.61) 0.54 (0.00 to 3.40)	-	0.66 (0.65) 0.49 (0.00 to 3.89)	0.69 (0.72) 0.49 (0.00 to 4.12)	-	0.70 (0.60) 0.56 (0.00 to 2.95)	0.516
Vertical tilt (°)	-	1.09 (0.98) 0.85 (0.00 to 6.83)	-	1.18 (1.36) 0.87 (0.00 to 15.27)	0.99 (0.86) 0.71 (0.00 to 4.63)	-	1.15 (1.06) 0.85 (0.00 to 9.07)	0.135

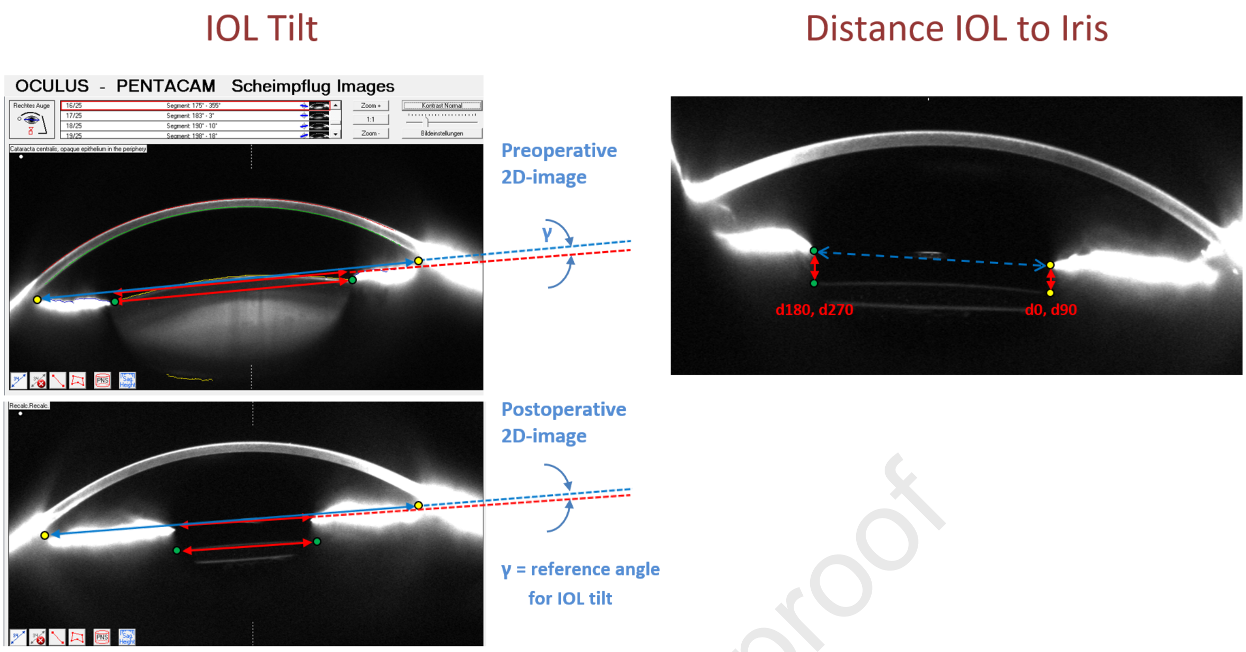
Preop = preoperative
[a]Values reported as mean (SD), median (range); [†]ANOVA repeated measures (surgery/preoperative to 12 months)

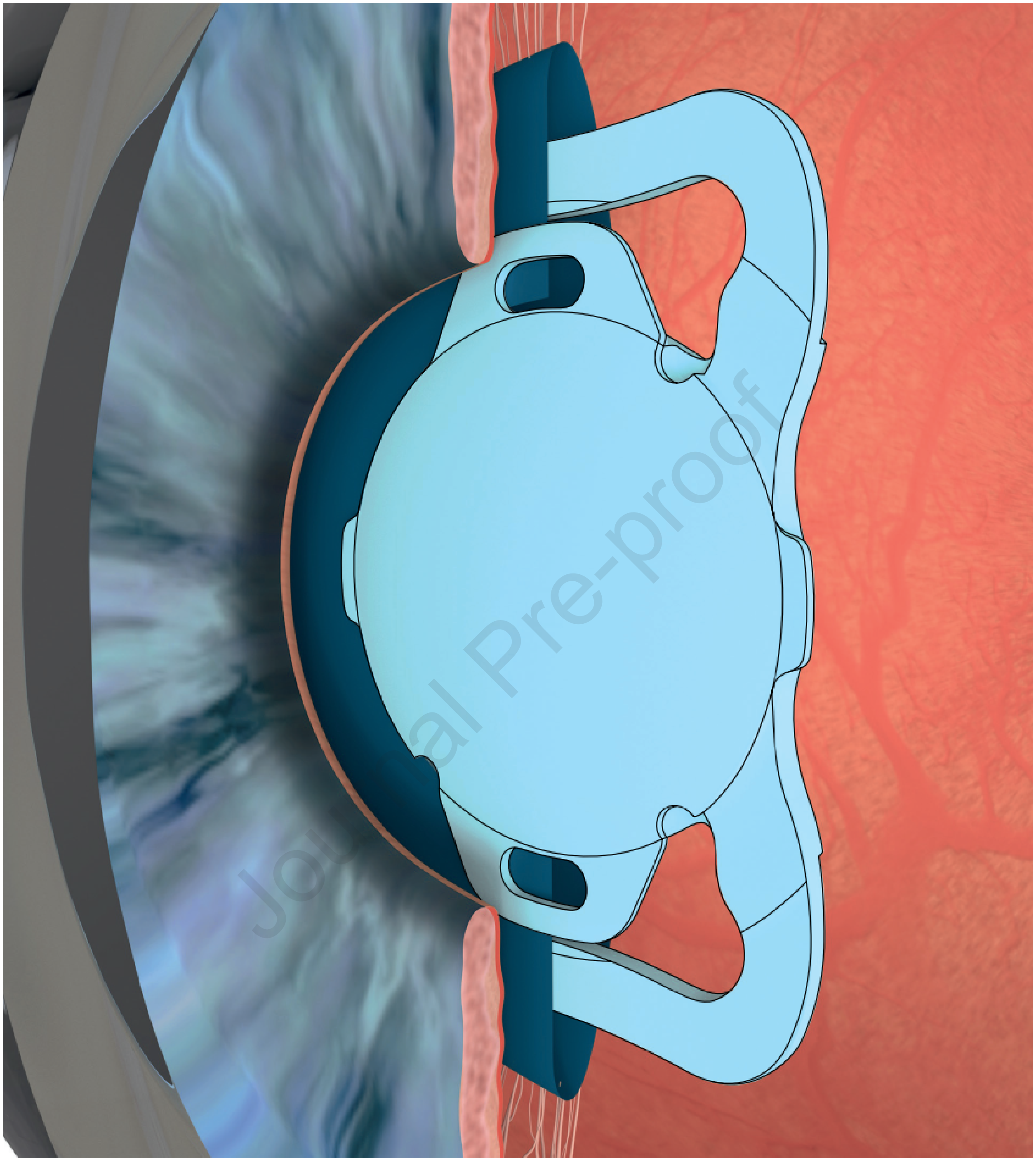
Table 4 – Distance between the iris and the Femtis FB-313 lens over the postoperative period[a]

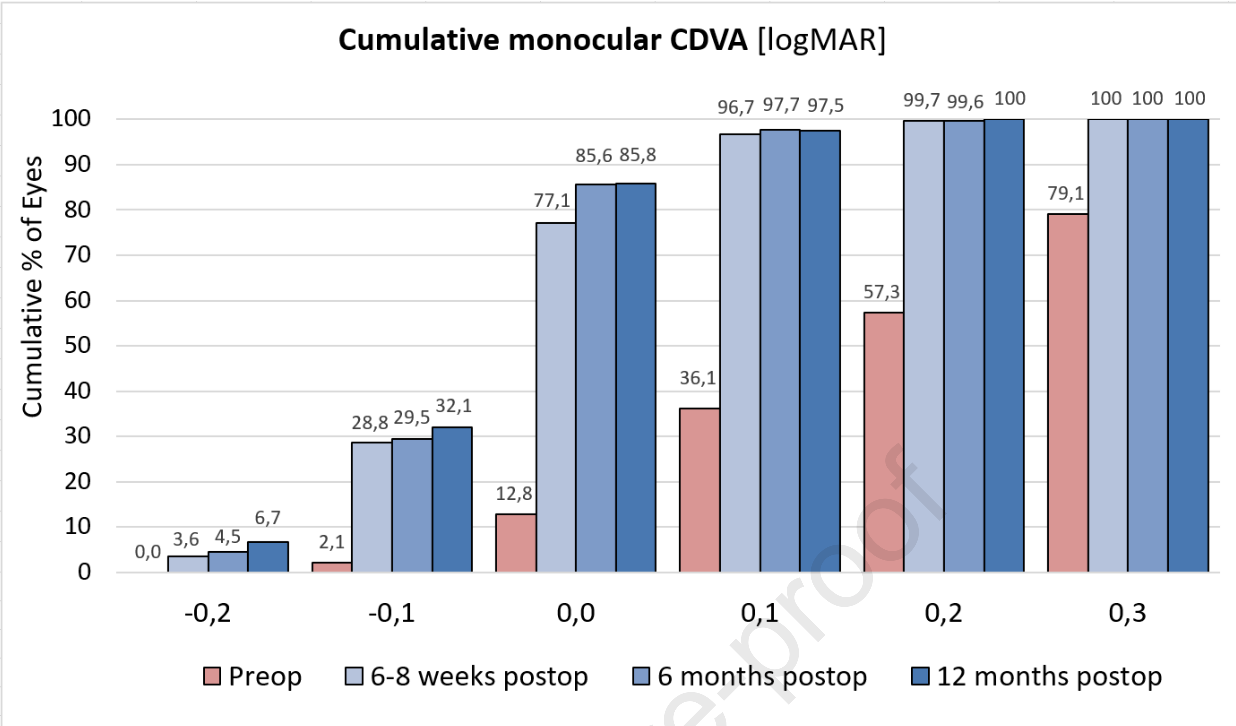
Meridian	Visit 2 6 to 8 weeks	Visit 3 6 months	Visit 4 12 months	P-Values[†]
Horizontal 0° (mm)	0.32 (0.12) 0.31 (0.08 to 0.72)	0.34 (0.12) 0.32 (0.09 to 0.66)	0.33 (0.12) 0.33 (0.08 to 0.70)	0.124
Horizontal 180° (mm)	0.34 (0.12) 0.33 (0.08 to 0.68)	0.35 (0.12) 0.35 (0.09 to 0.81)	0.35 (0.12) 0.33 (0.10 to 0.71)	0.304
Vertical 90° (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)	0.525
Vertical 270° (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)	0.585

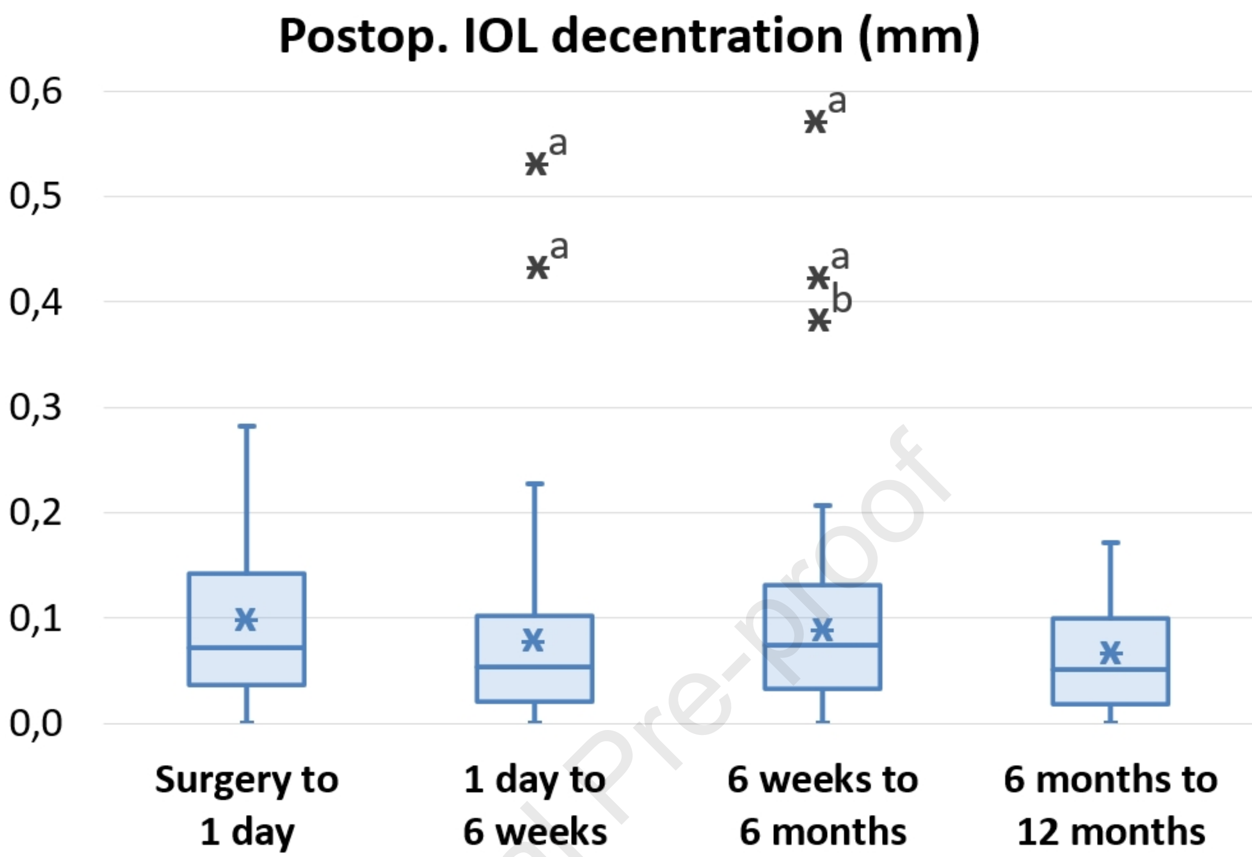
[a]Values reported as mean (SD), median (range); [†]ANOVA repeated measures


IOL rotation
α
IOL decentration
β

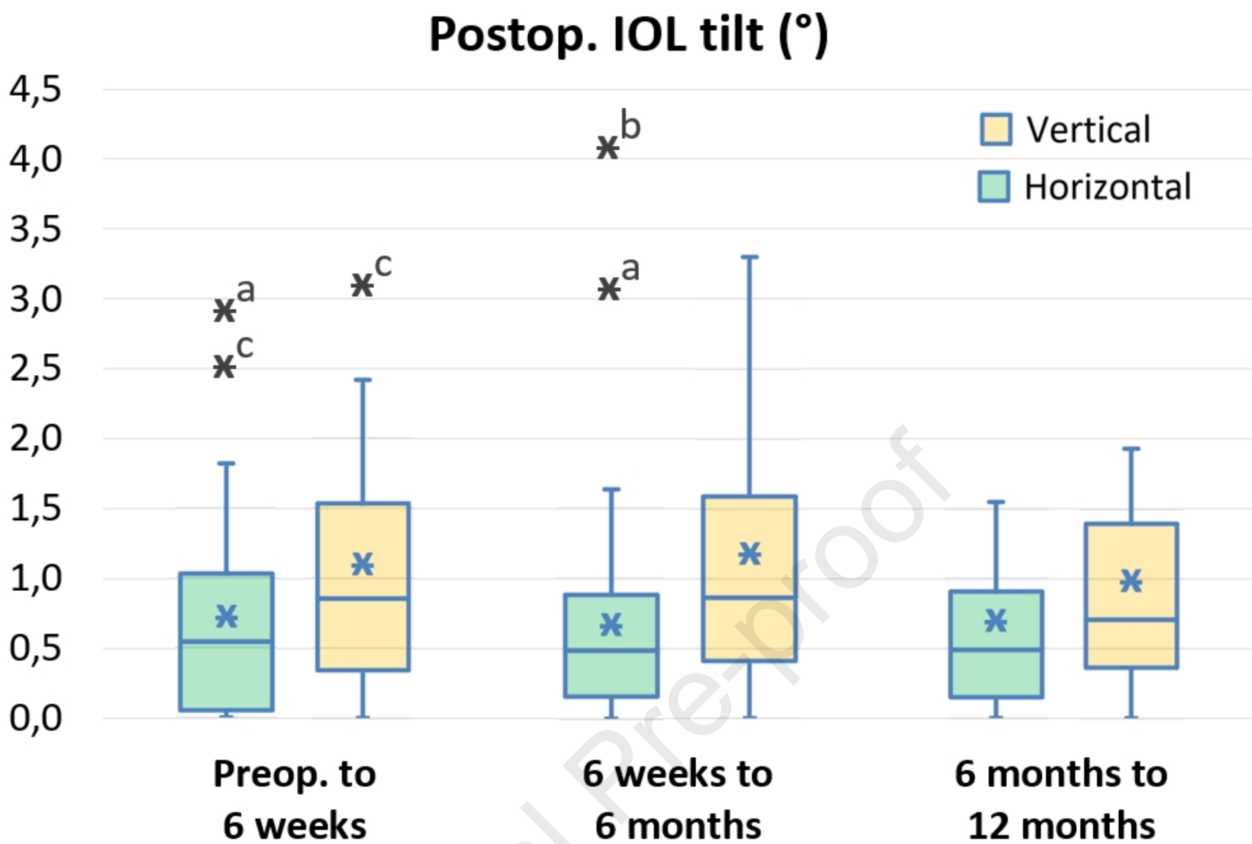

IOL Tilt
Distance IOL to Iris
OCULUS - PENTACAM Scheimpflug Images
Preoperative 2D-image
γ
Postoperative 2D-image
γ = reference angle for IOL tilt
d180, d270
d0, d90

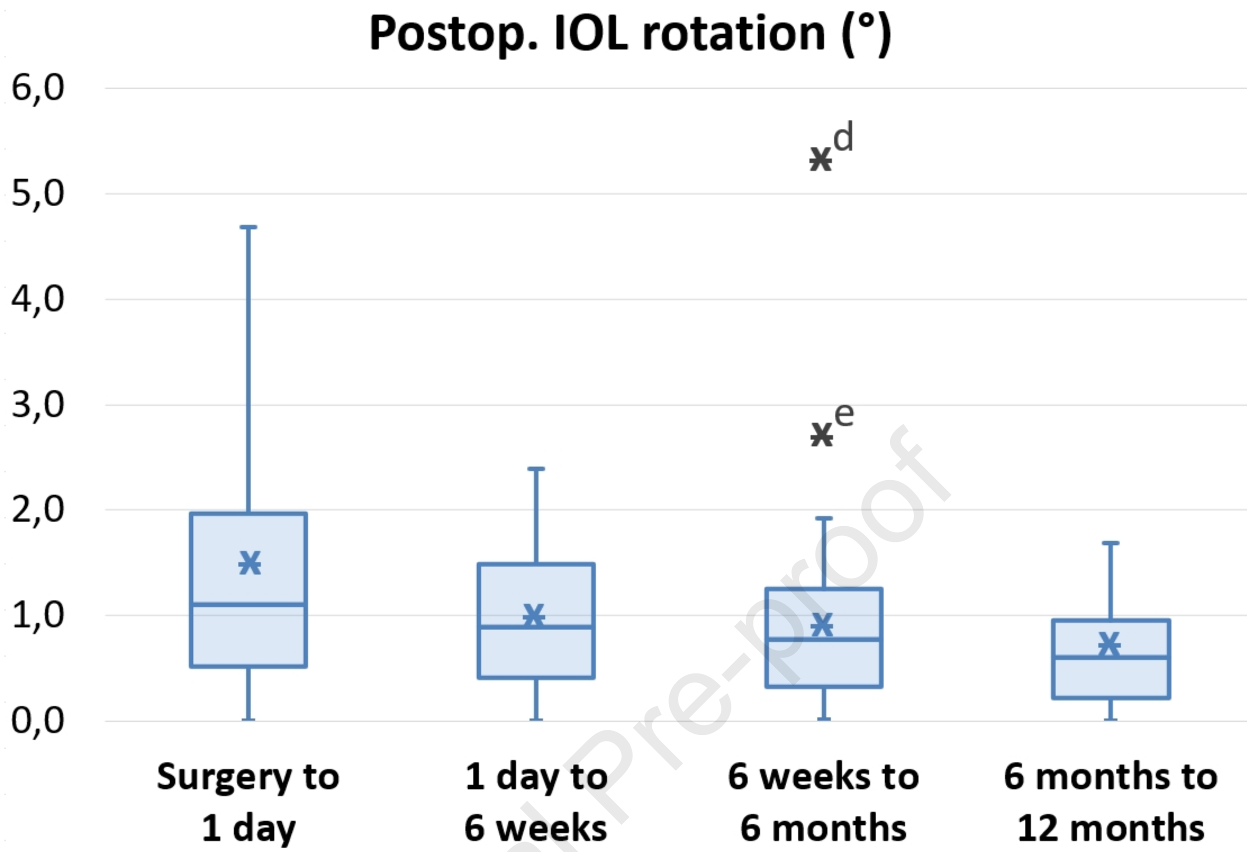


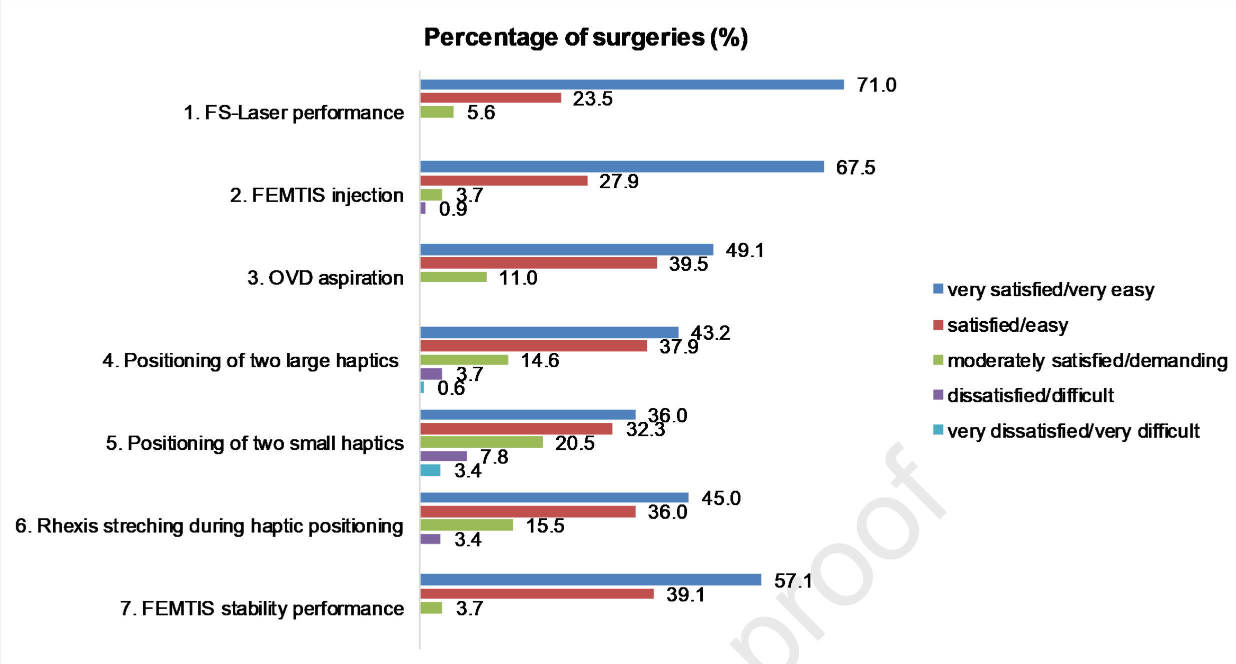

Cumulative monocular CDVA [logMAR]
Cumulative % of Eyes
100
90
80
70
60
50
40
30
20
10
0
0,0 3,6 4,5 6,7
2,1 28,8 29,5 32,1
12,8 77,1 85,6 85,8
36,1 96,7 97,7 97,5
57,3 99,7 99,6 100
79,1 100 100 100
-0,2
-0,1
0,0
0,1
0,2
0,3
Preop
6-8 weeks postop
6 months postop
12 months postop

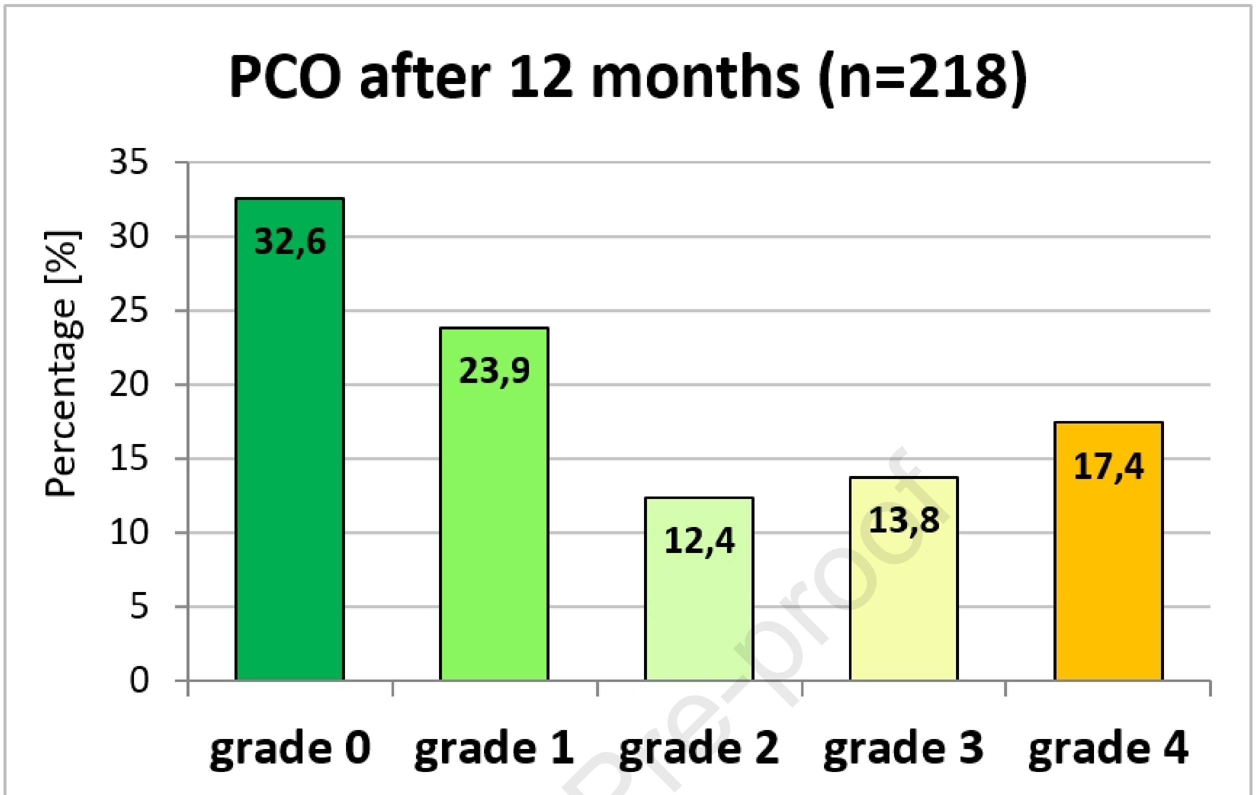


Postop. IOL decentration (mm)
0,6
0,5
0,4
0,3
0,2
0,1
0,0
a
a
a
a
b
Surgery to 1 day
1 day to 6 weeks
6 weeks to 6 months
6 months to 12 months


Postop. IOL tilt (°)
4,5
4,0
3,5
3,0
2,5
2,0
1,5
1,0
0,5
0,0
Vertical
Horizontal
a
b
c
Preop. to 6 weeks
6 weeks to 6 months
6 months to 12 months


Postop. IOL rotation (°)
6,0
5,0
4,0
3,0
2,0
1,0
0,0
d
e
Surgery to 1 day
1 day to 6 weeks
6 weeks to 6 months
6 months to 12 months


Percentage of surgeries (%)
1. FS-Laser performance
71.0
23.5
5.6
2. FEMTIS injection
67.5
27.9
3.7
0.9
3. OVD aspiration
49.1
39.5
11.0
4. Positioning of two large haptics
43.2
37.9
14.6
3.7
0.6
5. Positioning of two small haptics
36.0
32.3
20.5
7.8
3.4
6. Rhexis streching during haptic positioning
45.0
36.0
15.5
3.4
7. FEMTIS stability performance
57.1
39.1
3.7
very satisfied/very easy
satisfied/easy
moderately satisfied/demanding
dissatisfied/difficult
very dissatisfied/very difficult



PCO grading

0 – none visible at all
1 – visible but not reaching IOL optic edge
2 – slightly over IOL optic edge
3 – well inside IOL optic but visual axis clear
4 – across visual axis

Table of Contents Statement

This multicenter study showed 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.