# Comparison of Long-term Visual Outcome and IOL Position With a Single-optic Accommodating IOL After 5.5- or 6.0-mm Femtosecond Laser Capsulotomy

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## ABSTRACT

**PURPOSE:** To evaluate the long-term visual outcome and intraocular (IOL) position parameters with a single-optic accommodating IOL after 5.5- or 6.0-mm femtosecond laser capsulotomy.

**METHODS:** This prospective, randomized, pilot study comprised 17 eyes from 11 patients (7 men) with a mean age of 65.82±10.64 years (range: 51 to 79 years). All patients received a Crystalens AT-50AO (Bausch & Lomb) accommodating IOL after femtosecond laser refractive cataract surgery using either a 5.5-mm capsulotomy (5.5-mm group; 9 eyes) or 6.0-mm capsulotomy (6.0-mm group; 8 eyes). Near and distance visual acuities, manifest refraction spherical equivalent (MRSE), and IOL tilt and decentration were evaluated 1 year postoperatively.

**RESULTS:** No significant differences were noted between groups for postoperative uncorrected distance visual acuity, uncorrected near visual acuity, distance-corrected near visual acuity, and MRSE. Vertical and horizontal tilt were significantly higher in the 6.0-mm group than in the 5.5-mm group ($P$=.014 and $P$=.015, respectively). No significant difference was observed between groups regarding IOL decentration.

**CONCLUSIONS:** A 5.5-mm capsulotomy created with a femtosecond laser is associated with less IOL tilt and therefore may be superior to a 6.0-mm capsulotomy when implanting a single-optic accommodating IOL. [*J Refract Surg*. 2012;28(9):609-613.]

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Implantation of accommodating intraocular lenses (IOLs) is an option to treat presbyopia. Accommodating IOLs were designed to avoid optical side effects of multifocal IOLs, eg, decreased contrast sensitivity,[1,2] glare disability, and halos.[3,4]

The mechanism of action of accommodating IOLs remains controversial.[5] The recommended capsulorrhexis size for a single-optic accommodating IOL is 5.5 to 6.0 mm.[6] Until the introduction of femtosecond laser refractive cataract surgery,[7-11] the only way to perform a capsulorrhexis was via a manual procedure. In previous studies using femtosecond laser refractive cataract surgery,[10,11] a precisely sized and centered femtosecond laser capsulorrhexis proved to maintain centration of monofocal IOLs in a stable postoperative position.

The aim of this prospective pilot study was to evaluate long-term outcomes of a single-optic accommodating IOL after femtosecond laser refractive cataract surgery, comparing two different capsulotomy diameters.

## PATIENTS AND METHODS

This prospective, randomized, pilot study included 17 eyes from 11 patients (7 men, 4 women) with a mean age of 65.82±10.64 years (range: 51 to 79 years). All patients had a thorough discussion with the surgeon about the risks, benefits, and alternatives of the treatment. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee. Inclusion criteria were se-

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TABLE 1

**Preoperative Characteristics of Patients Who Underwent 5.5- or 6.0-mm Capsulotomy**

| | Mean±Standard Deviation (Range) | | |
|---|---|---|---|
| **Parameter** | **5.5-mm Group** | **6.0-mm Group** | ***P* Value*** |
| Eyes (n) | 9 | 8 | |
| Age (y) | 65.4±10.03 (53 to 78) | 66.25±11.98 (51 to 79) | .743 |
| MRSE (D) | 0.22±0.96 (−1.50 to +1.50) | 0.094±1.49 (−2.00 to +2.00) | .834 |
| Corneal astigmatism (D) | 0.64±0.22 (0.43 to 1.00) | 0.53±0.33 (0.08 to 0.97) | .448 |
| Mean K (D) | 42.27±0.71 (41.47 to 43.59) | 42.52±1.11 (41.07 to 44.45) | .625 |
| UDVA (decimal) | 0.13±0.05 (0.05 to 0.2) | 0.14±0.07 (0.05 to 0.25) | .744 |
| CDVA (decimal) | 0.21±0.06 (0.1 to 0.3) | 0.19±0.07 (0.1 to 0.3) | .569 |
| Axial length (mm) | 23.05±1.08 (21.51 to 24.4) | 23.67±0.60 (22.95 to 24.49) | .329 |
| IOL power (D) | 22.57±1.92 (20.50 to 25.50) | 21.13±0.99 (20.00 to 23.00) | .126 |

*MRSE = manifest refraction spherical equivalent, K = keratometry, UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, IOL = intraocular lens*
**Independent* t *test.*

nile cataract and age 50 years or older. Patients with diabetes, glaucoma, uveitis, previous ocular surgery and trauma, retinal diseases, anterior segment pathology (iris atrophy, synechiae, incomplete or damaged zonules, aniridia), non-dilating pupil, a difference between steep and flat keratometry (K) cylinder >1.00 diopter (D), and axial length <19.0 mm or >25.0 mm were excluded from the study.

Eyes were divided into two groups by computer-generated randomization tables. In 9 eyes, a 5.5-mm capsulotomy was performed (5.5-mm group), and in 8 eyes a 6.0-mm capsulotomy (6.0-mm group) was performed. Table 1 shows the preoperative characteristics in both groups. No statistically significant differences were present between groups in age, visual acuity (uncorrected and corrected), manifest refraction spherical equivalent (MRSE), K, corneal astigmatism, axial length, or power of the implanted IOL.

### Preoperative Assessment

Baseline preoperative examination included uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) measurements using a Snellen chart, MRSE, intraocular pressure by Goldmann applanation tonometry, slit-lamp evaluation, and funduscopy after pupil dilation.

### Intraocular Lens and Power Calculation

A Crystalens AT-50AO (Bausch & Lomb, Rochester, New York) accommodating IOL was implanted in all eyes, which has a biconvex aspheric 5.0-mm single-optic design from Biosil with a refractive index of 1.4301 and a total diameter of 11.5. Optical biometry was performed in all eyes (IOLMaster; Carl Zeiss Meditec, Jena, Germany). Keratometry was measured using the LenStar LS 900 (Haag-Streit International, Koeniz, Switzerland). The SRK/T formula with an A-constant of 119.1 was used for IOL power calculations for eyes with axial lengths measuring ⩾22.01 mm. The Holladay II formula was used for eyes with axial lengths measuring ⩽22.0 mm and for eyes with K flatter than 42.00 D independent of axial length. The target was emmetropia in all cases.

### Surgical Technique

The same surgeon (Z.Z.N.) performed all cataract extractions and IOL implantations using topical anesthesia (oxybuprocain). Pupils were dilated with one drop of tropicamide 0.5% every 15 minutes for 45 minutes preoperatively.

Surgery was started in a laser room outside the operating room, and a 5.5-mm (5.5-mm group) or 6.0-mm (6.0-mm group) capsulotomy was performed using the LenSx femtosecond laser system (Alcon LenSx Inc, Aliso Viejo, California). The eye was fixated with a curved patient interface and the exact location of the lens and capsule were determined using optical coherence tomography built into the laser. The capsulotomy procedure was performed by scanning a circular pattern starting at least 100 µm below the anterior capsule and ending at least 100 µm above the capsule. Proprietary energy and spot separation parameters, which had been optimized in previous studies, were used for all capsulotomies.

Following the laser procedure, all patients were brought into the operating room and standard phacoemulsification (Infiniti; Alcon Laboratories Inc, Ft Worth, Texas) was performed. A 2.8-mm clear corneal incision was created with a disposable keratome, viscoelastic material (Provisc, Alcon Laboratories Inc) was injected, and the cut capsule was removed with a capsulorrhexis forceps. After hydrodissection, phacoemulsification of the nucleus and aspiration of the residual cortex were performed. The accommodating IOL was implanted in the intact capsular bag. After IOL implantation, the viscoelastic material was removed from the anterior chamber and capsular bag by irrigation and aspiration. All incisions were left sutureless. Immediately after hydration of the corneal incision, one drop of atropine 1% was instilled. One day postoperatively, one drop of atropine 1% was instilled to completely relax the ciliary muscle for the first 7 days so the accommodating IOL would remain firmly in contact with the posterior capsule. Patients were instructed to instill one drop of dexamethasone 0.1%–tobramycin 0.3% (Tobradex, Alcon Laboratories Inc) five times daily for 1 week and four times daily for the following week.

### Postoperative Assessment

On the first postoperative day, patients had slit-lamp examination with dilated pupil to check the position of the accommodating IOL optic. Examinations at 1 week and 1, 3, 6, and 12 months after surgery were the same as preoperatively.

Uncorrected near visual acuity (UNVA) was measured using a Rosenbaum-Jaeger reading chart at 35 cm 12 months postoperatively; the chart was directly illuminated by a lamp with a 60-W bulb. Distance-corrected near visual acuity (DCNVA) was measured similarly to eliminate potential pseudoaccommodative effects of residual myopia and corneal cylinder. Uncorrected distance visual acuity, CDVA, UNVA, and DCNVA readings were converted to decimal notation for statistical analysis.

A Scheimpflug imaging system (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany) was used to evaluate IOL tilt and decentration 12 months postoperatively according to de Castro et al[12] as follows: IOL decentration is obtained from the distance between the IOL center and pupillary axis. Positive horizontal coordinates stand for nasal in the right eye and temporal in the left eye. Positive vertical coordinates stand for superior decentrations, and negative for inferior decentrations. By eliminating positive and negative signs, the magnitude of horizontal and vertical decentration could be determined without reference to nasal/temporal and superior/inferior orientation, respectively. Regarding IOL tilt, positive tilt around the x-axis indicates that the superior edge of the IOL is moved forward and vice versa for negative tilt. Positive tilt around the y-axis means, in the right eye, nasal tilt and indicates that the nasal edge of the IOL is moved backward and vice versa for a negative tilt around the y-axis in right eyes. A positive tilt around the y-axis stands for temporal tilt (nasal edge of the IOL moves forward) in left eyes. By eliminating positive and negative signs, the magnitude of horizontal and vertical tilt could be determined without reference to any orientation. The same examiner (K.K.) obtained the tilt measurements.

### Statistical Analysis

Statistical analysis of the results was performed using SPSS for Windows software (version 9.0; SPSS Inc, Chicago, Illinois). Departure from normal distribution assumption was tested by the Shapiro-Wilks W test. In the case of normal distribution, data were presented as mean±standard deviation, whereas median±interquartile range was used if data showed non-normal distribution. For comparison of pre- and postoperative data, paired *t* test or Wilcoxon rank sum test was used, and for analyzing between-group differences unpaired *t* test or Mann-Whitney test was used.

To evaluate clinical significance between groups regarding tilt and decentration parameters, the Chi-square test of homogeneity was applied to compare the distribution of dichotomized tilt and decentration values at the level of 5° and 0.4 mm, respectively.[13]

The significance level was set at $P<.05$ in all statistical analyses.

## RESULTS

No intraoperative complications or abnormal postoperative inflammations occurred. Mild corneal edema was found in four eyes on the first postoperative day, which resolved by the end of the first week. No cases of posterior capsule opacification occurred during the study period. All patients presented for 1-year follow-up.

Mean corneal astigmatism (difference between steep and flat K readings) was 0.64±0.22 D preoperatively and 0.78±0.20 D 12 months postoperatively in the 5.5-mm group and 0.53±0.33 D preoperatively and 0.84±0.32 D 12 months postoperatively in the 6.0-mm group. The difference between pre- and postoperative corneal astigmatism was not statistically significant in either group (5.5-mm group, $P=.851$; 6.0-mm group, $P=.058$; paired *t* test).

### Visual and Refractive Outcomes

Table 2 shows the mean UDVA, UNVA, and DCNVA in decimal notation and MRSE in the study groups.

TABLE 2

**12-month Postoperative Data of Eyes That Underwent 5.5-mm or 6.0-mm Capsulotomy***

| Parameter | 5.5-mm Group | 6.0-mm Group | *P* Value† |
|---|---|---|---|
| Eyes (n) | 9 | 8 | |
| MRSE (D) | −0.52±0.44 (−1.00 to 0.25) | −0.61±0.70 (−1.87 to 0.50) | .774 |
| Corneal astigmatism (D) | 0.78±0.20 (0.51 to 1.00) | 0.84±0.32 (0.40 to 1.21) | .723 |
| Mean K (D) | 42.52±0.89 (41.27 to 44.25) | 43.41±0.95 (42.05 to 44.65) | .101 |
| UDVA (decimal) | 0.8±0.2 (0.7 to 1.0) | 0.75±0.38 (0.6 to 1.0) | .399‡ |
| UNVA (decimal) | 0.63±0.21 (0.32 to 1) | 0.60±0.22 (0.32 to 1.0) | .750 |
| DCNVA (decimal) | 0.63±0.3 (0.4 to 0.8) | 0.57±0.23 (0.32 to 0.63) | .488‡ |

*MRSE = manifest refraction spherical equivalent, K = keratometry, UDVA = uncorrected distance visual acuity, UNVA = uncorrected near visual acuity, DCNVA = distance-corrected near visual acuity*
**Normal distribution data are presented as mean±standard deviation (range). Non-normal distribution data are presented as median±interquartile range.*
*†Independent t test.*
*‡Mann-Whitney test.*

TABLE 3

**Tilt and Decentration Parameters of Eyes That Underwent 5.5-mm or 6.0-mm Capsulotomy**

| | Mean±SD (Range) | | |
|---|---|---|---|
| Parameter | 5.5-mm Group | 6.0-mm Group | *P* Value* |
| Tilt (°) | | | |
| Vertical | 1.42±0.81 (0.49 to 2.99) | 4.29±2.52 (1.45 to 8.77) | .014 |
| Horizontal | 1.62±0.85 (0.36 to 2.55) | 4.77±2.62 (1.77 to 8.14) | .015 |
| Decentration (mm) | | | |
| Vertical | 0.083±0.079 (0.000 to 0.200) | 0.086±0.095 (0.010 to 0.280) | .976 |
| Horizontal | 0.136±0.109 (0.010 to 0.340) | 0.193±0.141 (0.010 to 0.350) | .414 |

**Independent t test.*

TABLE 4

**Distribution of Dichotomized Tilt Values at 5.0° in Eyes That Underwent 5.5-mm or 6.0-mm Capsulotomy**

| Parameter | 5.5-mm Group | 6.0-mm Group | *P* Value* |
|---|---|---|---|
| Vertical tilt | 0:9 | 2:8 | .156 |
| Horizontal tilt | 0:9 | 3:8 | .089 |

**Chi-square test.*

One year after surgery, 7 (77.8%) eyes in the 5.5-mm group and 4 (50%) eyes in the 6.0-mm group had UDVA of 20/25 (0.8) or better 12 months postoperatively. Uncorrected near visual acuity was J3 (0.5) or better in 8 (88.9%) eyes in the 5.5-mm group and 6 (75.0%) eyes in the 6.0-mm group. The difference between groups was not statistically significant (*P*=.75; independent *t* test). Median DCNVA was J3 in both groups postoperatively. Distance-corrected near visual acuity was J3 or better in 77.7% of eyes (7/9) in the 5.5-mm group and 75.0% of eyes (6/8) in the 6.0-mm group. The difference between groups was not statistically significant (*P*=.48; Mann-Whitney test). No statistically significant difference was noted between groups in MRSE preoperatively (*P*=.834, independent *t* test) and 1 year postoperatively (*P*=.14, Mann-Whitney test).

### Accommodating IOL Tilt and Decentration Parameters

Table 3 shows the mean horizontal and vertical accommodating IOL tilt and decentration parameters. Both vertical and horizontal tilt parameters were statistically significantly higher in the 6.0-mm group. No statistically significant difference was noted between groups in any decentration parameter. None of the implanted IOLs showed a decentration >0.4 mm.

In the 6.0-mm group, >5° vertical and horizontal tilt was measured in 2 (25%) and 3 (37.5%) eyes, respectively. In the 5.5-mm group, none of the eyes showed IOL tilt >5°. No significant difference was noted in the distribution of dichotomized tilt values at 5° between groups (Table 4).

## DISCUSSION

To our knowledge, this is the first pilot study to report single-optic accommodating IOL implantation after femtosecond laser capsulotomy and to evaluate accommodating IOL tilt and decentration taking into consideration capsulorrhexis size. Accommodating IOLs[5] were developed with the aim of providing accommodative capability and functional near vision and independence from spectacles after cataract extraction without the compromises of a multifocal IOL.[1-4] For the implantation of a 5.0-mm diameter single-optic accommodating IOL, the capsulorrhexis should be central, circular, and between 5.5 and 6 mm in diameter.[6] A large or eccentric capsulorrhexis increases the risk of IOL dislocation.[10,11]

The introduction of femtosecond laser refractive cataract surgery provides the means to perform more precise, accurate, reproducible, and stronger capsulotomies than those created with the conventional manual technique.[7-11,14] A properly sized, shaped, and centered femtosecond laser capsulotomy resulted in better IOL centration and less tilt when compared to a manual capsulotomy.[9-11] Kránitz et al[11] reported six-times higher odds for IOL decentration when the capsulorrhexis was performed manually compared to a femtosecond laser capsulotomy.

Until now there has been no clear evidence in the published literature regarding whether a 5.5- or 6.0-mm capsulorrhexis is the most suitable for a 5.0-mm diameter single-optic accommodating IOL (Crystalens AT-50AO). We therefore compared both diameters in this prospective study. We found no significant difference between the two study groups regarding postoperative UDVA, UNVA, and DCNVA. We also did not find a difference in IOL decentration between the 5.5-mm and 6.0-mm groups, and none of the implanted IOLs exceeded 0.4 mm of decentration. Altmann[15] warned that the advantage of an aspheric IOL can be lost in the case of decentration >0.5 mm. Holladay et al[16] indicated that the performance of aspheric IOLs is worse compared to spherical IOLs when decentration is >0.4 mm.

When evaluating the anteroposterior position of the accommodating IOLs, we found significantly higher horizontal and vertical tilt in the 6.0-mm group, and two (25%) IOLs exceeded 5.0° of vertical tilt and three (37.5%) IOLs exceeded 5° of horizontal tilt in the 6.0-mm group, whereas no IOL exceeded 5° in the 5.5-mm group. Guyton et al[13] reported that IOL tilt >5° can impair visual quality. Other authors[17,18] demonstrated a significant correlation between IOL tilt and ocular coma-like aberrations, and the quality of the retinal image improves by reducing IOL tilt.

Limitations of our study include the small number of eyes evaluated and the potential bias introduced by including both eyes of some patients.

Our results indicate that a 5.5-mm capsulotomy created with an intraocular femtosecond laser causes less IOL tilt than a 6.0-mm capsulotomy and may therefore be superior when implanting a single-optic accommodating IOL.

### AUTHOR CONTRIBUTIONS

*Study concept and design (A.S., Z.Z.N.); data collection (A.S., K.K., A.I.T., Z.Z.N.); analysis and interpretation of data (A.S., K.K., K.M., M.C.K.); drafting of the manuscript (A.S.); critical revision of the manuscript (K.K., A.I.T., K.M., M.C.K., Z.Z.N.); statistical expertise (A.S.); administrative, technical, or material support (A.S.); supervision (K.K., A.I.T., Z.Z.N.)*

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