ARTICLE

Comparison of visual recovery and refractive stability between femtosecond laser–assisted cataract surgery and standard phacoemulsification: Six-month follow-up

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PURPOSE: To compare visual recovery and refractive changes between femtosecond laser–assisted cataract surgery and standard cataract surgery.

SETTING: Center for Vision Science, Ruhr University Eye Clinic, Bochum, Germany.

DESIGN: Prospective randomized intraindividual cohort study.

METHODS: Eyes were treated with femtosecond laser–assisted cataract surgery or conventional phacoemulsification using pulsed ultrasound energy. Both groups had intraocular lens (IOL) implantation. The manifest refraction, corrected distance visual acuity, and anterior chamber depth were determined preoperatively and 2 hours, 3 to 4 days, 1 week, and 1, 2, 3, and 6 months postoperatively to determine the achieved deviation from target refraction, IOL position, and refractive stability.

RESULTS: One hundred eyes of 100 patients were treated with femtosecond laser–assisted cataract surgery; the fellow 100 eyes had conventional phacoemulsification. Six months postoperatively, 196 eyes were included and analyzed. At 6 months, 90 eyes (92%) in the femtosecond laser–assisted group and 70 eyes (71%) in the conventional group were within ±0.50 D of the target refractive outcome and 98 eyes (100%) in both groups were within ±1.00 D. The mean refractive spherical equivalent showed no significant change between 1 week and 1 month in the femtosecond laser–assisted group and between 1, 2, 3, and 6 months postoperatively in both groups.

CONCLUSION: Femtosecond laser–assisted cataract surgery yielded faster visual recovery, less deviation from the target refraction, and earlier stabilization of refraction.

Financial Disclosure: Dr. Dick is a member of the medical advisory board of Abbott Medical Optics, Inc. No other author has a financial or proprietary interest in any material or method mentioned.

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Within the past few years, femtosecond laser–assisted cataract surgery has been adopted worldwide. Recent publications about this emerging technology discuss several aspects, such as a reduction to zero ultrasound (US) energy and endothelial cell stability over time using a femtosecond laser.[1–7] Furthermore, results focus on the circularity and precision of the capsulotomy, highlighting its accuracy compared with that in the manual procedure.[8,9] A few studies[4,9,10] report faster recovery of visual acuity or more stable intraocular lens (IOL) centration with femtosecond laser–assisted cataract surgery than with manual techniques. Two studies[11,12] showed no significant difference in visual acuity between laser cases and manual cases.

Limitations of the published studies of refractive outcomes include small case series and inhomogeneous group designs. We question the validity of evidence supporting the superiority of visual outcomes with laser-assisted cataract surgery compared with regular phacoemulsification. We therefore performed a prospective intraindividual clinical study to compare laser-assisted cataract surgery with manual

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capsulorhexis and phacoemulsification in a single center. Our primary outcome measures were early and late corrected distance visual acuity (CDVA) and the deviation from the target refraction using the spherical equivalent (SE) refraction. Secondary outcome measures were anterior chamber depth (ACD) and keratometry values. We performed femtosecond laser–assisted capsulotomy and lens fragmentation in the laser group. All corneal incisions in both groups were created with steel keratomes to avoid potential differences in refractive outcomes resulting from the influence of different incision types.

PATIENTS AND METHODS

Patients in this prospective trial were scheduled for elective bilateral cataract surgery and implantation of an IOL by the same surgeon (H.B.D.). The trial received approval of the Ethical Committee, Ruhr University, Bochum, Germany, and all aspects of the Declaration of Helsinki were observed. The patients enrolled had a visually significant cataract, willingly volunteered for the trial, and provided written informed consent.

The inclusion criteria were a potential corrected visual acuity of 0.8 (20/25) in both eyes. Exclusion criteria included amblyopia, a history of serious coexistent ocular disease (eg, pseudoexfoliation, uncontrolled glaucoma, macular pathologies, high myopia, or hyperopia, defined as an axial length [AL] <21.5 mm or >27.5 mm), corneal astigmatism of more than 1.5 diopters (D), optic atrophy, ocular tumors, use of topical or systemic steroids or nonsteroidal antiinflammatory drugs during the previous 3 months, relevant corneal opacities, Fuchs dystrophy, cornea guttata, an age younger than 22 years, and participation in another clinical study. Furthermore, a dilated pupil of at least 6.0 mm preoperatively was necessary.

The Lens Opacities Classification System III (LOCS III)[13,14] nuclear opalescence grading score was used. Preoperative nuclear opalescence was estimated by an independent physician using a slitlamp (BQ 900, Haag-Streit AG) at maximum illumination without light filtering.

The IOL power calculations were performed using noncontact partial coherence laser interferometry (IOLMaster, Carl Zeiss Meditec AG) and the SRK/T formula.[15] In eyes with higher hyperopia (AL range 21.5 to 22.0 mm), the Haigis formula was used.[16] The same formula was used for the power calculations in both eyes of the same patient.

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Table 1. Capsulotomy and lens-softening pattern.

Parameter	Value
Capsulotomy	
Incision depth (μm)	600
Pulse energy (μJ)	4.0
Expected pupil diameter (mm)	>6.0
Capsulotomy diameter (mm)	5.0
Lens fragmentation	
Segmentation soft spacing (μm)	350
Segments (quadrants)	4
Anterior capsule safety (μm)	500
Posterior capsule safety (μm)	500
Anterior pulse energy (μJ)	8.0
Posterior pulse energy (μJ)	10.0
Horizontal spot spacing (μm)	10
Vertical spot spacing (μm)	20

Scheimpflug imaging using the Pentacam HR (Oculus Optikgeräte GmbH) was used to evaluate the ACD.

Randomization and Surgical Technique

All patients included received the same preoperative standardized management before the procedure. After placing the patient on the laser system's operating bed, the surgeon opened the corresponding envelope providing the information about which procedure to use; that is, femtosecond laser–assisted cataract surgery or regular phacoemulsification. Thereafter, sterile draping took place.

Femtosecond Laser–Assisted Cataract Surgery When randomization indicated a femtosecond laser–assisted procedure, the patient's bed was unlocked and the position was turned toward the laser system (Catalys Precision Laser System, Abbott Medical Optics, Inc.). This was followed by engagement of the patient's eye with the Liquid Optics Interface as previously described.[2,3] The capsulotomy diameter was 5.0 mm, and a standardized lens-softening pattern with a quadrant cut and 350 μm grid was used (Table 1). After laser pretreatment, small-incision phacoemulsification was performed using topical anesthesia. The 2-step clear corneal main incision was placed at the steep meridian using a 2.75 mm metal keratome (angled slit knife 2.75, Alcon Surgical, Inc.). The single-plane side-port incisions were placed approximately 3 clock hours from the main incision and created with a 1.2 mm metal keratome (dual-bevel angled side-port knife, Alcon Surgical, Inc.).

Standard Phacoemulsification In cases of standard phacoemulsification, the position of the bed remained fixed and the surgeon started the procedure. All patients had small-incision phacoemulsification using topical anesthesia. The 2-step clear corneal main incision was placed at the steep meridian using the same type of 2.75 mm metal keratome as in the laser group. The single-plane side-port incisions were placed approximately 3 clock hours from the main incision and created with a 1.2 mm metal keratome (dual-bevel angled side-port knife). After instillation of sodium hyaluronate 1.0% (Healon) into the anterior chamber to protect the endothelium, a continuous curvilinear capsulorhexis (CCC)

Table 2. Surgical differences in study groups.

Parameter	Laser Group	Conventional Group
Anesthesia	Topical	Topical
Pre-incision	Laser capsulotomy and lens softening	NA
Incisions	2.75 mm CCI; 2.0 mm × 1.2 mm side port	2.75 mm CCI; 2.0 mm × 1.2 mm side port
OVD	Sodium hyaluronate 1.0%	Sodium hyaluronate 1.0%
Capsulotomy/capsulorhexis	Complete capsulotomy extracted	CCC
Phacoemulsification	US stop-and-chop technique with or without US energy (60% max phaco power; 100 cm bottle height, 600 mm Hg max vacuum)	US chop technique with or without US energy (60% max phaco power; 100 cm bottle height, 600 mm Hg max vacuum)
Irrigation/aspiration	Bimanual	Bimanual
Capsule polishing	Yes	Yes
IOL implantation	Reinflate AC and capsular bag with OVD; insert IOL	Reinflate AC and capsular bag with OVD; insert IOL
Incisions	Hydrated	Hydrated

AC = anterior chamber; CCC = continuous curvilinear capsulorhexis; CCI = clear corneal incision; IOL = intraocular lens; NA = not applicable; OVD = ophthalmic viscosurgical device; US = ultrasound

was performed using a self-bent 19-gauge needle through a side-port incision. The intended diameter was 5.0 mm.

Both Methods No limbal relaxing incisions were performed. Cataract surgery was performed using the Stellaris phacoemulsification machine (Bausch & Lomb) in both treatment groups. The standard microflow needle with an inner tip diameter of 0.91 mm decreasing to 0.51 mm and an angulation of 30 degrees at the opening was used. Table 2 shows the US phacoemulsification settings and vacuum settings. The technique of choice was to establish an initial cracking/separation of the nucleus with the help of a Neuhann chopper (Geuder AG). After the nucleus was separated into quadrants, further chopping, if necessary, was performed under continuous (phacoemulsification) aspiration (maximum vacuum 600 mm Hg).

In both groups, the remaining cortex was removed with bimanual irrigation/aspiration through the opposite incisions. The phacoemulsification and aspiration were followed by polishing of the posterior capsule. Without enlarging the corneal tunnel, a heparin-coated preloaded hydrophobic IOL (Polylens H10, Polytech Ophthalmologie GmbH) was injected into the capsular bag. After the ophthalmic viscosurgical device was carefully removed, all eyes were initially covered with a patch.

Standard topical ofloxacin and dexamethasone eyedrops were administered 4 times daily for the first 5 days. After 5 days, ofloxacin was discontinued and dexamethasone eyedrops were used with a dosage that was gradually tapered over 6 weeks.

Statistical Analysis

For statistical analysis, the logMAR values were converted to their equivalent decimal notation and vice versa, as described by Westheimer.[17] Statistical evaluations were performed using Datagraph-med 4.20 (Pieger GmbH and Moerschbacher) following the guidelines for reporting refractive surgical data. Further statistical analysis was performed using SPSS software (version 22.0, SPSS, Inc.). Results are presented as the mean ± SD (range). The *t* test was used to compare the sample means. A *P* value less than 0.05 was considered statistically significant.

RESULTS

The study comprised 200 eyes (100 right eyes) of 100 patients (56 women) with a postoperative follow-up of 6 months. The mean age of the patients was 71.6 years (range 49 to 86 years).

The mean preoperative AL was 23.55 ± 1.06 mm (range 21.83 to 27.05 mm) in the femtosecond laser–assisted group and 23.55 ± 1.07 mm (range 21.88 to 27.13 mm) in the conventional group. The mean nuclear density (LOCS III) was 3.2 in the femtosecond laser–assisted group and 3.2 in the conventional group; the difference was not statistically significant. The mean preoperative ACD measured by Scheimpflug imaging was 2.59 ± 0.40 mm (range 1.63 to 3.67 mm) in the femtosecond laser–assisted group and 2.57 ± 0.41 mm (range 1.52 to 3.60 mm) in the conventional group. The preoperative SE refraction was +0.57 ± 2.36 D (range −9.75 to +5.38 D) and +0.55 ± 2.35 D (range −10.25 to +5.50), respectively. The mean preoperative decimal CDVA was 0.44 ± 0.14 (20/40) (range 0.16 to 0.63) in the femtosecond laser–assisted group and 0.43 ± 0.13 (20/40) (range 0.16 to 0.63) in the conventional group.

Intraoperatively, the mean applied effective phacoemulsification time was 0.0 ± 0.1 seconds (range 0.0 to 0.48 seconds) in the femtosecond laser–assisted group and 1.3 ± 1.1 seconds (0.07 to 5.31 seconds) in the conventional group.

Table 3. Refractive data: sphere, cylinder and spherical equivalent (mean ± SD) in both study groups over time.

	Mean (D) ± SD					
	Sphere		Cylinder		Spherical Equivalent	
Postop Visit	Laser Group	Conventional Group	Laser Group	Conventional Group	Laser Group	Conventional Group
3–4 days	0.30 ± 0.43	0.48 ± 0.79	−0.83 ± 0.50	0.80 ± 0.57	0.03 ± 0.59	0.08 ± 0.74
1 week	0.21 ± 0.33	0.26 ± 0.63	-0.72 ± 0.52	−0.88 ± 0.55	−0.05 ± 0.48	−0.18 ± 0.54
1 month	0.20 ± 0.23	0.26 ± 0.63	−0.72 ± 0.52	−0.88 ± 0.55	−0.05 ± 0.28	−0.18 ± 0.54
2 months	0.18 ± 0.31	0.35 ± 0.69	−0.77 ± 0.54	−0.79 ± 0.55	−0.05 ± 0.35	−0.11 ± 0.62
3 months	0.19 ± 0.24	0.42 ± 0.63	−0.68 ± 0.51	−0.77 ± 0.54	−0.04 ± 0.25	−0.11 ± 0.55
6 months	0.18 ± 0.25	0.38 ± 0.65	−0.66 ± 0.53	−0.78 ± 0.56	−0.05 ± 0.28	−0.11 ± 0.55

In 98 of 100 eyes in the femtosecond laser–assisted group, the capsulotomy was centered and 360-degree capsulotomy optic overlap was achieved. In the conventional group, 360-degree capsulorhexis optic overlap was achieved in 95 of 100 eyes.

Table 3 shows the refractive data from all postoperative visits. Figure 1 and Figure 2 show the achieved SE of refraction as a function of time in the femtosecond laser–assisted group and the conventional group, respectively. The mean refraction is shown at each time point and plotted as the solid line with dotted lines as ±1 SD.

The change in SE in the femtosecond laser–assisted group was significant in comparison with the measurement at the last visit postoperatively up to 1 week. After then, the changes were not statistically different up to 6 months. In the conventional group, a statistically significant change in SE could be detected in comparison with the measurement at the last visit up to 1 month postoperatively. After that timepoint, the changes were not statistically different up to 6 months. The changes at the measured 7 timepoints were less in the femtosecond laser–assisted group than in the conventional group, although the differences were not statistically significant.

Figure 3 and Figure 4 show a scattergram of the attempted SE versus achieved change in SE 6 months after surgery in the femtosecond laser–assisted group and the conventional group, respectively. The solid line indicates the attempted SE equals the achieved SE, while the dotted line represents an SE ±1.00 D from the attempted refraction. Ninety eyes (92%) in the femtosecond laser–assisted group and 70 eyes (71%) in the conventional group were within ±0.50 D of the target refractive outcome and 98 eyes (100%) in both groups were within ±1.00 D (Figure 5).

Figure 6 and Figure 7 show the efficacy in the femtosecond laser–assisted group and the conventional group, respectively. There were significant improvements in the postoperative uncorrected distance visual

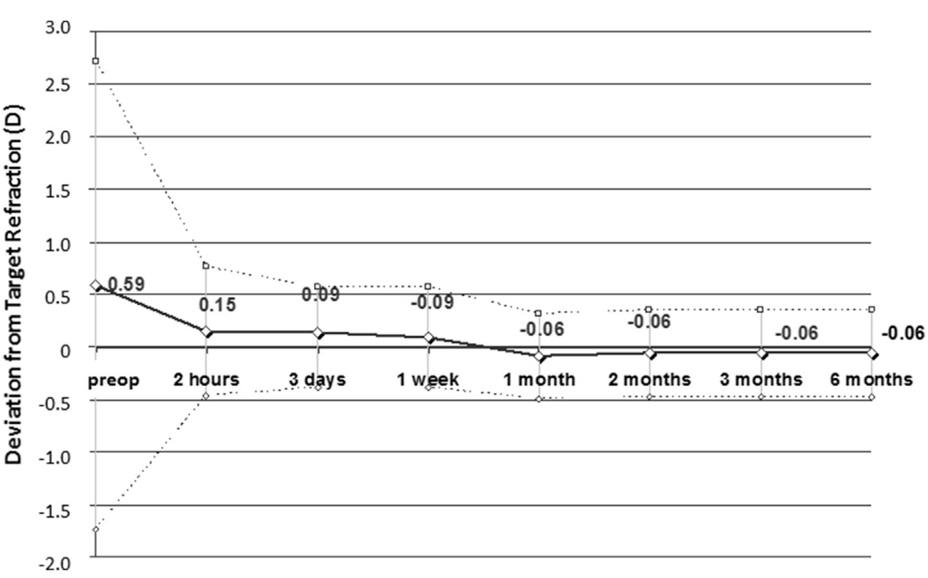

Figure 1. Changes in SE refraction in the femtosecond laser–assisted group over time.

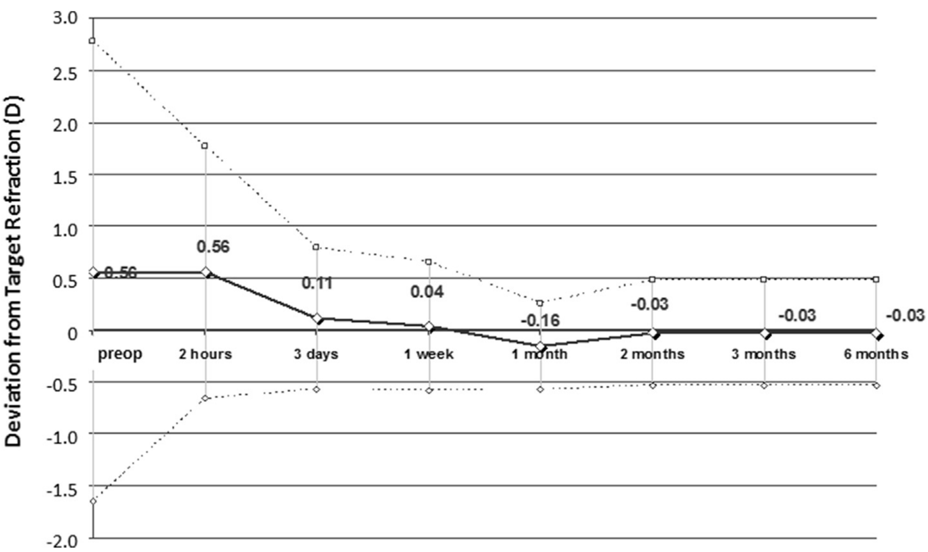

Figure 2. Changes in SE refraction in the conventional group over time.

acuity (UDVA). The mean UDVA improved faster in the femtosecond laser–assisted group than in the conventional group. There was a statistically significant between-group difference 2 hours, 3 days, and 1 week postoperatively ($P < .05$). Beginning from 1 month on, no statistically significant differences were detected. Figure 8 and Figure 9 show the increase of UDVA over in the femtosecond laser–assisted group and the conventional group, respectively.

The postoperative safety results at 6 months showed the gain in lines of UDVA was statistically significant in all eyes (Figure 10).

The mean ACD value in the conventional group changed from 3.87 ± 0.38 mm at the 3-day postoperative visit to 3.86 ± 0.34 mm at 1 week, 3.85 ± 0.36 mm at 1 month, 3.82 ± 0.32 mm at 2 months, 3.82 ± 0.33 mm at 3 months, and 3.81 ± 0.34 mm at 6 months. The mean ACD value in the femtosecond laser–assisted group changed from 3.88 ± 0.57 mm at the 3-day postoperative visit to 3.85 ± 0.34 mm at 1 week, 3.84 ± 0.36 mm at 1 month, 3.83 ± 0.33 mm 2 months, 3.82 ± 0.33 mm at 3 months, and 3.83 ± 0.32 mm at 6 months.

Between the study groups, there was a significant but not clinically relevant difference in ACD at the 1-week postoperative visit ($P = .042$). There were no significant differences in the other measurements between groups.

Complications

In 1 eye in the femtosecond laser–assisted group, an anterior tear of the capsulotomy occurred without further complications and a 360-degree optic overlap occurred thereafter. This eye was not excluded. All other cataract surgeries and femtosecond laser

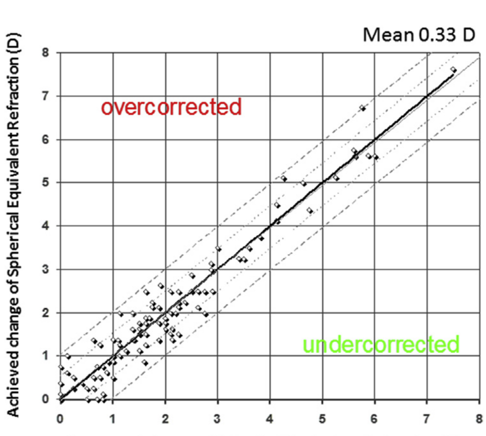

Figure 3. Change in attempted SE versus SE achieved in the femtosecond laser–assistedgroup.

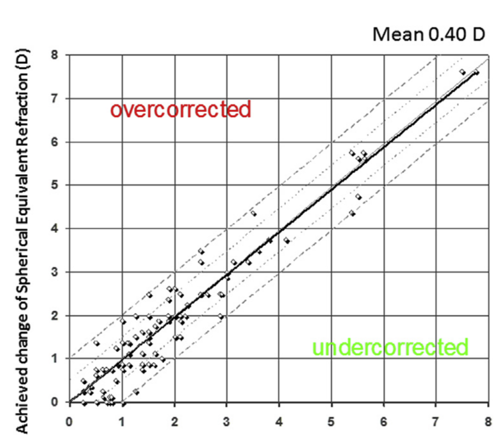

Figure 4. Change in attempted SE versus achieved SE in the conventional group.

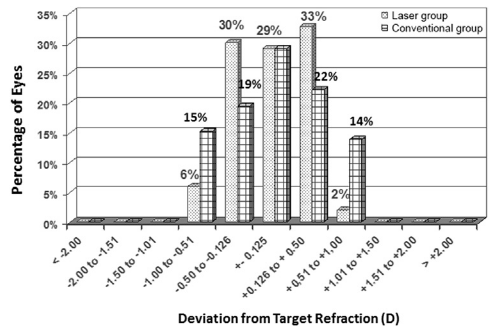

Figure 5. Accuracy of SE refraction in the femtosecond laser–assisted group and the conventional group 6 months postoperatively.

applications were uneventful. Postoperatively, 3 eyes (1 in femtosecond laser–assisted group; 2 in conventional group) developed clinically significant macular edema with a reduction in CDVA (20/63 to 20/32). One eye in the conventional group developed subclinical macular edema 1 month after surgery. After therapy, the CDVA increased to 20/20 in all cases. Elevated intraocular pressure (IOP) measured 2 hours postoperatively occurred in 5 eyes (conventional group: 24 and 35 mm Hg; femtosecond laser–assisted group: 25 mm Hg, 30 mm Hg, 33 mm Hg). The increase was treated using local eyedrops. After 1 week, no further IOP-reducing medications were necessary. No vitreous loss, fibrin reaction, or endophthalmitis occurred.

DISCUSSION

We assessed the results of femtosecond laser-assisted capsulotomy and lens fragmentation in eyes with senile cataract and analyzed the refractive stability over time and the deviation from the target refraction. Comparisons between the femtosecond laser–assisted group and the conventional phacoemulsification were performed intraindividually; that is, 1 eye was treated with the femtosecond laser and the contralateral eye was operated on manually using a standard technique. Furthermore, we measured the ACD after bilateral implantation of the same IOL model.

In our study, there was a small beneficial effect from the femtosecond laser–assisted capsulotomy and lens fragmentation technique compared with the manual capsulorhexis method. Femtosecond laser–assisted cataract surgery was a safe and precise procedure but enhanced visual outcomes only minimally. Manually performed cataract removal in standard cases in the hands of an experienced surgeon provided a similar level of refractive results after 6 months. Femtosecond laser pretreatment without corneal incisions is basically not a different method from the manual technique; however, the capsulotomy is more precise. There was an advantage in favor of the laser in the early postoperative visual recovery period (until 1 week) over conventional surgery. Furthermore, the refractive result stabilized earlier in the femtosecond laser–assisted group. There was a significant but clinically irrelevant tendency toward a lower deviation from the target refraction in the femtosecond laser–assisted group ($P < .05$). Ninety-two percent in that group and 70% in the conventional group were within ± 0.50 D of the target refraction.

Furthermore, in a study by Alió et al.,[18] femtosecond laser technology achieved a stable corneal wound structure of the incision and did not significantly change the higher-order aberrations. Okada et al.[19] reported that postoperative refraction

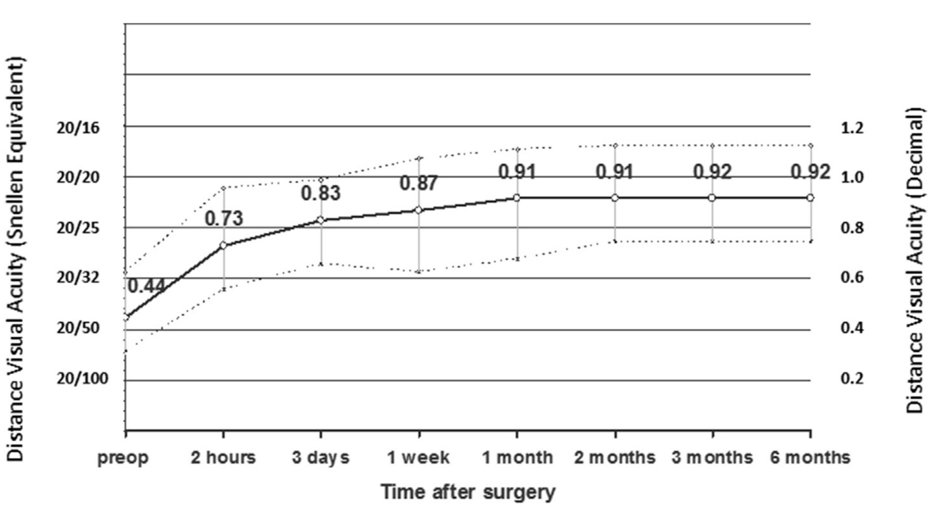

Figure 6. Changes in CDVA in the femtosecond laser–assisted group over time.

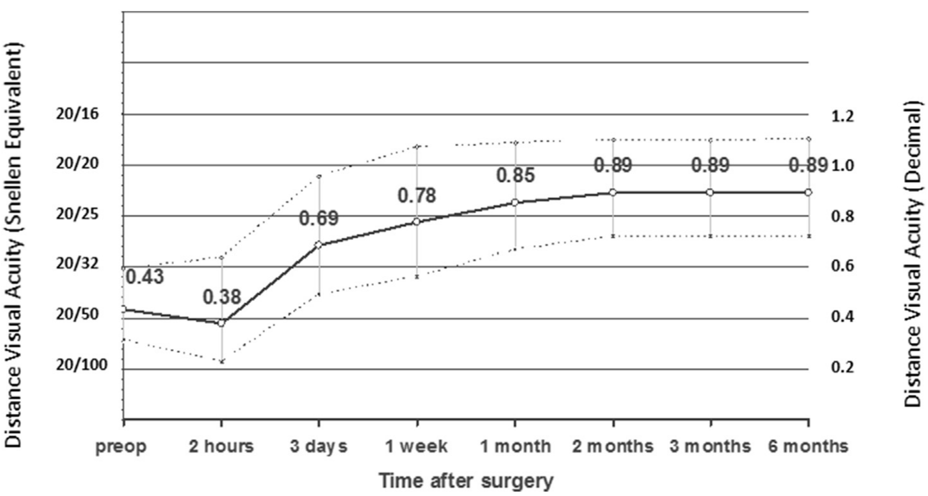

Figure 7. Changes in CDVA in the conventional group over time.

at 1 year was not related to centration or circularity of the capsulorhexis but rather that the decentration was associated with changes in the SE (0.4 mm with a 0.25 D change). In addition, incomplete capsulorhexis–optic overlap was associated with a 0.50 D change in spectacle cylinder from the 1-month to the 1-year follow-up.

Lawless et al.[11] found no significant difference in a retrospective consecutive cohort study of 61 eyes that had femtosecond laser–assisted cataract surgery and 29 eyes that had manual phacoemulsification. In a comparison of 48 eyes operated on with femtosecond laser technology and 51 eyes operated on manually, Mihaltz et al.[12] observed no statistically significant differences in sphere or cylinder. Furthermore, they noted no difference between UDVA and CDVA between the 2 groups. In other studies by this group,[9,10] the femtosecond laser capsulotomy was more precise in size and centration.

Further studies[1,10] indicate that femtosecond laser–assisted cataract surgery with a computed capsulotomy is different from standard CCC and US phacoemulsification, with less US energy used and less corneal edema in the early postoperative period. This might explain the slightly earlier visual recovery in the femtosecond laser–assisted cataract surgery group. Results in a previous trial with an intraindividual comparison of 53 patients[20] showed less capsular bag shrinkage at all timepoints (from 7 days to 3 months) in the femtosecond laser–assisted group than in the conventional group.

Furthermore, our study showed earlier stabilization of the ACD (no significant change after 1 week) in the femtosecond laser–assisted group, which might have

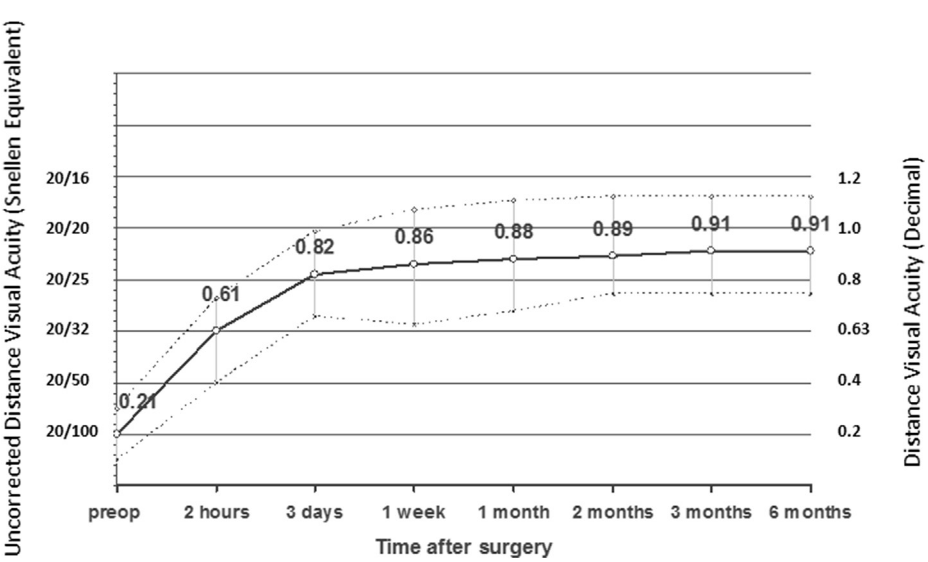

Figure 8. Changes in UDVA in the femtosecond laser–assisted group over time.

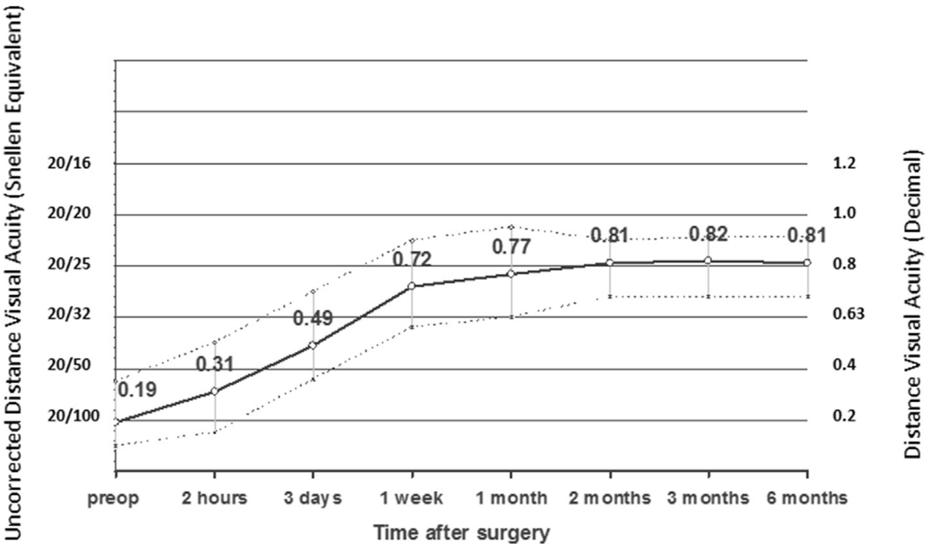

Figure 9. Changes in UDVA in the conventional group over time.

an effect on the UDVA. Anterior chamber inflammation measured as laser flare showed significantly lower values in the femtosecond laser–assisted group than in the conventional group in an intraindividual comparison until the third day.[21] This might affect UDVA as well as CDVA. All these aspects can lead to slightly faster postoperative visual recovery after femtosecond laser–assisted capsulotomy and lens fragmentation than after conventional cataract surgery.

The purpose of our intraindividual study was to determine the influence of capsulotomy and lens fragmentation performed during femtosecond laser–assisted cataract surgery and compare the results with those of conventional cataract surgery without the aspect of corneal or limbal relaxing incisions. Further studies might evaluate the effect of placing corneal incisions with femtosecond lasers based on optical coherence tomography guidance and compare the results with those of manual incisions.

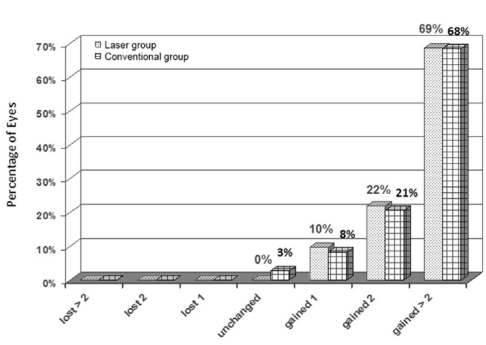

Figure 10. Preoperative versus 6-month postoperative CDVA by group.

WHAT WAS KNOWN

- Femtosecond laser–assisted cataract surgery has shown advantages related to capsulotomy and IOL centration in uneventful cataract surgery.

WHAT THIS PAPER ADDS

- Using femtosecond laser in cataract surgery resulted in faster visual recovery, earlier stabilization of the ACD, less deviation from the target refraction, and an earlier stabilization of refraction.

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