LenSx® Laser

Clinical Science Compendium

Summary of peer-reviewed clinical research

Medical Affairs North America

Alcon

INTRODUCTION

At Alcon, our surgical medical device products, such as the LenSx® Laser platform for cataract surgery, are designed, manufactured and marketed with a body of science developed through rigorous bench research and clinical studies. As the body of knowledge behind Alcon's products grows, so does the challenge of making our customers aware of its depth. Our medical affairs organization is thus focused on both high-quality data generation and its communication to the clinical community.

High-quality scientific publications are essential to convey the clinical community's knowledge and experience with new technology. This clinical science compendium provides a consolidated view of peer-reviewed publications for LenSx®, a market-leading femtosecond laser system indicated for use in cataract surgery, including anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea.

In addition to exploring this compendium, we encourage you to visit Alcon's Medical Affairs website—AlconScience.com—to learn more about how medical science matters to us. Beyond scientific publications relating to Alcon's portfolio, you will find more information on independent medical educational grants, teaching facility equipment placement, and areas of interest for investigator-initiated trials.

METHODOLOGY

The 79 articles summarized in this compendium were identified using the PubMed and Google Scholar databases incorporating the search terms "LenSx", "femtosecond laser-assisted Lasik", and femtosecond laser-assisted cataract surgery." Articles were included when they were published between January 1, 2009 and May 30, 2020, and contained research involving LenSx® for its indicated uses, including in patients undergoing cataract surgery for removal of the crystalline lens. Only manuscripts published in peer-reviewed journals and available in English were included in this compendium.

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Scanning Electron Microscopy Evaluation of Capsulorhexis in Femtosecond Laser-Assisted Cataract Surgery

Mastropasqua et al. *J Cataract Refract Surg.* 2013;39:1581-1586

OVERVIEW

STUDY DESIGN
Prospective nonrandomized single blinded study to evaluate capsulorhexis-cut quality obtained during femtosecond laser-assisted cataract surgery (FLACS) at different energy settings and a standard manual technique

STUDY SITE(S)
Single center in Italy

PATIENTS
Sixty (60) capsulorhexes of 60 patients

SURGICAL METHODOLOGY
Capsulorhexes obtained using conventional manual technique and FLACS with different laser energy settings; Group 1 (12 capsulorhexes, manual technique) and Groups 2 to 5 (each with 12 capsulorhexes, femtosecond laser at 7.0 µJ, 13.5 µJ, 14.0 µJ, and 15.0 µJ, respectively)

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.); LENSAR® Laser System (LENSAR, Inc.)

KEY ENDPOINT(S)
All samples were evaluated using scanning electron microscopy (SEM) to compare the thickness along the capsulorhexis edge and the overall irregularity of the cut surface

ANALYSIS AND CONCLUSIONS

Femtosecond laser-assisted cataract surgery resulted in better capsulorhexis geometry and circularity than the manual capsulorhexis; the cut surface was smoother in the manual group, while the degree of irregularity was higher at increasing energy settings in the femtosecond laser groups.

The authors suggest that these promising results should encourage future studies to obtain the optimized spot size and pulse-laser energy settings that maintain the advantages of the manual technique while adding the advantages of the femtosecond laser.

STUDY RESULTS

CAPSULORHEXIS GEOMETRY AND CUT-SURFACE QUALITY

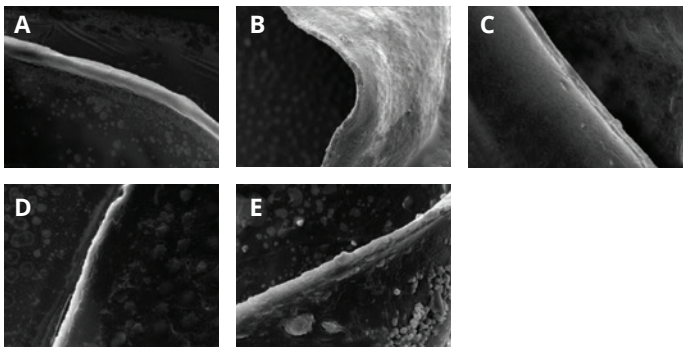
- Capsulorhexes obtained with the femtosecond laser at all energy settings were perfectly circular with negligible deformation
- Groups 2 and 5 showed a gradual increase in irregularity with increasing energy laser settings and comparable thickness homogeneity values; in particular, samples in Group 2 and Group 3 (7.0 µJ and 13.5 µJ, respectively) had mild superficial irregularities, Group 4 (14.0 µJ) had a higher degree of surface irregularity, and Group 5 (15.0 µJ) had the highest level of roughness and irregularity
- Capsulorhexes performed by manual technique (Group 1) had a significantly higher thickness at the capsulorhexis edge than those performed with the femtosecond laser at 13.5 µJ, 14.0 µJ, and 15.0 µJ (P<0.001) (**Table 1**)
  - Conversely, obtained with the femtosecond laser at 7.0 µJ (Group 2) had a significantly lower thickness than the other 3 laser cut groups (P<0.001)
- There was also a statistically significant correlation between the degree of irregularity and increasing energy (P<0.001) (**Table 1, Figure 1**)

Table 1. Results from the anterior capsule samples obtained from the 5 groups of cataracts surgery (Robust Tests of Equality of Means Table).

	Mean± SD	
Group	Thickness (mm)	Cut Surface Irregularity*
1 (manual)	8.35±0.93†	0.0±0.0
2 (laser, 7.0 µJ)	2.59±0.84‡	0.3±0.4
3 (laser, 13.5 µJ)	4.51±0.58§	0.7±0.8
4 (laser, 14.0 µJ)	4.60±0.51§	0.9±0.4
5 (laser, 15.0 µJ)	4.42±0.36§	1.1±0.6

**Spearman rank correlation coefficient (P<0.001); †Versus Groups 2, 3, 4, and 5 (P<0.001); ‡Versus Groups 1, 3, 4, and 5 (P<0.001); §Versus Groups 1 and 2 (P<0.001).*

Figure 2. Capsulorhexes obtained after manual technique cataract surgery and femtosecond laser–assisted cataract surgery. The SEM images (x1000) had the smoothest cut surface for the manual technique (**A**) and increasing roughness and irregularity at higher femtosecond laser energy from 7.0 µJ (**B**) to 13.5 µJ (**C**), 14.0 µJ (**D**), and 15.0 µJ (**E**).



Light Microscopy and Scanning Electron Microscopy Analysis of Rigid Curved Interface Femtosecond Laser-Assisted and Manual Anterior Capsulotomy

Ostovic et al. *J Cataract Refract Surg*. 2013;39:1587-1592*

OVERVIEW

STUDY DESIGN
Experimental study to assess the microanatomic edge structures of anterior lens capsule specimens derived from manual and femtosecond laser-assisted capsulotomies

STUDY SITE(S)
Single center in Germany

PATIENTS
Sixty (60) eyes with lens removal and intraocular lens (IOL) implantation; 30 received a manual capsulotomy, 30 received a femtosecond laser-assisted capsulotomy

SURGICAL METHODOLOGY
Femtosecond laser-assisted capsulotomy (rigid curved interface, pulse energy 15 µJ) and manual anterior capsulotomy

SURGICAL TECHNOLOGY
LenSx®
Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Cell configuration, capsule shape, and abnormalities assessed by light microscopy (LM) and scanning electron microscopy (SEM)

ANALYSIS AND CONCLUSIONS

Femtosecond laser-assisted capsulotomies with LenSx® (rigid, curved interface and 15 µJ pulse energy) showed tags, bridges, and demarcation lines along the cut and rough edges with valley- and mountain-like structures on SEM.

Further studies of the relationship between pulse energy, patient interface design, and capsule burst strength will help elucidate the optimum parameters for laser capsulotomy creation.

*This study was financially supported by Alcon.

STUDY RESULTS

SURGICAL OUTCOMES WITH MANUAL CAPSULOTOMIES

- After manual capsulotomies, LM showed intact cell nuclei and plasma; cells had intact cellular borders and were arranged directly at the edge of the cut
- No demarcation line was observed; the only tears found at the edge were those acquired using the continuous curvilinear capsulotomy method
- SEM analysis showed constant configuration of the manual capsulotomy edge at all magnifications; with magnifications of ×3000 and higher, the individual fibers of the capsule could be identified **(Figure 1)**
- No tags, bridges, or tears were seen in manual capsulotomies

SURGICAL OUTCOMES WITH FEMTOSECOND LASER-ASSISTED CAPSULOTOMIES

- After LenSx®, all 30 capsules showed a demarcation line along the cutting edge at LM magnifications higher than ×20; along the inner part of the line, in the direction of the capsule center, the cell configuration showed irregularities
- The cell nuclei and the cell plasma were partly destroyed and spread along the demarcation line
- Capsulotomies showed multiple tags, bridges, and stray impressions, even at some distance from the cutting edge; the tags had variable distances
- Individual laser spots and grooves could be identified with SEM at x100 magnification, and frayed tissue were visible with valley- and mountain-like structures at x10,000 magnification
- With increasing magnification, the edges of the capsulotomies showed a sawtooth pattern with individual grooves on the cut edge **(Figure 2)**; tags were still clearly visible

Figure 1. Visible anterior capsule fibers (continuous curvilinear capsulotomy; SEM x10,000 magnification).

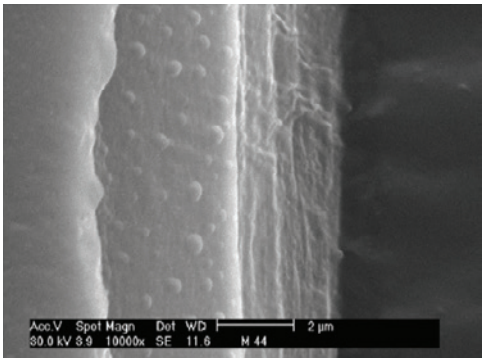
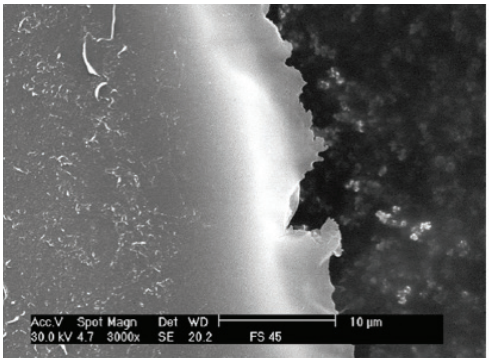


Figure 2. Sawtooth pattern along the demarcation line (LenSx®, SEM x3000 magnification).



Anterior Capsulotomy Integrity After Femtosecond Laser-Assisted Cataract Surgery

Surgical Outcomes

Surgical Complications

Abell et al. *Ophthalmology.* 2014;121:17-24

OVERVIEW

STUDY DESIGN

Prospective, multicenter, cohort study to compare the incidence of anterior capsular tears after femtosecond laser-assisted cataract surgery (FLACS) vs phacoemulsification cataract surgery (PCS) and to assess the ultrastructural features of anterior capsulotomy specimens using scanning electron microscopy (SEM).

STUDY SITE(S)

Four (4) centers in Australia

PATIENTS

All patients (N= 1626, 1626 eyes) >18 yrs of age undergoing FLACS or PCS with insertion of a posterior chamber intraocular lens (IOL); age was 71.0 years for the FLACS group and 71.9 for the PCS group.

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser (Alcon Laboratories, Inc), CATALYS® Precision Laser System (Johnson & Johnson Vision), LENSAR® Laser System (LENSAR, Inc.); CONSTELLATION® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Incidence of anterior capsule tear and comparative ultrastructural features of capsular samples from both PCS and FLACS cases

ANALYSIS AND CONCLUSIONS

Edge structure and integrity was compromised using all three FLACS systems (CATALYS®, LenSx®, and LENSAR®) raising safety concerns for capsular integrity after FLACS.

Laser anterior capsulotomy integrity seems to be compromised by postage-stamp perforations and additional aberrant pulses leading to an increased rate of anterior capsule tears.

STUDY RESULTS

ANTERIOR CAPSULE TEARS

- The incidence of anterior capsule tears in the FLACS group (n = 15/804) was significantly higher than that in the PCS group (n = 1/822) (1.87% vs. 0.12%; P = 0.0002)
  - All FLACS cases occurred with complete capsulotomy
  - In 7 cases, the anterior capsule tear extended to the posterior capsule
  - None of the patients with an anterior capsule tear were determined to have risk factors for capsular complications

HISTOPATHOLOGY (SEM SAMPLING)

- All laser platforms had FLACS samples with apparently misplaced laser perforations in normal parts of the tissue (**Figure 1**)
  - Aberrant pits were approximately 2 to 4 µm apart and occurred at a range of 10 to 100 µm radially from the capsule edge
- Postage-stamp perforations were present in every FLACS sample (**Figure 2A,B**), but not in the PCE samples (**Figure 2C**)
- Three laser samples, one from each laser platform (CATALYS®, LenSx®, and LENSAR®), were found to have an anterior capsulotomy tag (**Figure 3**)
  - These findings may be consistent with eye movement during laser capsulotomy

Figure 1. A, CATALYS® femtosecond laser capsulotomy with multiple rows of misplaced laser pulses (white arrow) on the posterior surface of the anterior capsule extending from the capsule edge (black arrows), which in this picture is folded back on itself to reveal the underside of the capsule (original magnification, x900). **B**, LENSAR® laser capsulotomy with a row of misplaced laser pits approximately 35 mm from the capsule edge (original magnification, x600). **C**, CATALYS® femtosecond capsule edge that appears to have been cut in 2 distinct planes, perhaps created during subsequent passes of the laser capsulotomy, but each pass is slightly misaligned (original magnification, x10 000).

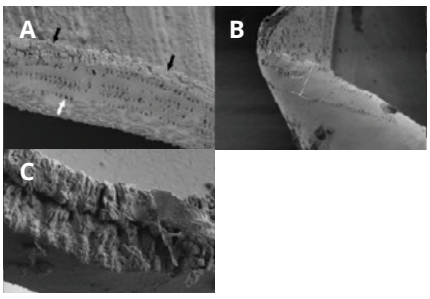


Figure 2. A, Jagged and undulating edge of the LenSx® femtosecond laser capsulotomy (original magnification, x1100). **B**, LENSAR® femtosecond capsulotomy showing the jagged edge at closer magnification that consists of small focal tags (circled). Outward tags would correspond to a notch in the anterior capsule in vivo (original magnification, x1400). **C**, Manual capsulorrhexis showing a smooth and consistent edge (black arrows), which is at the same magnification as **A** (Original magnification, x1100).

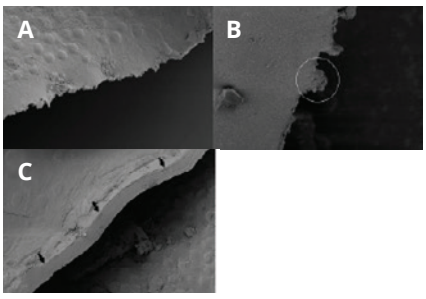
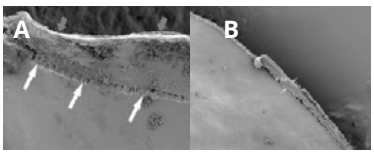


Figure 3. A, Anterior capsule tag (white arrows) extending obliquely from the capsule edge (grey arrows) from the LenSx® laser (original magnification, x1500). **B**, Anterior capsule tag (white arrows) some distance from the capsule edge from the CATALYS® laser (original magnification, x300).



Electron Microscopy of Laser Capsulotomy Edge: Interplatform Comparison

Surgical Outcomes

Surgical Complications

Bala et al. *J Cataract Refract Surg.* 2014;40:1382-1389

OVERVIEW

STUDY DESIGN

Experimental study to compare morphology of capsulotomy edges generated by commercially available femtosecond lasers with manual capsulorhexis

STUDY SITE(S)

Single center in Australia

PATIENTS

Fifty-four (54) capsules from 49 patients with a mean age of 68 years

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® pre-SoftFit™ and post-SoftFit™ (Alcon Laboratories, Inc.), VICTUS I®, VICTUS II® (Bausch + Lomb), and CATALYS® Precision Laser System (Johnson & Johnson Vision)

KEY ENDPOINT(S)

Scanning electron microscopy (SEM) images were used to assess the coefficient of variation (CoV) of pixilation along the capsule edge, homogeneity, and anomalies, such as tags

ANALYSIS AND CONCLUSIONS

In this study, laser capsulotomies appraoched the smoothness of the manual capsulorhexis.

The LenSx® post-SoftFit™ platform showed the least anomalies and the smallest difference for the CoV and homogeneity metrics compared with the manual method.

*This study was financially supported by Alcon.

STUDY RESULTS

- The mean CoV values showed the manual edge (101.6%±0.6% [standard deviation]) was smoother than the edges created with LenSx® pre-SoftFit™ (105.2%±1.2%) (P<0.001), LenSx® post-SoftFit™ (102.7%±1.4%) (P=0.04), VICTUS I® (104.9%±0.9%) (P<0.001), CATALYS® (104.5%±1.6%) (P<0.001), and VICTUS II® (104.7%±1.6%) platforms (**Figure 1, Figure 2A**)
- Tags occurred with LenSx® pre-SoftFit™ (5/10), LenSx® post-SoftFit™ (1/10), VICTUS I® (1/4), and VICTUS II® (3/10) platforms
  - Misdirected pulses were seen with the CATALYS® (4/10) and VICTUS II® (4/10) platforms
  - All lasers (0.19 to 0.23) (P<0.001) except the LenSx® post-SoftFit™ (0.25±0.03) (P=0.23) generated less homogenous capsulotomies than the manual technique (0.27±0.04) (**Figure 2B**)

Figure 1. Examples of capsulotomies generated by the laser platforms. A: Manual. B: LenSx® pre-SoftFit™. C: LenSx® post-SoftFit™. D: CATALYS®. E: VICTUS I®. F: VICTUS II®.

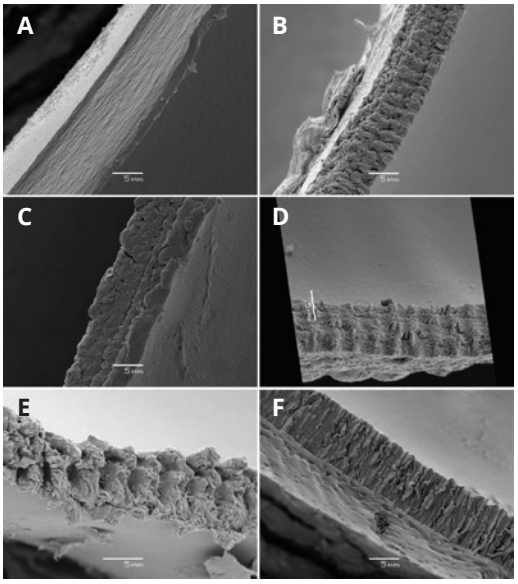
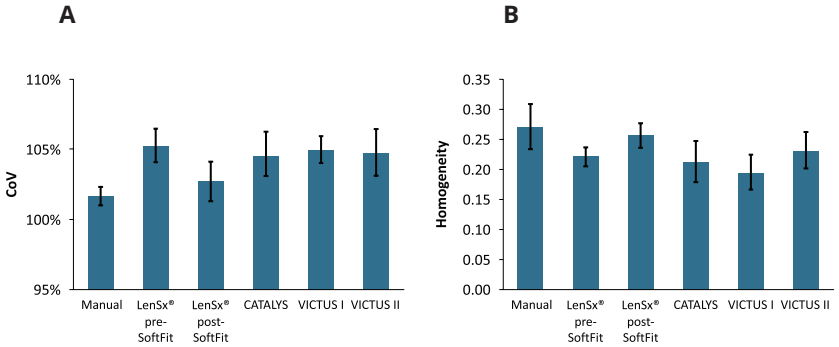


Figure 2. **A**) Mean CoV of the pixel value along the capsule edge generated by different techniques and laser platforms. Error bars represent the standard deviation (CoV Z coefficient of variation). **B**) Mean homogeneity (gray-level co-occurrence matrix measure) of the pixel value along the capsule edge generated by different techniques and laser platforms. Error bars represent standard deviation.



Morphological Changes in the Edge Structures Following Femtosecond Laser Capsulotomy with Varied Patient Interfaces and Different Energy Settings

Kohnen et al. *Graefes Arch Clin Exp Ophthalmol.* 2014;252:293-298

OVERVIEW

STUDY DESIGN
Experimental clinical study to ascertain the morphological changes in the edge structure of femtosecond laser-derived capsulotomy specimens using varying patient interfaces and different laser pulse energies

STUDY SITE(S)
Germany (sites not specified)

PATIENTS
Thirty (30) eyes

SURGICAL METHODOLOGY
Femtosecond laser-derived capsulotomy; surgery performed using either a rigid curved contact interface (Group 1, 15 eyes) or a curved interface with a soft contact lens between cornea and interface (Group 2, 15 eyes)

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.); laser pulse energy set to 15 µJ in Group 1 and to 5 µJ in Group 2

KEY ENDPOINT(S)
Cell configuration, capsule shape, and edge abnormalities analyzed on a morphological basis

ANALYSIS AND CONCLUSIONS

A soft contact lens interface with a laser pulse energy of 5 µJ resulted in fewer tags and bridges, smoother edges, and a more regular and thinner demarcation line on specimens edges of femtosecond laser-performed capsulotomies compared to a rigid curved 15 µJ interface application.

The authors noted that femtosecond laser technology seems to be a promising and safe procedure in refractive and cataract lens surgery; nevertheless, some side-effects from the laser beams on human tissue have to be considered when recommending this procedure.

STUDY RESULTS

GROUP 1: LASER PULSE ENERGY SET TO 15 µJ

- With light microscopy (LM) analysis, irregularities of the cell's configuration with partly destroyed nuclei were observed in the peripheral part of the anterior capsule
- The demarcation line seen in this group had a width of between 30 and 80 µm, with some foothills up to 200 µm **(Figure 1)**
- Capsulotomies showed multiple tags, bridges, and stray impressions, even at some distance away from the cutting edge; tags had variable distances, and sawtooth patterns and microgrooves could be seen with increasing magnifications
- With scanning electron microscopy (SEM) analysis, edges with a sawtooth pattern and microgrooves were observed, but individual capsule fibers could not be identified
- At 10,000x magnification, frayed tissue was clearly visible; a "valleys and mountains" configuration could be seen, and tags were clearly visible on multiple spots along the cut

GROUP 2: LASER PULSE ENERGY SET TO 5 µJ

- With LM analysis in Group 2, the demarcation line seen in Group 1 was also observed, but in smaller dimensions without outliers (<40 µm) **(Figure 2)**
- With SEM analysis, specimens showed slightly different findings than in Group 1; the edges still had irregularities and tags, but these were distinctly lower than those created by the higher laser pulse energy settings in Group 1
- After increasing the magnification scale, edges were subjectively smoother and individual fibers were visible
- When using a magnification of 10,000x, differences between the "highest and lowest" points in the valleys and mountains were not as large as those seen in Group 1, and the sawtooth pattern wasn't as distinct

Figure 1. Demarcation line along the cutting edge of the femtosecond laser acquired capsulotomies using 15 µJ with partially high dimensions. Light microscopy, 10x **(A)** and 20x **(B)** magnification, Masson Goldner trichrome staining.

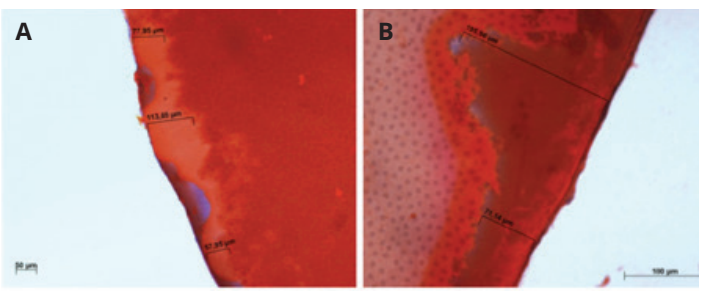
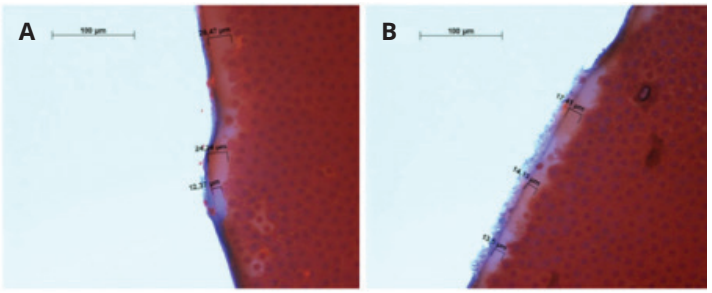


Figure 2. Demarcation line with smaller expansions along the cutting edge of the femtosecond laser acquired capsulotomies using 5 µJ. Light microscopy, 20x magnification **(A, B)**, Masson Goldner trichrome staining.



Cell Death and Ultrastructural Morphology of Femtosecond Laser–Assisted Anterior Capsulotomy

Mayer et al. *Invest Ophthalmol Vis Sci.* 2014;55:893-898

OVERVIEW

STUDY DESIGN
Experimental study to evaluate cell death and ultrastructural effects on capsulotomy specimens derived from femtosecond laser-assisted cataract surgery (FLACS)

STUDY SITE(S)
Single center in Germany

PATIENTS
Twenty-six (26) eyes in 26 patients assigned to an anterior capsulotomy using a femtosecond laser with pulse energy set to 15 µJ (10 eyes, group 1), 5 µJ (10 eyes, group 2), or manual anterior capsulorhexis (6 eyes, group 3)

SURGICAL METHODOLOGY
Femtosecond laser capsulotomy (15 µJ pulse energy using a rigid curved interface, 5 µJ pulse energy using a curved interface combined with a soft contact lens), and manual capsulorhexis (6 eyes, group 3)

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
Cell death analysis using the TUNEL kit, ultrastructural analyses using atomic force microscopy (AFM), and scanning electron microscopy (SEM)

ANALYSIS AND CONCLUSIONS

This study found that cutting edges of LenSx® performed capsulotomies are precise and laser spot lesions are within planned size.

Cell death reaction depends on the laser pulse energy settings and can be reduced to the level observed in a manual capsulorhexis.

*This study was financially supported by Alcon.

STUDY RESULTS

CELL DEATH

- Cell death was found in all capsule specimens along the cutting edge but was significantly more pronounced following FLACS with 15 µJ pulse energy (P<0.01 for Group 1 vs Group 2) (**Figure 1**)
  - Cell death was comparable between LenSx® with 5 µJ pulse energy and manual techniques
- In the manual group there was a regular distribution of lens epithelial cells and no cell demarcation area (**Figure 2A**).
- In the LenSx® groups, there were irregularities of the cell configuration with partly destroyed nuclei observer in the peripheral part along a demarcation line of the anterior capsule (**Figure 2B and 2C**)

ATOMIC FORCE MICROSCOPY AND SCANNING ELECTRON MICROSCOPY

- Cutting edges revealed a regular 2-step "valley and mountain" like structure along the cutting edge in the 2 laser cut groups (**Figure 3**)
  - In higher magnifications, cutting edges were smoother and more roundly shaped in group with 5 µJ pulse energy 2 compared to 15 µJ pulse energy
- Mean spot size diameters of 3.1±0.4 µm (horizontal distance, group 1) and 2.9±0.3 µm (horizontal distance, group 2) in accordance with a planned 3 µm laser separation (Not shown)
- Cutting edges revealed a regular 2-step "valet and mountain" like structure along the cutting edge in the 2 laser cut groups
  - Mean spot size diameters of 3.1±0.4 µm (horizontal distance, group 1) and 2.9±0.3 µm (horizontal distance, group 2) in accordance with a planned 3 µm laser separation

Figure 1. Quantification of TUNEL-positive cells in anterior capsulotomy specimens along the cutting edge.

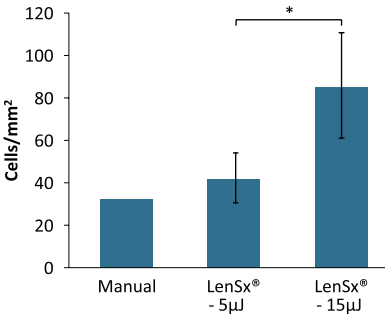


Figure 2. Morphological aspects of the cutting edge in manually performed capsulorhexis (**A**) compared with LenSx® capsulotomies (15 µJ [**B**], 5 µJ [**C**]) with irregularities of the cell configuration and partly destroyed nuclei in the peripheral part along the demarcation line (hematoxylin-eosin staining; magnification, X100)

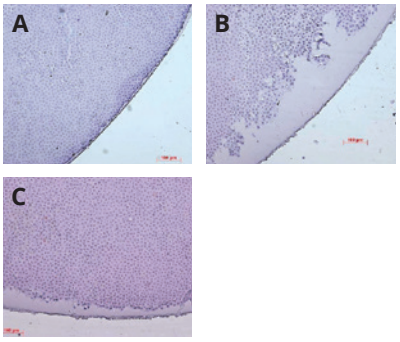
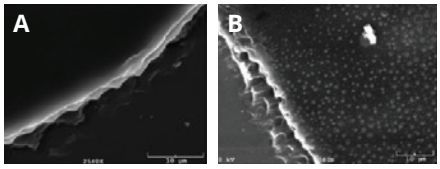


Figure 3. Scanning electron microscopy of cutting edges in LenSx® capsulotomies with a smoother cutting line using 5 µJ (**A**) compared with 15 µJ (**B**) (magnification, x2540 [A] and x1700 [B]) magnification, X100)



Analysis of Femtosecond Laser Assisted Capsulotomy Cutting Edges and Manual Capsulorhexis Using Environmental Scanning Electron Microscopy

Serrao et al. *J Ophthalmol.* 2014;2014:520713

OVERVIEW

STUDY DESIGN

Study to investigate the structure and irregularity of the capsulotomy cutting edges created by two femtosecond laser platforms in comparison with manual continuous circular capsulorhexis using environmental scanning electron microscopy (eSEM)

STUDY SITE(S)

Italy; number of centers not specified

PATIENTS

Fifteen (15) consecutive patients (mean age 65±5 years); 5 patients in the LenSx® group, 5 patients in the VICTUS® group, 5 patients in the manual group

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and manual continuous circular capsulorhexis (CCC)

SURGICAL TECHNOLOGY

LenSx® Laser (Alcon Laboratories, Inc.), VICTUS® Femtosecond Laser Platform (Bausch & Lomb)

KEY ENDPOINT(S)

Objective metrics, including arithmetic mean deviation of the surface (Sa) and the root-mean-square deviation of the surface (Sq), used to evaluate irregularity of femtosecond laser capsulotomies and manual CCC cutting edges

ANALYSIS AND CONCLUSIONS

The capsulotomy edges obtained with the LenSx® and VICTUS® femtosecond lasers showed distinct irregularities, independent of the laser platform, that may be at risk of increased capsular tears during phacoemulsification.

During the learning curve, cataract surgeons should be conservative when pulling the capsule during hydrodissection and nucleus manipulations; implementation of a robust eye tracking system would greatly improve the smoothness of capsulotomy edges.

STUDY RESULTS

SURGICAL OUTCOMES

- The LenSx® capsulotomy cutting edges showed a postage stamp like pattern, with several bumps and notches of variable width, ranging between 3 and 10 µm, that were spread across the edge; linear cracks (length ranging between 4 and 9 µm; width <3 µm) were also seen across the edges, but no stacks of collagen fibers were observed, likely related to a high thermal effect excerpted on the collagen fibers **(Figure 1)**
- The VICTUS® capsulotomy cutting edges showed micro-can opener structure, and stacks of collagen fibers could be seen at the capsular edges in some specimens **(Figure 1)**; linear cracks (width <3 µm) and notches (width ranging between 3 and 9 µm) were also seen at the capsular edge
- The manual CCC cutting edges showed clear stacks of collagen fibers, and the edges were smooth and regular in all cases; no microdiscontinuities of the edge were seen in any case **(Figure 2)**
- Overall, the manual CCC had statistically significantly smoother cutting edges than the LenSx® and VICTUS® laser capsulotomies **(Table 1)**
- Both the Sa and the Sq values were statistically significantly lower (P<0.05) in manual CCC than in femtosecond laser capsulotomy cutting edges; there were no differences in Sa and Sq values between the two laser platforms **(Table 1)**
- No significant differences in Ssk values were found between the femtosecond laser capsulotomies and the manual CCC cutting edges (Ssk describes the asymmetry of the surface height distribution); the Sku values were less positive or showed negative values in the laser samples, indicating a flatter height distribution than manual CCC (overall, kurtosis represents a measure of the randomness of surface heights) **(Table 1)**

Figure 1. VICTUS® **(A)** and LenSx® **(B)** capsulotomy cutting edges. The stacks of collagen fibers at the capsular edge could be seen in some specimens (3/5) treated by the VICTUS® laser. This was not the case for the LenSx® specimens, likely related to a high thermal effect excerpted on the collagen fibers.

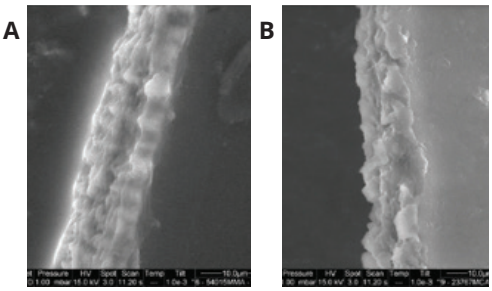


Figure 2. Manual CCC cutting edge. The stacks of collagen fibers are clearly shown at the edge of the capsule; the edge morphology is smooth, with no irregularity.

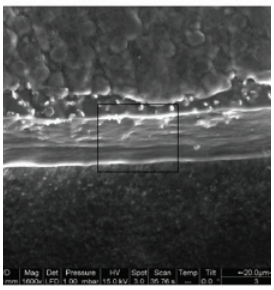


Table 1. Irregularity analysis (mean±SD) of the femtosecond laser capsulotomy and manual CCC cutting edges.

	Sa (µm)*	Sq (µm)*	Ssk (no unit)	Sku (no unit)
LenSx® capsulotomies	5.98±0.56	1.18±0.24	0.35±0.24	−0.43±0.63
VICTUS® capsulotomies	6.49±0.33	1.32±0.16	0.63±0.24	0.00±0.42
Manual CCC	4.94±0.56	0.57±0.13	0.39±0.14	0.44±0.65

Sa, arithmetic mean deviation of the surface; SKU, kurtosis of the topography height distribution; Ssk, skewness of the topography height distribution; Sq, root-mean-square deviation of the surface.
**Statistically significant differences between groups, P<0.05*

Comparison of Manual, Femtosecond Laser, and Precision Pulse Capsulotomy Edge Tear Strength in Paired Human Cadaver Eyes

Thompson et al. *Ophthalmology*. 2016;123:265-274

OVERVIEW

STUDY DESIGN
A 3-arm study in paired human cadaver eyes to compare the anterior lens capsulotomy edge tear strength created by manual continuous curvilinear capsulorhexis, femtosecond laser capsulotomy, and a new automated precision pulse capsulotomy device

STUDY SITE(S)
United States (centers not specified)

PATIENTS
Forty-four (44) eye specimens from 22 donors; age range of donors: 50 to 78 years

SURGICAL METHODOLOGY
Femtosecond laser capsulotomy, manual continuous curvilinear capsulorhexis (CCC), and precision pulse capsulotomy (PPC)

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.), ZEPTO® Precision Cataract Surgery platform (Mynosys Cellular Devices Inc.)

KEY ENDPOINT(S)
Capsulotomy edge tear strength in millinewtons (mN)

ANALYSIS AND CONCLUSIONS

This study of paired fellow human cadaver eyes showed that PPC consistently produced a stronger capsulotomy edge than LenSx® or manual CCC.

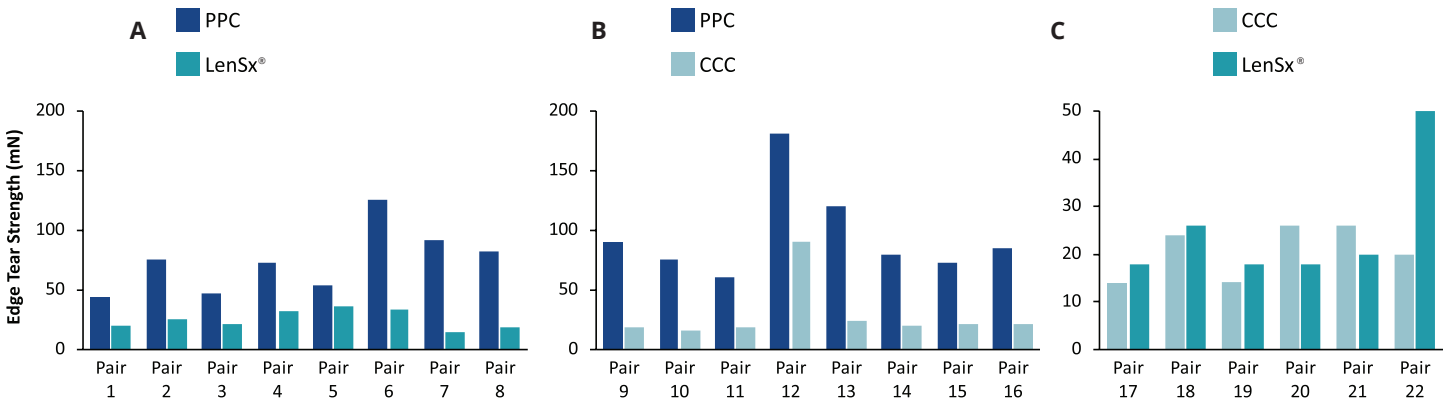
The authors noted that the stronger PPC edge suggested in the study ultimately may confer a greater margin of surgical safety, particularly in eyes with intrinsically weaker capsule biomechanics.

STUDY RESULTS

SURGICAL OUTCOMES

- The PPC edge was noticeably stronger in each of the 8 pairs of eyes comparing PPC and LenSx® **(Figure 1A)** and in each of the 8 pairs comparing PPC with manual CCC **(Figure 1B)**
- In each of the 6 pairs of eyes comparing manual CCC with LenSx®, the latter was stronger in 4 of the pairs **(Figure 1C)**; in the other 2 pairs, the manual CCC edge was slightly stronger than the LenSx®
- The PPC edge tear strength was greater than that of LenSx® by an average factor of 3.1-fold (PPC mean 73.3±24.9 mN vs. LenSx® mean 26.1±6.8 mN; P=0.012)
- The PPC tear strength was greater than that of manual CCC by an average factor of 4.1-fold (PPC mean 95±35.2 mN vs. manual CCC mean 29.1±23.1 mN; P=0.012)
- There was no significant difference in the tear strength of capsulotomies produced by manual CCC (mean 21.3±4.9 mN) and LenSx® (mean 24.5±11.4 mN)

Figure 1. Capsule edge tear strengths in fellow eyes of the same pair in **(A)** the PPC versus LenSx® comparison group (pairs 1-8), **(B)** the PPC versus CCC comparison group (pairs 9-16), and **(C)** the CCC versus LenSx® comparison group (pairs 17-22).



CCC, continuous curvilinear capsulorhexis
PPC, precision pulse capsulotomy

Intereye Comparison of Femtosecond Laser-Assisted Cataract Surgery Capsulotomy and Manual Capsulorhexis Edge Strength

Chan et al. *J Cataract Refract Surg.* 2017;43:480-485*

OVERVIEW

STUDY DESIGN
Prospective nonrandomized case study to compare the breaking force required to tear the explanted capsule after femtosecond laser-assisted cataract surgery in the worse eye and manual cataract surgery in the contralateral eye

STUDY SITE(S)
Single center in Australia

PATIENTS
Seventy-eight (78) eyes of 39 patients (mean age of 69 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery in the eye with worse vision, manual cataract surgery in the contralateral eye

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Breaking force and strain in grams after each explanted capsule was stretched mechanically; morphologic imperfections when a large contralateral difference in capsule strength was found

ANALYSIS AND CONCLUSIONS

This study demonstrated that, on average, femtosecond laser capsulotomies created by LenSx® were as strong as manual capsulotomies in paired living human eyes.

The investigators concluded that because laser capsulotomies are generally more predictable than their manual counterparts, femtosecond lasers could have the potential to improve refractive surgical outcomes after cataract surgery.

*This study was supported by an IIT grant from Alcon, Inc

STUDY RESULTS

SURGICAL OUTCOMES

- The stress–strain graph of the capsules showed a near linear curve, fracturing at their elastic limit, which was the breaking point; **Figure 1** shows the breaking force of each patient included in the study
- The mean breaking force was not significantly different between manual capsulorhexes (2.3 g ± 2.0 [SD]) and LenSx® capsulotomies (2.0 ± 2.2 g, P=0.52)
- The breaking strain for the manual samples (33.8% ± 18.3%) and for the LenSx® samples (34.6% ± 18.6%) were also not significantly different (P=0.81)
- When the LenSx® capsulotomy was much weaker than the manual capsulorhexis, 5 patients with the greatest intereye difference in breaking force (see **Figure 1**) were selected for additional analysis
- Scanning electron microscopy images showed the corrugations of the laser pulses abruptly ended at a point where the edge becomes smooth; the latter represented the edge generated by the tear created by the measurement clamp (**Figure 2**)
- No anomalous laser tags or perforations were noted that would explain the difference in breaking force (**Figure 2**)

Figure 1. Bar graph representing the breaking force for paired sample of 39 patients. Light and dark bars represent paired-eye samples after manual capsulorhexis and LenSx® capsulotomy, respectively, of each patient.

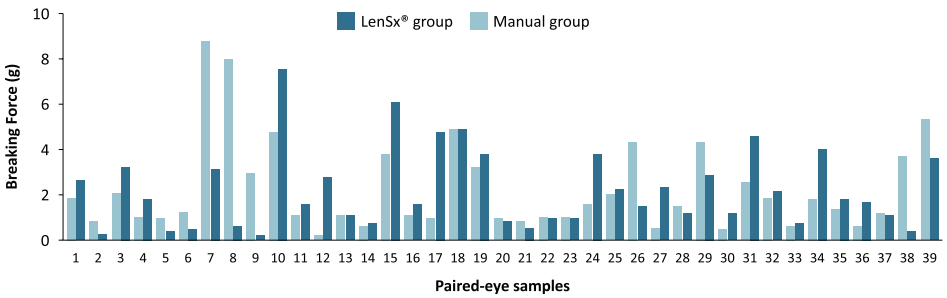
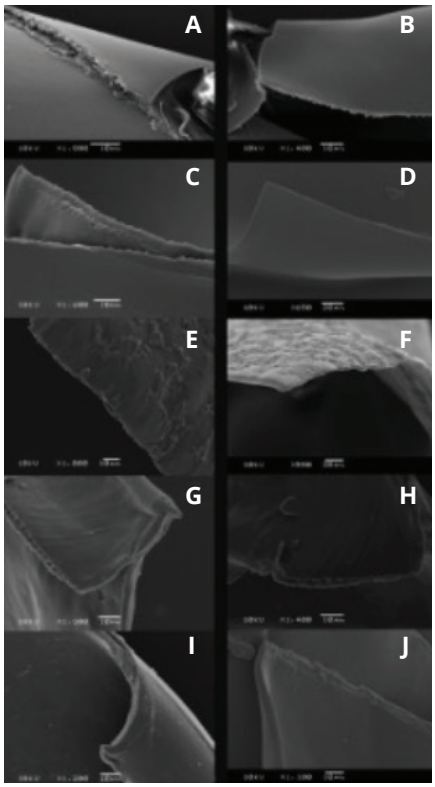


Figure 2. LenSx® scanning electron microscopy of patients 7 (**A** and **B**), 8 (**C** and **D**), 9 (**E** and **F**), 26 (**G** and **H**), and 38 (**I** and **J**) who had the greatest difference in breaking strength between manual and laser cataract surgery (see **Figure 1**).



Femtosecond Laser-Assisted Capsulotomy: Histological Comparison of Four Different Laser Platforms

Surgical Outcomes

Surgical Complications

Hengerer et al. *J Refract Surg.* 2017;33:670-675

OVERVIEW

STUDY DESIGN
Histological analysis to compare capsulotomies from different laser systems with regard to tissue alteration, laser spot formation, and energy settings

STUDY SITE(S)
Germany (sites not specified)

PATIENTS
Not applicable for histological study; 10 human anterior lens capsulotomy disks from each laser system

SURGICAL METHODOLOGY
Femtosecond laser-assisted capsulotomy with 4 different laser platforms

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.), VICTUS® Femtosecond Laser Platform (Bausch & Lomb), CATALYS® Precision Laser System (Johnson & Johnson Vision), LENSAR® Laser System (LENSAR Inc.)

KEY ENDPOINT(S)
Amount of cellular damage around the cutting edges compared with the energy levels and laser spot settings used

ANALYSIS AND CONCLUSIONS

All capsulotomies revealed a circular demarcation zone of different sizes along the cutting edges; differences between damaged tissue zones correlated with the laser systems and their energy settings.

Aberrant laser spots along the cutting edge may result in weakening of the remaining tissue, thereby enhancing the risk for capsular ruptures during surgery.

STUDY RESULTS

HISTOLOGICAL FINDINGS

- All capsulotomies revealed a circular demarcation zone of different sizes along the cutting edges **(Figure 1)**
  - Higher spot energy levels led to a rougher edge design, and smaller laser spots with closer spot separation showed a smoother surface construction of the capsular rim
- Light microscopy showed a radial tissue damage of 36.0 12.3 µm after VICTUS® laser capsulotomy, 8.9 ± 2.9 µm after CATALYS® laser capsulotomy, 25.2 ± 5.6 µm after LENSAR® laser capsulotomy, and 39.8 ± 5.1 µm after LenSx® laser capsulotomy **(Figure 2)**
  - The amount of tissue damage when comparing each laser platform with the others was statistically significantly different (LenSx® vs VICTUS®, P=0.015; other platforms, P=0.000)
- Differences between the damaged tissue zones correlated with the laser systems and their energy settings
  - Histological damage was 4.0 times higher with VICTUS®, 2.8 times higher with LENSAR®, and 4.7 times higher with the LenSx® in comparison to CATALYS®
  - The calculated applied energy for the laser systems was 3.1 times higher with VICTUS® (3,923 mJ), 1.8 times higher LENSAR® (1.8 mJ), and 5.2 times higher with LenSx® (654 mJ) in comparison to CATALYS® (126 mJ)

Figure 1. Histologic images of the different laser systems after staining with Masson's trichrome. **(A)** VICTUS® (original magnification ×400); **(B)** CATALYS® (original magnification ×200); **(C)** LENSAR® (original magnification ×400); and **(D)** LenSx® (original magnification ×200).

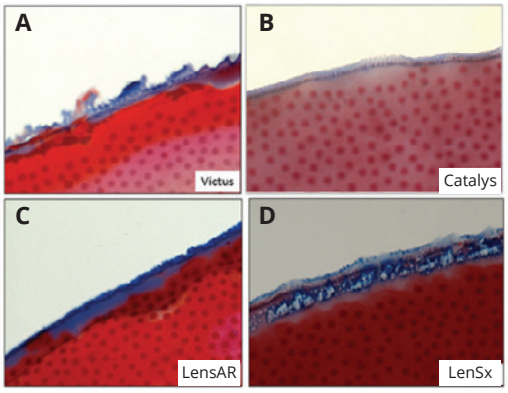
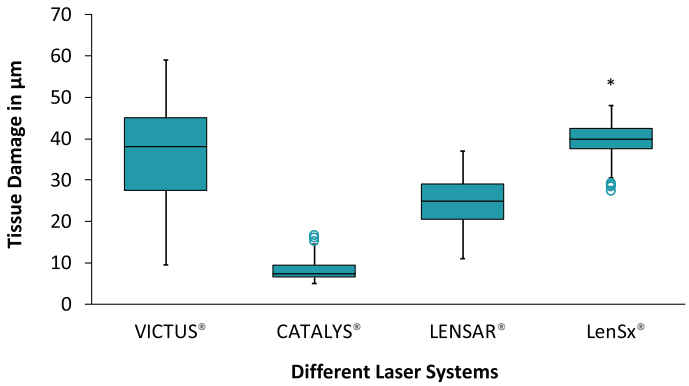


Figure 2. Tissue damage (µm) by different laser systems (mean ± standard deviation).



Comparison of Maximum Stretch Forces Between Femtosecond Laser-Assisted Capsulotomy and Continuous Curvilinear Capsulorhexis

Surgical Outcomes

Surgical Complications

Takagi et al. *J Ophthalmol.* 2017;2017:3489373

OVERVIEW

STUDY DESIGN
Experimental study compared capsule edge strength between femtosecond laser capsulotomy (FLC) and continuous curvilinear capsulorhexis (CCC) of different sizes and irregularities

STUDY SITE(S)
Single center in Japan

PATIENTS
Not applicable. Porcine eyes: FCS (n=not specified) or CCC (teardrop shaped: *n* = 12; heart-shaped:*n* = 11; eccentric:*n* = 10)

SURGICAL METHODOLOGY
Femtosecond laser capsulotomy (FLC) and continuous curvilinear capsulorhexis (CCC) of different sizes and shapes to simulate irregularities and eccentricities seen in the clinic

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Capsulotomies assessed for circularity and maximal stretch force and distance

ANALYSIS AND CONCLUSIONS

Femtosecond laser capsulotomy with LenSx® confers stable capsule edge strength and that the technique has advantages over teardrop-shaped CCC.

While capsule edge strength after CCC varied depending on size or irregularities, LenSx® had the advantage of stable maximum stretch forces.

STUDY RESULTS

CIRCULARITY AND STRETCH FORCE (BASED ON SIZE)

- Average CCC diameters were 4.27 ±0.32 mm, 5.38 ± 0.22 mm, and 6.58 ± 0.25mm in the small CCC, middle CCC, and large CCC subgroups, respectively
- The CVs of diameter in the small CCC, middle CCC, and large CCC subgroups were 0.318 , 0.230, and 0.335, respectively
- The coefficient of variance (CV) of diameter in the LenSx® group (0.098) was smaller than that in the CCC group (0.407)
- There were no significant differences in circularity among the three CCC subgroups and LenSx® group (P=0.0608) (**Figure 1**)
- There was no significant difference in maximum stretch force between the CCC group (172.28 ± 71.2 mN) and the LenSx® group (134.11 ± 13.13 mN)
- The maximum stretch force in the middle CCC subgroup (180.56 ± 41.51 mN), in which the CCC diameter was similar to that of the LenSx® group, was significantly higher than that in the LenSx® group (134.11 ± 13.13 mN, P=0.038)

CIRCULARITY AND STRETCH FORCE (BASED ON SHAPE)

- Circularity in the heart-shaped and teardrop-shaped CCC subgroup was significantly lower than that in the middle CCC subgroup and LenSx® group (P<0.0001 in all cases) (**Figure 2A**)
- Teardrop-shaped CCC showed significantly lower maximum stretch forces than same-sized CCC and LenSx®
- Heart-shaped CCC showed significantly lower maximum stretch forces than same-sized CCC (**Figure 2B**)

Figure 1. Comparison of capsule opening circularity among the LenSx® group and the small CCC, middle CCC, and large CCC subgroups.

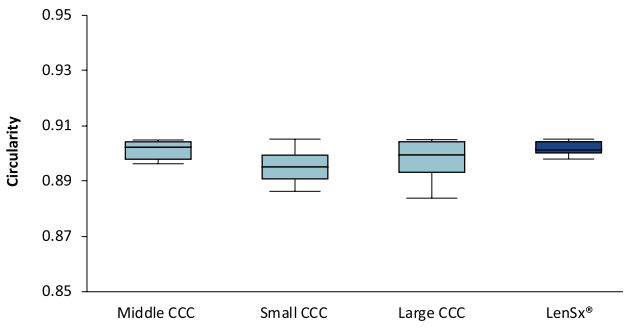
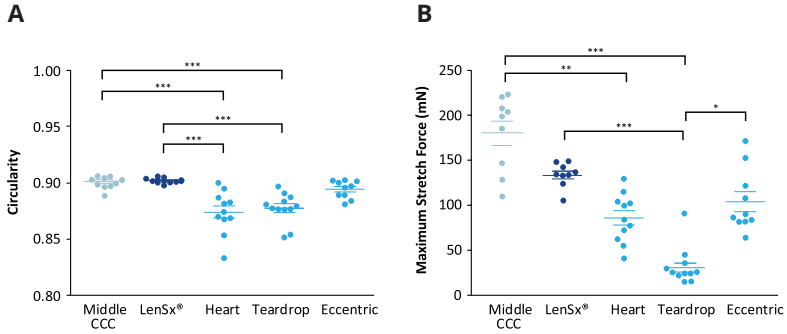


Figure 2. Comparison of circularity (**A**) and stretch force (**B**) among the CCC subgroups and the LenSx® group.



**P< 0.05, **P< 0.001, and ***P< 0.0001. CCC: continuous curvilinear capsulorhexis*

Initial Clinical Evaluation of an Intraocular Femtosecond Laser in Cataract Surgery

Nagy et al. *J Refract Surg.* 2009;25:1053-1060*

Surgical Outcomes

Surgical Complications

Visual Acuity

OVERVIEW

STUDY DESIGN

Experimental study to evaluate femtosecond laser lens fragmentation and anterior capsulotomy in cataract surgery

STUDY SITE(S)

Hungary

PATIENTS

Twenty two (22) *ex vivo* porcine eyes; Nine (9) eyes of 9 patients (4 men, 5 women) scheduled for cataract/IOL surgery;

SURGICAL METHODOLOGY

Ex vivo porcine eyes were used to evaluate anterior capsulotomy and phacofragmentation procedures performed with an intraocular femtosecond laser; these procedures were then performed in patients

SURGICAL TECHNOLOGY

LenSx® Laser (Alcon Laboratories, Inc)

KEY ENDPOINT(S)

Capsulotomy diameter accuracy and reproducibility, phacofragmentation parameters, optical coherence tomography and post-operative assessment including visual acuity were used to evaluate human procedures. *Ex vivo* porcine eyes were evaluated using scanning electron microscopy

ANALYSIS AND CONCLUSIONS

Authors evaluated *ex vivo* porcine eyes and a case series of patients to establish the accuracy and reproducibility of LenSx® during capsulotomy and phacofragmentation.

These initial results demonstrate high precision of capsulorrhexis and reduced phacoemulsification power in porcine and human eyes are associated with LenSx® technology.

*Dr. Sarayba was an employee of LenSx Lasers Inc.

STUDY RESULTS

CAPSULOTOMY ASSESSMENTS

- For an intended 5-mm capsulorrhexis in porcine eyes, average achieved diameters were 5.88±0.73 mm using a standard manual technique and 5.02±0.04 mm using LenSx® (**Table 1**).
  - In all LenSx® patients , the achieved diameter of the specimen (in both axes) equaled the intended diameter to within the accuracy of the caliper, producing a mean diameter error of 0.0 mm
  - No radial tears were observed after any of the procedures
- SEM revealed equally smooth cut edges of the capsulotomy with LenSx® and the manual technique (**Figure 1**).
- The stretching ratio of capsule apertures created by the LenSx® laser was greater than that created by manual anterior capsulotomy (P<0.001).

PHACOFRAGMENTATION

- Average phaco power was reduced 43% (P<0.001) in porcine eyes undergoing phacofragmentation, with a 51% reduction in effective phaco time (P<0.001)
  - In all patient cases, lenses that underwent LenSx® surgery were easily divided into segments, with decreased phaco power/time requirements to complete the lens removal than eyes not undergoing laser phacofragmentation

POSTOPERATIVE ASSESSMENTS

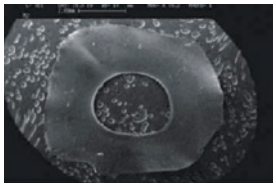
- Slit lamp evaluation results were again consistent with standard procedures performed by the same surgeon and all patients had normal pupil examination, with no evidence of iris damage, atrophy, or transillumination defects observed in any eye during the course of the study
- Corrected distance visual acuity was 20/40 or better in 7/9 eyes (77.8%) at 1 day and in 9/9 eyes (100%) at 1 week. At 1 month postoperatively, all eyes were 20/20.
- None of the eyes had intraocular pressure >21 mmHg at any time point in the study and no complications or adverse events were reported

Table 1. Capsulotomy diameter comparison for 5-mm intended capsulorrhexis in *ex vivo* porcine eyes.

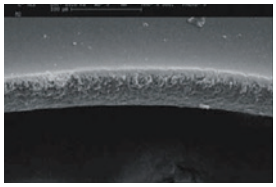
	Mean±SD (Range) [95% CI]	
Measured Axis	**Manual Capsulorrhexis (n=12)**	**LenSx® Femtosecond Laser (n=10)**
X-diameter	5.76±0.72 (4.71 to 6.80) [5.30-6.21]	5.02±0.04 (4.94 to 5.07) [4.99-5.05]
Y-diameter	6.00±0.81 (4.90 to 7.39) [5.48-6.51]	5.02±0.04 (4.94 to 5.07) [4.99-5.05]
Mean diameter	5.88±0.73 (4.88 to 6.83) [5.42-6.34]	5.02±0.04 (4.94 to 5.07) [4.99-5.05]
Mean error (%) (mm)	0.88 (17.6)	0.02 (0.4)

CCC, continuous curvilinear capsulorhexis

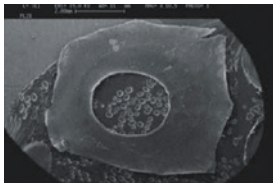
Figure 1. Scanning electron microscopy of capsulotomies in porcine eyes created manually by the surgeon and those created with LenSx®.



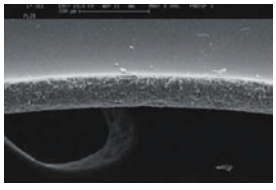
Manual Cystome Capsulorrhexis (Porcine Eye, 10x)



Manual Cystome Capsulorrhexis (Porcine Eye, 300x)



LenSx® Capsulotomy (Porcine Eye, 10x)



LenSx® Capsulotomy (Porcine Eye, 300x)

Femtosecond Laser Capsulotomy and Manual Continuous Curvilinear Capsulorrhexis Parameters and Their Effects on Intraocular Lens Centration

Kránitz et al. *J Refract Surg.* 2011;27:558-563

OVERVIEW

STUDY DESIGN
Experimental clinical study to measure and compare sizing and positioning parameters of femtosecond laser capsulotomy vs manual continuous curvilinear capsulorrhexis

STUDY SITE(S)
Single center in Hungary

PATIENTS
Twenty (20) eyes of 20 patients in the femtosecond laser capsulotomy group (mean age of 63.78 years; range: 28 to 86 years); 20 eyes of 20 patients in the manual capsulorrhexis group (mean age of 71.69 years; range: 52 to 84 years)

SURGICAL METHODOLOGY
Femtosecond laser capsulotomy and manual continuous curvilinear capsulorrhexis (CCC)

SURGICAL TECHNOLOGY
LenSx® Laser, ACCURUS® Surgical System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Intraocular lens (IOL) decentration, circularity, vertical and horizontal diameters of capsulotomies, and capsule overlap measured 1 week, 1 month, and 1 year after surgery

ANALYSIS AND CONCLUSIONS

This is the first study to describe the better centration of intraocular lenses one year after cataract surgery when capsulorrhexis is performed with a femtosecond laser (LenSx®) rather than manual CCC.

The authors suggested that potential clinical advantages can be achieved during refractive cataract surgery through effective prevention of optic decentration with precisely controlled shape, size, and centration of capsulotomy with femtosecond laser.

STUDY RESULTS

SURGICAL OUTCOMES

- Vertical diameter of CCC was statistically significantly higher in the first week and month after surgery **(Table 1)**
- Significantly higher values of capsule overlap over 1 year and circularity in the first week showed more regular capsulotomies in the LenSx® group **(Table 1)**
- Horizontal decentration of the IOL was also significantly higher in the CCC group during the first year **(Table 1)**

Table 1. Parameters of capsulotomies and intraocular decentrations in eyes that underwent CCC or femtosecond laser capsulotomy with LenSx®.

	1 Week		1 Month		1 Year	
Parameter	**CCC**	**LenSx®**	**CCC**	**LenSx®**	**CCC**	**LenSx®**
Vertical diameter, mm	4.79±0.36	4.51±0.11*	4.62±0.34	4.47±0.21*	4.67±0.42	4.54±0.22
Horizontal diameter, mm	4.60±0.47	4.60±0.18	4.64±0.31	4.57±0.24	4.69±0.37	4.61±0.31
Circularity	0.83±0.02	0.86±0.01*	0.84±0.03	0.85±0.02	0.85±0.02	0.84±0.03
Distance min, mm	0.17±0.21	0.42±0.16*	0.26±0.24	0.47±0.19*	0.12±0.18	0.46±0.16*
Distance max, mm	1.09±0.21	0.95±0.17*	1.12±0.17	0.96±0.23*	1.09±0.14	1.00±0.24
Overlap	0.17±0.19	0.47±0.24*	0.24±0.23	0.53±0.25*	0.13±0.19	0.54±0.31*
Horizontal decentration, mm	0.28±0.16	0.12±0.11*	0.26±0.14	0.13±0.09*	0.30±0.16	0.15±0.12*
Vertical decentration, mm	0.18±0.14	0.23±0.17	0.19±0.13	0.19±0.19	0.20±0.10	0.22±0.10

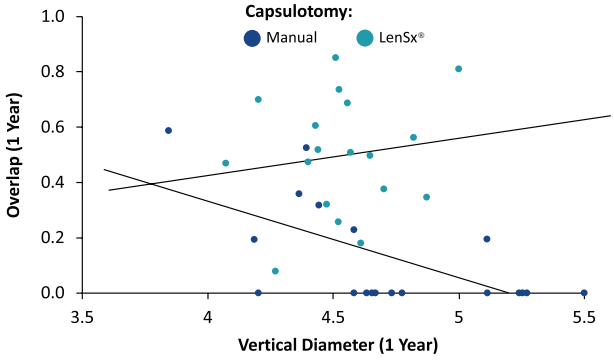
CCC = continuous curvilinear capsulorrhexis.
**P<0.05 between groups at the given time point using repeated measures analysis of variance.*
Values presented as mean ± standard deviation.

- A significant difference was noted between the two groups in dichotomized horizontal decentration values at 0.4 mm with chi-square test after 1 week and 1 year (P=0.035 and P=0.016, respectively)

PREDICTIVE FACTORS AND CORRELATION

- In univariable general estimating equation models, type of capsulorrhexis was found to be a significant predictor of horizontal decentration (odds ratio: 5.95, 95% confidence limit: 1.58-22.22, P<0.01); when predictors of horizontal IOL decentration were explored, only capsulorrhexis overlap showed a significant effect (P=0.002)
- Vertical diameter showed significant correlation to the overlap in the CCC group at all three time points (1 week: r=-0.91; 1 month: r=-0.76, P<0.01; 1 year: r=-0.62, P<0.01), whereas no significant correlation was noted in the LenSx® group (P>0.05) **(Figure 1)**

Figure 1. Correlation of vertical diameter to overlap 1 year after surgery with CCC or LenSx®.



Internal Aberrations and Optical Quality after Femtosecond Laser Anterior Capsulotomy in Cataract Surgery

Visual Acuity

Higher-Order Aberrations

Optical Quality

Mihältz et al. *J Refract Surg*. 2011;27:711-6

OVERVIEW

STUDY DESIGN

Prospective study to compare ocular and internal aberrations after femtosecond laser anterior capsulotomy and continuous curvilinear capsulorrhexis (CCC) in cataract surgery

STUDY SITE(S)

Not specified

PATIENTS

Ninety-nine (99) eyes of 81 patients; 51 eyes of 38 patients treated with continuous curvilinear capsulorrhexis (mean age 70.7 years); 48 eyes of 43 patients treated with femtosecond laser (mean age 75.0 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery or continuous curvilinear capsulorrhexis (CCC)

SURGICAL TECHNOLOGY

LenSx® Laser, ACCURUS® Surgical System, AcrySof® MA60AC intraocular lens (IOL) (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Uncorrected and corrected visual acuities, ocular and internal aberrations, Strehl ratio, and modulation transfer function (MTF)

ANALYSIS AND CONCLUSIONS

Capsulotomy performed with the LenSx® platform induced significantly less internal aberrations compared to eyes that underwent CCC, which may result in better optical quality after the procedure.

The authors concluded that the decreased internal aberrations measured in the study are a results of the better IOL position due to better sizing of the capsulorrhexis performed with LenSx®.

STUDY RESULTS

VISUAL ACUITY

- No statistically significant differences were noted between the LenSx® and CCC groups in uncorrected distance visual acuity (0.86 ± 0.15 vs 0.88 ± 0.08, respectively) or corrected distance visual acuity (0.97 ± 0.08 vs 0.97 ± 0.06, respectively) **(Table 1)**

HIGHER ORDER ABERRATIONS

- The LenSx® group had significantly lower values of intraocular vertical tilt compared to the CCC group (-0.05 ± 0.36 vs 0.27 ± 0.57, respectively), and also lower values of intraocular vertical coma (-0.003 ± 0.11 vs 0.1 ± 0.15, respectively)
- No statistically significant differences were noted in any ocular, corneal, or other internal aberrations between the two groups

OPTICAL QUALITY

- The LenSx® group had significantly higher Strehl ratios compared to the CCC group (0.02 ± 0.024 vs 0.01 ± 0.007, respectively) **(Table 1)**
- The MTF value was also significantly increased in the LenSx® group at all studied cycles per degree (cpds); the differences were statistically significant (P<0.05) for all values **(Table 1)**
- **Figure 1** shows point spread function images of two patients whose visual performance was representative of each group; the plot of the CCC eye shows more astigmatic and coma-like degradation of the retinal image, whereas that of the LenSx® eye is smaller and round

Figure 1. Representative point spread function images in the **(A)** LenSx® and **(B)** manual continuous curvilinear capsulorrhexis groups.

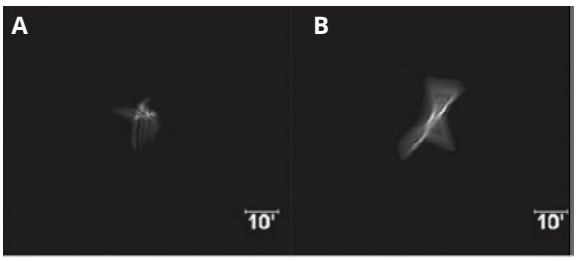


Table 1. Cumulative visual quality characteristics in the LenSx® and manual continuous curvilinear capsulorrhexis groups.

Parameter	Manual CCC	LenSx®	P-value
UDVA	0.88±0.08	0.86±0.15	>0.05
CDVA	0.97±0.06	0.97±0.08	>0.05
Strehl ratio	0.01±0.007	0.02±0.024	0.001
MTF (cpd)			
5	0.25±0.15	0.32±0.19	0.04
10	0.10±0.06	0.17±0.12	0.001
15	0.07±0.04	0.11±0.08	0.001
20	0.05±0.04	0.08±0.07	0.008
25	0.04±0.03	0.06±0.06	0.003
30	0.03±0.02	0.05±0.05	0.002
35	0.02±0.02	0.04±0.04	0.006
40	0.02±0.02	0.04±0.04	0.003
45	0.02±0.01	0.03±0.03	0.005
50	0.02±0.01	0.03±0.03	0.002
55	0.01±0.01	0.03±0.02	0.002
60	0.01±0.01	0.02±0.02	0.006

CCC, continuous curvilinear capsulorrhexis; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; MTF, modulation transfer function; cpd, cycles per degree
**Unpaired t test.*

Comparison of Intraocular Lens Decentration Parameters after Femtosecond and Manual Capsulotomies

Nagy et al. *J Refract Surg.* 2011;27:564-569

OVERVIEW

STUDY DESIGN
Study to evaluate a femtosecond laser-assisted technique and a manual technique (continuous curvilinear capsulorrhexis) to perform anterior capsulotomy in cataract eyes

STUDY SITE(S)
Single center in Hungary

PATIENTS
One hundred and eleven (111) eyes of 81 patients; 57 eyes of 52 patients treated with continuous curvilinear capsulorrhexis (mean age 68 years); 54 eyes of 53 patients treated with femtosecond laser (mean age 65 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted capsulotomy or continuous curvilinear capsulorrhexis (CCC)

SURGICAL TECHNOLOGY
LenSx® Laser, ACCURUS® Surgical System, AcrySof® MA60AC intraocular lens (IOL) (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Circularity and area of capsulotomy, IOL decentration, average keratometry, and axial length 1 week after surgery.

ANALYSIS AND CONCLUSIONS

Femtosecond laser capsulorrhexis with LenSx® was more regularly shaped, did not correlate with pupil size and axial length, and showed better IOL centration and IOL/capsule overlap than manual capsulorrhexis.

A decentered IOL with an incomplete anterior capsule overlap may cause myopization and a higher incidence of posterior capsule opacification due to an incomplete barrier effect; longer-follow up is needed to confirm these possibilities.

STUDY RESULTS

SURGICAL OUTCOMES

- No intra- or postoperative complications were noted in either the LenSx® or manual CCC groups
- No statistically significant differences were noted between the LenSx® and manual CCC groups with respect to axial length, refractive state, and area of capsulotomy **(Table 2)**
- Circularity values were significantly higher in the LenSx® group than in the CCC group (P=0.032) **(Table 2)**
- Incomplete overlap of capsulotomies was observed in 28% of eyes in the CCC group and 11% in the LenSx® group; this difference was statistically significant (P=0.033) **(Table 2)**

CORRELATIONS WITH OUTCOMES

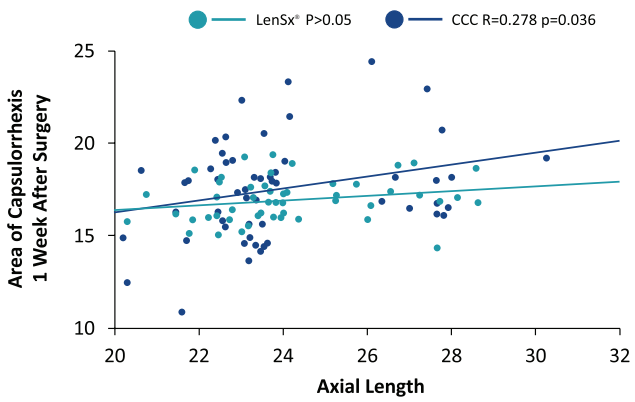
- Significant correlations were noted between axial length and area of capsulotomy, and between average keratometry and area of the capsulotomy in the CCC group (R=0.278, P=0.036; and R=-0.29, P=0.033, respectively), but neither correlated in the LenSx® group (P>0.05) **(Figure 1)**
- In the CCC group, the pupillary area correlated significantly with the area of capsulorrhexis (R=0.27, P=0.039)
- Values of IOL centration showed a significant correlation with axial length in the CCC group (R=0.30, P=0.026), but there was no correlation in the LenSx® group (P>0.05)

Table 1. Comparison of lens decentration parameters in the LenSx® and manual continuous curvilinear capsulorrhexis groups.

Parameter	LenSx®	Manual CCC	P-value*
Axial length (mm)	23.78±2.46	23.39±3.46	>0.05
Refractive state (SE)	-0.75±7.1	-0.75±5.5	>0.05
Area of capsulotomy (mm^2)	16.91±1.78	17.78±2.8	>0.05
Circularity of capsulotomy	0.86±0.04	0.85±0.03	0.032
Complete overlap (%)	89	72	0.033
Incomplete overlap (%)	11	28	0.033

CCC, continuous curvilinear capsulorrhexis; SE, spherical equivalent refraction.
**Mann-Whitney U test.*

Figure 1. Correlation between axial length and area of capsulorrhexis 1 week after surgery in the LenSx® and manual continuous curvilinear capsulorrhexis groups.



Comparison of IOL Power Calculation and Refractive Outcome after Laser Refractive Cataract Surgery with a Femtosecond Laser Versus Conventional Phacoemulsification

Filkorn et al. *J Refract Surg.* 2012;28:540-544

OVERVIEW

STUDY DESIGN
Prospective study to compare intraocular lens (IOL) power calculation and refractive outcome between patients who underwent laser refractive cataract surgery with a femtosecond laser or with conventional cataract surgery

STUDY SITE(S)
Not specified

PATIENTS
One hundred thirty-four (134) eyes; 57 eyes of 57 patients treated with standard phacoemulsification (mean age 63.37 years, range: 23 to 86 years); 77 eyes of 77 patients treated with femtosecond laser (mean age 65.18 years, range: 23 to 88 years)

SURGICAL METHODOLOGY
Implantation of IOLs with femtosecond laser-assisted cataract surgery or standard phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, ACCURUS® Surgical System (Alcon Laboratories, Inc.); IOLs included AcrySof® MA30AC, n=37, MA60AC, n=23, SA60AT, n=8 (Alcon Laboratories, Inc); LI60AO, n=43 (Bausch & Lomb); L-302-1, n=16 (Oculentis); and 690AB, n=7 (Medicontur)

KEY ENDPOINT(S)
The refractive outcome analyzed using mean absolute error (MAE; difference between predicted and achieved postoperative spherical equivalent refraction) 6-12 weeks after surgery

ANALYSIS AND CONCLUSIONS

Femtosecond laser-assisted cataract surgery with LenSx® resulted in a significantly better predictability of IOL power calculation than conventional phacoemulsification surgery.

This difference is possibly due to a more precise capsulorrhexis with the LenSx® platform, resulting in a more stable IOL position.

STUDY RESULTS

REFRACTIVE OUTCOMES

- At least 6 weeks after surgery, MAE was 0.38±0.28 D for all eyes in the LenSx® group and 0.50±0.38 D for all eyes in the conventional group
- Overall, 41.6% of eyes were within ±0.25 D of target refraction in the LenSx® group compared to 28.1% of eyes in the conventional group, and all eyes were within ±1.50 D in both groups **(Figure 1)**
- The correlation between axial length and MAE in the two groups is shown in **Figure 2**; significant cubic correlation was found in the conventional group (r=0.14, P=0.011), whereas no correlation was found in the LenSx® group (P>0.05)
- In multivariable modeling, the type of surgery showed significant effect on postoperative MAE after adjusting for the effect of axial length and IOL type (P=0.04); in the LenSx® group, MAE was lower than in the conventional group, with an average difference of 0.12 D
- The difference was the greatest in short (axial length <22.0 mm, 0.43±0.41 vs 0.63±0.48) and long (axial length >26.0 mm, 0.33±0.24 vs 0.63±0.42) eyes
- No correlation was found between mean error and axial length in the LenSx® group, while a weak but significant correlation (r=−0.29, P=0.03) was found in the conventional group (more myopic errors in eyes with long axial length)

Figure 1. Cumulative refractive predictability of the eyes in the LenSx® and conventional groups.

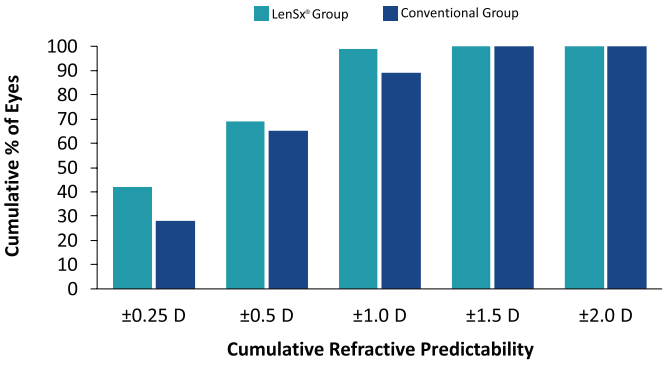
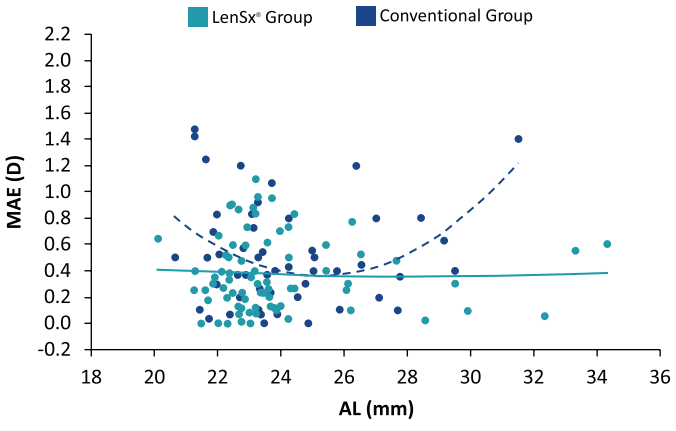


Figure 2. Correlation between axial length (AL) and mean absolute error (MAE) following laser refractive cataract surgery with LenSx® or conventional phacoemulsification.



Intraocular Lens Tilt and Decentration Measured by Scheimpflug Camera Following Manual or Femtosecond Laser-Created Continuous Circular Capsulotomy

Surgical Outcomes
Visual Acuity
Refractive Outcomes

Kránitz et al. *J Refract Surg.* 2012;28:259-263

OVERVIEW

STUDY DESIGN
Prospective randomized study to compare intraocular lens (IOL) decentration and tilt following a circular capsulotomy created with a femtosecond laser to a manually performed continuous curvilinear capsulorrhexis

STUDY SITE(S)
Single center in Hungary

PATIENTS
Twenty (20) eyes of 20 patients in the femtosecond laser capsulotomy group (mean age of 63.55 years); 25 eyes of 25 patients in the manual capsulorrhexis group (mean age of 68.24 years)

SURGICAL METHODOLOGY
Femtosecond laser and manual continuous curvilinear capsulorrhexis (CCC)

SURGICAL TECHNOLOGY
LenSx® Laser, AcrySof® SA60AT IOL (Alcon Laboratories, Inc.); Scheimpflug camera (Pentacam®, Oculus Optikgeräte GmbH)

KEY ENDPOINT(S)
Intraocular lens decentration and tilt, uncorrected and corrected distance visual acuity (UDVA, CDVA) and manifest refraction measured up to 1 year postoperatively

ANALYSIS AND CONCLUSIONS

This study demonstrated that the use of a femtosecond laser (LenSx®) to create an anterior curvilinear capsulotomy results in less IOL decentration and tilt and better CDVA than the use of a manual CCC.

The authors suggested that in the future, unique femtosecond laser capsulotomy diameters will be defined for IOLs with different optical diameters and principles of operation to ensure more standardized surgical procedures.

STUDY RESULTS

Table 1. Intraocular lens positioning parameters in eyes that underwent femtosecond laser (LenSx®) and manual continuous curvilinear capsulorrhexis.

Parameter	Manual CCC	LenSx®	P-value
Horizontal tilt (°)	2.75±1.67	1.53±1.08	0.007*
Vertical tilt (°)	4.34±2.40	2.15±1.41	<0.001*
Horizontal decentration (µm)	270.83±190.85	164.25±113.78	0.034*
Vertical decentration (µm)	148.40±101.59	131.00±124.72	>0.05
Total decentration (µm)	334.91±169.67	230.27±111.54	0.022*

CCC, continuous curvilinear capsulorrhexis
**P<0.05 between groups using t test for independent samples.*

Table 2. Corrected distance visual acuity in eyes that underwent femtosecond laser (LenSx®) and manual continuous curvilinear capsulorrhexis.

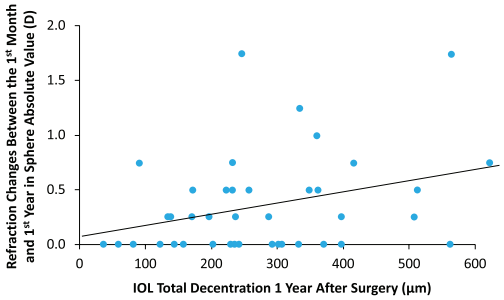
CDVA, decimal	Manual CCC	LenSx®	P-value
One week	0.77±0.25	0.89±0.17	>0.05
One month	0.84±0.16	0.94±0.11	0.031*
One year	0.92±0.09	0.97±0.06	0.038*

CC, continuous curvilinear capsulorrhexis, CDVA, corrected distance visual acuity
**P<0.05 between groups using t test for independent samples.*

SURGICAL OUTCOMES
- Significant differences in centration and tilt were noted between the LenSx® and manual CCC groups
- Horizontal and vertical tilt were significantly higher in the manual CCC group (P=0.007 and P<0.001, respectively), as were horizontal and total decentration (P=0.034 and P=0.022, respectively) **(Table 1)**
- Significant differences were found in the homogeneity of dichotomized IOL vertical tilt and both horizontal and total decentration distribution (P=0.008, P=0.036, and P=0.017, respectively)

CORRELATIONS WITH VISUAL ACUITY/REFRACTIVE OUTCOMES
- CDVA was significantly better in the LenSx® group 1 month and 1 year after surgery (**Table 2**); no differences were observed for UDVA
- Linear regression analysis showed significant correlation between IOL vertical tilt and CDVA (R^2=0.17, β=-0.41, 95% confidence limit: -0.69 to -0.13, P=0.005)
- Total IOL decentration showed a significant correlation with changes in manifest refraction values between 1 month and 1 year after surgery (R=0.33, P=0.032) (**Figure 1**)
- Manifest refraction changes in spherical or cylindrical values did not show a correlation with IOL tilt parameters

Figure 1. Correlation between the absolute value of IOL total decentration and the absolute value of changes in manifest refraction spherical equivalent between the first postoperative month and year.



Macular Morphology Assessed by Optical Coherence Tomography Image Segmentation After Femtosecond Laser-Assisted and Standard Cataract Surgery

Nagy et al. *J Cataract Refract Surg*. 2012;38:941-946

OVERVIEW

STUDY DESIGN
Prospective, case-control study to evaluate and compare thickness changes in the retinal layers in the macula after femtosecond laser-assisted surgery and conventional phacoemulsification

STUDY SITE(S)
Single center in Hungary

PATIENTS
Twenty-five (25) eyes of 25 patients; study group: 12 patients (7 men, 5 women, mean age [range]: 55.2 years [30 to 77 years]); control group: 13 patients (5 men, 5 women, 62.0 years [43 to 83 years])

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser and INFINITI® Vision System (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
Regional thickness data in the central area, inner rings, and outer rings were obtained and absolute and relative thicknesses of the individual retinal layers compared; relative thickness was calculated as the ratio of the retinal layer to the total retinal thickness; visual acuity

ANALYSIS AND CONCLUSIONS

After cataract surgery, subclinical macular edema was detectable mainly in the outer nuclear layer in both groups; this macular edema was due to changes in the outer nuclear layer of the retina, comprising of the photoreceptors.

However, macular edema was significantly less using the LenSx® platform suggesting that it may provide an option that is less traumatic for cataract surgery than manual techniques.

STUDY RESULTS

VISUAL ACUITY
- All surgeries were uneventful
- For patients undergoing LenSx® (study group), the mean Snellen corrected distance visual acuity (CDVA) was 0.4±0.29 preoperatively and 1.00±0.00 at a mean of 59±28.7 days postoperatively
- For patients undergoing conventional phacoemulsification (control group), the mean Snellen CDVA was 0.45±0.29 preoperatively and 0.95±0.08 at a mean of 62.77±23.03 days postoperatively.

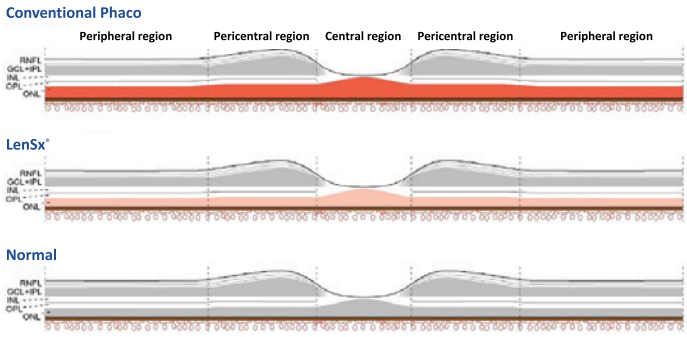
OPTICAL COHERENCE TOMOGRAPHY
- Statistically significant differences were found in absolute outer nuclear layer thickness and relative outer nuclear layer thickness in the inner and outer macular rings (**Table 1**)
- After adjusting for effective phaco time in multivariate modeling, type of surgery showed a significantly lower relative outer nuclear layer ratio in the inner retinal ring (0.26 with 95% confidence interval [CI], 0.25-0.27 versus 0.28 with 95% CI, 0.27-0.29; P=.03) and in the outer retinal ring (0.27 with 95% CI, 0.25-0.28 versus 0.29 with 95% CI, 0.28-0.31; P=.02) in the LenSx® group
- Subclinical macular edema after uneventful phacoemulsification is due to changes in the outer nuclear layer of the retina, comprising the photoreceptors (**Figure 1**)

Table 1. Thickness of retinal layers showing statistically significant differences by group.

	LenSx® group		Manual Group		
Parameter	**Mean**	**SD**	**Mean**	**SD**	**P Value**
Pericentral central region					
ONL	87.54	10.31	96.51	10.46	0.04*
ONL/TR	0.27	0.03	0.29	0.02	0.02*
Peripheral region					
ONL	73.00	8.62	80.89	9.53	0.04*
ONL/TR	0.26	0.01	0.28	0.02	0.02*

**statistical significance; ONL, outer nuclear layer; SD, standard deviation; TR, total rating.*

Figure 1. Mean thickness of the individual layers in the control group (conventional phacoemulsification) and the study group (LenSx®) and in a healthy macular structure (the later calculated from a normative database). The outer layer nuclear layer (red or pink) increase is almost undetectable in the study group and is very visible in the control group.



GCL + IPL, ganglion cell layer ad inner plexiform layer complex; INL, inner nuclear layer, ONL, outer nuclear layer; RNFL, retinal nerve fiber layer.

Central Corneal Volume and Endothelial Cell Count Following Femtosecond Laser-Assisted Refractive Cataract Surgery Compared to Conventional Phacoemulsification

Takács et al. *J Refract Surg.* 2012;28:387-391

OVERVIEW

STUDY DESIGN
Prospective study to compare the effect of conventional phacoemulsification and femtosecond laser-assisted cataract surgery on the cornea using Scheimpflug imaging and noncontact specular microscopy

STUDY SITE(S)
Single center in Hungary

PATIENTS
Thirty-eight (38) eyes of 38 patients in the femtosecond laser group (mean age of 65.81 years), 38 eyes of 38 patients in the conventional phacoemulsification group (mean age of 66.93 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.), Scheimpflug camera (Pentacam®, Oculus Optikgeräte GmbH)

KEY ENDPOINT(S)
Central corneal thickness, 3-mm corneal volume, and Pentacam Nucleus Staging (PNS) assessed with Scheimpflug camera; volume stress index at 1 day and 1 month postoperatively; endothelial cell count assessed by noncontact specular microscopy at 1 day, 1 week, and 1 month postoperatively.

ANALYSIS AND CONCLUSIONS

This study found that femtosecond laser-assisted cataract surgery with LenSx® cause less corneal swelling in the early postoperative period and may cause less trauma to corneal endothelial cells than manual phacoemulsification.

Limitations of this study included a lack of extended analysis of endothelial cell morphology, patients were not matched according to lens density, and randomization was done by the surgeon and not by randomization tables.

STUDY RESULTS

SURGICAL OUTCOMES

- PNS showed a statistically significant positive correlation with effective phacoemulsification time in both groups (r=0.35, P<0.05, LenSx® group, and r=0.5, P<0.05, conventional phacoemulsification group)
- Central corneal thickness was significantly higher in the conventional phacoemulsification group (607 ± 91 µm) than in the LenSx® group (580 ± 42 µm) on day 1, but did not differ significantly preoperatively and at 1 week and 1 month **(Table 1)**
- The final multivariable model (which included central endothelial cell count, PNS, preoperative central corneal thickness, and group as predictors) indicated that type of surgery had a significant effect on central corneal thickness at the first postoperative day
- Central endothelial cell count (P<0.05), PNS (P<0.05), and preoperative central corneal thickness (P<0.001) had a significant effect on postoperative central corneal thickness
- A significant positive correlation between the 3-mm corneal volume increase at postoperative day 1 and endothelial cell loss at 1 month was observed in both groups
- Volume stress index at postoperative day 1 was significantly lower in the LenSx® group than in the conventional phacoemulsification group ($3.0 \pm 2.3 \times 10^{-5}$ vs $5.3 \pm 6.0 \times 10^{-5}$, respectively, P<0.05), but did not differ significantly at 1 month **(Figure 1)**

Figure 1. Volume stress index in eyes in the LenSx® and conventional phacoemulsification groups (P<0.05 at 1 day and P>0.05 at 1 month).

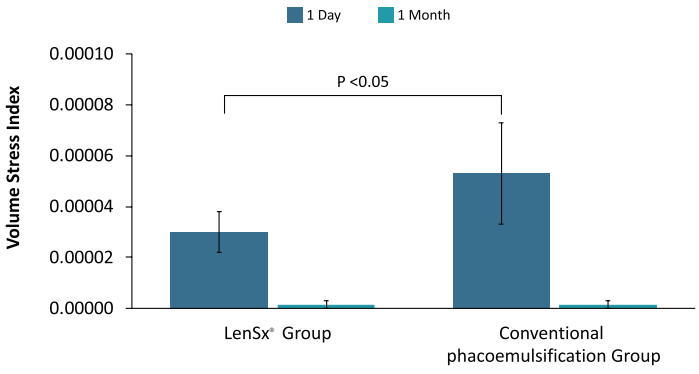


Table 1. Comparison of central corneal thickness in the LenSx® and conventional phacoemulsification groups.

	Central Corneal Thickness (µm)			
Group	Preoperative	1 Day	1 Week	1 Month
LenSx® Laser	545±31	580±42*	554±36	545±31
Conventional phacoemulsification	550±39	607±91*	559±52	557±42

**P<0.05 compared to preoperative values using repeated measures analysis of variance.*

Comparison of the Anterior Capsulotomy Edge Created by Manual Capsulorhexis and 2 Femtosecond Laser Platforms: Scanning Electron Microscopy Study

Al Harthi et al. *J Cataract Refract Surg.* 2014;40:2106-12

OVERVIEW

STUDY DESIGN
Prospective case series to compare the scanning electron microscopy (SEM) features of the anterior capsule edge created by continuous curvilinear capsulorhexis (CCC) and femtosecond laser-assisted capsulotomy using angular second moment and contrast

STUDY SITE(S)
Single center in Saudi Arabia

PATIENTS
Twenty-nine (29) capsule specimens from 29 patients; age range: 26-80 years

SURGICAL METHODOLOGY
Anterior capsule specimens obtained by manual CCC or femtosecond laser-assisted capsulotomy

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.) or VICTUS® Femtosecond Laser Platform (Bausch & Lomb)

KEY ENDPOINT(S)
Comparison of capsule edges using SEM; associations between capsule edge irregularities and clinical intraoperative findings

ANALYSIS AND CONCLUSIONS

Both the LenSx® and VICTUS® laser platforms created an irregular capsulotomy edge, and the angular second moment and contrast quantified capsule edge irregularities for further comparisons.

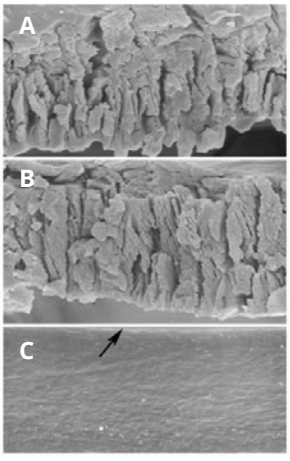
The authors suggest that these measures could be used to quantify efforts to reduce capsule-edge irregularity from femtosecond laser-lens capsule interaction.

STUDY RESULTS

CAPSULE EDGES

- The capsule edges from the CCC were smooth with minimal irregularities, whereas the capsule edges from both the LenSx® and VICTUS® laser platforms showed marked irregularities **(Figure 1)**
- Pairwise comparison showed that manual CCC was significantly different (P<0.001) from both laser groups in angular second moment and contrast **(Table 1)**
- Neither angular second moment (P=0.151) nor contrast (P=0.394) was significantly different between the two laser groups

Figure 1. Scanning electron micrographs of capsule edges (original magnification x4000). Both LenSx® **(A)** and VICTUS® **(B)** produced capsule edges with an irregular surface). Manual CCC **(C)** produced a smooth anterior capsule edge, indicated by the arrow.



CORRELATION ANALYSIS

- A correlation analysis between laser energy and angular second moment/contrast was performed to determine if angular second moment or contrast would show minimal variation when femtosecond laser energy or other parameters remained constant
- Angular second moment showed a weak negative correlation (r=−0.24) with laser energy in the VICTUS® group, but no correlation in the LenSx® group or with other laser parameters
- Contrast showed a weak positive correlation with laser energy (r=0.424) in the VICTUS® group but no correlation in the LenSx® group
- Spot separation in the LenSx® group and spot spacing in the VICTUS® group showed no relationship with angular second moment or contrast

Table 1. Pairwise comparison of angular second moment and contrast values for manual CCC and the LenSx® and VICTUS® laser platforms.

Metric	Mean	Standard Deviation	P-value
Angular second moment			
Manual CCC	0.002	0.001	<0.001
VICTUS®	0.0007	0.002	<0.001
Manual CCC	0.002	0.001	<0.001
LenSx®	0.0006	0.002	<0.001
Contrast			
Manual CCC	47.8	11.4	<0.001
VICTUS®	146.8	102.1	<0.001
Manual CCC	47.8	11.4	<0.001
LenSx®	122.9	32.0	<0.001

CCC, continuous curvilinear capsulorhexis.

Analysis of Planned and Postoperatively Measured Flap Thickness After LASIK Using the LenSx Multifunctional Femtosecond Laser System

Surgical Outcomes

Visual Acuity

Juhasz et al. *J Refract Surg.* 2014;30:622-626

OVERVIEW

STUDY DESIGN
Prospective study to evaluate outcomes of femtosecond laser-assisted LASIK regarding corneal flap parameters by comparing designed and postoperatively measured flap thickness

STUDY SITE(S)
Single center in Hungary

PATIENTS
Thirty-eight (38) eyes of 20 patients diagnosed with myopia and myopic astigmatism

SURGICAL METHODOLOGY
Femtosecond laser-assisted LASIK and intrastromal photoablation

SURGICAL TECHNOLOGY
LenSx® Laser for intracorneal flaps, WaveLight® Allegretto Wave® Eye-Q excimer laser for intrastromal photoablation (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Flap thickness measured using anterior segment optical coherence tomography (AS-OCT); visual acuity

ANALYSIS AND CONCLUSIONS

Visual acuity and optical coherence tomography results from this study suggest that the multifunctional LenSx® laser platform offers high degrees of safety, predictability, and reliability for LASIK flap creation.

The authors noted that precise predictable thickness, planar shape, and easy-to-lift LASIK flaps could be created with the LenSx® platform, while also enabling several steps of cataract surgery, such as clear corneal incision, capsulorhexis, and lens fragmentation.

STUDY RESULTS

FLAP PARAMETERS

- The mean value of the postoperatively measured flap thickness was 141.95 ± 7.59 µm **(Table 1)**; flaps had a planar shape and there was no significant difference between the thickness of the nine points in each cornea (P=0.058)
- There was no statistically significant difference between planned and postoperatively measured flap thickness (preoperatively: 140.00 ± 0.0 µm; 3 months postoperatively: 140.28 ± 8.0 µm, P=0.4067)
- AS-OCT revealed a planar structure of the corneal flap with even thickness in the periphery and central part of the cornea; the stromal bed was even and regular in structure and no folds or stromal lines were observed
- No complications or adverse events were recorded regarding lost, misplaced, or misaligned flap, corneal ulcer or perforation, and corneal microbial or intraocular infection

VISUAL ACUITY

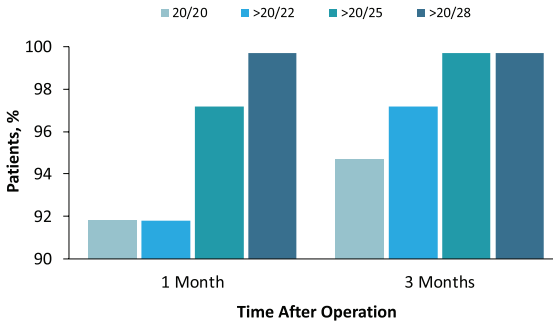
- One month after treatment, uncorrected distance visual acuity (UDVA) was 20/20 in 92.1% and 20/25 or better in 97.4% of patients; 3 months after surgery, UDVA was 20/20 in 94.7% and 20/25 or better in 100% of patients **(Figure 1)**
- Corrected distance visual acuity remained stable after surgery and proved to be 20/20 in 100% of patients 1 and 3 months postoperatively

Table 1. Flap thickness of the relevant nine measurements in the two meridians and deviation from the desired flap thickness after LenSx® surgery.

Parameter	Peripheral	Paracentral	Central	Paracentral	Peripheral
0° meridian Mean ± SD (µm) Deviation (µm)	142.32±7.45 -2.32	141.18±7.54 -1.18	142.37±7.41 -2.37	141.58±8.43 -1.58	142.74±8.1 -2.74
90° meridian Mean ± SD (µm) Deviation (µm)	142.84±7.53 -2.84	142.03±7.29 -2.03	142.37±7.41 -2.37	139.74±18.41 0.26	142.76± 7.06 -2.76

SD, standard deviation.

Figure 1. Uncorrected distance visual acuity results 1 and 3 months after surgery with the LenSx® laser platform.



The Effect of Femtosecond Laser Capsulotomy on the Development of Posterior Capsule Opacification

Surgical Outcomes

Surgical Complications

Kovács et al. *J Refract Surg.* 2014;30:154-158

OVERVIEW

STUDY DESIGN

Retrospective evaluation and comparison of the effects of femtosecond laser-assisted anterior capsulotomy and manual anterior capsulorhexis on posterior capsule opacification (PCO) development

STUDY SITE(S)

Single center in Hungary

PATIENTS

Forty (40) eyes of 40 patients underwent femtosecond laser-assisted anterior capsulotomy and 39 eyes of 39 patients underwent manual anterior capsulorhexis (CCC group)

SURGICAL METHODOLOGY

Femtosecond laser-assisted anterior capsulotomy or manual anterior capsulorhexis, followed by standard phacoemulsification of the nucleus and aspiration of the residual

SURGICAL TECHNOLOGY

LenSx® Laser; INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

PCO level measured using Open-Access Systematic Capsule Assessment (OSCA) software 18 to 26 months after surgery; postoperative intraocular lens position (ie, tilt and decentration)

ANALYSIS AND CONCLUSIONS

Femtosecond laser-assisted anterior capsulotomy using LenSx® proved to be a safe procedure for postoperative PCO rates.

Authors postulated that due to better intraocular lens position, femtosecond laser-assisted anterior capsulotomy using LenSx® resulted in slightly decreased PCO scores.

STUDY RESULTS

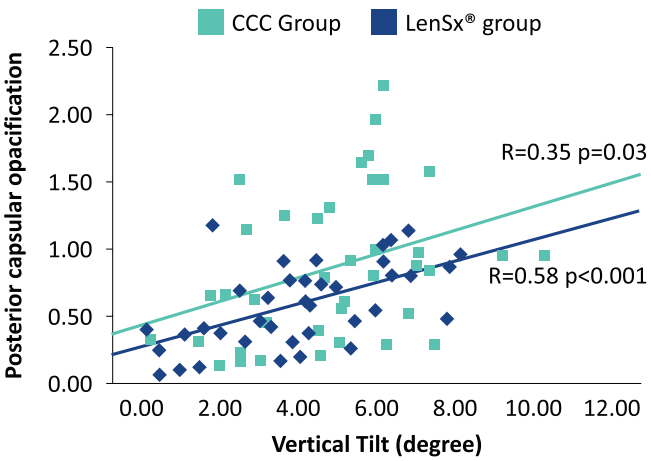
- Vertical tilt, horizontal and total decentration of intraocular lenses, and PCO proved to be significantly higher in the CCC group (P = 0.03, 0.04,0 .03, and 0.01, respectively) (**Table 1**)
  - After adjusting for axial length and follow-up time, manual anterior capsulorhexis was found to be a significant predictor of higher PCO scores in the multivariable regression model (β: 0.33; 95% CI: 0.01 to 0.65; P = 0.04)
- Vertical tilt affected PCO scores after adjusting for axial length and follow-up time (β: 0.07; 95% CI: 0.01 to 0.12; P = 0.02)
  - Among postoperative intraocular lens position parameters, only vertical tilt showed significant correlation with PCO levels in both LenSx® and CCC groups (**Figure 1**)

Table 1. Descriptive statistics of the two groups.

	LenSx® Group (n=40)		CCC Group (n=39)		
Parameter	**Mean**	**SD**	**Mean**	**SD**	**P Value**
Age (y)	65.50	12.94	68.95	10.84	.37
Gender (female:male)	28:12		29:10		.67[a]
Axial length (mm)	23.25	1.48	23.82	1.93	.31
Follow-up (months)	22.37	4.36	21.74	5.46	.30
Horizontal tilt (degrees)	2.01	2.24	2.24	1.36	.69
Vertical tilt (degrees)	3.50	2.13	5.10	2.23	.03
Vertical decentration (µm)	106.32	114.66	158.50	101.27	.14
Horizontal decentration (µm)	154.74	126.24	260.50	187.07	.05
Total decentration (µm)	212.01	126.62	320.54	172.07	.03
PCO level (OSCA score)	0.58	0.30	0.84	0.52	.01

[a]Chi-square test. CCC, manual capsulorhexis; SD, standard deviation; PCO, posterior capsule opacification; OSCA, Open- Access Systematic Capsule Assessment.

Figure 1. Significant correlation between vertical intraocular lens tilt and posterior capsular opacification in the LenSx® group (r = 0.58; P< 0.001) and manual anterior capsulorhexis (CCC) group (r = 0.35; P = 0.03).



Optical Coherence Tomography and 3-Dimensional Confocal Structured Imaging System-Guided Femtosecond Laser Capsulotomy Versus Manual Continuous Curvilinear Capsulorhexis

Surgical Outcomes

Visual Acuity

Refractive Outcomes

Mastropasqua et al. *J Cataract Refract Surg.* 2014;40:2035-2043

OVERVIEW

STUDY DESIGN

Prospective randomized clinical study to compare the features of capsulotomy obtained during femtosecond laser-assisted cataract surgery (FLACS) with those of continuous curvilinear capsulorhexis obtained using a standard manual technique

STUDY SITE(S)

Single center in Italy

PATIENTS

Ninety (90) eyes of 90 patients; 30 eyes in the LenSx® FLACS group (mean age 69.3 years; range: 65 to 75 years), 30 eyes in the LENSAR® FLACS group (mean age of 69.2 years; range: 65 to 75 years), 30 eyes in the continuous curvilinear capsulorhexis group (mean age of 69.1 years; range: 65 to 75 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and continuous curvilinear capsulorhexis (CCC)

SURGICAL TECHNOLOGY

LenSx® Laser, CONSTELLATION® Vision System; AcrySof® SN60WF intraocular lens (IOL) (Alcon Laboratories, Inc.), LENSAR® Laser System (LENSAR Inc.)

KEY ENDPOINT(S)

Surgical outcomes, corrected and uncorrected distance visual acuity (CDVA, UDVA), refractive outcomes assessed up to 180 days postoperatively

ANALYSIS AND CONCLUSIONS

The femtosecond laser systems (LenSx®, LENSAR®) created capsulotomies with better circularity than manually created CCCs, and also produced better IOL centration immediately after surgery and over time with better refractive results.

The capsulotomy area was also more predictable in the femtosecond laser groups than the CCC area in the manual group, with less deviation between the intended area versus the obtained area.

STUDY RESULTS

SURGICAL OUTCOMES

- All capsulotomies and CCCs were successfully completed without intraoperative or postoperative complications
- Circularity was statistically significantly better in the femtosecond laser groups than in the manual CCC group at 7 days (P<0.05); all three groups improved slightly at 30 and 180 days with no statistically significant differences between groups **(Figure 1)**
- At 180 days, mean deviation between the obtained capsulotomy or capsulorhexis and the intended area was 0.58±0.44 mm^2 in the LenSx® group and 0.69±0.58 mm^2 in the LENSAR® group; these deviations were statistically significantly lower than in the manual group (P<0.001)
- Both laser groups had better intraocular lens (IOL) centration than the manual group at all timepoints (P<.001); **Figure 2** shows distance between the pupil centroid and IOL centroid over time

VISUAL ACUITY/REFRACTIVE OUTCOMES

- Differences in UDVA and CDVA between the three groups at all timepoints were not statistically significant; the improvement in UDVA and CDVA in all three groups was statistically significant between 7 days and all subsequent timepoints (P<0.001)
- The residual spherical equivalent and mean absolute error were statistically significantly smaller in the two femtosecond laser groups than in the manual CCC group (P=0.038) and increased significantly over time in all groups (P<0.001)

Figure 1. Variations in circularity over time by group. Data are expressed as the mean and standard error (*P<0.05, contrast analysis versus manual CCC group).

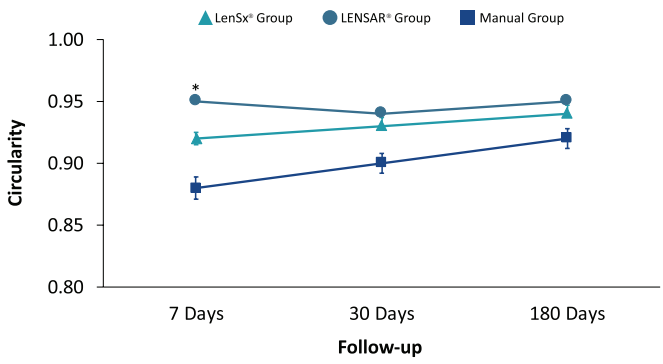
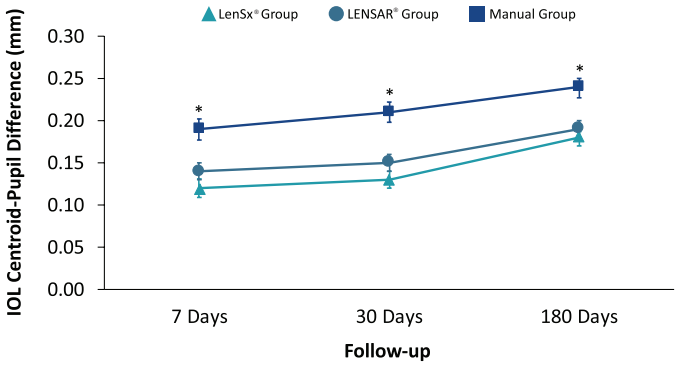


Figure 2. Variations in the distance between the pupil centroid and IOL centroid over time by group. Data are expressed as the mean and standard error (*P<0.05, contrast analysis versus manual CCC group).



In Vitro Immunohistochemical and Morphological Observations of Penetrating Corneal Incisions Created by a Femtosecond Laser Used for Assisted Intraocular Lens Surgery

Surgical Outcomes

Surgical Complications

Mayer et al. *J Cataract Refract Surg.* 2014;40:632-638

OVERVIEW

STUDY DESIGN

In vitro experimental study to compare inflammatory cell response and morphological aspects of femtosecond laser-created corneal incisions

STUDY SITE(S)

Single center in Germany

PATIENTS

Twenty-two (22) human corneoscleral buttons; corneal tunnel incisions were made on 16 buttons and no treatment was performed on 6 controls

SURGICAL METHODOLOGY

Corneal tunnel incisions were created using a femtosecond laser with 7 µJ pulse energy on the outer periphery and manually using a phaco knife on the respective opposite side (180 degrees)

SURGICAL TECHNOLOGY

LenSx® Laser with SoftFit™ Patient Interface (Alcon Laboratories, Inc)

KEY ENDPOINT(S)

Inflammatory reaction was evaluated using standard immunofluorescence analyses for monocytes (CD11b) and for dendritic cells (HLA-DR); morphological changes and apoptosis was assessed using van Gieson staining and terminal deoxynucleotidyl transferase deoxy-UTP-nick end labeling was performed (TUNEL)

ANALYSIS AND CONCLUSIONS

Femtosecond laser-created corneal incisions in human corneas with LenSx® showed a significantly higher cell death rate than manually performed incisions, indicating an upregulated postoperative wound-healing response.

No differences in inflammatory cell response were observed.

STUDY RESULTS

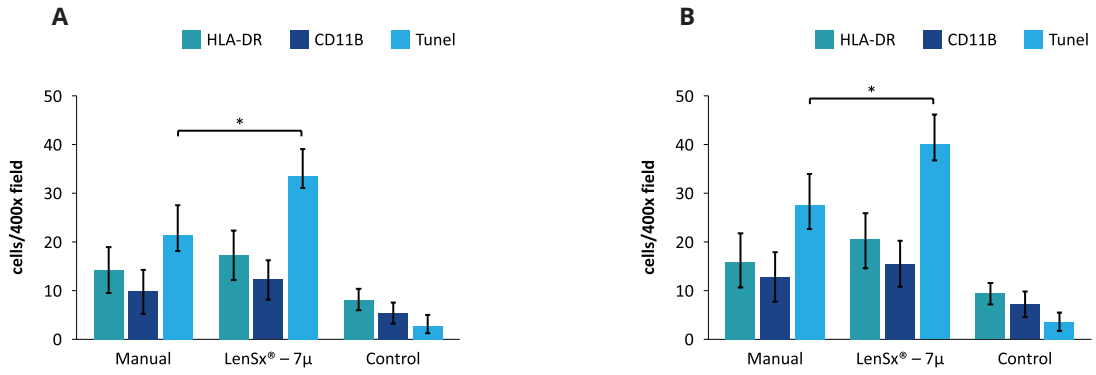
INFLAMMATORY RESPONSE AND APOPTOSIS

- No statistically significant differences in inflammatory cell response between LenSx® corneal incisions and manually performed incisions were observed (**Figure 1A** and **B**)
  - The ratio of dendritic cells between LenSx® and manual incisions was 1:2 after both 12 and 48 hours in culture (12 hours: mean 17.3±5.1 vs 14.2±4.5 cells/x400 field, 48 hours: mean 20.3±5.6 vs 16.3±5.5 cells/x400 field) (P=0.07)
  - The ratio of CD11b-positive cells (monocytes) between LenSx® and manual incisions was 1:2 after both 12 and 48 hours of organ culture (12 hours: mean 12.1±4.2 vs 9.7±4.5 cells/x400 field, 48 hours: mean 15.5 ± 4.7 vs 12.9 ± 5.2 cells/x400 field) (P=0.08).
- Apoptosis was significantly more pronounced in the LenSx® incisions (**Figure 1A** and **B**)
- The ratio of dendritic cells between LenSx® incisions and manual incisions was 1:2 (12 hours and 48 hours; P=0.07), the ratio of monocytes was 1:2 (12 hours and 48 hours; P=0.08), and the ratio of apoptotic cells was 1:5 (12 hours) and 1:6 (48 hours) (P=0.02) (**Figure 1A** and **B**)

MORPHOLOGY

- LenSx® laser incisions showed a more sawtooth-like cutting edge than manual incisions

Figure 1. Different inflammatory and cell death quantifications after 12 hours (**A**) and 48 hours (**B**) of organ culture after surgical treatment.



**significant difference in apoptotic cell response between groups, P=0.02; TUNEL, terminal deoxynucleotidyl transferase deoxy-UTP-nick end labeling.*

Impact of Crystalline Lens Opacification on Effective Phacoemulsification Time in Femtosecond Laser-Assisted Cataract Surgery

Surgical Outcomes

Surgical Complications

Mayer et al. *Am J Ophthalmol.* 2014;157:426-432.e1*

OVERVIEW

STUDY DESIGN
Retrospective, consecutive, nonrandomized, comparative case series to compare effective phacoemulsification time in cataract surgery performed by manual phacoemulsification vs femtosecond laser-assisted lens fragmentation

STUDY SITE(S)
Single center in Germany

PATIENTS
One hundred fifty (150) eyes of 86 patients; 88 eyes underwent femtosecond laser-assisted cataract surgery (mean age of 67.75 years), 62 eyes underwent cataract removal with manual phacoemulsification (mean age of 69.42 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and residual lens work-up with pulsed ultrasound energy; manual phacoemulsification using pulsed ultrasound energy

SURGICAL TECHNOLOGY
LenSx® Laser, INFINITI® Vision System for pulsed ultrasound energy (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Effective phacoemulsification time and endothelial cell loss

ANALYSIS AND CONCLUSIONS

Significant reduction in phacoemulsification time was achieved in this study using a femtosecond laser-assisted procedure (LenSx® Laser).

With increasing preoperative crystalline lens opacification, the effect increased, allowing for shorter effective phacoemulsification time, especially in denser cataracts in the scope of the opacifications analyzed in this trial.

**This study was financially supported by Alcon.*

STUDY RESULTS

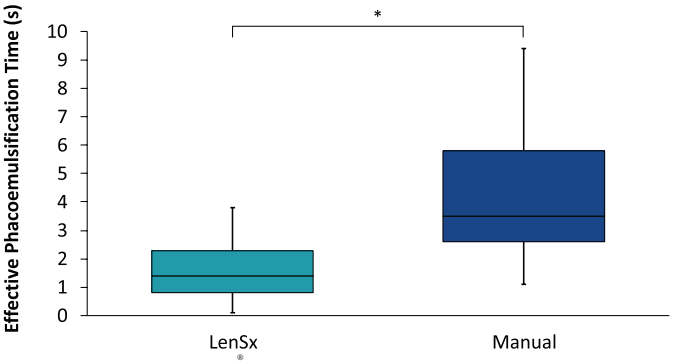
PHACOEMULSIFICATION TIME AND ENDOTHELIAL CELL LOSS

- The mean overall effective phacoemulsification time was significantly lower in the LenSx® group compared with the manual group (1.58 ± 1.02 vs 4.17 ± 2.06, P = 0.001) **(Figure 1)**
- The reduction in mean effective phacoemulsification time was significant between groups for all PNS-O grades in favor of LenSx® (P=0.01)
- The slope of the PNS-P regression line for effective phacoemulsification time was slightly sleeper for the manual group (0.81 + 0.23x, R^2=0.274) than for the LenSx® group (0.33 + 0.09x, R^2=0.386); however, this difference was not statistically significant (P=0.10) **(Figure 2)**
- Lower effective phacoemulsification times were recorded throughout all subjects in the LenSx® group, with 76 eyes (86.3%) having a time <3 seconds, 60 cases (68.2%) having a time <2 seconds, and 15 cases (17.0%) having a time <0.5 seconds
- There was a significantly lower reduction of mean endothelial cells in the LenSx® group compared to the manual group at 4 weeks postoperatively (mean losses: 114.90±87.09 (4.70%) cells/mm^2 vs 173.10±111.16 (6.79%) cells/mm^2, respectively, P=0.02)

SURGICAL COMPLICATIONS

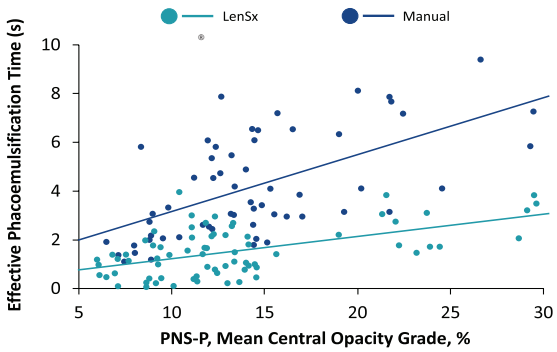
- In both groups, a complete anterior capsulotomy was detected in all eyes without adhesions or macroscopic visible tags
- No eye developed anterior capsule tears, posterior capsule rupture, zonular dehiscence, vitreous prolapse or loss, or phacoemulsification burns or bites
- A second docking attempt was required twice in the LenSx® group; however, there were no aborted dockings or suction loss during live imaging or femtosecond laser treatment

Figure 1. Effective phacoemulsification time comparison between femtosecond laser-assisted cataract surgery (LenSx®) and manual surgery.



**Significant difference between groups; P=0.001.*

Figure 2. Correlation of effective phacoemulsification time and PNS-P [%] in the manual and LenSx® groups; slopes of regression lines did not differ significantly (P=0.10).



PNS-P, Pentacam nucleus staging.

Evaluation of Femtosecond Laser-Assisted and Manual Clear Corneal Incisions and Their Effect on Surgically Induced Astigmatism and Higher-Order Aberrations

Nagy et al. *J Refract Surg.* 2014;30:522-525

OVERVIEW

STUDY DESIGN
Prospective randomized study to evaluate femtosecond laser-assisted and manual clear corneal incisions and their effect on surgically induced astigmatism (SIA) and corneal higher-order aberrations (HOAs)

STUDY SITE(S)
Single center in Hungary

PATIENTS
Twenty (20) eyes of 20 patients in the manual group (mean age 62.27 years), 20 eyes of 20 patients in the femtosecond laser group (mean age 70.4 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional manual phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, AcrySof® SA60AT intraocular lens (IOL) (Alcon Laboratories, Inc.), Scheimpflug camera (Pentacam®, Oculus Optikgeräte GmbH)

KEY ENDPOINT(S)
Corneal topography readings and corneal wavefront aberrations (diameter: 9.0 mm) 3 months postoperatively

ANALYSIS AND CONCLUSIONS

No significant difference was found between the LenSx® and manual groups with respect to the induced HOAs or the magnitude of SIA, but a significant difference was found for angular deviation between the measured and planned axes of induced astigmatism.

This difference in angular deviation may be due to better predictability of location, size, and direction of the corneal incisions with LenSx®; this may assist in the minimization of SIA and induced corneal aberrations during IOL implantation.

STUDY RESULTS

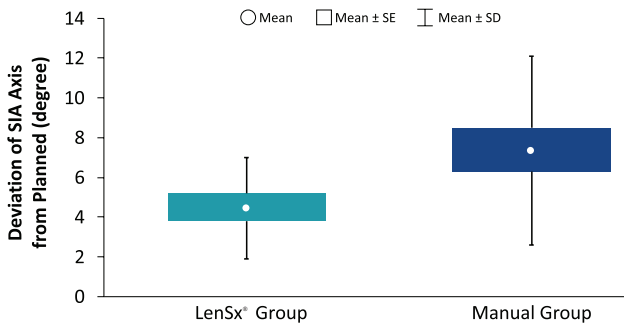
SURGICALLY INDUCED ASTIGMATISM

- There was no significant difference in SIA between the groups (LenSx® group: 0.47 ± 0.13 vs manual group: 0.41 ± 0.14; P=0.218) 3 months postoperatively
- However, the deviation of the SIA axis from the previously planned axis was significantly smaller in the LenSx® group compared to the manual group (4.47 ± 2.59 degrees vs 7.38 ± 4.72 degrees, respectively; P=0.048) **(Figure 1)**

CORNEAL ABERRATIONS

- No significant differences (preoperatively or postoperatively) in corneal aberration data were found between the groups 3 months postoperatively
- Within both groups corneal HOAs increased significantly (LenSx® group: 0.13 ± 0.09 to 0.18 ± 0.12, P=0.025; manual group: 0.13 ± 0.05 to 0.15 ± 0.05, P=0.002) **(Table 1)**
- Lower-order and total corneal aberration values remained stable in both groups (P>0.05) **(Table 1)**

Figure 1. The deviation of the SIA axis from the previously planned axis was significantly different between the LenSx® and manual groups 3 months postoperatively.



SE, spherical equivalent; SD, standard deviation.

Table 1. Lower- and higher-order aberrations and total corneal wavefront errors at baseline and 3 months postoperatively.

	LenSx® Group (Median ± Quartile Range)		Manual Group (Median ± Quartile Range)		P-value[a]	
Aberration	Baseline	3-Month Postop	Baseline	3-Month Postop	Baseline	3-Month Postop
RMS Total	0.77 ± 0.56	0.83 ± 0.29	0.63 ± 0.34	0.53 ± 0.18	0.293	0.065
RMS LOA	0.76 ± 0.57	0.79 ± 0.26	0.61 ± 0.33	0.51 ± 0.18	0.283	0.072
RMS HOAb	0.13 ± 0.09	0.18 ± 0.12	0.13 ± 0.05	0.15 ± 0.05	0.472	0.078

RMS, root mean square; LOA, lower-order aberration; HOA, higher-order aberration; postop, postoperative
aP=between-groups difference using Mann–Whitney U test; bP<0.05 using Wilcoxon paired test.

Comparing the Intraoperative Complication Rate of Femtosecond Laser-Assisted Cataract Surgery to Traditional Phacoemulsification

Chen et al. *Int J Ophthalmol.* 2015;8:201-203

OVERVIEW

STUDY DESIGN
Retrospective chart review to compare the complication rate of femtosecond laser-assisted cataract surgery and traditional phacoemulsification for the first 18 months after surgery

STUDY SITE(S)
Single center in the United States

PATIENTS
Eight hundred twenty-six (826) eyes, 273 consecutive eyes receiving femtosecond laser-assisted cataract surgery and 553 eyes receiving traditional phacoemulsification

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Intraoperative complications

ANALYSIS AND CONCLUSIONS

This study showed that LenSx® was associated with a statistically significant decrease in complications compared to traditional phacoemulsification, with an overall complication rate of 1.8% for LenSx® and 5.8% for traditional phacoemulsification.

According to the authors, these results suggest that LenSx® is considerably safer than traditional phacoemulsification, a conclusion that is supported by other studies comparing the two approaches.

STUDY RESULTS

INTRAOPERATIVE COMPLICATIONS

- There was a statistically significant difference in total intraoperative complications for the two procedures (P<0.05)
- Of 273 eyes treated with LenSx®, intraoperative complications were noted in five (1.8%) cases, including detachment of Descemet's membrane, open posterior capsule, and corneal abrasions (**Table 1**)
  - Complication rates for individual surgeons ranged from 0% to 5.3%
- Of 533 eyes treated with traditional phacoemulsification, intraoperative complications were noted in 32 (5.8%) cases, including detachment of Descemet's membrane, an open posterior capsule, anterior chamber hemorrhage, vitreous loss, zonular dehiscence, lens material in the vitreous, and corneal abrasions (**Table 2**)
  - Complication rates for individual surgeons ranged from 0% to 23.4%

Table 1. Complications of laser-assisted cataract surgery and traditional phacoemulsification.

Complications	LenSx®	Traditional
None	273	553
Descemet's membrane detachment	1	1
Lens material in vitreous	0	2
Posterior capsule open	2	10
Significant anterior chamber hemorrhage	0	2
Significant iris damage	0	0
Vitreous loss	0	11
Zonular dehiscence	0	5
Corneal abrasion	2	1
Total complications	5	32
Complication rate (%)	1.8	5.8

Anterior Capsulotomy Outcomes: A Comparison Between Two Femtosecond Laser Cataract Surgery Platforms

Surgical Outcomes

Surgical Complications

Pantanelli et al. *J Refract Surg.* 2015;31:821-825

OVERVIEW

STUDY DESIGN
Retrospective case series to compare capsulotomy outcomes between two femtosecond laser platforms for cataract surgery

STUDY SITE(S)
Single center in the United States

PATIENTS
Two hundred and five (205) eyes of 162 consecutive patients (mean age 68.32 years; range: 38 to 92 years); 97 eyes in the LenSx® platform, 108 eyes in the CATALYS® group

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.), CATALYS® Precision Laser System (Johnson & Johnson Vision)

KEY ENDPOINT(S)
Capsulotomies graded as one of the following: complete treatment pattern (type 1), microadhesions (type 2), incomplete treatment pattern (type 3), and complete pattern but not continuous (type 4)

ANALYSIS AND CONCLUSIONS

The study found that both the LenSx® and CATALYS® laser platforms offered satisfactory outcomes with respect to capsulotomy creation; microadhesions were seen in only 3 of the 205 capsulotomies and did not lead to intraoperative or postoperative complications.

The authors emphasized that careful assessment by the surgeons during femtosecond laser-assisted cataract surgery is required to avoid possible complications resulting from capsulotomy malformations.

STUDY RESULTS

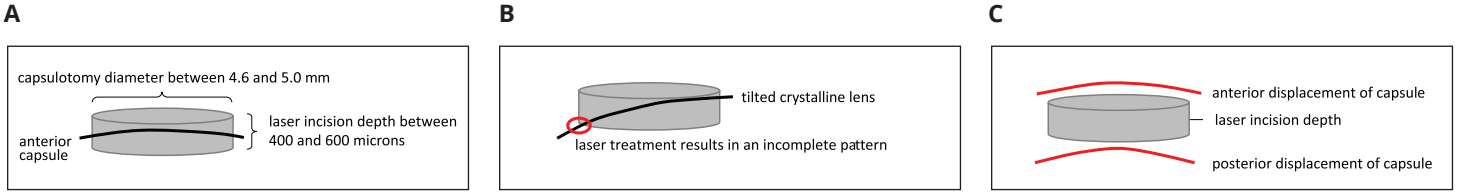
SURGICAL OUTCOMES

- Ninety-four capsulotomies in the LenSx® group were graded as type 1 (96.91%), and three were graded as type 2 (3.09%)
- The cases graded as type 2 were not consecutively performed and there was no evidence that the cataract grading could be associated with the capsulotomy outcomes
- No intraoperative or postoperative complications were observed with these three cases
- All capsulotomies in the CATALYS® group were graded as type 1 (100%)
- There was no statistically significant difference between the LenSx® and CATALYS® groups (P>0.05)
- No intraoperative complications (specifically, no posterior capsular extension or vitreous loss) were noticed in any of the eyes included in the study

SURGICAL GUIDANCE

- Surgeons should be aware that two parameters may result in an incomplete capsulotomy during femtosecond laser-assisted cataract surgery: 1) the inability of the laser imaging system to detect crystalline lens tilt and 2) eye movement (vertical or horizontal) during capsulotomy creation
- **Figure 1a** shows an ideal laser capsulotomy treatment; the plane of the capsule is set in the middle of the incision depth (range: 450 to 600 microns), taking into account the capsulotomy diameter (range: 4.6 to 5.0 mm)
- **Figure 1b** shows what can happen If these parameters are not accounted for; in this case a lens tilt of only 7.5° is sufficient to cause an incomplete capsulotomy pattern
- **Figure 1c** shows that any movement in the vertical plane during capsulotomy treatment can momentarily lead to capsule displacement beyond the spiral cylindrical treatment pattern, resulting in no treatment
- The authors also noted that femtosecond laser technology has improved rapidly; these improvements, along with intraoperative instructions for the patient to stop all movements, may reduce suboptimal capsulotomy outcomes

Figure 1. (A) Schematic sagittal view of an ideal capsulotomy treatment. The anterior capsule (black curved line) lies in the middle of the anticipated treatment area (grey cylinder), resulting in a complete 360° capsulotomy cut. **(B)** Schematic sagittal view of a crystalline lens tilt with anterior capsule tilt; a lens tilt of 7.5° to 13° (depending on the preset capsulotomy diameter and incision depth) is sufficient to cause an incomplete capsulotomy (red circle). **(C)** Schematic sagittal view in the case of vertical (anterior or posterior) displacement of the anterior capsule outside the anticipated treatment area (ranging from 400 to 600 microns), resulting in no capsule treatment.



Postoperative IOL Axial Movements and Refractive Changes After Femtosecond Laser-assisted Cataract Surgery Versus Conventional Phacoemulsification

Surgical Outcomes

Visual Acuity

Refractive Outcomes

Toto et al. *J Refract Surg.* 2015;3:524-530

OVERVIEW

STUDY DESIGN
Prospective study to evaluate intraocular lens (IOL) axial movements and refractive changes following femtosecond laser-assisted cataract surgery and conventional cataract surgery

STUDY SITE(S)
Single center in Italy

PATIENTS
Eighty eyes (80) of 80 candidates for cataract extraction (age range: 65 to 75 years) were randomized into two groups: femtosecond laser (40 eyes) and manual (40 eyes)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
IOL axial movements and refractive changes during a 6-month follow-up period, influence of capsulorhexis features on postoperative IOL axial changes, and prediction error for femtosecond laser and conventional cataract surgery

ANALYSIS AND CONCLUSIONS

LenSx® surgery was related to a lower overall variability of anterior chamber depth compared to conventional cataract surgery with more stable postoperative refraction.

Nevertheless, no differences were observed between the two techniques in the refractive predictability of IOL power calculation.

STUDY RESULTS

VISUAL OUTCOME AND REFRACTION

- Differences in corrected distance visual acuity between the two groups were not statistically significant; all patients showed a corrected distance visual acuity 0.3 logMAR or greater (> 20/40 Snellen) at each follow-up visit
- Median absolute error was not significantly different between the two groups with standard formulas ranging between 0.29 and 0.64 (Hoffer Q) in the LenSx® group and between 0.24 (SRK-T) and 0.55 D (Hoffer Q) in the manual group
- At 30 and 180 days, the mean spherical equivalent showed a hyperopic shift in the LenSx® group (0.17 ± 0.23 D) and a myopic shift in the manual group (-0.23 ± 0.10 D) from 7 days postoperatively (P<0.001) (**Table 1**)

ANTERIOR CHAMBER DEPTH (ACD)

- The mean ACD increased between 7 days and 180 days in the LenSx® group and decreased during the same period in the manual group
- The overall ACD variation was significantly lower in the LenSx® group compared to the manual group during follow-up (P<0.001) (**Figure 1**)

Table 1. Postoperative outcomes by group (Mean±SD).

	7 Days		30 Days		180 Days		P value		
Variables	LenSx® Group	Manual Group	LenSx® Group	Manual Group	LenSx® Group	Manual Group	Timea	Groupb	Interactionc
Subjective SE (D)	-0.21 ± 0.38	-0.28 ± 0.75	0.04 ± 0.80	-0.28 ± 0.62	0.05 ± 0.67	-0.51 ± 0.34	.050	< .001	.009
Capsulorhexis area (mm²)	20.01 ± 1.94	15.42 ± 3.37	20.10 ± 1.65	15.53 ± 2.81	21.02 ± 1.64	15.01 ± 3.41	.899	< .001	.245
IOL centroid-pupil centroid distance (mm)	0.13 ± 0.03	0.19 ± 0.06	0.14 ± 0.04	0.21 ± 0.06	0.18 ± 0.03	0.24 ± 0.06	< .001	< .001	.891

Probability that effect of surgery on the addressed variable is influenced by:
[a]The differences between the means of the two groups at the three time periods.
[b]The differences between the means within the LenSx® group at two times and the means within the manual group at two times.
[c]Probability that the effect of time is greater in one distinct group (interaction time 3 group).
SD, standard deviation; SE, spherical equivalent; D, diopters; IOL, intraocular lens.

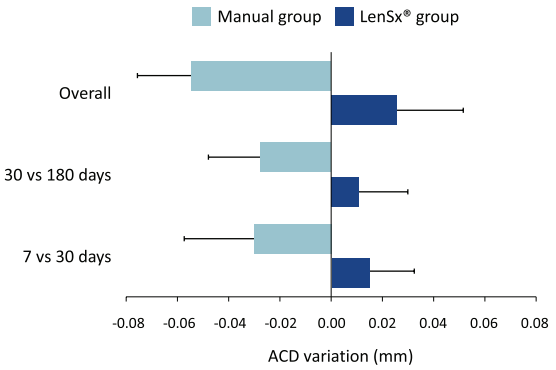
CAPSULOTOMY/CAPSULORHEXIS AREA

- Statistically significant differences were seen in the area of the capsulotomy or capsulorhexis between the groups (P<.001), whereas the effect of time after surgery was not statistically significant (P=0.899).
- Manually produced capsulorhexis has significantly lower areas than capsulotomies obtained with LenSx® at all time periods (P<0.05, contrast analysis)
  - The capsulotomy area increased slightly from 7 to 180 days in the LenSx® group (0.6 ± 1.5 mm²) and decreased slightly in the manual group (-0.5 ± 1.8 mm²) (**Table 1**)
- There was a deviation of the obtained capsulotomy/capsulorhexis area (1.6 ± 0.7 mm²) compared to the expected intended area at 180 days after surgery in the LenSx® group and a deviation of 3.4 ± 1.3 mm² (P<0.001) in the manual group

IOL CENTRATION

- The distance between the pupil centroid (geometric center) and IOL centroid was significantly lower in the LenSx® group compared to manual group at all time periods (P< 0.001) (**Table 1**)

Figure 1. Mean postoperative change of anterior chamber depth (ACD). The bars represent the standard error of the mean. Negative values indicate a decrease and positive values an increase in ACD. ACD was defined as the distance from the central corneal epithelium to the anterior intraocular lens surface.



P< 0.001 for the manual group.

Induced Inflammation and Apoptosis in Femtosecond Laser-Assisted Capsulotomies and Manual Capsulorhexes: An Immunohistochemical Study

Toto et al. *J Refract Surg.* 2015;31:290-294

OVERVIEW

STUDY DESIGN
Noninterventional, nonrandomized, single-blinded observational study to evaluate cellular inflammation and apoptosis induced cataract surgery using a conventional manual technique and a femtosecond laser-assisted procedure at different energy settings using two laser systems

STUDY SITE(S)
Italy

PATIENTS
Fifty-six (56) patients divided into four groups: the manual group (14 capsulorhexes) performed with the manual technique; the 7.0-µJ group (14 capsulotomies); the 10-µJ group (14 capsulotomies); and the 13.0-µJ group (14 capsulotomies)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LENSAR® laser system (7.0-µJ group; LENSAR, Inc.); LenSx® Laser (10-µJ group and the 13.0-µJ groups; Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
All samples were stained for cellular apoptosis analysis (TUNEL assay) and cellular induced inflammation (NF-κB)

ANALYSIS AND CONCLUSIONS

Inflammatory response and cell death increased at increasing laser energies for both laser systems (LENSAR® and LenSx®).

The authors suggested that an effective capsulotomy in femtosecond laser-assisted cataract surgery with minimal detrimental apoptotic and inflammatory effects is possible if the laser system is set to use the minimum energy level.

STUDY RESULTS

CELLULAR INFLAMMATION

- One-way analysis of variance of the percentage of NF-κB positive cells showed a difference between the four groups (F [3.52] = 14.717, P<0.001) (**Figure 1**)
  - Post-hoc analysis showed a difference in the percentage of NF-κB positive cells between the 13.0-µJ group and the manual, 7.0-µJ, and 10-µJ groups (P<0.001, =0.037, and <0.001, respectively) (**Figure 2**)

Figure 1. Inflammatory (NF-κB positive staining, red arrows) cells in a representative capsulotomy/capsulorhexis patient sample for each of the four groups. Green arrows indicate negative cells (original magnification x630).

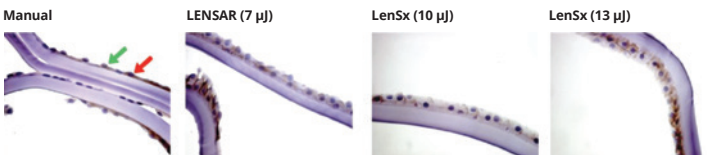
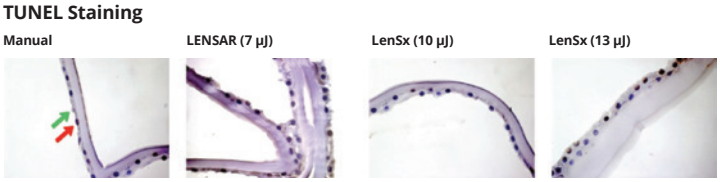


Figure 3. Apoptotic (TUNEL positive staining, red arrows) positive cells in a representative capsulotomy/capsulorhexis patient sample for each of the four groups. Green arrows indicate negative cells (original magnification x630).



APOPTOSIS

- One-way analysis of variance showed a difference in the percentage of TUNEL positive cells between the four groups (F [3.52] = 139.561, P<0.001) (**Figure 3**)
  - Post-hoc analysis of differences in TUNEL positive cells indicated a significant difference between the 7.0-µJ and 10-µJ groups (P<0.017) and between the 13.0-µJ group and the manual, 7.0-µJ, and 10-µJ groups (P<0.001, for all) (**Figure 4**)

Figure 2. Box plot of the percentage of inflammatory (NF-κB positive stain) cells.

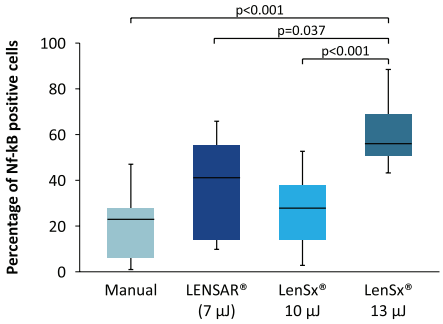
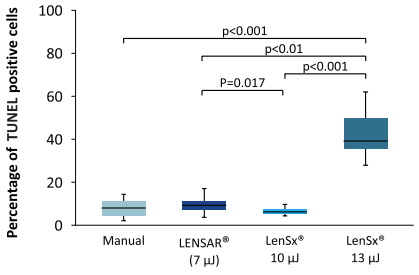


Figure 4. Box plot of the percentage of apoptotic (TUNEL positive stain) cells.



Evaluation of Dry Eye After Femtosecond Laser-Assisted Cataract Surgery

Yu et al. *J Cataract Refract Surg.* 2015;41:2614-2623

OVERVIEW

STUDY DESIGN
Prospective consecutive nonrandomized comparative cohort study to compare dry eye signs and symptoms after femtosecond laser-assisted cataract surgery and conventional phacoemulsification

STUDY SITE(S)
Single center in China

PATIENTS
One hundred thirty-seven (137) eye of 137 patients; femtosecond laser group: mean age of 69.0 years, range of 42-88 years; manual group: mean age of 71.8 years, range of 40 to 85 years

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.); Stelaris System (Bausch + Lomb)

KEY ENDPOINT(S)
Dry eye markers including ocular surface disease index (OSDI) and subjective symptom questionnaire, tear-film assessment (Keratograph 4 corneal topography), Schirmer testing I, and fluorescein staining at day 1, week 1, and month 1

ANALYSIS AND CONCLUSIONS

Both femtosecond laser-assisted cataract surgery with LenSx® and conventional phacoemulsification worsened dry eye postoperatively; LenSx® was associated with a higher risk for staining and dry eye symptoms, and produced more severe ocular staining in patients with preexisting dry eye.

Results from this study suggest that it would be beneficial for patients undergoing either LenSx® or conventional phacoemulsification cataract surgery to be evaluated earlier for dry eye and to receive appropriate treatment postoperatively.

STUDY RESULTS

DRY EYE SIGNS AND SYMPTOMS

- The percentage of patients considered to have dry eye before surgery was similar in both groups (53.4% in the LenSx® group and 51.5% in the manual group); 1 week after surgery this increased to 72.6% and 70.3%, respectively
- Eyes in both groups showed a decrease in tear production, with the lowest Schirmer scores seen at week 1 (7.230 ± 6.387 in the LenSx® group, 7.330 ± 6.274 manual group) and no recovery by month 1; there were no significant differences between the two groups at any study visit
- Compared with manual surgery patients, LenSx® patients had significantly higher OSDI scores (P=0.014) and subjective symptom scores (P=0.016) at week 1; no differences between groups were observed at month 1
- A lessening of tear film stability was observed in both groups, peaking at week 1 and recovering by month 1, with no significant difference between groups (**Figure 1**)
- Fluorescein scores increased at all periods postoperatively in both groups; in the LenSx® group, fluorescein staining scores were significantly higher at day 1 (P=0.011), week 1 (P=0.047), and month 1 (P=0.025) compared with the manual group
- A previous diagnosis of dry eye was associated with greater fluorescein staining in the LenSx® group at day 1 (P=0.016) and month 1 (P=0.009), and analysis of the change from baseline showed a similar tendency (P=0.016 and 0.032, respectively) (**Table 1**)

Figure 1. Changes over time in (**A**) noninvasive first break-up time and (**B**) mean break-up time between the LenSx® and manual groups

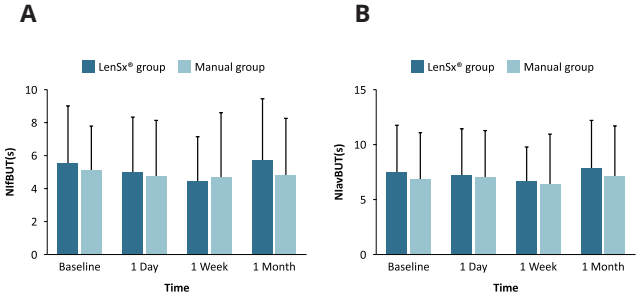


Table 1. Subgroup analysis of fluorescein staining in pre-existing dry eye patients.

	LenSx® group w(n=39)		Manual group (n=33)		
Parameters	**Mean ± SD**	**Range**	**Mean ± SD**	**Range**	**P-value**
Fluorescein staining score					
Baseline	0.540 ± 0.555	0, 2	0.550 ± 0.506	0, 1	0.876**
Day 1	1.560 ± 0.754	0, 4	1.180 ± 0.584	0, 3	0.016**
Week 1	0.870 ± 0.522	0, 2	0.730 ± 0.674	0, 2	0.242**
Month 1	0.690 ± 0.521	0, 2	0.360 ± 0.489	0, 1	0.009**
Change from baseline at day 1	1.03 ± 0.668	0, 3	0.64 ± 0.822	-1, 3	0.016**
Change from baseline at week 1	0.33 ± 0.621	-1, 1	0.18 ± 0.808	1, 2	0.276**
Change from baseline at month 1	0.15 ± 0.670	-1, 2	-0.18 ± 0.584	1, 1	0.032**

** *Mann-Whitney U test*

Laser-Assisted Cataract Surgery: Soft Lens Assisted Interface (SoftFit) Versus Direct Contact Interface

Surgical Outcomes

Surgical Complications

Asena et al. *Eur J Ophthalmol.* 2016;26:242-247

OVERVIEW

STUDY DESIGN
Nonrandomized consecutive case series to determine the safety of the Laser SoftFit™ patient interface by comparing intraoperative results with the contact interface of the LenSx® femtosecond laser platform

STUDY SITE(S)
Single center in Turkey

PATIENTS
One hundred (100) eyes of 63 patients; group 1 (LenSx® contact interface; mean age 69.26 years, range: 48-89 years); group 2 (SoftFit™ patient interface; mean age 64.72 years, range: 31-86 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery (FLACS) with or without a soft lens-assisted contact patient interface

SURGICAL TECHNOLOGY
LenSx® Laser and SoftFit™ Patient Interface (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Intraoperative complications (corneal folds) and surgical results (incomplete and free capsulotomies, incomplete phacofragmentation, and unopened incisions)

ANALYSIS AND CONCLUSIONS

Using the Laser SoftFit™ patient interface with FLACS (LenSx®) decreased the incidence of corneal folds, resulting in better capsulotomy outcomes compared to the original contact interface of the LenSx® platform.

The authors suggest that a possible correlation between corneal folds and incomplete capsulotomies and incomplete phacofragmentation deserves further investigation in a future study.

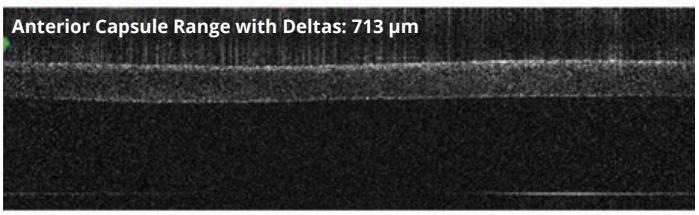
STUDY RESULTS

INTRAOPERATIVE COMPLICATIONS

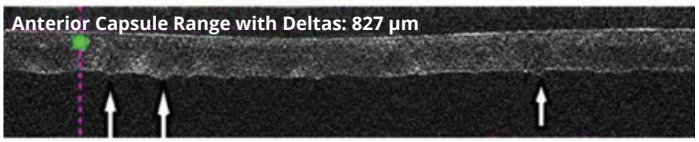
- The LenSx® Laser was used for FLACS in 2 groups; in group 1 the laser was docked to applanate the cornea onto the eye using the curved contact patient interface directly, and in group 2 by using the SoftFit™ interface
- During the surgical procedures, corneal folds were encountered more frequently among group 1 patients than group 2 patients (P=0.0001); **(Table 1, Figure 1)** corneal folds were present in all patients with incomplete capsulotomies

Figure 1. (A) Optical coherence tomography appearance of a cornea with LenSx® and SoftFit™ interface. No fold is observed. **(B)** Optical coherence tomography appearance of a cornea with LenSx® and a direct contact patient interface. There are folds on the posterior corneal surface (arrows).

A



B



SURGICAL RESULTS

- Incomplete capsulotomy was more frequently seen in group 1 patients (P=0.027) **(Table 1)**
- No anterior capsular tags or peripheral capsular tears were noted in any patient
- Free capsulotomy was more commonly encountered in group 2 patients (P=0.0001) **(Table 1)**
- Incomplete phacofragmentation and unopened corneal incisions were seen at a similar rate in both groups (P=0.436 and P=0.204, respectively **(Table 1)**
- No suction loss was observed during the surgeries

Table 1. Comparison of intraoperative results of the two groups.

	Group 1[a] n=50	Group 2[a] n=50	P-value[b]
Corneal fold, n (%)	21 (42)	3 (6)	0.0001
Incomplete capsulotomy, n (%)	6 (12)	0 (0)	0.027
Free capsulotomy, n (%)	9 (18)	46 (92)	0.0001
Incomplete phacofragmentation, n (%)	5 (10)	2 (4)	0.436
Unopened incision, n (%)	5 (10)	1 (2%)	0.204

[a]Group 1: contact femtosecond laser with LenSx® platform; group 2: contact femtosecond laser with LenSx® platform and SoftFit™ patient interface.
[b]Fisher exact test.

Effects of Femtosecond Laser-Assisted Cataract Pretreatment on Pupil Diameter: A Comparison Between Three Laser Platforms

Diakonis et al *J Refract Surg.* 2016;32:84-88

OVERVIEW

STUDY DESIGN
Prospective observational cases series to assess pupil diameter before and after femtosecond laser-assisted cataract surgery pretreatment and compare the outcomes of three laser platforms

STUDY SITES(S)
Single center in the United States

PATIENTS
One hundred ninety-eight (198) eyes of 161 patients; mean age of 69.58 years (range: 38 to 92 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery (FLACS) pretreatment with three different laser platforms

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.); CATALYS® Precision Laser System (Johnson & Johnson Vision); VICTUS® Femtosecond Laser Platform (Bausch & Lomb)

KEY ENDPOINT(S)
Pupil diameter assessed immediately before and 3 minutes after FLACS

ANALYSIS AND CONCLUSIONS

FLACS pretreatment seemed to induce significant pupillary miosis with all laser platforms (LenSx®, CATALYS®, and VICTUS®) assessed in this study.

The authors advise that surgeons be aware of and prepared for this phenomenon during FLACS; pretreatment with topical nonsteroidal agents and intracameral mydriatics is highly recommended to prevent potential miosis-related complications.

STUDY RESULTS

PUPILLARY MIOSIS

- Mean pupillary miosis (decrease in pupil diameter from pretreatment to 3 minutes after FLACS) was 1.42 ± 1.26 mm for the LenSx®, 0.66 ± 0.89 mm for the CATALYS®, and 0.14 ± 0.34 mm for the VICTUS® groups
- Overall, 8 of the 198 eyes (4.0%) demonstrated a pupil diameter of less than 5 mm after FLACS (miotic pupil is clinically significant for cataract extraction) and 48 eyes (24.24%) demonstrated a pupil diameter of 6 mm or less (small pupil diameter for cataract extraction) **(Table 1)**
- There was a statistically significant decrease in pupil diameter for all groups individually (P<0.05), as well as statistically significant difference among the three groups (P< 0.05); LenSx® induced the highest degree of miosis, followed by CATALYS® and finally VICTUS®
- There was also a correlation of pupil diameter before FLACS and pupillary miosis; a larger pupil diameter prior to FLACS was associated with higher degrees of miosis (P=0.002)

TABLE 1. Pupil diameter for LenSx®, CATALYS® and VICTUS® eyes before and after FLACS.

Group	<5 mm	≥ 5 or ≤ 6 mm	>6 mm
LenSx® (n=79 eyes)			
Before FLACS	0 (0%)	0 (0%)	79 (100%)
After FLACS	6 (7.6%)	27 (34.2%)	46 (58.2%)
CATALYS® (n=68 eyes)			
Before FLACS	0 (0%)	0 (0%)	68 (100%)
After FLACS	2 (2.9%)	8 (11.8%)	58 (85.3%)
VICTUS® (n=51 eyes)			
Before FLACS	0 (0%)	2 (3.9%)	49 (96.1%)
After FLACS	0 (0%)	5 (9.8%)	46 (90.2%)
Total (n=198 eyes)			
Before FLACS	0 (0%)	2 (1%)	196 (99%)
After FLACS	8 (4.0%)	40 (20.2%)	150 (75.8%)

Clinical Outcomes Using Standard Phacoemulsification and Femtosecond Laser-Assisted Surgery with Toric Intraocular Lenses

Espaillat et al. *Clin Ophthalmol.* 2016;10:555-556

Visual Acuity
Refractive Outcomes
Higher-Order Aberrations

OVERVIEW

STUDY DESIGN
Retrospective study to investigate differences in outcomes in eyes implanted with a toric intraocular lens (IOL) where surgery was performed with or without the use of LenSx femtosecond laser system

STUDY SITES(S)
Single center in the Dominican Republic

PATIENTS
One hundred fifteen (115) eyes; 62 eyes of 40 patients treated with standard phacoe-mulsification (mean age 71.7 years, range: 43 to 86 years); 53 eyes of 41 patients treated with femtosecond laser (mean age 69.2 years, range: 30 to 84 years)

SURGICAL METHODOLOGY
Implantation of toric IOLs with femtosecond laser-assisted cataract surgery or standard phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser; toric (monofocal or multifocal) one-piece lenses (AcrySof® SN6ATx or SND1TT); Centurion® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Higher order aberrations (HOAs), refractive outcomes, and visual acuity at 1 month and 1 year after cataract surgery

ANALYSIS AND CONCLUSIONS

In uncomplicated cataract surgery with implantation of toric IOLs, there were no clinically significant differences between standard phacoemulsification and the LenSx® Laser related to visual acuity, spherical equivalent refraction, or residual refractive astigmatism after one year.

The authors suggest that further research is warranted to examine image quality and subjective visual improvements for patients in order to better establish the potential value of LenSx® relative to standard phacoemulsification in this regard.

STUDY RESULTS

VISUAL ACUITY
- There was no statistically significant difference in uncorrected distance visual acuity (UDVA) between the standard phacoemulsification and LenSx® groups (P=0.10) at either 1 month or 1 year postoperative
- There was no statistically significant difference in mean corrected distance visual acuity (CDVA) in either group at either 1 month or 1 year postoperative (P>0.05 in both the cases) **(Figure 1)**

REFRACTIVE OUTCOMES
- Mean spherical equivalent refraction after surgery was not statistically significantly different between the groups at either 1 month (standard: −0.09±0.40 D, LenSx®: −0.05±0.40 D; P=0.52) or 1 year (standard: −0.01±0.39 D, LenSx®: 0.09±0.34 D; P=0.15) **(Figure 2)**
- Average postoperative cylinder was also not statistically significantly different between the two groups at either 1 month (P=0.43) or 1 year (P=0.12)

HIGHER-ORDER ABERRATIONS
- Total ocular HOAs were significantly different between the groups (P<0.05), but absolute differences appeared to be the same
- Internal vertical coma was significantly lower in the LenSx® group at 1 year (P=0.03), but no significant difference was observed for internal vertical tilt values (P=0.12)
- A correlation analysis showed no statistically significant correlations between any of the tilt and coma values (ocular, corneal, or interior) and UDVA or CDVA at either 1 month or 1 year (P>0.05 in all cases)

Figure 1. Cumulative distance-corrected visual acuity at 1 year in the standard phacoemulsification and LenSx® groups.

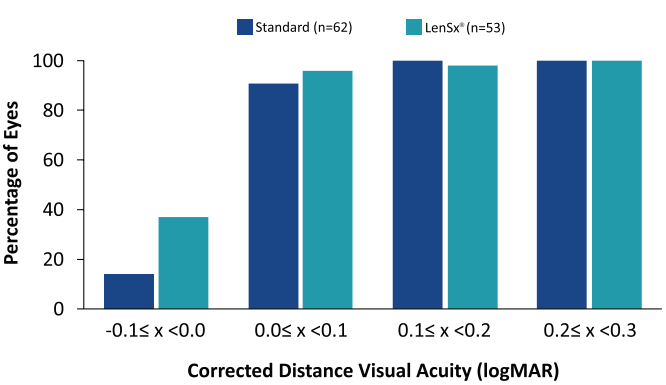
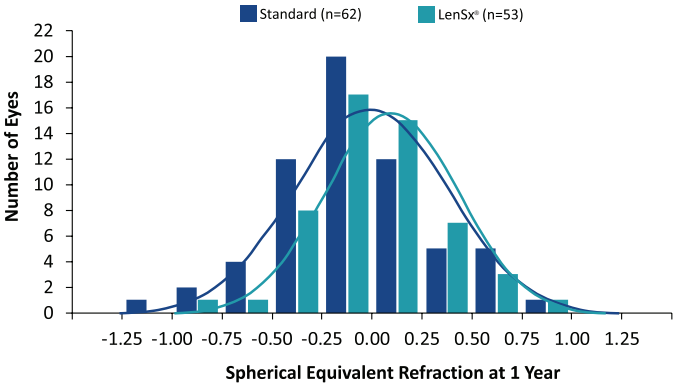


Figure 2. Spherical equivalent refraction at 1 year in the standard phacoemulsification and LenSx® groups.



Standard Manual Capsulorhexis/Ultrasound Phacoemulsification Compared to Femtosecond Laser-Assisted Capsulorhexis and Lens Fragmentation in Clear Cornea Small Incision Cataract Surgery

Surgical Outcomes | Visual Acuity | Refractive Outcomes

Kanellopoulos et al. *Eye Vis (Lond).* 2016 Jul 29;3:20*

OVERVIEW

STUDY DESIGN
Single-center, single-intervention, prospective study to compare femtosecond laser-assisted capsulorhexis/ lens fragmentation versus standard manual capsulorhexis/ultrasound phacoemulsification in clear cornea cataract surgery

STUDY SITE(S)
Single center in Greece

PATIENTS
One hundred thirty-three (133) eyes of 133 patients. Group A (manual capsulorhexis/ ultrasound phacoemulsification); mean age of 69.92 years (range: 51 to 88 years); group B (femtosecond laser-assisted capsulorhexis/ lens fragmentation); mean age of 67.33 years (range: 40 to 85 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted capsulorhexis and lens fragmentation; standard manual capsulorhexis and ultrasound phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser for capsulorhexis; CONSTELLATION® Vision System for ultrasound phacoemulsification and cataract removal (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Refraction, visual acuity, keratometry, tomography, pachymetry, endothelial cell counts, intraocular pressure (IOP), and type of intraocular lens (IOL) implanted followed up to 1 year

ANALYSIS AND CONCLUSIONS

Mean spherical equivalent refraction and visual acuity were comparable with laser cataract surgery (LenSx® platform) compared with manual capsulorhexis and ultrasound phacoemulsification.

Improved astigmatism correction may be among the benefits of LenSx® cataract surgery, while transient corneal edema delaying visual rehabilitation by a day or so may pose a temporary disadvantage.

*This study was financially supported by Alcon.

STUDY RESULTS

VISUAL ACUITY AND REFRACTIVE OUTCOMES
- In group A (manual capsulorhexis), postoperative uncorrected distance visual acuity (UDVA) was 20/20 or better in 61.5% of eyes and 20/25 or better in 78.5% of eyes **(Figure 1)**
- In group B (LenSx®), UDVA was 20/20 or better in 62.7% of eyes and 20/25 or better in 85.1% of eyes **(Figure 1)**
- Linear regression scatterplots of achieved versus attempted spherical equivalent had excellent regression coefficients (r^2=0.983 in group A and 0.979 in group B)
- Overall, 75.2% cases in group A and 80.6% in group B (P=0.8732) were within ±0.50 D of targeted refractive equivalent; a slight trend of under-correction was noted in group A (**Figure 2**)

TORIC IOL EVALUATION
- Toric IOLs were implanted in 27/66 of group A patients and 25/67 of group B patients
- Preoperative manifest cylinder was -1.05 ± 0.89 in toric subgroup A and -0.96 ± 0.80 in toric subgroup B; 3 month postoperative residual manifest cylinder was -0.53 ± 0.38 D in toric subgroup A and -0.41 ± 0.24 D in toric subgroup B (P=0.075)

CORNEAL THICKNESS
- Near-term transient corneal swelling was observed, and the increase was significantly larger in group B compared to group A at one day and one week (P<0.01); deturgescence was noted after one month in both groups, indicating the transient nature of this post-operative corneal swelling

ENDOTHELIAL CELL DENSITY
- A slightly increased drop of endothelial cell density was observed in group B compared to group A (-6 % versus -3 %), but none of the changes noted were statistically significant

Figure 1. Corrected distance visual acuity (preoperative) and uncorrected distance visual acuity results (3 months after surgery) with **(A)** manual capsulorhexis and **(B)** LenSx® laser platform.

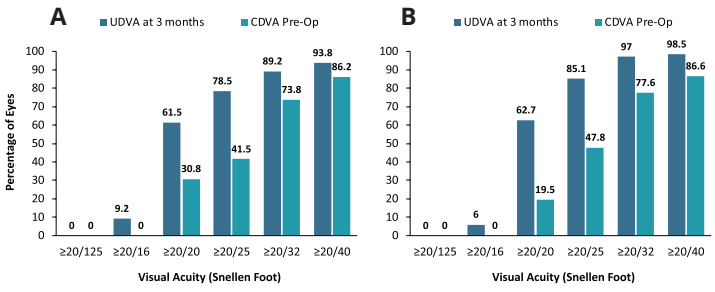
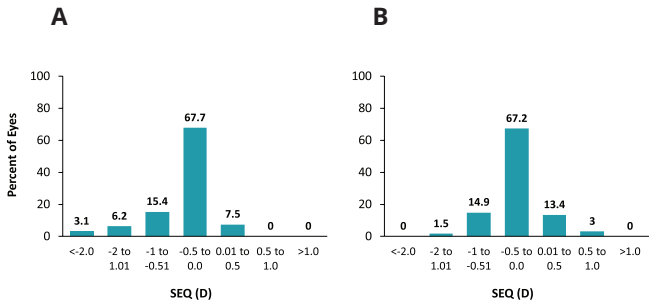


Figure 2. Spherical equivalent refractive accuracy with **(A)** manual capsulorhexis and **(B)** LenSx® laser platform.



Correlation between Anterior Chamber Characteristics and Laser Flare Photometry Immediately After Femtosecond Laser Treatment before Phacoemulsification

Pahlitzsch et al. *Eye (Lond).* 2016;30:1110-1117

OVERVIEW

STUDY DESIGN
Prospective pilot to assess the anterior chamber (AC) characteristics and its correlation to laser flare photometry immediately after femtosecond laser-assisted capsulotomy and photodisruption

STUDY SITE(S)
Single center in Germany

PATIENTS
Ninety-seven (97) eyes in 97 patients (mean age of 68.6 years); three groups analyzed according to flare values 10 minutes after treatment: flare <100 photon counts/ms (n=28), flare 100–249 photon counts/ms (n=47) and flare >249 photon counts/ms (n=22)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and photodisruption

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.), OCULUS Pentacam® (Oculus Inc.), KOWA FM-700 laser flare meter (Kowa Company, Ltd)

KEY ENDPOINT(S)
AC depth, AC volume, AC angle, central corneal thickness and thinnest corneal thickness, axial length, white-to-white distance, pupil diameter, and number of endothelial cells assessed immediately after surgery (maximum 20 minutes) and 1 day postoperatively

ANALYSIS AND CONCLUSIONS

This study was the first to compare alterations of AC characteristics due to LenSx® capsulorhexis and photodisruption related to flare photometry; a flat AC, low AC volume, and a narrow AC angle were parameters were found to be associated with higher intraocular inflammation.

These criteria could be used for patient selection in femtosecond laser-assisted cataract surgery to reduce postoperative intraocular inflammation.

STUDY RESULTS

SURGICAL OUTCOMES

- AC depth, AC volume, AC angle, and corneal thickness showed significant differences between the three cohorts preoperatively, indicating a deeper AC in the flare <100 photon counts/ms group and thus demonstrating a reduced intraocular inflammation in patients with a deep AC morphology
- Ten minutes after LenSx® surgery, AC depth **(Figure 1)**, AC volume and AC angle were significantly larger in the flare <100 group than in the flare 100–249 group (P=0.002, P=0.023, P=0.007 respectively)
- Similar findings were demonstrated in the flare <100 group compared to the flare cohort >249 group; AC depth **(Figure 1)**, AC volume and AC angle were significantly deeper in the flare <100 group 10 minutes after LenSx® surgery (P=0.001, P=0.007, P=0.003)
- The AC angle also differed significantly between the flare <100 and flare >249 groups at the day 1 follow-up assessment (P=0.040)
- The number of endothelial cells were significantly different between the flare <100 and flare >249 groups at day 1 follow up (P=0.038)
- Ten minutes after LenSx® surgery, the central and thinnest corneal thickness showed a significant difference between the flare <100 and flare 100–249 groups (P=0.003, P=0.011, respectively), as well as between the flare 100–249 and flare >249 groups (P=0.046, P=0.023) **(Figure 2)**

Figure 1. Boxplot analysis of the anterior chamber depth preoperatively and 10 minutes after LenSx® surgery in the three flare analysis cohorts.

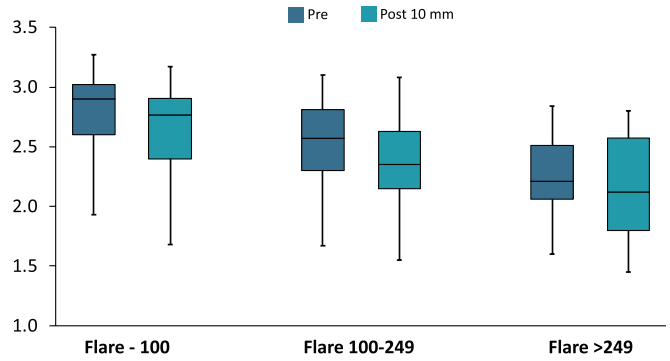
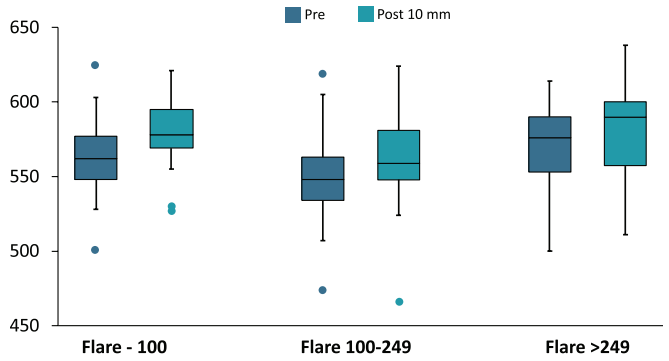


Figure 2. Boxplot analysis of the central cornea thickness preoperatively and 10 minutes after LenSx® surgery in the three flare analysis cohorts.



Comparative Analysis of the Performance of Two Different Platforms for Femtosecond Laser-Assisted Cataract Surgery

Rivera et al. *Clin Ophthalmol.* 2016;10:2069-2078

Surgical Outcomes

Surgical Complications

Visual Acuity

OVERVIEW

STUDY DESIGN

Randomized controlled prospective intraindividual comparative study to analyze and compare the intraoperative and postoperative outcomes of cataract surgery performed with two different femtosecond laser platforms

STUDY SITE(S)

Single center in the United States

PATIENTS

Ninety (90) eyes of 45 patients; mean age of 73.2 years (age range: 61 to 86 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery

SURGICAL TECHNOLOGY

LenSx® Laser (Alcon Laboratories, Inc.), CATALYS® Precision Laser System (Johnson & Johnson Vision)

KEY ENDPOINT(S)

Changes in corrected distance visual acuity (CDVA) and corneal endothelial density 1 day, 1 week, and 1 month after surgery; uncorrected distance visual acuity (UDVA), integrity of the anterior segment and intraocular pressure (IOP) 1 day after surgery; correlations with nuclear sclerosis density

ANALYSIS AND CONCLUSIONS

This study demonstrated that cataract surgery with either LenSx® or CATALYS® is a safe procedure, associated with reduced phacoemulsification time and energy, and preservation of corneal endothelium integrity.

However, both systems differ in the performance of capsulotomy and the procedure of docking (including time to initiate docking and incidence of subconjunctival hemorrhage), with an advantage for CATALYS® over LenSx®.

STUDY RESULTS

SURGICAL OUTCOMES/VISUAL ACUITY

- A significantly higher cumulative dissipated energy (P=0.032), average phacoemulsification power (P=0.043), and average torsional amplitude (P<0.001) were found in the LenSx® group compared to the CATALYS® group
- A significantly larger number of syringes (P=0.003) to seal the corneal incision, a longer patient interface preparation time (P<0.001), more severe perception of pressure by patient (P=0.014), and more cases of subconjunctival hemorrhage (P<0.001) were found in the LenSx® group
- In contrast, suction time was significantly longer in the CATALYS® group (P<0.001)
- A complete capsulotomy was achieved in a significantly larger number of eyes in the CATALYS® group compared to the LenSx® group (P=0.002); anterior and posterior capsular tears were not reported in any group
- No statistically significant differences were found between groups with respect to corneal incisions (P≥0.071), postoperative corrected distance visual acuity (P≥0.48), and endothelial cell density changes (P≥0.14) (**Figure 1**)
- No statistically significant differences between groups in IOP (17.1±3.9 vs 16.2±4.7, P=0.22) and LogMAR UDVA (0.26±0.24 vs 0.27±0.24, P=0.71) were found the day after surgery
- At 1 day after surgery, significant corneal edema was observed in 53.3% (24 eyes) and 44.4% (20 eyes) in the CATALYS® and LenSx® groups, respectively (P=0.399)
- The incidence of clinically relevant flare was 26.7% (12 eyes) and 28.9% (13 eyes) in the CATALYS® and LenSx® groups, respectively (P=0.814)
- No correlation was found between cumulative dissipated energy and nuclear sclerosis density in the CATALYS® group (r=0.024, P=0.874), while a poor and not statistically significant correlation was found between these two parameters in the LenSx® group (r=0.272, P=0.071) (**Figure 2**)

Figure 1. Change in endothelial cell density during the follow-up in the LenSx® and CATALYS® groups.

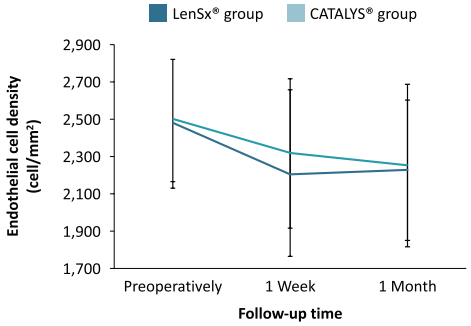
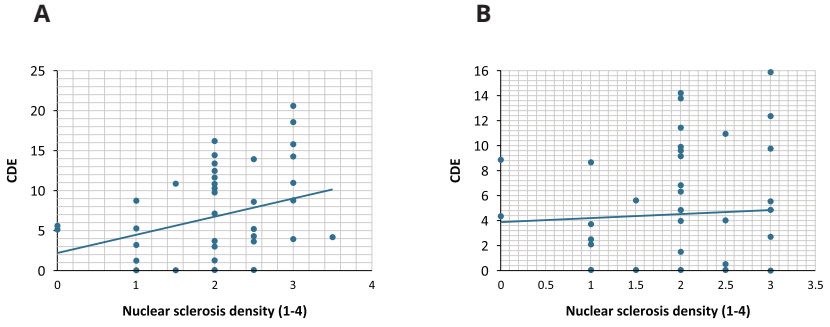


Figure 2. Scattergram showing the relationship between nuclear sclerosis density and cumulative dissipated energy (CDE) in the (**A**) LenSx® and (**B**) CATALYS® groups.



Comparative Evaluation of Femtosecond Laser-Assisted Cataract Surgery and Conventional Phacoemulsification in White Cataract

Titiyal et al. *Clin Ophthalmol.* 2016;10:1357-1364

Surgical Outcomes

Surgical Complications

Visual Acuity

OVERVIEW

STUDY DESIGN

Prospective comparative study to compare femtosecond laser-assisted capsulotomy with conventional manual capsulorhexis in cases of white cataract

STUDY SITE(S)

Single center in India

PATIENTS

Eighty (80) eyes of 80 patients with white cataract; mean age of 62.9 years in the femtosecond laser group, 64.8 years in the manual group

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser with SoftFit™ Patient Interface (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Primary outcome: capsulotomy/capsulorhexis characteristics; secondary outcomes: intraoperative phacoemulsification parameters, intraoperative complications, and postoperative visual acuity

ANALYSIS AND CONCLUSIONS

LenSx® creates single-step, circular, adequately sized capsulotomies and eliminates the difficulty associated with capsulorhexis in white cataracts; release of white milky fluid during femtosecond laser delivery is the most important factor affecting creation of a free-floating capsulotomy.

No significant difference in terms of the intraoperative complications and the final visual outcome were observed between the LenSx® and conventional phacoemulsification groups.

STUDY RESULTS

OVERALL OUTCOMES

- A continuous capsulotomy/capsulorhexis was achieved in 97.5% (39/40) of eyes in both the LenSx® and manual groups
- In the LenSx® group, free-floating capsulotomies were achieved in 52.5% (21/40) of eyes; 37.5% (15/40) had microadhesions and 10% (4/40) had incomplete area of capsulotomy in 1–2 clock hours
  - One case of anterior capsular extension with radial tear was noted during LenSx® surgery, which occurred while polishing the anterior capsule after IOL implantation (**Figure 1**)
- In the manual group, a multistep capsulorhexis was performed in 70% (28/40) of cases
- The mean diameter of the capsulotomy/capsulorhexis was 4.9±0.1 mm in the LenSx® group and 5.3±0.4 mm in the manual group (P<0.001, difference 0.39; 95% CI: 0.27, 0.52)
- The mean circularity index was 0.996±0.003 in the LenSx® group and 0.910±0.047 in the manual group (P<0.001, difference: 0.09 [95% CI: 0.07, 0.10])
- The cumulative dissipated energy, total ultrasound time, total aspiration time, and total surgical time were comparable between the two groups (**Table 1**)
- There was no difference between groups in terms of visual outcomes and intraoperative complications

OUTCOMES BASED ON FLUID VS NO FLUID

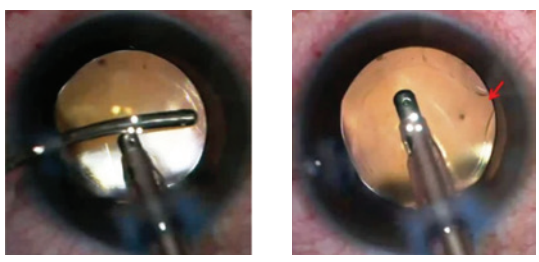
- Each group was subdivided based on the release of white milky fluid on initiation of the capsulotomy/capsulorhexis, and the "fluid" cases were compared with the "no fluid" cases
- Continuous capsulotomies were achieved in 94.1% (16/17) of cases with fluid and 100% (23/23) of cases with no fluid (P=0.042)
- A continuous capsulorhexis was achieved in 100% (19/19) of cases with fluid and 95.2% (20/21) cases with no-fluid (P=1.0)
- The incidence of residual adhesions and incomplete capsulotomies was higher in cases with release of white milky fluid (P=0.003)

Table 1. Comparison of phacoemulsification parameters between the LenSx® and manual phacoemulsification groups.

Phacoemulsification Parameter	LenSx® (mean ± SD)	Manual (mean ± SD)	Difference (95% CI)	P-value
Cumulative dissipated energy (seconds)	18.1±11.5	21.0±10.9	−2.9 (−7.8, 2.1)	0.25
Total ultrasound time (seconds)	68.4±34.0	78.4±33.4	−10.0 (−25.0, 5.0)	0.19
Total aspiration time (seconds)	340.1±73.7	308.0±76.5	32.1 (−1.3, 65.6)	0.06
Total duration of surgery (minutes)	15.7±3.3	14.9±3.0	0.9 (−5.0, 2.3)	0.207

Independent samples t-test was applied. A P-value <0.005 was considered significant.

Figure 1. Anterior capsular tear during LenSx® surgery. (**A**) Polishing of anterior capsule in a case of Type II capsulotomy (microadhesions). (**B**) Anterior capsular tear and extension in 1 clock hour during polishing of anterior capsule (arrow: site of anterior capsular tear with extension).



Neodymium: YAG Capsulotomy Rates Associated with Femtosecond Laser-Assisted Versus Manual Cataract Surgery

Tran et al. *J Cataract Refract Surg.* 2016;42:1470-1476

OVERVIEW

STUDY DESIGN
Retrospective case study to compare the neodymium:YAG (Nd:YAG) posterior capsulotomy rates after cataract surgery performed using a femtosecond laser system versus manual techniques.

STUDY SITE(S)
Two (2) clinical sites and 2 surgery centers in the United States

PATIENTS
One thousand five hundred thirty-four (1534) eyes; femtosecond laser group (mean age of 67.4 years, range: 27 to 90 years), manual group (mean age of 70.3 years, range: 26 to 100 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.); intraocular lens (IOL) material included silicone, hydrophobic acrylic and hydrophilic acrylic; designs included monofocal, multifocal, toric and accommodating

KEY ENDPOINT(S)
Capsulotomy rates related to manual capsulorhexis and capsulorhexis with a femtosecond laser system were compared, with consideration of IOL design and material

ANALYSIS AND CONCLUSIONS

This study showed that Nd:YAG capsulotomy rates were lower with LenSx® surgery than with manual cataract surgery; this was more apparent with IOL materials and designs associated with lower overall rates in general.

The investigators concluded that larger case-controlled prospective studies might be necessary to determine whether capsulotomy rates are lower with femtosecond laser-assisted cataract surgery than with a manual technique when the overall capsulotomy rate for a given IOL design or material is higher.

STUDY RESULTS

CAPSULOTOMY OUTCOMES

- No statistically significant difference in posterior capsule opacification grade was observed between the LenSx® and manual groups (P=0.13)
- The percentage of Nd:YAG capsulotomies performed was significantly lower in the LenSx® group than in the manual group (P=0.04)
- For eyes that had a capsulotomy, the time between the original surgery and capsulotomy was statistically significantly lower in the LenSx® group (P<0.01), which appeared to be a function of the higher ratio of multifocal IOLs in that group

EFFECTS OF IOL MATERIAL AND DESIGN

- The capsulotomy rates were higher with the silicone and hydrophilic acrylic IOL materials, with no statistically significant difference between the rates by surgery group (**Table 1**)
- The hydrophobic acrylic IOL material was associated with a lower overall rate of capsulotomy; there was a statistically significant difference between the surgery groups, with a lower capsulotomy rate in the LenSx® group than in the manual group (P<0.01) (**Table 1**)
- There was a statistically significant difference between the LenSx® group and the manual group for the monofocal IOL design only (P<0.01)

VISUAL ACUITY

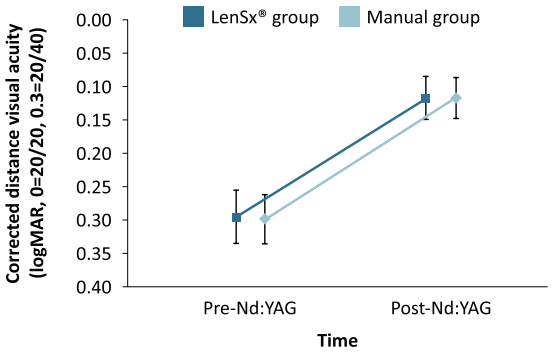
- After Nd:YAG capsulotomies, a statistically significant improvement in corrected distance visual acuity (CDVA) was observed for both groups (**Figure 1**); the mean CDVA increase was nearly 2 lines

Table 1. Nd:YAG capsulotomy rates by group and IOL material.

Parameter	Eyes (n)	Nd:YAG (n)	Nd:YAG Rate (%)	Odds Ratio (95% CI)
Hydrophilic acrylic IOL (all monofocal)				
LenSx®	46	15	32.6	0.81 (0.35, 1.88)
Manual	60	17	28.3	
Hydrophobic acrylic IOL				
LenSx®	779	60	7.7	1.78 (1.23, 2.60)*
Manual	478	62	13.0	
Silicone IOL (all accommodating)				
LenSx®	144	37	25.7	1.01 (0.39, 2.59)
Manual	27	7	25.9	

CI, confidential interval; IOL, intraocular lens; Nd:YAG, neodymium:YAG laser capsulotomy.
**Statistically significant.*

Figure 1. Corrected distance visual acuity before and after Nd:YAG capsulotomy by surgery group.



Note: Vertical bars denote 95% confidence intervals

Comparative Outcomes of Femtosecond Laser-Assisted Cataract Surgery and Manual Phacoemulsification: A Six-Month Follow-Up

Yu et al. *Clin Exp Ophthalmol.* 2016;44:472-480

OVERVIEW

STUDY DESIGN
Prospective consecutive nonrandomized comparative cohort study to explore efficacy and safety outcomes in patients undergoing femtosecond laser-assisted cataract surgery versus manual phacoemulsification cataract surgery

STUDY SITE(S)
Single center in China

PATIENTS
One hundred twenty-four (124) eyes of 106 patients; femtosecond laser group (mean age of 69.66 years, range: 46 to 85 years), manual group (mean age of 72.74 years, range: 43 to 85 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Macular central subfield thickness (CST), cube volume (CV), cube average thickness (CAT), endothelial cell density (ECD), central corneal thickness (CCT) and photon count value (PCV) over 6 months

ANALYSIS AND CONCLUSIONS

This study demonstrated that LenSx® and manual phacoemulsification for cataract extraction are equally safe and efficacious when an experienced surgeon is performing both procedures

The authors noted that LenSx® may be associated with lower flare values following cataract surgery, which may be particularly advantageous in patients who are at higher risk for postoperative anterior inflammation.

STUDY RESULTS

SURGICAL OUTCOMES/COMPLICATIONS

- CST, CV and CAT increased postoperatively and did not return to preoperative levels by 6 months; values were similar between the LenSx® and manual groups throughout the follow-up, and comparison of changes from baseline also showed no significant differences (**Figure 1**)
- ECD decreased postoperatively and remained stable during follow-up; LenSx® was associated with greater endothelial cell loss (from 2590 ± 197 cells/mm^2 at baseline to 2156 ± 454 cells/mm^2 at month 6) than was manual phacoemulsification (from 2731 ± 251 cells/mm^2 to 2383 ± 448 cells/mm^2), but this difference was not significant
- Mean preoperative ECD was lower in the LenSx® group (2590 ± 197 cells/mm^2) than in the manual group (2731 ± 251 cells/mm^2) (P = 0.001); in both groups, there was a decrease in ECD measurements postoperatively, but no significant differences were seen between groups
- CCT in both groups increased, reaching a maximum level on day 1 and tending to decrease thereafter; no significant differences were observed between groups
- In both groups, mean PCV increased to day 1, week 1 and month 1; at month 6, eyes in the LenSx® group had lower flare values than those in the manual group (6.52 ± 1.99 and 8.51 ± 4.00 ph/ms, respectively, P=0.001), but no significant difference in change from baseline was observed between groups (**Figure 2**)
- Best corrected visual acuity (BCVA, logMAR) improved postoperatively in both the LenSx® group (from 0.512 ± 0.251 at baseline to 0.082 ± 0.120 at month 6) and the manual group (from 0.504 ± 0.261 to 0.092 ± 0.118) ; no significant differences were observed between groups

Figure 1. Changes in central corneal thickness (CCT) over time.

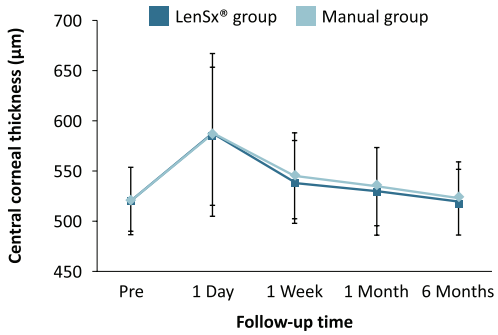
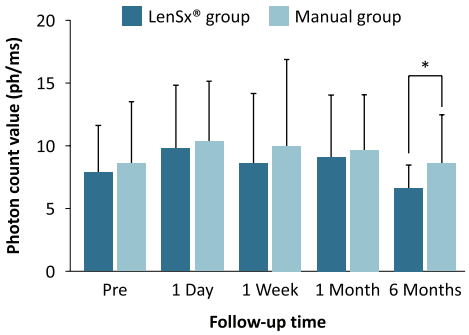


Figure 2. Changes in photon count value (PCV) over time.



Comparison of Corneal Endothelial Cell Loss Between Two Femtosecond Laser Platforms and Standard Phacoemulsification

Al-Mohtaseb et al. *J Refract Surg.* 2017;33:708-712

OVERVIEW

STUDY DESIGN

Prospective nonrandomized comparative study to analyze and compare changes in endothelial cell density (ECD) and cumulative dissipated energy (CDE) in patients having cataract surgery with two different femtosecond laser platforms and standard phacoemulsification

STUDY SITE(S)

Single center in the United States

PATIENTS

One hundred twenty (120) eyes; femtosecond laser group, mean age of 66.7 years, range: 44 to 85 years; manual phacoemulsification group, mean age of 69.5 years; range: 50 to 85 years

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery (FLACS) and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser, CENTURION® Vision System (Alcon Laboratories, Inc.); CATALYS® Precision Laser System (Johnson & Johnson Vision)

KEY ENDPOINT(S)

Changes in endothelial cell density (ECD) and cumulative dissipated energy (CDE)

ANALYSIS AND CONCLUSIONS

This study showed that pretreatment with femtosecond laser-assisted cataract surgery using two different platforms resulted in a decrease in CDE and less endothelial cell loss when compared to standard phacoemulsification at 1 month postoperatively.

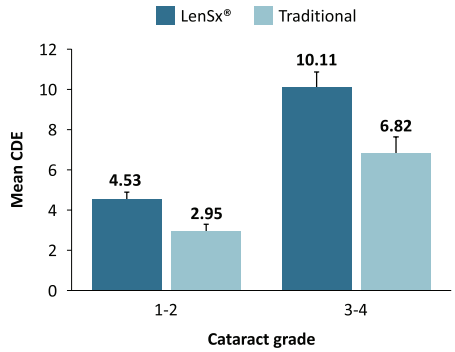
The decrease in endothelial cell loss was more prominent in the dense cataract group; therefore, femtosecond laser-assisted cataract surgery may be most beneficial in those specific cases.

STUDY RESULTS

SURGICAL COMPLICATIONS

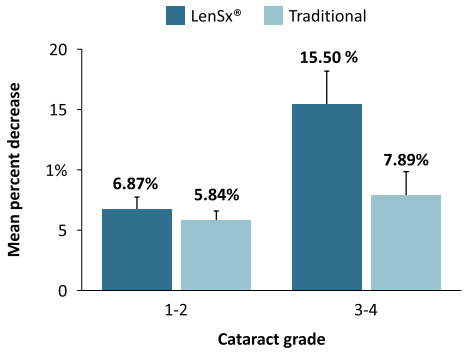
- Intraoperatively, CDE use was significantly lower in the FLACS group compared to the standard phacoemulsification group (4.65 ± 3.61 and 6.11 ± 3.52, respectively; P=0.01)
- The percentage of endothelial cell loss was significantly lower in the FLACS group (6.00% ± 8.02%) compared with standard phacoemulsification (9.06% ± 8.77% for) at 1 month postoperatively (P=0.04)
- No significant difference in central corneal thickness was observed between the FLACS and standard phacoemulsification groups after 1 month
- Results were also analyzed based on cataract density (grade 1 to 4 nuclear sclerosis); grades 1-2 represent early cataracts and grades 3-4 represent advanced cataracts
- In this subanalysis, CDE was significantly less in the FLACS group compared with the standard phacoemulsification group in both the early and advanced cataract group (P=0.002) (**Figure 1**)
- The percent decrease in endothelial cell loss in the advanced cataract group was statistically lower with FLACS (7.89% ± 9.76%) when compared with standard phacoemulsification (15.50% ± 11.09%) (P=0.02) (**Figure 2**)
- A statistical comparison between the CATALYS® and LenSx® platforms did not yield significant differences in terms of CDE, balanced salt solution use, total operating room time, percentage of endothelial cell loss, or change in central corneal thickness

Figure 1. Intraoperative cumulative dissipated energy (CDE) based on cataract density.



Error bars: ± 1 standard error

Figure 2. Postoperative percent decrease in endothelial cell density based on cataract density.



Error bars: ± 1 standard error

Retinal and Choroidal Thickness After Femtosecond Laser-Assisted and Standard Phacoemulsification

Asena et al. *Clin Ophthalmol.* 2017;11:1541-1547

OVERVIEW

STUDY DESIGN
Nonrandomized, retrospective, cross-sectional study to compare short-term changes in retina and choroidal tissue after femtosecond laser-assisted cataract surgery and standard phacoemulsification surgery

STUDY SITE(S)
Single center in Turkey

PATIENTS
Fifty-two (52) eyes of 52 patients; femtosecond laser group, mean age of 70.5 years, range: 59 to 84 years; manual phacoemulsification group, mean age of 70.2 years; range: 51 to 90 years

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser with SoftFit™ Patient Interface, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Central retinal thickness (CRT) and choroidal thickness (CT) at day 1, 1 week later, and after 1 month

ANALYSIS AND CONCLUSIONS

Conventional phacoemulsification had a more pronounced effect on choroidal thickness than did LenSx®; this finding may be of relevance for reducing the incidence of pseudophakic cystoid macular edema (PCME) associated with cataract surgery.

The authors noted that a prospective design with a larger sample size is needed to find meaningful differences with respect to PCME and to assess the effects of the two methods on posterior segment structures, especially for patients with comorbidities such as age-related macular degeneration.

STUDY RESULTS

SURGICAL COMPLICATIONS

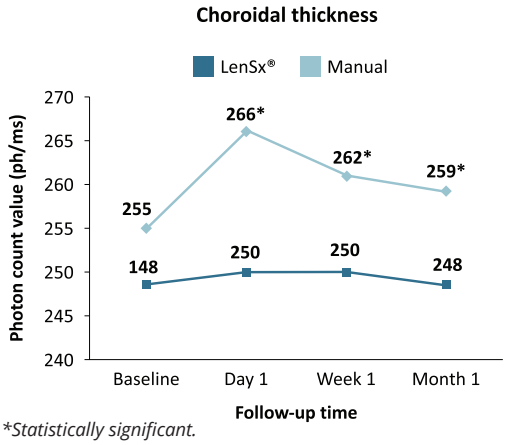
- CRT was not different at any visit (day 1, week 1, and month 1) compared with baseline retinal thickness in either the LenSx® or manual phacoemulsification groups (**Table 1**)
- In the LenSx® group, there was no significant difference between baseline CT (248.7±32.2) and postoperative CT values at day 1 (250.6±35.6), week 1 (250.7±33.9) or month 1 (248.5±33.5) (P=0.37, 0.10, and 0.59, respectively) (**Table 1, Figure 1**)
- In the manual group, significant differences were observed between baseline CT (255.5±36.2) and postoperative CT values at day 1 (266.8±43.9), week 1 (262.9±40.0) or month 1 (259.1±35.4) (P=0.003, 0.02, and 0.02, respectively) (**Table 1, Figure 1**)
- Observed power was 0.849 for CT and 0.323 for CRT; this observed power for CRT weakens the statistical power of the study
- Multiple regression analysis revealed that age, gender, spherical equivalent, axial length, anterior chamber depth, intraocular pressure, baseline CRT, and baseline CT were not predictors of significant choroidal thickening at day 1, week 1, or month 1 in the manual group

Table 1. Preoperative and postoperative values central retinal thickness (CRT) and choroidal thickness (CT) in the LenSx® and manual phacoemulsification groups.

Groups	Baseline	Day 1 (P-value)	Week 1 (P-value)	Month 1 (P-value)
LenSx®				
CRT	200.7±48.1	199.6±30.6 (0.98)	204.9±32.5 (0.58)	206.3±36.2 (0.24)
CT	248.7±32.2	250.6±35.6 (0.37)	250.7±33.9 (0.10)	248.5±33.5 (0.59)
Manual				
CRT	212.3±31.6	218.2±36.7 (0.89)	214.7±36.2 (0.42)	218.2±38.8 (0.28)
CT	255.5±36.2	266.8±43.9 (0.003*)	262.9±40.0 (0.02*)	259.1±35.4 (0.02*)

P-value demonstrates the difference between the values of CRT and CT at day 1, week 1, and month 1 compared with baseline.
**Statistically significant. Data presented as mean ± standard deviation. CRT, central retinal thickness; CT, choroidal thickness.*

Figure 1. Choroidal thickness increased significantly in the manual phacoemulsification group but did not change in the LenSx® group.



*Statistically significant.

Factors Affecting Corneal Incision Position During Femtosecond Laser-Assisted Cataract Surgery

Bala et al. *J Cataract Refract Surg.* 2017;43:1541-1548

OVERVIEW

STUDY DESIGN
Retrospective case series to compare the expected versus actual position and dimension of corneal incisions during femtosecond laser-assisted cataract surgery.

STUDY SITE(S)
Single center in Australia

PATIENTS
Sixty-one (61) eyes of 50 sequential patients

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery (FLACS)

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Expected versus actual position and dimension of corneal incisions; correlations with globe tilt, globe displacement, and biometric data

ANALYSIS AND CONCLUSIONS

Using LenSx® for FLACS, the primary incisions were close to the expected dimensions, whereas the secondary incision position was affected by eye tilt and eccentric docking.

This variation often affects the superior and inferior secondary incisions differently giving rise to a sense of inconsistency; this could potentially be improved with optical coherence tomography guidance.

STUDY RESULTS

CORNEAL INCISIONS

- The primary incision internal and external exits were within 142 µm ± 70 (SD) and 151 ± 75 µm of the planned position **(Figure 1)**
- The superior secondary incision external exit was displaced centrally (321 ± 84 µm) and the internal exit was displaced peripherally (84 ± 102 µm) **(Figure 2)**
- The inferior secondary incision external exit was displaced centrally (278 ± 142 µm) and the internal exit was displaced peripherally (190 ± 133 µm)

CORRELATION ANALYSIS

- Multivariate analysis showed that the main incision external and internal opening position did not correlate with the biometric parameters or ocular tilt or displacement (adjusted R^2=0.003; P=0.41)
- Multivariate analysis also showed that globe tilt and displaced docking of the eye were correlated with the displaced external (adjusted R^2=0.36; P<0.001) and internal (adjusted R^2=0.15; P<0.001) openings of the superior secondary incision
- Globe tilt and displaced docking of the eye were correlated with the displaced external (adjusted R^2=0.67; P<0.001) and internal (adjusted R^2=0.46; P<0.001) openings of the inferior secondary incision

Figure 1. Effect of eccentric docking and eye tilt on the position of the corneal incisions with LenSx® (light green circles represent external exit and dark blue circles represent internal exit). Positive values indicate superior displacement or tilt. The main incision is not influenced by eye tilt **(A)** or displaced docking **(B)**.

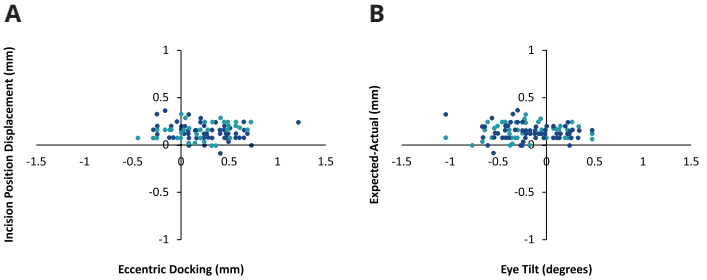
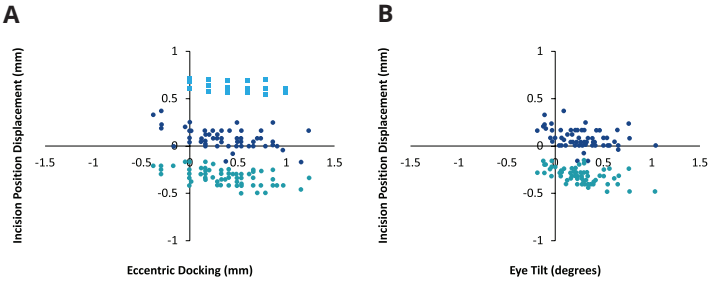


Figure 2. Effect of eccentric docking and eye tilt on the position of the corneal incisions with LenSx® (light green circles represent external exit and dark blue circles represent internal exit). Positive values indicate superior displacement or tilt. The superior incision position correlates with eye tilt **(A)** and eccentric displaced docking **(B)** Superior rotation leads to inferior displacement of the incision and the slope is similar to the slope of the change in interface contact lens thickness (blue squares).



Outcomes of Femtosecond Laser-Assisted Cataract Surgery Performed by Surgeons-In-Training

Brunin et al. ***Graefes Arch Clin Exp Ophthalmol.*** **2017; 255:805–809**

Surgical Outcomes
Surgical Complications
Visual Acuity
Refractive Outcomes

OVERVIEW

STUDY DESIGN
Retrospective study to compare intraoperative factors and post-operative outcomes of femtosecond laser-assisted cataract surgery and manual cataract surgery

STUDY SITE(S)
Single academic center in the United States

PATIENTS
One hundred and twenty-five (125) patients received surgery (femtosecond laser, n=57; manual, n=68); data were available for 53 patients (femtosecond laser, n=23; manual, n=31) by postoperative year 1

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx®
Laser (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
Intraoperative data: pupil size at the start of the case, intraoperative complications, and cumulative dissipated energy (CDE) used during phacoemulsification; postoperative data: month and year number one included corneal edema, CDVA, and manifest refraction; percentage of patients achieving a refractive prediction error (RPE) ±0.25, ±0.50, and ±1.00

ANALYSIS AND CONCLUSIONS

Femtosecond laser-assisted cataract surgery has been established to be safe in most circumstances, but its overall superiority to manual cataract surgery has not been proven.

This study confirms that femtosecond laser-assisted cataract surgery performed by resident surgeons is safe and effective and results in decreased CDE and equivalent complication rates, visual acuity, corneal edema, and refractive outcomes at 1 month and 1 year when compared to manual cataract surgery.

STUDY RESULTS

SURGICAL OUTCOMES

- No significant preoperative differences between LenSx® (n = 57) and manual (n = 68) groups
- Operative complication rates were similar in cases with sufficient data and follow-up with a higher rate of posterior capsule tear in the manual group (**Tables 1** and **2**)
- Mean CDE (percent-seconds) was lower in the LenSx® group (LenSx®: 14.5 ± 7.5; manual: 21.6 ± 11.5; P<0.01)
- CDVA (LogMAR) was comparable at 1 month postoperatively (LenSx®: 0.004 ± 0.08; manual: 0.024 ± 0.11; P=0.24) and 1 year postoperatively (LenSx®: 0.013 ± 0.06; manual: 0.032 ± 0.09; P=0.37)
- No difference in RPE at 1 month postoperatively (LenSx®: 0.38 ± 0.24 D; manual: 0.41 ± 0.49 D; P=0.66) and 1 year postoperatively (LenSx®: 0.49 ± 0.63 D; manual: 0.34 ± 0.26 D; P=0.31) (**Figures 1** and **2**)

Table 1. Operative complications: all cases.

Groups	LenSx* (n=76)	Manual (n=101)
Wound burn	1	0
Anterior capsular tear	3	3
Posterior capsular tear	0	3
Vitreous loss	0	1
IOL not in capsular bag	0	1
Total patients, n (%)	4 (5.2)	7 (7.9)

**In the LenSx group, three cases were aborted after attempts with laser.*

Table 2. Operative complication cases with complete data and follow-up

Groups	LenSx* (n=57)	Manual (n=68)
Wound burn	1	0
Anterior capsular tear	2	2
Posterior capsular tear	0	1[a]
Vitreous loss	0	1[a]
IOL not in capsular bag	0	1[a]
Total patients, n (%)	3 (5.3)	3 (4.4)

[a]Same patient.

Figure 1. Postoperative month 1 RPEs.

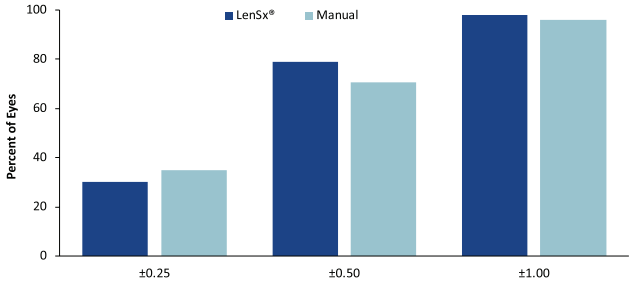
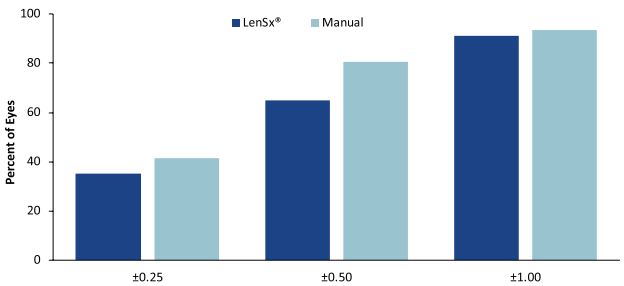


Figure 2. Postoperative year 1 RPEs.



Clinical Outcomes of Femtosecond Laser–Assisted Cataract Surgery Versus Conventional Phacoemulsification Surgery for Hard Nuclear Cataracts

Surgical Outcomes

Surgical Complications

Visual Acuity

Chen et al. *J Cataract Refract Surg.* 2017;43:486-491

OVERVIEW

STUDY DESIGN

Prospective consecutive nonrandomized comparative cohort study to compare outcomes between femtosecond laser-assisted cataract surgery and conventional phacoemulsification cataract surgery in patients with hard nuclear cataract

STUDY SITE(S)

Single center in China

PATIENTS

Ninety-five (95) eyes (47 in the femtosecond laser group; 48 in the conventional group)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification using stop-and chop-technique

SURGICAL TECHNOLOGY

LenSx® Laser (Alcon Laboratories, Inc), Stellaris® Vision Enhancement System (Bausch + Lomb)

KEY ENDPOINT(S)

Intraocular pressure, endothelial cell density (ECD), central corneal thickness (CCT), corrected distance visual acuity (CDVA), and uncorrected (UDVA)

ANALYSIS AND CONCLUSIONS

Conventional phacoemulsification to treat hard nuclear cataracts is challenging because of its association with a higher percentage of endothelial cell loss, corneal edema, and more postoperative complications.

This study demonstrated that, compared with conventional phacoemulsification, LenSx® surgery for hard nuclear cataracts conserved phacoemulsification power, provided a significant reduction in corneal endothelial damage, and led to faster visual rehabilitation.

STUDY RESULTS

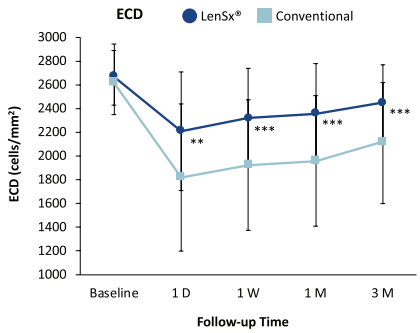
SURGICAL OUTCOMES

- Effective phacoemulsification time, absolute phaco time, and mean ultrasound power were lower in the LenSx® group (P< 0.001, P<0.001, and P<0.001, respectively)
- ECD in the conventional group was lower and the changes in endothelial cell loss was different between the 2 groups throughout the follow-up (both P<0.001); in both groups, the ECD throughout the postoperative period was significantly less than the preoperative levels (P<.001) (**Figure 1, Table 1**)
- CCT increased after surgery; postoperatively, there was significant between-group difference at 1 day (570.98 ± 51.40 µm versus 599.21 ± 59.40 µm; P=0.015) and 1 month (537.45 ± 35.96 µm versus 558.71 ± 48.82 µm; P= 0.018), returning to preoperative levels 1 month postoperatively in the LenSx® group and at 3 months in the conventional group
- Compared with the preoperative levels, the visual acuity, including the UDVA and CDVA, improved after surgery (P<0.05); moreover, there were no statistically significant differences in UDVA between the 2 groups throughout the follow-up (**Figure 2**)

Table 1. Comparison of postoperative endothelial cell loss between the LenSx® and conventional groups.

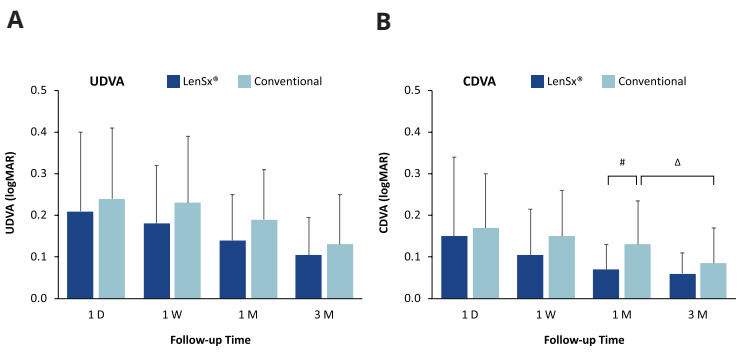
	Mean Endothelial Cell Loss, %±SD		
Examination	LenSx® Group	Conventional Group	P Value
1 day	17.18±16.28	30.81±21.80	0.001
1 week	13.10±13.13	26.44±20.79	<0.001
1 month	11.42±12.10	25.67±18.87	<0.001
3 months	7.85±8.59	19.96±16.81	<0.001

Figure 1. ECD over time.



**<0.05; **P<0.01; ***P<0.001; CCT, central corneal thickness; ECD, endothelial cell density.*

Figure 2. UDVA (**A**) and CDVA (**B**) over postoperative time.



 # P<0.05 difference between the 2 groups; ΔP<0.05 compared with final corrected distance visual acuity in the conventional group; CDVA, corrected distance visual acuity; UDVA, uncorrected distance visual acuity.

Is Laser Assisted Capsulotomy Better than Standard CCC?

Surgical Outcomes

Surgical Complications

Gavris et al. *Rom J Ophthalmol.* 2017;61:18-22

OVERVIEW

STUDY DESIGN
Prospective comparative study to compare the safety and intraoperative difficulties of femtosecond laser-assisted capsulorhexis and manual capsulorhexis for removal of white intumescent cataract

STUDY SITE(S)
Single center in Romania

PATIENTS
Twenty-eight (28) eyes of 28 patients with white intumescent cataract

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery (FLACS) or manual capsulorhexis (continuous curvilinear capsulorhexis, CCC)

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.); Utrata capsulorhexis forceps

KEY ENDPOINT(S)
Surgical success (obtaining a curvilinear, continuous, intact capsulorhexis)

ANALYSIS AND CONCLUSIONS

Results from this study confirm the safety and efficacy of both the LenSx® platform and manual capsulorhexis as surgical approaches for intumescent white cataracts.

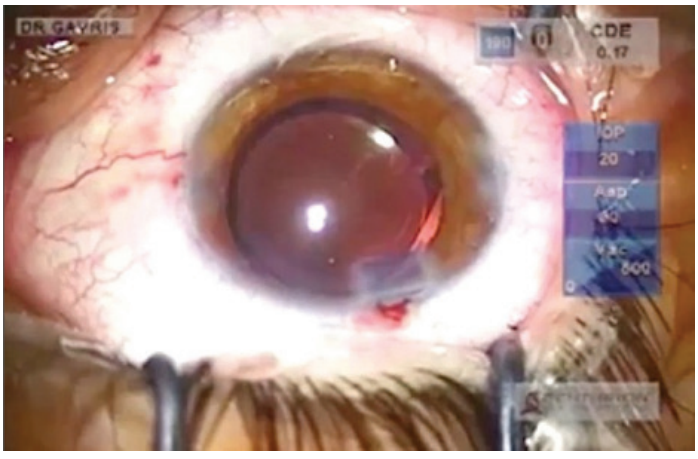
The authors suggest that the superior outcome achieved with LenSx® (the capsulorhexis was round, well centered and of the desired size) make it the preferred choice for treatment of intumescent white cataract in which the risk of capsulorhexis skidding is greater than in other types of cataract.

STUDY RESULTS

SURGICAL OUTCOMES

- In the group in which the capsulorhexis was performed with the LenSx® Laser, the capsule was completely detached in 13 cases (92.86%) (free-floating capsulotomy); in one case (7.14%) the capsule had a few bridges which detached easily, without endangering the capsulorhexis integrity
  - The size of the capsulorhexis was the desired size of 4.9 mm in all cases **(Figure 1)**
- In the group in which capsulorhexis was performed with the Utrata forceps, the capsulorhexis was complete, circular and relatively well centered in all cases, but the size varied between 4.5 and 5.5 mm
  - This approach depends on the surgeon's skill and experience and requires good local anesthesia, coloring of the anterior capsule with Trypan Blue, use of a large quantity of cohesive viscoelastic substances, and sometimes requires use of micro-incision forceps
  - The size and centering of the capsulorhexis are not always identical with intended values

Figure 1. Capsule with a size of 4.9 mm after surgery with the LenSx® Laser.



Impact of the Femtosecond Laser in Line with the Femtosecond Laser-Assisted Cataract Surgery (FLACS) on the Anterior Chamber Characteristics in Comparison to the Manual Phacoemulsification

Pahlitzsch et al. *Semin Ophthalmol.* 2017;32:456-461

OVERVIEW

STUDY DESIGN
Prospective study to assess the alterations of the anterior chamber conditions including laser flare photometry after femtosecond laser-assisted cataract surgery compared with manual phacoemulsification

STUDY SITE(S)
Single center in Germany

PATIENTS
One hundred and ten (110) eyes of 110 patients; 70 patients in the femtosecond laser group (mean age of 67.2 years) and 40 patients in the phacoemulsification group (mean age of 69.5 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Laser flare photometry, anterior chamber (AC) depth, AC volume, AC angle, lens density, pupil diameter, endothelial cell count and pachymetry immediately after surgery and one day postoperatively

ANALYSIS AND CONCLUSIONS

The results of this study demonstrated that the additive laser energy of LenSx® surgery did not cause harm to the cornea or anterior chamber.

The authors concluded that these findings did not show statistically significant superiority of LenSx® over conventional phacoemulsification, but might help to select appropriate patient cohorts for femtosecond laser-assisted cataract surgery.

STUDY RESULTS

SURGICAL COMPLICATIONS

- One day after surgery, there was a significant difference in AC depth between the LenSx® group (3.77 mm) and the phacoemulsification control group (4.05 mm) (P=0.023) (**Figure 1**)
- The AC angle was also significantly different between the LenSx® group (35.56°) and the phacoemulsification control group (37.63°) (P=0.016) one day after surgery
- No significant differences in AC volume were observed between groups (**Figure 2**)
- No significant differences were observed between groups for central and thinnest pachymetry (P=0.165, P=0.291, respectively) or endothelial cell count (P=0.979) (**Figure 3**)
- The phacoemulsification group demonstrated a nonstatistically significant difference in flare photometry (15.80 photons/ms) compared with the LenSx® group (26.62 photons/ms) (p=0.322)

Figure 1. Boxplot diagram of anterior chamber depth preoperative and one day post-surgery in the LenSx® and manual phacoemulsification groups.

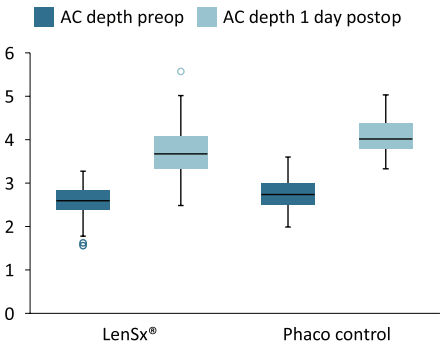


Figure 2. Boxplot diagram of anterior chamber volume preoperative and one day post-surgery in the LenSx® and manual phacoemulsification groups.

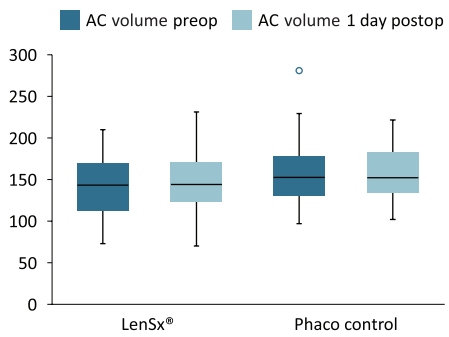
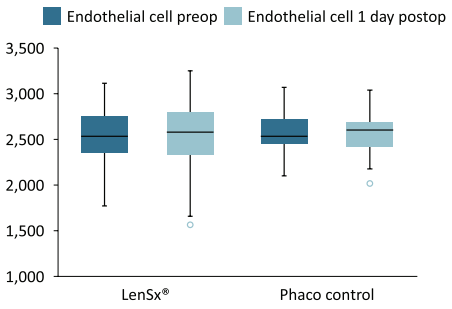


Figure 3. Boxplot diagram of the number of endothelial cells preoperative and one day post-surgery in the LenSx® and manual phacoemulsification groups.



Outcomes Study Between Femtosecond Laser-Assisted Cataract Surgery and Conventional Phacoemulsification Surgery Using an Active Fluidics System

Surgical Outcomes

Surgical Complications

Hida et al. *Clin Ophthalmol.* 2017;11:1735-1739

OVERVIEW

STUDY DESIGN
A prospective randomized comparative study to compare intraoperative parameters between femtosecond laser-assisted cataract surgery (FLACS) and conventional phacoemulsification

STUDY SITE(S)
Single center in Brazil

PATIENTS
Four hundred (400) eyes, 200 in each group (conventional surgery vs FLACS)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery (FLACS) and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, CENTURION® Vision System with Active Fluidics™ (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
Cumulative dissipated energy (CDE), torsional time (s), longitudinal time (s) (Intelligent Phaco IP), case time (s), fluid usage (s) and aspiration (ASP) time (s), as provided by the display on the user interface at the end of phacoemulsification; endothelial cell counts at 1 month.

ANALYSIS AND CONCLUSIONS

LenSx® in conjunction with the Active Fluidics™ system can reduce the ultrasound energy use during cataract surgery, despite increasing case time, fluid usage, and ASP time.

The authors suggest that the use of new technologies modifies surgical efficiency in different degrees; manual phacoemulsification performed by an experienced surgeon with good technology and appropriate fluidic settings provides similar surgical outcomes.

STUDY RESULTS

SURGICAL OUTCOMES

- There were no intraoperative complications
- The LenSx® group showed significantly less CDE and torsional time (**Figures 1 and 2**)
- Use of balanced salt solution (BSS), total case time, aspiration (ASP) time and longitudinal time (Intelligent Phaco IP) were significantly lower on the conventional group (**Figures 3 and 4**)
- Endothelial cell loss was not significantly different between groups

Figure 1. Comparison of cumulative dissipated energy between LenSx® and conventional surgery using the CENTURION® Vision System with Active Fluidics™.

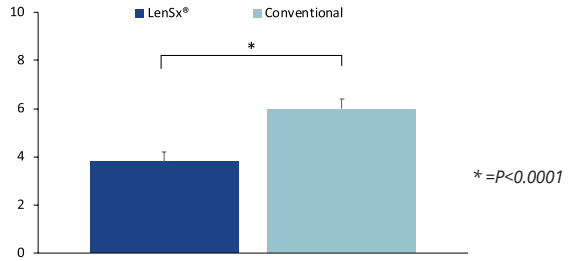


Figure 2. Comparison of torsional time (s) between LenSx® and conventional surgery using the CENTURION® Vision System with Active Fluidics™.

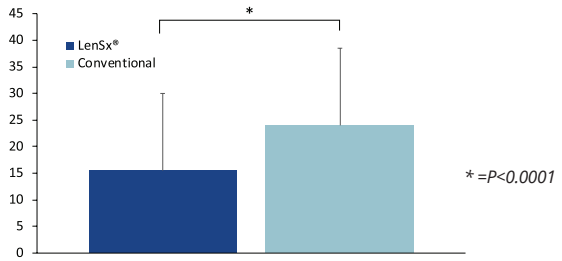


Figure 3. Comparison of phacoemulsification time (s) between LenSx® and conventional surgery using the CENTURION® Vision System with Active Fluidics™.

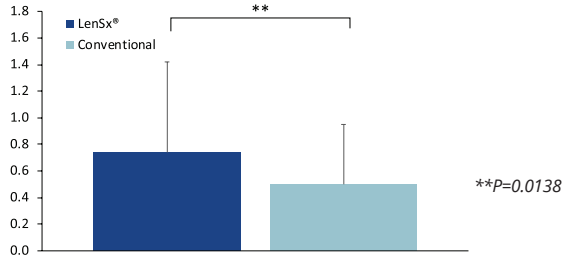
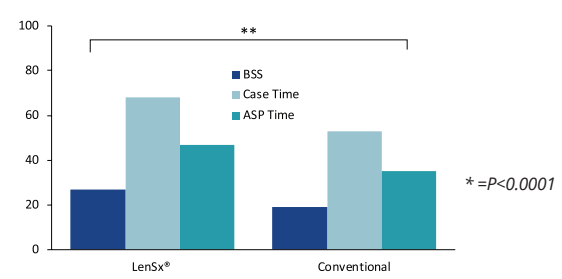


Figure 4. Comparison of fluid usage (balanced salt usage, BSS), case time (sec), and ASP time (sec) between LenSx® and conventional surgery using the CENTURION® Vision System with Active Fluidics™.



Resident Surgeon Efficiency in Femtosecond Laser-Assisted Cataract Surgery

Pittner et al. *Clin Ophthalmol.* 2017;11:291-297

OVERVIEW

STUDY DESIGN
This was a retrospective cohort study to compare resident surgeon performance efficiencies in femtosecond laser-assisted cataract surgery (FLACS) versus conventional phacoemulsification

STUDY SITE(S)
Single large Veterans Affairs center in the United States

PATIENTS
Two hundred and five (205) patients, including 159 patients receiving conventional manual phacoemulsification (mean age of 71 years) and 46 patients receiving FLACS (mean age of 74 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc); Stellaris® MICS™ (Bausch + Lomb)

KEY ENDPOINT(S)
Review of medical records for operative procedure times, total operating room times, and surgical complications; review of digital video records for quantitative interval measurements of core steps of the procedures, including completion of incisions, anterior capsulotomy, nucleus removal, cortical removal, and intraocular lens implantation

ANALYSIS AND CONCLUSIONS

In early cases, resident completion of femtosecond cataract surgery with a LenSx® Laser is generally less efficient when trainees have more experience with traditional phacoemulsification.

This study found there is a potential for longer FLACS operative times by senior residents when training programs are introducing femtosecond laser technology into residency curricula, with complications among FLACS cases occurring close to expected trainee rates for conventional phacoemulsification.

STUDY RESULTS

SURGICAL OUTCOMES

- Total room time, operation time, and corneal incision completion time were found to be significantly longer in the femtosecond laser group versus the traditional phacoemulsification group (each P<0.05) (**Table 1**)
- Mean duration for manual completion of anterior capsulotomy was shorter in the laser group (P<0.001) (**Table 1**)
- There were no statistically significant differences in the individual steps of nucleus removal, cortical removal, or intraocular lens placement (**Table 1**)
- Surgical complication rates were not significantly different between the groups

Table 1. Summary of performance time analysis of conventional phacoemulsification group and femtosecond laser pretreatment group.

	Conventional Phacoemulsification		LenSx®		Absolute difference		
Interval	M	SE	M	SE	M	SE	P Value
Total OR time	68.59	5.66	75.61	6.08	7.02	3.02	0.02*
Operative time	42.59	4.74	49.96	5.07	7.37	2.45	0.001*
Incision	3.82	0.12	4.60	0.31	0.79	0.31	0.01*
Anterior capsulotomy	3.23	0.18	1.38	0.15	1.84	0.42	<0.001*
Nucleus removal	12.54	0.48	12.73	1.05	0.19	1.15	0.87
Cortical removal	5.37	0.27	6.17	0.86	0.80	0.71	0.26
IOL placement	0.93	0.05	0.96	0.11	0.02	0.12	0.86

*Notes: All times are shown in minutes. *Statistically significant. Due to patients being nested within operating residents, significance (P value) was determined using a multivariable linear mixed-effects model controlling for patient age and allowing random intercepts for each resident surgeon.*
Abbreviations: IOL, intraocular lens; M, mean; OR, operating room; SE, standard error of the mean.

Differences in Energy Expenditure for Conventional and Femtosecond-Assisted Cataract Surgery Using 2 Different Phacoemulsification Systems

Yesilirmak et al. *J Cataract Refract Surg*. 2017;43:16-21

OVERVIEW

STUDY DESIGN
Prospective comparative nonrandomized clinical study to compare the mean cumulative dissipated energy in patients having femtosecond laser-assisted or conventional phacoemulsification cataract surgery using two different phacoemulsification platforms

STUDY SITE(S)
Single center in the United States

PATIENTS
Five hundred and seventy (570) eyes of 570 patients; mean age across 4 treatment groups 68.8 to 69.7 years

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery or conventional phacoemulsification cataract surgery with either gravity-fluidics torsional or active-fluidics torsional phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, CENTURION® Vision System (active fluidics), INFINIT® Vision System (gravity fluidics) (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Mean cumulative dissipated energy (CDE)

ANALYSIS AND CONCLUSIONS

The active-fluidics phacoemulsification platform achieved lower CDE values than the gravity-fluidics platform for conventional cataract extraction; LenSx® pretreatment with the active-fluidics platform further reduced CDE.

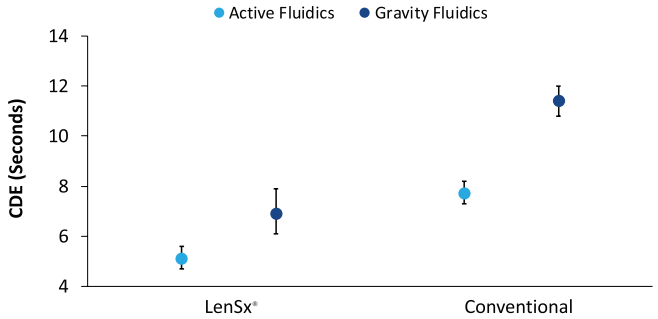
Although a reduction in CDE might help reduce postoperative recovery time, additional benefits from advances in fluidic controls and decreased operative time might provide additional corneal protection.

STUDY RESULTS

SURGICAL OUTCOMES

- Overall, the active-fluidics platform significantly reduced CDE compared with the gravity-fluidics platform during conventional phacoemulsification surgery, and CDE was further reduced in patients who had LenSx® pretreatment with the active-fluidics platform
- In LenSx® cases (145 eyes), the mean CDE (percent-seconds) was 5.18 ± 4.58 (SD) with active fluidics and 7.00 ± 6.85 with gravity fluidics **(Figure 1, Table 1)**
- In conventional cases (425 eyes), the mean CDE was 7.77 ± 6.97 with active fluidics and 11.43 ± 9.12 with gravity fluidics **(Figure 1, Table 1)**
- In both LenSx® cases and conventional cases, the CDE was lower with the active-fluidics platform than with the gravity-fluidics platform (P=0.029, LenSx® group; P<0.001 conventional group) **(Table 1)**
- The mean CDE was significantly lower in the LenSx® group than in the conventional group with both phacoemulsification platforms (P=0.0008 for the active-fluidics platform; P=0.0003 for the gravity-fluidics platform) **(Table 1)**
- There was no statistically significant difference in CDE values in any case between the two surgeons performing the procedures

Figure 1. Comparison of mean values between phacoemulsification platforms based on surgical technique.



CDE, cumulative dissipated energy

Table 1. Cumulative dissipated energy values by phacoemulsification platform in LenSx® cases and conventional cases.

	Mean ± SD		
Surgery type	Active-Fluidics Platform	Gravity-Fluidics Platform	P-value
LenSx® Laser	5.18 ± 4.58	7.00 ± 6.85	0.029
Conventional	7.77 ± 6.97	11.43 ± 9.12	<0.001
P-value	0.0008	0.0003	–

Morphologic Features and Surgically Induced Astigmatism of Femtosecond Laser Versus Manual Clear Corneal Incisions

Zhu et al. *J Cataract Refract Surg.* 2017;43:1430-1435

Surgical Outcomes

Surgical Complications

Visual Outcomes

OVERVIEW

STUDY DESIGN

Prospective randomized case series comparing the morphologic features and surgically induced astigmatism (SIA) between laser and manual clear corneal incisions (CCIs) after femtosecond laser-assisted cataract surgery

STUDY SITE(S)

Single center in China

PATIENTS

Ninety-three (93) eyes (89 patients); Laser CCI group (n=45, mean age 65.42 ± 12.72 years) and manual CCI group (n=45, mean age 65.47 ± 13.62 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery with a CCI created with the laser or manually

SURGICAL TECHNOLOGY

LenSx® Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Corrected distance visual acuity, corneal topography, and anterior segment optical coherence tomography were assessed at the 1-day, 1-week, 1-month, and 3-month follow-ups

ANALYSIS AND CONCLUSIONS

LenSx®-created CCIs for cataract surgery caused more SIA than manually created CCIs.

The authors suggested that this could have resulted from inaccurate or uncertain corneal incision positioning of the femtosecond machine and recommended manual creation of CCIs in femtosecond laser-assisted cataract surgery.

STUDY RESULTS

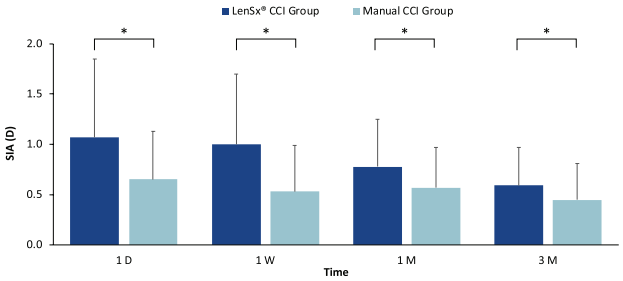
SURGICALLY INDUCED ASTIGMATISM

- SIA was significantly lower in the manual CCI group than the LenSx® CCI group at all visits (P<0.05); however, there was no difference in the axis of the SIA between the 2 groups at any visit (P>0.05) (**Figure 1**)

CLEAR CORNEAL INCISIONS

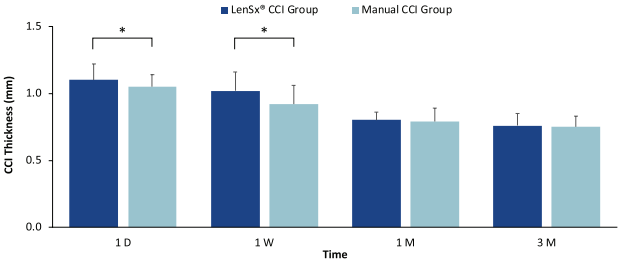
- At the 1-day and 1-week follow-ups, the mean CCI thickness was significantly smaller in the manual CCI group (P<0.05) (**Figure 2**)

Figure 1. Comparison of changes in SIA between the 2 groups over time.



**statistically significant difference; CCI, clear corneal incision; SIA, surgically induced astigmatism.*

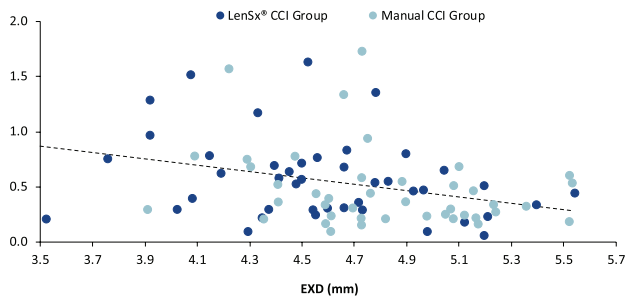
Figure 2. Comparison of changes in CCI thickness between the 2 groups over time.



**statistically significant difference; CCI, clear corneal incision.*

- No differences were found in corneal thickness at the incision site between the 2 groups 1 and 3 month post-surgery
- In the LenSx® CCI group, the perpendicular linear distance between the external wound opening and the corneal vertex central line was statistically shorter than in the manual CCI group (P<0.05) (**Figure 3**)
- At 3 months, the SIA was correlated with the perpendicular linear distance with a Pearson correlation coefficient of -0.341 (P=0.001)

Figure 3. Correlation between SIA 3 months after surgery and the perpendicular linear distance between the external wound opening and the corneal vertex central line. The diagonal line represents the regression line.



CCI, clear corneal incision; EXD, perpendicular linear distance between the external wound opening and the corneal vertex central line; SIA, surgically induced astigmatism.

Clinical and Ex Vivo Laboratory Comparison of the Self-Sealing Properties and Dimensional Stability Between the Femtosecond Laser and Manual Clear Corneal Incisions

Surgical Outcomes

Ex Vivo Experimental Outcomes

Kojima et al. *Acta Ophthalmol.* 2018;96:e510-e514

OVERVIEW

STUDY DESIGN

Prospective clinical and ex vivo experimental studies to compare self-sealing features and dimensional stability between femtosecond laser and manual knife corneal incisions

STUDY SITE(S)

Single center in Japan

PATIENTS

Fifty seven (57) eyes from 57 patients: 29 in the LenSx group (mean age of 63.7 years), 28 in the knife incision group (mean age of 67.3 years); 8 fresh porcine eyes.

SURGICAL METHODOLOGY

Corneal incisions made using femtosecond laser-assisted cataract surgery or conventional (manual knife) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser, CENTURION® Vision System (Alcon Laboratories, Inc.); 2.5-mm-wide slit knife (Beaver Visitec)

KEY ENDPOINT(S)

Self-sealing properties of the incision based on surgery scores; determination of wound leakage; observation of corneal incision surface by scanning electron microscopy (SEM) and quantification of surface smoothness using the angular second moment

ANALYSIS AND CONCLUSIONS

This study found that higher femtosecond laser energy tended to widen a clear corneal incision when mechanical stress was applied, and the histological differences at the inner tunnel surface may cause differences in wound stability of the corneal incision.

The investigators concluded that these results reveal an issue with femtosecond laser corneal incisions, and they recommended that a lower energy setting be used for femtosecond laser corneal incisions with higher self-sealing properties.

STUDY RESULTS

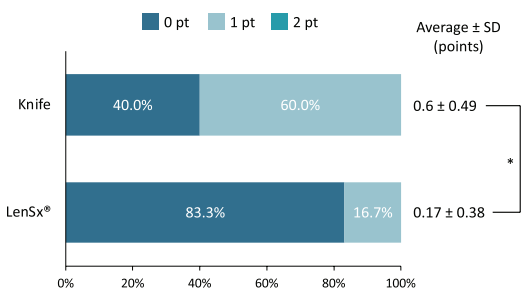
SURGICAL OUTCOMES

- Scoring of self-sealing properties was as follows: a score of 2 was given when hydration was not needed; 1 when hydration at a portion of the corneal wound area was needed; 0 when hydration of the total wound area was necessary
- In the knife group, 40% and 60% of patients had scores of 0 and 1 point, respectively (**Figure 1**); in the LenSx® group, 83.3% and 16.7% had scores of 0 and 1 point, respectively
- The mean self-sealing score in the LenSx® group (0.17 ± 0.38 points) was significantly lower than that in the knife group (0.60 ± 0.49 points; P=0.0012)
- The angular second moment in the knife group (0.00032 ± 0.00010) was significantly higher than that of the LenSx® (6 µJ, 0.00014 ± 0.00052; 9 µJ, 0.00009 ± 0.00001) group (knife versus LenSx® [6 µJ], P=0.03; knife versus LenSx® [9 µJ], P<0.001)
- Angular second moment in the LenSx® group with 3 µJ energy (0.00026 ± 0.00073) was significantly higher than that of the 9-µJ LenSx® group (P<0.0001)

EXPERIMENTAL OUTCOMES

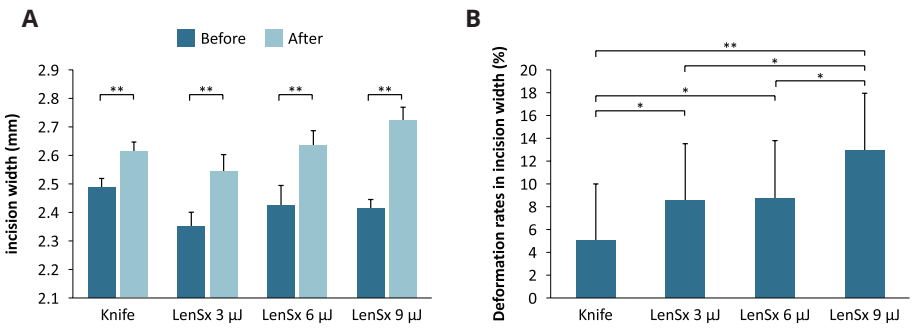
- In both the knife and LenSx® groups, a significant increase in the width of the wound was confirmed (**Figure 2**; knife, P=0.0001; LenSx® [3 µJ], P< 0.0001; LenSx® [6 µJ], P<0.0001; LenSx® [9 µJ], P<0.0001)
- Deformation rates during the stress test in the knife group was significantly lower than those in the LenSx® group (knife versus LenSx® [3 µJ], P<0.0001; LenSx® [6 µJ], P<0.0001; LenSx® [9 µJ], P<0.0001)
- Deformation rates during the stress test in the knife group was significantly lower than those in the LenSx® group (knife versus LenSx® [3 µJ], p = 0.044; knife versus LenSx® [6 µJ], P=0.026; knife versus LenSx® [9 µJ], P<0.0001)
- Moreover, deformation rates in the 9 µJ LenSx® group was significantly higher than that in the 3 and 6 µJ LenSx® groups (9 µJ versus 3 µJ, P=0.0072; 9 µJ versus 6 µJ, P=0.0013)

Figure 1. Distribution of self-sealing features in a corneal incision after cataract surgery.



*SD, standard deviation. * represents P<0.05.*

Figure 2. Changes in the width of the incision after the wound stress test (**A**) and deformation rate due to the wound stress test (**B**).



** and ** represent P<0.05 and P<0.001, respectively.*

Refractive Outcomes After Limbal Relaxing Incisions or Femtosecond Laser Arcuate Keratotomy to Manage Corneal Astigmatism at the Time of Cataract Surgery

Roberts et al. *J Cataract Refract Surg*. 2018;44:955-963*

OVERVIEW

STUDY DESIGN

Randomized case-controlled trial to compare the results of manual limbal relaxing incisions during conventional phacoemulsification surgery with femtosecond laser arcuate keratotomies during femtosecond laser-assisted cataract surgery to manage corneal astigmatism

STUDY SITE(S)

Single center in the UK

PATIENTS

Ones hundred-four (104) eyes of 104 patients; (51) limbal relaxing incisions (mean age of 72.5 years), and 53 femtosecond arcuate keratotomies (mean age of 69.7 years)

SURGICAL METHODOLOGY

Manual limbal relaxing incisions (LRIs) or femtosecond laser arcuate keratotomy

SURGICAL TECHNOLOGY

LenSx® Laser, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Visual acuity, postoperative refraction, and corneal topography recorded 4 weeks postoperatively; vector analysis using the Alpins method

ANALYSIS AND CONCLUSIONS

The LenSx® arcuate keratotomy group achieved a higher correction index and a smaller difference vector, and showed less postoperative cylinder than LRI patients.

The investigators concluded that LenSx® arcuate keratotomies might offer more efficacious and accurate correction of corneal cylinder than LRIs.

*This study was supported by an IIT grant from Alcon, Inc.

STUDY RESULTS

SURGICAL OUTCOMES

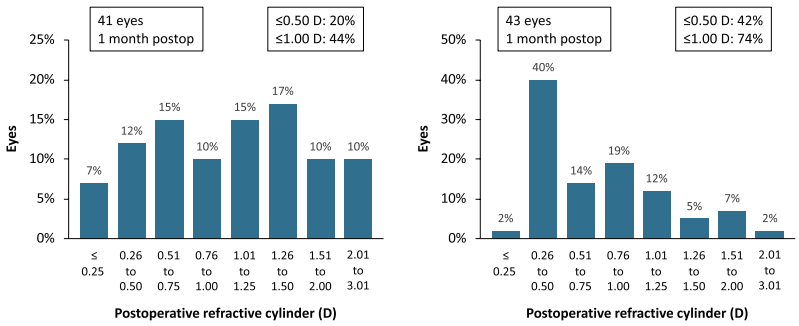
- The mean target induced astigmatism was 1.50 D for the LRI group and 1.38 D for the LenSx® group, with 1.02 D and 1.23 D surgically-induced astigmatism (P=0.21), resulting in the LenSx® arcuate keratotomy group having a smaller difference vector (1.17 D versus 0.89 D; P=0.02) indicating better correction and a greater correction index (0.48 versus 0.73; P=0.02; **Table 1**)
- Forty-four percent of patients in the LenSx® arcuate keratotomy group and 20% in the LRI group attained a postoperative cylinder of less than 0.50 D (p = 0.01) and 18 patients (44%) versus 32 patients (74%) had less than 1.00 D of cylinder (P=0.003; **Figure 1**)
- The mean corneal astigmatism was reduced from 1.38 ± 0.40 D to 0.89 ± 0.54 D in the LenSx® arcuate keratotomy group and from 1.50 ±0.46 D to1.17 ± 0.69 D in the LRI group (P=0.02); postoperative refractive cylinder was 0.90 ± 0.50 D and 1.18 ± 0.90 D, respectively (P=0.05)
- Postoperatively, no patient in the LRI group had complications; 2 patients in the LenSx® arcuate keratotomy group had cystoid macular edema and 1 had a steroid response leading to an intraocular pressure of 30 mm Hg at 4 weeks

Table 1. Vector analysis of postoperative results.

Parameter	LRI		LenSx® AK		P Value
	Mean	SD	Mean	SD	
TIA vector (D) Arithmetic mean Summated vector mean	1.50 0.31 x 160	0.46	1.38 0.21 x 174	0.40	0.16
SIA vector (D) Arithmetic mean Summated vector mean	1.02 0.07 x 161	0.91	1.23 0.16 x 93	0.77	0.21
Correction Index Geometric mean	0.48	0.57	0.73	0.49	0.02
Difference vector (D) Arithmetic mean Summated vector mean	1.17 0.25 x 160	0.69	0.89 0.37 x 178	0.54	0.02
Index of success Geometric mean	0.81	0.49	0.65	0.4	0.07
Angle of error (degrees) Arithmetic mean Absolute mean	-3.35 22.10	29.90 20.19	2.35 17.99	25.95 18.69	0.30 0.28

LenSx® AK, LenSx® arcuate keratotomy; LRI, limbal relaxing incision; SIA, surgically induced astigmatism; TIA, target induced astigmatism.

Figure 1. Preoperative and postoperative refractive astigmatism of LRIs (left) and LenSx® arcuate keratotomies right).



LRIs, limbal relaxing incisions.

Effects of Femtosecond Laser-Assisted Cataract Surgery on Dry Eye

Shao et al. *Exp Ther Med.* 2018;16:5073-5078

OVERVIEW

STUDY DESIGN

Randomized study to investigate the effect of femtosecond laser-assisted cataract surgery on tear film and ocular surface function (dry eye) compared with conventional coaxial micro-incision phacoemulsification.

STUDY SITE(S)

Single center in China

PATIENTS

Three hundred eyes: 150 eyes of 123 femtosecond laser-assisted cataract surgery patients (mean age of 65.7 years); 150 eyes of 110 conventional coaxial micro-incision phacoemulsification patients (mean age of 69.0 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Ocular surface disease index (OSDI), breakup time (BUT), tear meniscus height (TMH), Schirmer's I test (SIt) and corneal fluorescein staining (CFS) scores; symptoms such as dryness, foreign body sensation and burning sensation

ANALYSIS AND CONCLUSIONS

Both LenSx® and conventional phacoemulsification can reduce the tear film stability of patients in the short term, thus affecting the ocular surface function with statistically significant differences only in the early stage.

The effects of LenSx® on corneal fluorescein staining and dry eye symptoms are greater than those of conventional phacoemulsification.

STUDY RESULTS

SURGICAL OUTCOMES

- Compared with preoperative levels, OSDI in both groups was significantly higher at day 1 and week 1 postoperatively (P<0.05); the main symptom was foreign body sensation (**Table 1**)
- There was a statistically significant difference in OSDI in the LenSx® group at 1 month compared with preoperative levels (P=0.011), but no statistically significant difference in the phacoemulsification group; there were no statistically significant differences in OSDI in either group after 3 months
- Compared with the phacoemulsification group, OSDI in the LenSx® group was significantly higher at day 1 and week 1 postoperatively (P<0.05); foreign body sensation and discomfort were more severe than in the phacoemulsification group, with no statistically significant differences between groups at 1 month and 3 months
- SIt values in both groups were higher at week 1 postoperatively, increased at 1 through 3 months, and returned to preoperative levels by month 3; there was no statistically significant difference in SIt between the groups
- CFS scores in both groups were significantly higher compared with preoperative levels (P<0.05; **Table 2**); CFS scores were highest at day 1 postoperatively, gradually decreased and returned to preoperative levels by 3 months. CFS scores in the LenSx® group were significantly higher than those in the phacoemulsification group at day 1, week 1 and month 1 (P=0.008, 0.017 and 0.046, respectively)
- The first and average BUT in both groups at week 1 postoperatively were significantly shortened compared with preoperative levels (P<0.05), indicating that the stability of the tear film had decreased
- BUT returned to preoperative levels by month 3 (with no statistically significant differences at 1 and 3 months compared with preoperative levels); first and average BUT was not statistically significant between groups
- TMH in both groups was slightly higher at day 1 postoperatively, significantly lower at week 1 (P<0.05), and returned to preoperative levels at months 1 and 3; there was no statistically significant difference in TMH between the groups

Table 1. OSDI before and after cataract surgery in the operated eyes of the study patients.

Time	LenSx®	Phaco group	P Value
Baseline	0.45 ± 0.23	0.47 ± 0.39	0.965
Post-operative 1 day	5.34 ± 0.49	4.04 ± 0.33	0.028
Post-operative 1 week	4.99 ± 0.53	3.47 ± 0.55	0.048
Post-operative 1 month	2.23 ± 0.66	1.83 ± 0.71	0.680
Post-operative 3 months	0.59 ± 0.30	0.51 ± 0.39	0.394

OSDI, ocular surface disease index; phaco, phacoemulsification.

Table 2. CFS scores before and after cataract surgery in the operated eyes of the study patients.

Time	LenSx®	Phaco group	P Value
Baseline	0.46 ± 0.20	0.38 ± 0.22	0.788
Post-operative 1 day	2.34 ± 0.31	1.22 ± 0.28	0.008
Post-operative 1 week	1.88 ± 0.29	1.02 ± 0.21	0.017
Post-operative 1 month	0.97 ± 0.20	0.48 ± 0.14	0.046
Post-operative 3 months	0.51 ± 0.39	0.46 ± 0.35	0.775

CFS, corneal fluorescein staining; phaco, phacoemulsification.

Femtosecond Laser-Assisted Cataract Surgery in Fuchs Endothelial Corneal Dystrophy: Long-Term Outcomes

Fan et al. *J Cataract Refract Surg.* 2018;44:864-870

OVERVIEW

STUDY DESIGN
Prospective case series used to compare the corneal endothelial cell loss and central corneal thickness (CCT) after conventional phacoemulsification surgery or femtosecond laser-assisted cataract surgery in patients with Fuchs endothelial corneal dystrophy and senile cataract

STUDY SITE(S)
Single center in China

PATIENTS
Thirty-one (31) eyes

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery or conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx®
Laser (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
The endothelial cell density (ECD), rate of ECD loss, cumulative dissipated energy (CDE), and CCT 3 days and 1, 3, 6, and 12 months postoperatively

ANALYSIS AND CONCLUSIONS

For eyes with Fuchs endothelial corneal dystrophy and cataract, the CCT 12 months after surgery remained thicker than the preoperative thickness; the femtosecond group (LenSx®), with a lower CDE, tended to have a thinner CCT and less endothelial cell loss than the phacoemulsification group.

The authors suggest that although femtosecond laser–assisted cataract surgery alone in cases of mild or moderate Fuchs endothelial corneal dystrophy with a transparent central cornea is a challenge, it provides better visual rehabilitation and fewer complications than waiting and then performing corneal transplantation combined with cataract surgery.

STUDY RESULTS

SURGICAL OUTCOMES

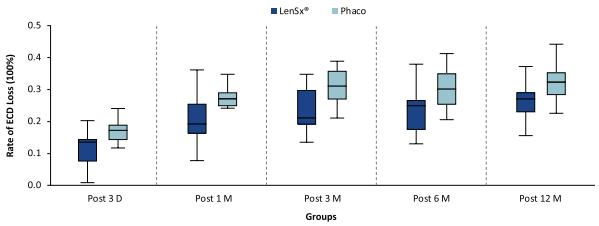
- The mean CDE was significantly less in the LenSx® group than in the phacoemulsification group (P=0.008) (**Table 1**)
- The preoperative and postoperative ECDs were similar in the 2 groups (P>0.05)
- The rate of ECD loss tended to be higher in the phacoemulsification group from 1 to 12 months postoperatively (P>0.05) (**Figure 1**)
- The postoperative CCT was significantly thicker in the phacoemulsification group than in the femtosecond group at 1 month (P Z .029), 3 months (P Z .032), and 6 months (P Z .039)In both groups, the postoperative CCT at all follow-up visits were greater than the preoperative CCT (all P<0.01) (**Figure 2**)
- No bullous keratopathy or other intraoperative complications occurred in either group during the 12- month follow-up

Table 1. Patient demographics and preoperative data.

Parameter	Group		P Value
	LenSx®	Phaco	
Eyes, n	15	16	--
Mean age, y	66.1 ± 9.2	63.9 ± 12.5	0.585*
Sex, n			0.787†
Male	3	2	
Female	7	6	
Mean cataract grade, LOCS III			
NO	3.6 ± 1.1	3.8 ± 1.1	0.589*
NC	3.9 ± 0.8	3.7 ± 1.1	0.623*
Mean CDVA, logMAR	0.61 ± 0.45	0.71 ± 0.38	0.480*
Mean CCT, µm	548.7 ± 30.1	546.0 ± 31.7	0.812*
Mean ECD, cells/mm²	2071 ± 536	2080 ± 585	0.965*
Mean CDE, %-sec	4.50 ± 2.43	7.17 ± 2.80	0.008*

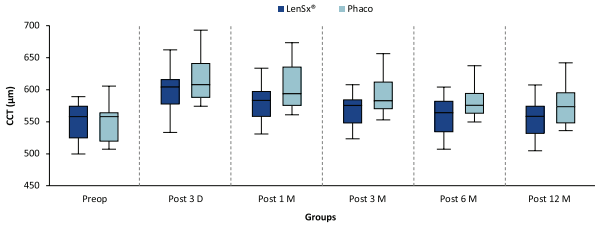
Means ± SD.
CCT, central corneal thickness; CDE, cumulative dissipated energy; CDVA, corrected distance visual acuity; ECD, endothelial cell density; LOCS III, Lens Opacities Classification System III; logMAR, logarithm of the minimum angle of resolution; NC, nuclear color; NO, nuclear opalescence.
**Independent t test. †Chi-square test.*

Figure 1. Rate of ECD loss over time by group.



ECD, endothelial cell density

Figure 2. Central corneal thickness over time by group.



CCT, central corneal thickness

Evaluation of a Multifunctional Femtosecond Laser for the Creation of Laser In Situ Keratomileusis Flaps

Slade et al. *J Cataract Refract Surg.* 2018;44:280-286*

Surgical Outcomes
Surgical Complications
Visual Outcomes
Refractive Outcomes

OVERVIEW

STUDY DESIGN
Prospective case series pilot study to characterize the performance of a multifunctional femtosecond laser system (LenSx®) for the creation of laser in situ keratomileusis (LASIK) flaps

STUDY SITE(S)
Two surgical centers in the United States

PATIENTS
Fifty-eight (58) eyes of 30 patients

SURGICAL METHODOLOGY
Femtosecond laser-initiated LASIK surgery

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Central flap thickness accuracy and precision; flap dissection quality, stromal bed quality, and amount of opaque bubble layer formation during surgery; visual acuity and refractive outcomes evaluated at 1 and 3 months postoperatively

ANALYSIS AND CONCLUSIONS

The LenSx® platform created flaps that were accurate, precise, uniform, and easy to lift; the flaps had a very smooth stromal bed with minimum opaque bubble layer.

The authors noted that the expanded capability to include cornea and refractive applications in addition to cataract procedures with LenSx® could facilitate patient access within a single clinic and create economic value.

*This study was financially supported by Alcon.

STUDY RESULTS

SURGICAL OUTCOMES
- After LenSx® surgery, flap thickness accuracy was 3.3 µm ± 3.8 (SD) at 1 month postoperatively and 1.3 µm ± 2.6 at 3 months postoperatively
- A total of 78.3% of flaps were lifted with no resistance and 16.7% were lifted with minimal resistance using a blunt instrument
- All stromal beds (100%) were determined by investigators to have a very smooth surface (grade 5 on a 0 to 5 scale)
- No opaque bubble layer was observed in 73.3% of eyes; 26.7% of eyes showed an opaque bubble layer occurring on less than 24% of the stromal bed surface **(Figure 1)**

VISUAL ACUITY AND REFRACTIVE OUTCOMES
- At 3 months postoperatively, most eyes (84.5%) had an uncorrected distance visual acuity of 20/20 and 98.3% had a corrected distance visual acuity of 20/20 **(Figure 2)**
- At 3 months postoperatively, the prediction refraction error was 0.5 D or less in 91.4% of eyes and 1.0 D or less in all 58 eyes

SURGICAL COMPLICATIONS
- The most common ocular adverse event was punctate keratitis (11.7%)
- No adverse event (AE) or serious AE related to LenSx® surgery was reported; the one serious AE that did occur was flap microstriae of mild severity, which resolved spontaneously by 2 days postoperatively

Figure 1. Presence and severity of the opaque bubble layer graded by the investigator during LenSx® surgery (grade 0 = no opaque bubble layer; grade 1 = between 1% and 24% of stromal bed area; grade 2 = between 25% and 49% of stromal bed area; grade 3 = between 50% and 74% of stromal bed area; grade 4 = between 75% and 99% of stromal bed area; grade 5 = 100% of stromal bed area).

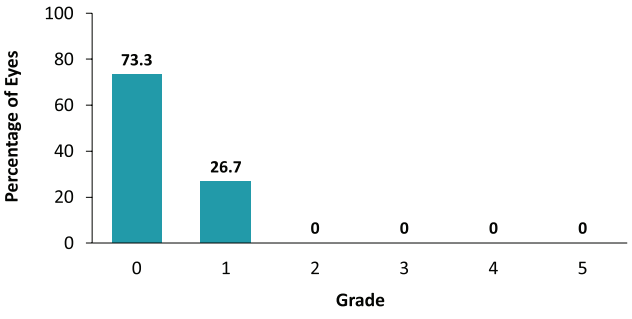
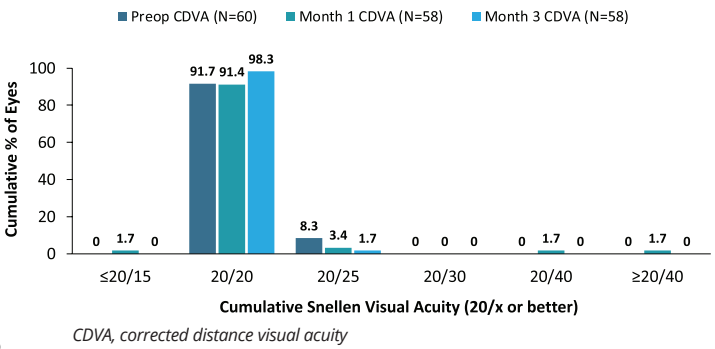


Figure 2. Corrected distance visual acuity (Snellen) at baseline and at 1 month and 3 months postoperatively; patients were manually refracted to their best correction before testing.



CDVA, corrected distance visual acuity

Human Lens Epithelial Cell Apoptosis and Epithelial to Mesenchymal Transition in Femtosecond Laser-Assisted Cataract Surgery

Surgical Outcomes

Histological Outcome

Sun et al. *Int J Ophthalmol.* 2018;11:401-407

OVERVIEW

STUDY DESIGN

Experimental randomized study to evaluate human lens epithelium cell apoptosis and epithelial to mesenchymal transition (EMT) induced by femtosecond laser with LenSx® or LENSAR® surgery compared with manual cataract surgery by phacoemulsification

STUDY SITE(S)

Single center in China

PATIENTS

Sixty (60) cataract patients divided evenly for LenSx® (mean age of 61.3 years), LENSAR® (mean age of 59.9 years) or manual phacoemulsification (mean age of 59.8 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser (Alcon Laboratories, Inc.); LENSAR® Laser System (LENSAR Inc.)

KEY ENDPOINT(S)

Hematoxylin-eosine (HE) staining, transferase deoxy-UTP-nick end labeling (TUNEL) fluorescein analysis (immunofluorescence staining), immunohistochemistry assay (E-cadherin and N-cadherin antibodies), and real-time quantitative polymerase chain reaction (PCR) for ALPHA-SMA, FSP-1, and vimentin were performed to observe human lens epithelium cell (LEC) changes

ANALYSIS AND CONCLUSIONS

Femtosecond laser may affect the apoptosis and EMT of lens epithelium cells which are under the peeled central lens capsule.

In this study, the increased apoptosis rates and decreased EMT of lens epithelium cell could contribute to compromised LEC migration and reduced incidence of posterior capsular opacification in the two femtosecond laser-assisted cataract surgery groups.

STUDY RESULTS

SURGICAL OUTCOMES

- All the surgical treatments were uneventful and a complete anterior lens capsule removal was possible in all groups
- In the LenSx® group, the overall time required of capsulotomy and lens pre-fragmentation was 29.91±5.68s; the energy was 6 μJ in capsulorrhexis and 12 μJ in lens fragmentation
- In the LENSAR® group, the overall time required of capsulotomy and lens pre-fragmentation was 12.54±2.19s; the energy was 7 μJ in capsulorrhexis and 12 μJ in lens fragmentation

HISTOLOGICAL OUTCOMES

- By staining of lens anterior capsule, the capsule cutting edge showed irregularity and roughness in the LenSx® and LENSAR® groups and a smooth edge in the manual group (**Figure 1**)
- Cell distribution near the demarcation line of the anterior capsule seemed to be the same in 3 groups under lower magnifications (**Figure 1A, 1E, 1I**), but irregularities of the cell configuration with partly swollen and destroyed nuclei were observed in the LenSx® and LENSAR® groups under 1000× magnification (**Figure 1B, 1F, 1J**)
- Lens epithelium cell number significantly decreased in the LenSx® group (16.98 ± 3.78) and LENSAR® group (15.07 ± 5.74) compared with the manual group (27.46 ± 8.83) (**Figures 1D, 1H , 1L**; P<0.05)
- The lens anterior capsule edge in the LENSAR® group was more irregular than in the LenSx® group (**Figure 1E, 1I**), and the exfoliated cells in LenSx® group had a distance of approximately 3-4 LECs rows, while only 1-2 LECs rows distance could be found in the LENSAR® group (**Figure 1H, 1L**)
- In the apoptosis analysis by TUNEL assay, apoptotic cells were rarely found at central area and randomly found at peripheral region (**Figure 2A-2D**) in the manual group; in the LenSx® and LENSAR® groups, apoptotic cells were found at every region counted with no difference between central and peripheral regions (**Figure 2E-2L**) and no marked difference between groups
- The apoptosis cell rate was 88.43% ± 14.5% in the LenSx® group, 84.75% ± 1 8.9% in the LENSAR® group and 19.02% ± 21.9% in the manual group; the difference between the femtosecond laser groups and the manual group was statistically significant (P<0.05)
- The lens epithelium cell apoptosis rate in the LenSx® and LENSAR® groups correlated with femtosecond laser duration according to Pearson correlation analysis (n=60, r=0.815)
- Decreased N-cadherin expression, alpha-SMA and FSP-1 level in the femtosecond laser groups demonstrated inhibition of cell EMT

Figure 1. HE staining of lens anterior capsule in the manual group (**A-D**), LenSx® group (**E-H**), and LENSAR® group (**I-L**)

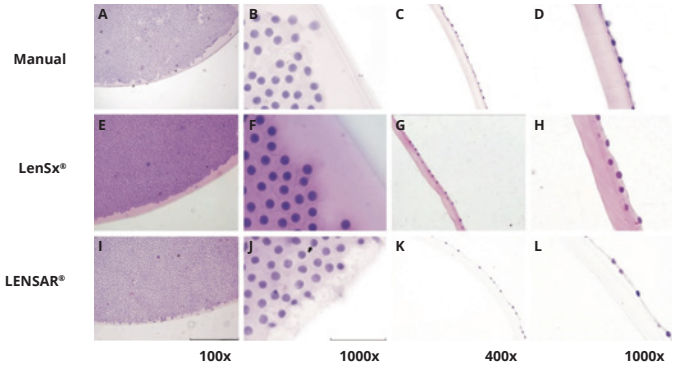
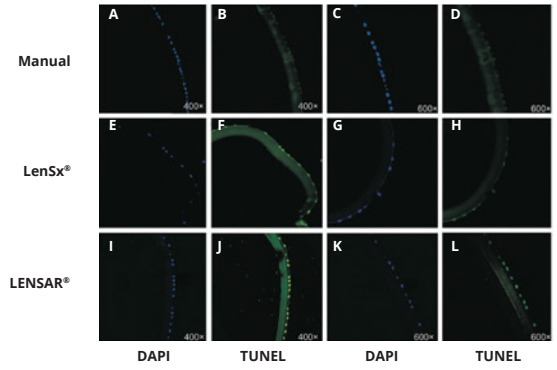


Figure 2. Apoptosis analysis by TUNEL staining.



Impact of Clear Corneal Incision Morphology on Incision-Site Descemet Membrane Detachment in Conventional and Femtosecond Laser-Assisted Phacoemulsification

Titiyal et al. *Curr Eye Res.* 2018;43:293-299

OVERVIEW

STUDY DESIGN
Nonrandomized prospective comparative study to assess intraoperative morphology of clear corneal incisions (CCI) and its impact on incision-site descemet membrane detachment (DMD) in conventional phacoemulsification and femtosecond laser-assisted cataract surgery

STUDY SITE(S)
Single center in India

PATIENTS
One hundred and twenty-nine (129) eyes of 129 patients conventional co-axial phacoemulsification (n = 77, mean age of 60.5 years) or femtosecond laser-assisted cataract surgery (n = 52, mean age of 59.5 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, CENTURION® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Incision architecture and incision-site DMD assessed using microscope-integrated intraoperative optical coherence tomography (iOCT) and anterior segment intraoperative optical coherence tomography on postoperative day 1 and 30; visual acuity was assessed on 1 and 30

ANALYSIS AND CONCLUSIONS

Ragged slit (versus smooth slide) morphology of the proximal opening of the CCI is the most important predictive factor for incision-site DMD; maximum incidence of incision site DMD was observed during the step of final stromal hydration and can be easily assessed by iOCT during the operation.

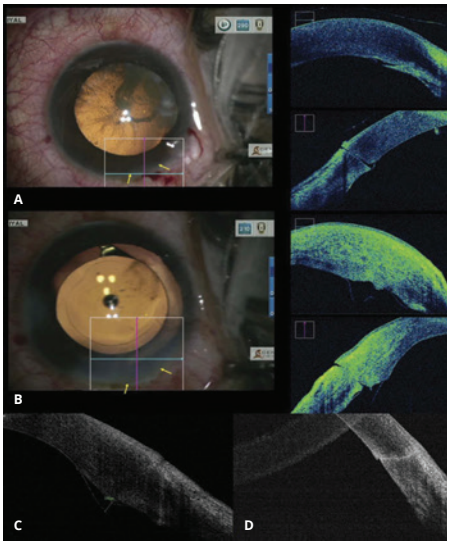
LenSx® surgery creates biplanar CCI with superior apposition and a lesser incidence of incision-site DMD than keratome-assisted CCI.

STUDY RESULTS

SURGICAL OUTCOMES

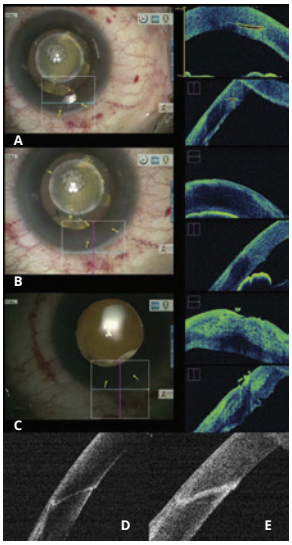
- Smooth slit (SS) or ragged slit (RS) morphology of the proximal opening of CCI was observed immediately after creation [conventional phacoemulsification: 68.8% SS, 31.2% RS; LenSx®: 86.5% SS, 13.5% RS]
- **Figure 1** is an example of RS morphology after conventional phacoemulsification and **Figure 2** is an example of SS morphology after surgery with LenSx®
- Incision-site DMD was observed in 87.1% cases with RS and 16.3% cases with SS morphology (P<0.001)
- Incision-site DMD was more frequent in the conventional phacoemulsification group (38/77) than in the LenSx® group (5/52) (P<0.001) and most commonly observed during the step of stromal hydration (83.7%)
- Incision-site DMD was self-resolving and did not persist in any group at 1 month
- Visual acuity was comparable in both groups on postoperative days 1 and 30; logMAR UDVA was 0.071 ± 0.097 in group I and 0.083 ± 0.104 in group II (p = 0.53), logMAR CDVA was 0.008 ± 0.039 in group I and 0.004 ± 0.027 in group II (p = 0.53)

Figure 1. CCI with RS morphology with conventional phacoemulsification.



ASCOT, Anterior segment optical coherence tomography; CCI, clear corneal incision; DMD, descemet membrane detachment; iOCT, microscope-integrated intraoperative optical coherence tomography; RS, ragged slit
*(**A**) RS morphology with localized descemet membrane disturbance observed on iOCT immediately after creation of CCI; (**B**) Localized incision-site DMD observed on iOCT after stromal hydration; (**C**) Postoperative day 1 ASOCT showing incision-site DMD; (**D**) Postoperative day 30 ASOCT showing well-apposed CCI without DMD. Arrows indicate width of CCI.*

Figure 2. CCI with SS morphology with LenSx®.



ASCOT, Anterior segment optical coherence tomography; CCI, clear corneal incision; FLACS, femtosecond laser-assisted cataract surgery; iOCT, microscope-integrated intraoperative optical coherence tomography; SS, smooth slit.
*(**A**) FLACS corneal incision with biplanar architecture as seen on iOCT; (**B**) SS morphology of CCI after opening it with femtosecond flap lifter; (**C**) Well-apposed CCI observed on iOCT after stromal hydration; (**D**) Postoperative day 1 ASOCT showing well-apposed biplanar CCI; (**E**) Postoperative day 30 ASOCT showing well-apposed biplanar CCI. Arrows indicate width of CCI.*

Scanning Electron Microscopy Analysis of the Anterior Capsulotomy Edge: A Comparative Study Between Femtosecond Laser-Assisted Capsulotomy and Manual Capsulorhexis

Tognetto et al. *J Ophthalmol.* 2018;2018:8620150

OVERVIEW

STUDY DESIGN

Experimental comparative study to compare the capsule edges ultrastructure obtained by two femtosecond laser-assisted cataract surgery platforms and manual continuous curvilinear capsulorhexis (CCC) using scanning electron microscopy (SEM).

STUDY SITE(S)

Single center in Italy

PATIENTS

One hundred and fifty (150) anterior capsule specimens of 150 eyes with senile cataract: manual CCC group (50 eyes), CATALYS® group (50 eyes), LenSx® group (50 eyes)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser (Alcon Laboratories, Inc.); CATALYS® Precision Laser System (Johnson & Johnson Vision)

KEY ENDPOINT(S)

All samples imaged by SEM for evaluation and comparison of the regularity of the cut surface and thickness of the capsule edge

ANALYSIS AND CONCLUSIONS

Despite the presence of slight cut surface irregularities, both femtosecond laser capsulotomies showed better geometry and circularity than the manual ones.

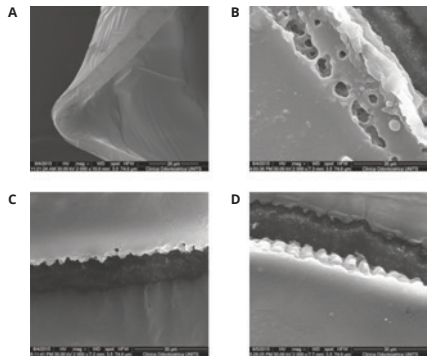
Capsulotomy specimens obtained using both femtosecond laser capsulotomies showed laser-induced alterations of the capsule edge when compared with smooth and regular edges obtained using manual CCC.

STUDY RESULTS

SURGICAL OUTCOMES

- SEM images of all capsule specimens in FSL groups showed a perfectly circular geometry whereas some deformations such as folding and tears were observed in the manual CCC group
- The manual CCC group showed a smooth and regular capsule edge without any surface irregularity; conversely, the femtosecond laser groups showed postage-stamp perforations on the capsule edge (**Figure 1**)
- The cut surface irregularity value in the CATALYS® was 1.4 ± 0.63, while it was 0.7 ± 0.49 in the LenSx® group (P<0.05; **Table 1**)
- The manual CCC group had a significantly lower thickness of the capsule edge than the femtosecond laser groups (P<0.05)
- No statistically significant difference in the capsule edge thickness between the femtosecond laser groups was found (P=0.244)
- High-magnification SEM images revealed some differences between the femtosecond laser groups; samples in the CATALYS® group showed aberrant laser-induced perforations of 2.33 ± 0.44 μm in size near the capsule edge not found in the LenSx® group

Figure 1. High-magnification SEM images of the capsulotomy cutting edge. (**A**) SEM images show a smooth and regular surface without cut surface irregularity in the manual CCC group; (**B**) SEM images show aberrant laser-induced perforation near the capsule edge in the CATALYS® group; (**C**) SEM images show postage-stamp perforations with several bumps and notches of variable width that were spread across the capsule edge in both (**C**) the CATALYS® group and (**D**) the LenSx® group.



CCC, continuous curvilinear capsulorhexis; SEM, scanning electron microscopy. Original magnification: 2000x.

Table 1. Results from the anterior capsule samples obtained from the manual CCC and femtosecond laser procedures.

Group	Mean±SD		
	Cut surface irregularity	Laser-induced perforation (μm)	Thickness (μm)
Manual CCC	0±0	0±0	5.59±0.32
Manual CCC	1.4±0.63	2.33±0.44	6.39±0.59
Manual CCC	0.7±0.49	0±0	6.05±0.65

SD, standard deviation.

Evaluation of the Effectiveness of Combined Femtosecond Laser-Assisted Cataract Surgery and Femtosecond Laser Astigmatic Keratotomy in Improving Post-Operative Visual Outcomes

Wang et al. *BMC Ophthalmol.* 2018;18:161

OVERVIEW

STUDY DESIGN
A prospective interventional case series to determine postoperative refractive and visual outcomes and astigmatic changes after femtosecond laser astigmatic keratotomy in femtosecond laser-assisted cataract surgery

STUDY SITE(S)
Single center in China

PATIENTS
25 eyes of 25 patients with corneal astigmatism (1.0–3.0D); mean age of 68.6 years (range: 55 to 89 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and femtosecond astigmatic keratotomy (FSAK)

SURGICAL TECHNOLOGY
LenSx® Laser with SoftFit™ Patient Interface, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Visual acuity, subjective and objective refraction, and corneal astigmatism 3 months after surgery using an OPD-Scan III topographer; vector analysis of astigmatic changes using Alpins vector method

ANALYSIS AND CONCLUSIONS

Combined femtosecond laser-assisted cataract surgery and FSAK with LenSx® may be an effective approach to manage preoperative astigmatism in cataract surgery, although slight undercorrection may exist during short-term follow-up.

The limitations of the current study are its small sample size and 3-month short-term follow-up.

STUDY RESULTS

SURGICAL OUTCOMES

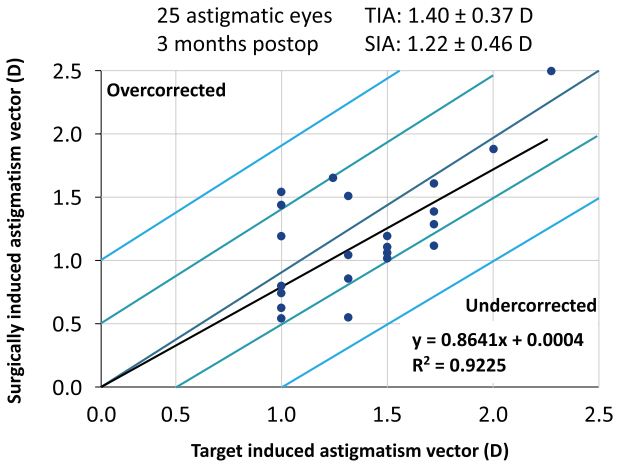
- Postoperatively at 3 months, refractive and corneal astigmatism were both reduced significantly (P<0.05), concurrent with improved uncorrected distance visual acuity and corrected distance visual acuity (**Table 1**)
- The rate of spectacle use was significantly reduced at 3 months postoperatively from 60% to 12% (P=0.001)
- The mean magnitude of the target-induced astigmatism (TIA) vector (1.40 ± 0.37D) was slightly higher than the mean magnitude of the surgically induced astigmatism (SIA) vector (1.22 ± 0.46D; **Figure 1**)
  - The magnitude of error (-0.18 ± 0.36D), as well as the correction index (0.88 ± 0.29), demonstrated slight undercorrection
- The refractive astigmatism angle of error was 0.85 ± 13.69°, which was close to zero, indicating that the SIA was counter-clockwise to TIA

Table 1. Preoperative and 3 months postoperative astigmatic change and visual acuity outcomes.

	Refractive astigmatism (D)	Corneal astigmatism (D)	MRSE (D)	UDVA (logMAR)	CDVA (logMAR)
Pre-operative	1.57 ± 1.27	1.41 ± 0.39	-1.93 ± 4.98	0.72 ± 0.23	0.40 ± 0.10
Post-operative 3 months	0.70 ± 0.36	0.69 ± 0.31	-0.15 ± 0.91	0.13 ± 0.11	0.09 ± 0.10
t	3.694	10.115	-1.782	3.091	2.855
P	0.001	0.000*	0.087	0.005*	0.009*

CDVA corrected distance visual acuity; D, diopters; logMAR, logarithm of the minimum angle of resolution; MRSE manifest refraction spherical equivalent; P, p-value; t, t-value from t-test; UDVA uncorrected distance visual acuity.
**P ≤ 0.05*

Figure 1. Scatter plot of TIA versus SIA.



D, diopters; SIA, surgically induced astigmatism; TIA, target induced astigmatism

Comparison of Phacoemulsification Parameters Between Manual and Femtosecond Laser-Assisted Cataract Surgery

Yesilirmak et al. *Can J Ophthalmol.* 2018;53:542-547

OVERVIEW

STUDY DESIGN
Prospective nonrandomized comparative study to compare the nucleus removal time (NRT) and cumulative dissipated energy (CDE) outcomes of traditional phacoemulsification cataract surgery and femtosecond laser-assisted cataract surgery performed by cornea attendings and fellows

STUDY SITE(S)
Single center in the United States

PATIENTS
Four hundred and ten (410) eyes of 410 patients with grade 1–4 nuclear sclerosis (Lens Opacities Classification System III)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, CENTURION® Vision System (Alcon Laboratories, Inc.), CATALYS® Precision Laser System (Johnson & Johnson Vision), VICTUS® Femtosecond Laser Platform (Bausch + Lomb)

KEY ENDPOINT(S)
NRT (time between first entering and last removing of phaco tip) and CDE (measured by the phacoemulsification platform as reported on the display at conclusion of each procedure); comparisons of NRT and CDE performed for nuclear sclerosis grades 2 and 3

ANALYSIS AND CONCLUSIONS

Inexperienced surgeons seemed to require more time and used more ultrasound energy during traditional phacoemulsification when compared with experienced surgeons.

The use of femtosecond lasers seemed to significantly improve the NRT of experienced and inexperienced surgeons; this result suggests that use of femtosecond laser platforms (at least CATALYS® with the grid pattern) may be a useful training aid for residents while they are mastering chopping of the nucleus.

STUDY RESULTS

SURGICAL OUTCOMES

- The attending group included 56 CATALYS®, 45 LenSx®, 25 VICTUS®, and 135 traditional cases, while the fellow group included 16 CATALYS®, 15 LenSx®, 66 VICTUS®, and 52 traditional cases; there was no statistically significant difference in cataract grade between groups
- NRT was significantly lower only when using the CATALYS® system compared with the LenSx® and VICTUS® platforms and traditional surgery, in both the attending group (P=0.006, P=0.002, P<0.000, respectively) and the fellow group (P=0.049, P=0.038, P=0.011, respectively; **Table 1**)
- With respect to CDE, there was no significant difference when using the femtosecond laser systems compared with traditional surgery in both attending and fellow groups (P>0.05; **Table 1**)
- NRT was significantly higher in the fellow group (269.10 ± 117.67) than in the attending group (218.87 ± 109.67) (P=0.007), and CDE was also higher (7.30 ± 4.83 vs. 5.76 ± 3.66, respectively) (P=0.020); however, in femtosecond laser cases, there was no significant difference in NRT and CDE between the fellow and the attending groups (**Table 2**)

Table 1. Differences between each laser platform and traditional surgery in both attending and fellow groups.

Group	Outcome Measure	CATALYS®	LenSx®	VICTUS®	Traditional	p*	p†	p‡	p§	p¶	p**
Attendings	NRT (seconds) CDE (J)	158.66 ± 62.00 4.70 ± 2.91	203.56 ± 66.60 5.03 ± 2.79	205.12 ± 57.99 5.13 ± 2.48	218.87 ± 109.67 5.76 ± 3.66	0.006 0.562	0.002 0.562	0.930 0.870	<0.000 0.055	0.356 0.156	0.361 0.293
Fellows	NRT (seconds) CDE (J)	174.50 ± 99.54 5.97 ± 3.64	209.87 ± 126.49 6.07 ± 2.70	223.30 ± 86.81 6.46 ± 3.47	269.10 ± 117.67 7.30 ± 4.83	0.049 0.928	0.038 0.627	0.123 0.636	0.011 0.246	0.119 0.210	0.066 0.294

CDE, cumulative dissipated energy; NRT, nucleus removal time.
**P-value between CATALYS® and LenSx®; †p value between CATALYS® and VICTUS®; ‡p value between LenSx® and VICTUS®; §p value between CATALYS® and traditional; ¶P-value between LenSx® and traditional; **P-value between VICTUS® and traditional.*

Table 2. Difference between attending and fellow groups.

Surgical Platform	Outcome Measure	Attendings (Mean ± SD)	Fellows (Mean ± SD)	*p*-value
CATALYS®	NRT (seconds) CDE (J)	158.66 ± 62.00 4.70 ± 2.91	174.50 ± 99.54 5.97 ± 3.64	0.439 0.151
LenSx®	NRT (seconds) CDE (J)	203.56 ± 66.60 5.03 ± 2.79	209.87 ± 126.49 6.07 ± 270	0.834 0.212
VICTUS®	NRT (seconds) CDE (J)	205.12 ± 57.99 5.13 ± 2.48	223.30 ± 86.81 6.46 ± 3.47	0.336 0.08
Traditional	NRT (seconds) CDE (J)	218.87 ± 109.67 5.76 ± 3.66	269.10 ± 117.67 7.30 ± 4.83	0.007* 0.020*

**Statistically significant. CDE, cumulative dissipated energy; NRT, nucleus removal time.*

Outcomes of Conventional Phacoemulsification Versus Femtosecond Laser-Assisted Cataract Surgery in Eyes With Fuchs Endothelial Corneal Dystrophy

Zhu et al. *J Cataract Refract Surg.* 2018;44:534-540

OVERVIEW

STUDY DESIGN

Retrospective case series to compare the outcomes in eyes with Fuchs endothelial corneal dystrophy after standard phacoemulsification or femtosecond laser-assisted cataract surgery

STUDY SITE(S)

Single center in the United States

PATIENTS

Two hundred and seven (207) eyes of 207 patients diagnosed with Fuchs endothelial corneal dystrophy; n=64 in the femtosecond laser group, n=143 in conventional phacoemulsification group

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser, CENTURION® Vision System (Alcon Laboratories, Inc.); CATALYS® Precision Laser System, WHITESTAR SIGNATURE® Phacoemulsification System (Johnson & Johnson Vision); VICTUS® Femtosecond Laser Platform (Bausch + Lomb)

KEY ENDPOINT(S)

Corrected distance visual acuity (CDVA), central corneal thickness (CCT), and corneal edema at each visit; clinically significant corneal decompensation was defined by corneal edema with CDVA worse than 20/50 lasting more than 3 months, any case resulting in keratoplasty, or both

ANALYSIS AND CONCLUSIONS

Compared with conventional phacoemulsification, femtosecond laser-assisted cataract surgery did not lower the rate of corneal decompensation in eyes with mild to moderate Fuchs endothelial corneal dystrophy.

Concurrent endothelial keratoplasty with cataract surgery (triple procedure) should be considered in eyes with moderate Fuchs endothelial corneal dystrophy.

STUDY RESULTS

SURGICAL OUTCOMES

- The proportion of cases progressing to clinically significant decompensation (13% overall) was similar between the femtosecond laser and conventional groups (P>0.05; **Table 1**)
- The proportion of cases progressing to clinically significant corneal decompensation within the defined 3-month period and the overall rates of corneal transplantation were not significantly different between groups (P>0.05)
  - Univariate Cox survival analysis also found no difference between groups (hazard ratio, 1.0; 95% confidence interval, 0.4-2.7; P=0.96)
- The proportion of eyes with postoperative edema on clinical examination at 1 month was significantly higher in the femtosecond laser group than in the conventional group (P<0.05; **Table 1**)
- Using visual acuity as an adjunct for clinically significant edema, the incidence of severe corneal edema (ie, CDVA worse than 20/400 or CCT > 700 µm) was significantly greater in the femtosecond laser group than in the conventional group (P<0.05)

Table 1. Postoperative corneal edema and decompensation by group.

Parameter	Femtosecond (n = 64)	Conventional (n=143)	*p*-value
Decompensation, n (%)	11 (17)	15 (10)	0.18‡
Transplantation, *n (%)	6 (9)	12 (8)	0.81‡
Edema at 1 month, n (%)	30 (47)	43 (30)	0.03‡
Edema at 3 months, n (%)	15 (23)	27 (19)	0.57‡
Edema at 6 months, n (%)	11 (17)	16 (11)	0.34‡
Severe edema, n (%)	15 (23)	16 (11)	0.04‡
Mean CCT† (µm) ± SD	636 ± 91	636 ± 97	0.91§
Mean edema duration (mo) ± SD	3.0 ± 6.4	2.0 ± 4.7	0.19§

CCT, central corneal thickness; CDVA, corrected distance visual acuity; SD, standard deviation.
Decompensation, clinically significant corneal decompensation defined by edema with CDVA <20/50 lasting >3 months and/or any case resulting in corneal transplantation; severe edema, clinically significant severe edema characterized by CDVA <20/400 or CCT >700 µm.
**One patient in conventional group had Descemet membrane endothelial keratoplasty; the remaining had Descemet-stripping automated endothelial keratoplasty.*
†Postoperative CCT was not available for every patient; values were calculated from 21 (femtosecond laser) and 40 (conventional); ‡Pearson chi-square with Yates correction;
§Student t test.

- The mean (± standard deviation [SD] time to transplantation was similar in both groups (6.0 months ± 5.2)
- There was no statistically significant difference in the measured CDVA at each postoperative visit between group (**Table 2**); however, there was a persistent decline in visual acuity from baseline through 1 week postoperatively, corresponding to the higher rate of severe corneal edema (P<0.05) in the femtosecond laser group
- More advanced Fuchs endothelial corneal dystrophy (grades 2.5 to 4.0) correlated significantly with greater corneal edema duration (P<0.05) and higher incidences of severe corneal edema (P<0.01) and visibly prolonged edema up to 6 months postoperatively (P<0.05)
- A denser cataract (grades 2.5-4.0) was also shown to correlate significantly with a higher incidence of severe edema and greater postoperative CCT (both P<0.05)
- Clinical factors that correlated significantly with ultimate decompensation included the presence of clinically evident edema 1 month postoperatively and the presence of severe edema in the early postoperative period (both P<0.001)

Table 2. Postoperative changes in logMAR CDVA* from baseline by group.

Δ CDVA	Femtosecond	Conventional	*p*-value†
1 day	-0.237 ± 0.461	-0.104 ± 0.459	0.06
1 week	-0.069 ± 0.362	0.068 ± 0.421	0.04
1 month†	0.057 ± 0.241	0.112 ± 0.465	0.29

Δ, change from baseline; CDVA, corrected distance visual acuity; logMAR, logarithm of the minimal angle of resolution.
**Converted from Snellen; positive value = improved CDVA from baseline; negative value = worsen than at baseline;*
†Student t test.

Intraocular Pressure Rises During Laser In Situ Keratomileusis: Comparison of 3 Femtosecond Laser Platforms

Preclinical Data

Bolivar et al. *J Cataract Refract Surg.* 2019;45:1172-1176

OVERVIEW

STUDY DESIGN
Experimental study to measure intraocular pressure (IOP) elevations in porcine eyes

STUDY SITE(S)
Single center in Spain

PATIENTS
Not applicable — preclinical animal study; 21 freshly enucleated porcine eyes

SURGICAL METHODOLOGY
LASIK with three different femtosecond laser platforms; IOP recorded during suction and cutting phases

SURGICAL TECHNOLOGY
Two dual femtosecond lasers with curved interfaces (LenSx® [Alcon Laboratories, Inc.] and VICTUS® [Bausch & Lomb]), and one femtosecond laser with a flat interface (IntraLase iFS 150 kHz [Johnson & Johnson Vision])

KEY ENDPOINT(S)
Changes in IOP, total surgical time

ANALYSIS AND CONCLUSIONS

Preliminary results from this study suggest that the iFS and VICTUS® systems induced higher IOP increases and required longer surgical times to cut a LASIK flap than the LenSx® system.

More studies are needed to confirm these findings and their possible clinical relevance regarding ocular safety, the potential impact on LASIK flap quality, and the final outcomes of the surgical procedure.

STUDY RESULTS

CHANGES IN INTRAOCULAR PRESSURE

- The mean IOP increase during suctioning was significantly higher with the iFS system (78.14 ± 23.6 mm Hg) than with the VICTUS® system (20.28 ± 6.7 mm Hg, P=0.0001) (**Table 1**)
- The LenSx® system performed the suctioning and applanation phases simultaneously, making it impossible to obtain the results of the suctioning phase alone
- The mean IOP elevation during the cutting phase was significantly lower with the LenSx® system (20 ± 5.3 mm Hg) than with the iFS (108.1 ± 17.0 mm Hg) and VICTUS® (96.4 ± 16.8 mm Hg) systems (P=0.0001) **(Table 1)**
- These results show that although increases in IOP should theoretically be smaller with corneal applanation using a flat patient interface that with a curved interface, this is not always the case

SURGICAL TIME

- The total surgical time was significantly lower with the LenSx® system (17.21 ± 0.7 seconds) than with the iFS (25.10 ± 4.3 seconds) and VICTUS® (33.40 ± 0.7 seconds) systems (P=0.0001) (**Table 1**)
- These results show that the total time needed to complete the procedure was significantly longer with the platforms that use an independent suction ring (i.e., iFS and VICTUS®)

Table 1. Mean intraocular pressure increases and corneal flap cutting times by femtosecond laser group.

Parameter	iFS Group (n=7)	VICTUS® group (n=7)	LenSx® Group (n=7)	P-value
Baseline IOP (mm Hg) Mean ± SD Range	21.14 ± 3.44 18, 26	20.71 ± 7.89 11, 30	21.14 ± 5.15 20, 27	0.9873
ΔIOP phase 1 (mm Hg) Mean ± SD Range	78.14 ± 23.62* 37, 110	20.28 ± 6.65 13, 30	NA	0.001
ΔIOP phase 2 (mm Hg) Mean ± SD Range	108.14 ± 16.97 86, 129	96.42 ± 16.83 70, 117	20 ± 5.29* 15, 30	0.001
Total surgical time (s) Mean ± SD Range	25.10 ± 4.26* 20.48, 31.43	33.40 ± 3.1 31.12, 40.31	17.21 ± 0.68* 16.20, 18.50	0.001

ΔIOP, intraocular pressure rise; phase 1, suctioning phase; phase 2, cutting phase.
**P<0.05 compared with VICTUS®.*

Higher Order Aberrations in Femtosecond Laser-Assisted Versus Manual Cataract Surgery: A Retrospective Cohort Study

Ernest et al. *J Refract Surg.* 2019;35:102-108

OVERVIEW

STUDY DESIGN
Retrospective cohort study to evaluate differences in higher order aberrations (HOAs) between femtosecond laser-assisted cataract surgery and manual cataract surgery

STUDY SITE(S)
Single center in the United States

PATIENTS
Fifty-seven (57) eyes in the LenSx® group (mean age of 66.0 years) and 50 eyes in the manual phacoemulsification group (mean age of 66.5 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Primary endpoint was internal coma <0.32 µm, secondary endpoints included patient-reported vision quality

ANALYSIS AND CONCLUSIONS

More eyes achieved internal coma <0.32 µm following LenSx® compared to manual cataract surgery, supporting the hypothesis that femtosecond laser-assisted cataract surgery produces statistically significant improvements in HOAs relative to manual cataract surgery.

There was a correlation between internal coma and patient-reported satisfaction, and eyes with excellent patient satisfaction all had internal coma less than 0.20 µm.

STUDY RESULTS

HIGHER-ORDER ABERRATIONS

- The proportion of eyes reaching internal coma <0.32 µm was significantly greater following LenSx® (54 of 57 eyes, 94.7%) relative to manual cataract surgery (39 of 50 eyes, 78.0%) (OR = 5.08, 95% CI = 1.24 to 20.85, P=0.024)
- Median internal coma was 0.10 µm for LenSx® and 0.12 µm for manual cataract surgery (P=0.005); using generalized estimating equations (GEE) to account for within-patient correlation, mean ± SD values were 0.12 ± 0.12 µm for LenSx® and 0.28 ± 0.41 µm for manual cataract surgery (mean difference of -0.15 µm, 95% CI = -0.30 to -0.006, P=0.041)
- Overall, a mesopic pupil size of 5 mm or greater was significantly associated with the proportion of eyes reaching internal coma <0.32 µm (P=0.002), <0.20 µm (P<.001), and as a continuous variable (P=0.01)
- The average internal coma increased by a greater amount for manual cataract surgery than for LenSx® for every increase in mesopic pupil size >5.75 mm (**Figure 1**)

PATIENT-REPORTED OUTCOMES

- There was no significant difference between LenSx® and manual cataract surgery in terms of patient-reported quality of vision (GEE [mean ± SD]: LenSx® = 18.8 ± 9.3, manual cataract surgery = 21.2 ± 10.7, mean difference of -2.4, 95% CI = -7.9 to 3.2, P = 0.40)
- All eyes (n = 15) with satisfaction scores of 0 to 10 had internal coma <0.20 µm, compared to those with scores of 11 to 20 (27 of 29 eyes, 93.1%), 21 to 30 (19 of 30 eyes, 63.3%), and >30 (8 of 15 eyes, 53.3%) (P<0.001) (**Figure 2**)

Figure 1. Scatterplot of the relation between mesopic pupil size and internal coma.

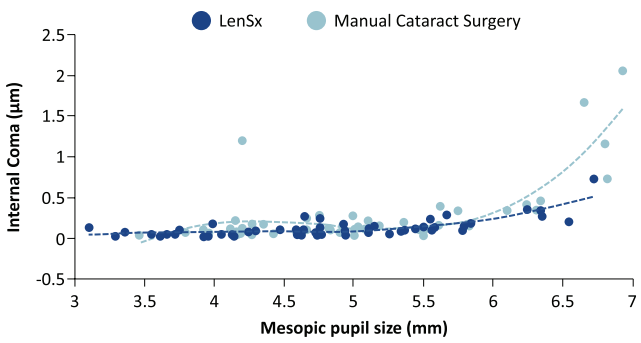
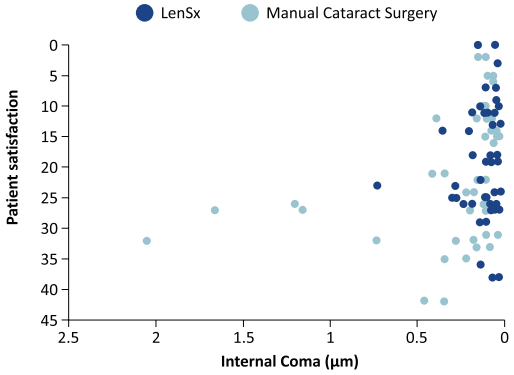


Figure 2. Scatterplot of the relation between internal coma and patient-reported satisfaction scores.



Correcting Corneal Astigmatism with Corneal Arcuate Incisions During Femtosecond Laser Assisted Cataract Surgery

Hiep et al. *Open Access Maced J Med Sci.* 2019;7:4260-4265

Surgical Outcomes
Surgical Complications
Visual Acuity
Refractive Outcomes
Patient-Reported Outcomes

OVERVIEW

STUDY DESIGN
Clinical intervention study to assess the efficacy and safety of arcuate corneal incisions for treating corneal astigmatism during femtosecond laser-assisted cataract surgery

STUDY SITE(S)
Single center in Vietnam

PATIENTS
Forty-five (45) eyes of 33 patients (mean age of 50.15 ± 16.672 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery to produce corneal arcuate incisions

SURGICAL TECHNOLOGY
LenSx® Laser, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Uncorrected and corrected distance visual acuity (UDVA, CDVA), refraction spherical equivalent, corneal astigmatism 1 week and 3 months after surgery; features of arcuate corneal incisions (quantity, depth, length and morphology), spectacle independence at a distance and surgical complications

ANALYSIS AND CONCLUSIONS

This study demonstrated that use of LenSx® to produce corneal arcuate incisions reduced corneal astigmatism by approximately 64% compared to before surgery; no complications were reported and more than 80% of patients were spectacle free after surgery.

Limitations of his study include the small sample size (45 cases) and short follow-up time (3 months); the investigators concluded that larger studies with longer follow-up time are needed to support the conclusions of this study more fully.

STUDY RESULTS

SURGICAL OUTCOMES

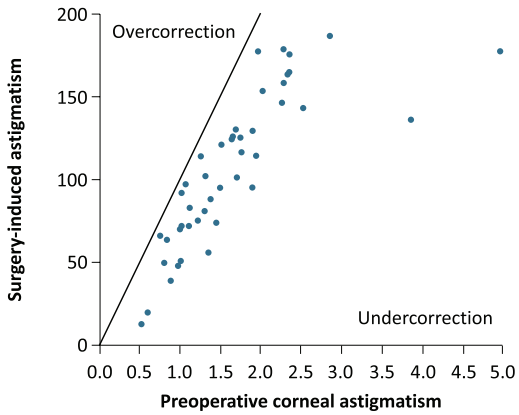
- The mean length of an arcuate corneal incision to correct astigmatism with LenSx® was 53.78 ± 17,638 degrees
- After surgery with LenSx® to produce corneal arcuate incisions, corneal astigmatism significantly decreased from 1.65 ± 0.828 D preoperatively to 0.59 ± 0.549 D three months after surgery (P<0.001) (**Table 1**)
- Surgery-induced astigmatism was 1.05 ± 0.449 D; this indicates a surgery correction index of 0.64 (the ratio between surgery induced astigmatism and preoperative corneal astigmatism) and therefore an undercorrection in the study (**Figure 1**)
- Both UDVA and CDVA significantly improved by month 3; UDVA decreased from 1.44 ± 0.714 preoperatively to 0.10 ± 0.103 at month 3 (P<0.001), while CDVA decreased from 0.72 ± 0.456 to 0.07 ± 0.104 (P<0.001) (**Table 1**)
- At month 3, manifest refraction spherical equivalent was within ± 1.0 D in 100% of study eyes and within ± 0.5 D 95.6% of study eyes; this rate was very high and partly explains the good visual acuity achieved in this study
- Overall, 83.2% of patients did not require use of spectacles after the surgery, 100% reported being satisfied with the outcome (81.8% reported high satisfaction), and no complications such as corneal perforation or dislocated incision were reported

Table 1. Preoperative and postoperative corneal astigmatism, refraction and visual acuity outcomes.

	Corneal Astigmatism (D)	MRSE (D)	UDVA (logMAR)	CDVA (logMAR)
Preoperative	1.65 ± 0.828	-1.95 ± 4.987	1.44 ± 0.714	0.72 ± 0.456
1 week postoperative	1.18 ± 0.761	-0.27 ± 0.398	0.23 ± 0.141	0.12 ± 0.132
1 month postoperative	0.80 ± 0.599	-0.11 ± 0.299	0.14 ± 0.122	0.08 ± 0.124
3 months postoperative	0.59 ± 0.549	-0.08 ± 0.255	0.10 ± 0.103	0.07 ± 0.104
P-value*	< 0.001	< 0.001	< 0.001	< 0.001

*MRSE, manifest refraction spherical equivalent; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity. *Preoperative vs 3 months postoperative.*

Figure 1. Scatter plot of preoperative corneal astigmatism and surgery-induced astigmatism.



Ultrasound Power and Irrigation Volume in Different Lens Opacity Grades: Comparison of Femtosecond Laser-Assisted Cataract Surgery and Conventional Phacoemulsification

Horta et al. *Clinics (Sao Paulo).* 2019;74:e1294.

OVERVIEW

STUDY DESIGN
Prospective, consecutive, investigator-masked nonrandomized parallel cohort study to compare the amount of ultrasound energy and irrigation volume in conventional phacoemulsification cataract surgery versus femtosecond laser-assisted phacoemulsification at different nuclear-cortical cataract grades

STUDY SITE(S)
Single center in Brazil

PATIENTS
One hundred and sixty (160) eyes from 109 patients; divided into 4 groups (Phaco1, Phaco2, LenSx®1 and LenSx® 2) according to surgical technique (conventional phacoemulsification [Phaco] or femtosecond laser-assisted cataract surgery [LenSx®]) and the Lens Opacity Classification System III (LOCS) grade (LOCS <11 [group 1] and ≥11 [group 2])

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Effective phacoemulsification time (EPT), indicating the ultrasound energy, and balanced salt solution (BSS) use, indicating the irrigation volume, to indirectly estimate damage to the corneal endothelium caused by cataract surgery

ANALYSIS AND CONCLUSIONS

This study found that, compared to conventional cataract surgery, LenSx® surgery for different levels of corticonuclear cataracts significantly reduces effective phacoemulsification time and does not change the use of balanced salt solution.

The authors concluded that further research is needed to quantify the reduction in effective phacoemulsification time necessary to effectively protect the corneal endothelium and decrease cell death.

STUDY RESULTS

EFFECTIVE PHACOEMULSIFICATION TIME

- No significant differences were observed in mean LOCS grades between the Phaco1 (8.21±1.44) and LenSx®1 (7.90±1.90) groups (P=0.73) or between the Phaco2 (13.15±2.55) and LenSx®2 (12.72±2.18) groups (P=0.95) (**Table 1**)
- The average LOCS grade in group 1 (LOCS<11) was significantly lower than in group 2 (LOCS≥11); therefore, it was possible to compare the groups (Phaco1 vs. LenSx®1 and Phaco2 vs. LenSx®2) without bias related to cataract grade
- There was a statistically significant reduction of 53% in the average EPT between the Phaco1 group (5.80±2.86, 1.82 range 14.52) and the LenSx®1 group (2.73±1.88, 0.1 to 8.65) (p=0.00), and a 33% reduction between the Phaco2 group (12.55±8.38, 4.73 to 43.03) and LenSx®2 group (8.38±9.32, 1, from 66 to 57.00) (p=0.00) (**Table 1**)
- EPT was similar in the Phaco1 group (5.33) and LenSx®2 group (5.44); therefore, with similar degrees of LOCS classification, the LenSx® groups had lower average EPTs than the manual phacoemulsification groups (**Figure 1**)

USE OF BALANCED SALT SOLUTION

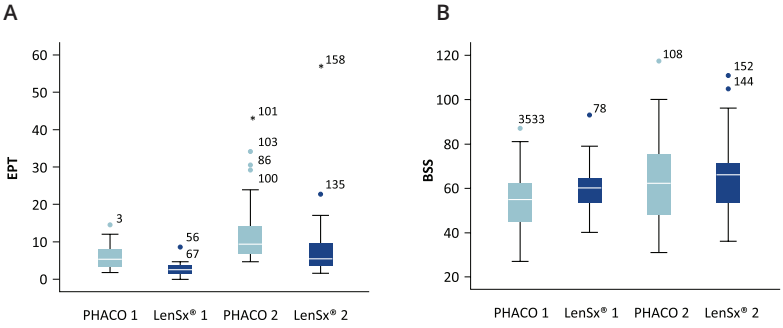
- The manual phacoemulsification groups had lower mean use of balanced salt solutions than did the LenSx® groups when similar degrees of LOCS classifications were compared; howev-er, there were no significant differences in mean use of balanced salt solutions between the Phaco1 (55.73±12.45) and LenSx®1 (59.37±10.93) groups (P=0.48) or between the Phaco2 (64.34±21.00) and LenSx®2 (65.71±17.60) groups (P=0.47) (**Figure 1**)

Table 1. Average LOCS grade, EPT and BSS used in each group as well as the p-value of the statistical comparisons between groups 1 and 2.

	Phaco1	LenSx®1	P-value	Phaco2	LenSx®2	P-value
Eyes	42	34	-	45	39	-
LOCS	13.15± 2.55	12.72± 2.18	0.95	8.21± 1.44	7.90± 1.90	0.73
EPT	5.80± 2.86	2.73± 1.88	0.00	12.55± 8.38	8.38± 9.32	0.00
BSS	56.09± 12.12	59.82± 10.75	0.48	63.53± 19.44	65.71± 17.60	0.47

BSS, balanced salt solution; EPT, effective phacoemulsification time; LOCS, Lens Opacity Classification System III.

Figure 1. (**A**) Effective phacoemulsification time and (**B**) use of balanced salt solution by group.



Tomographic Analysis of Anterior and Posterior Surgically Induced Astigmatism After 2.2 mm Temporal Clear Corneal Incisions in Femtosecond Laser-Assisted Cataract Surgery

Kohnen et al. *J Cataract Refract Surg.* 2019;45:1602-1611

OVERVIEW

STUDY DESIGN
Prospective interventional case series to evaluate surgically induced astigmatism (SIA) of temporal clear corneal incisions (CCIs) on anterior and posterior corneal curvature after femtosecond laser-assisted cataract surgery using Scheimpflug tomographic measurements

STUDY SITE(S)
Single center in the Germany

PATIENTS
Fifty-three (53) eyes of 38 patients; mean age of 64.3 years

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.), Scheimpflug camera (Pentacam®, Oculus Optikgeräte GmbH)

KEY ENDPOINT(S)
Astigmatic changes in anterior corneal astigmatism (CA_{ant}), posterior corneal astigmatism (CA_{post}), and total corneal refractive power astigmatism (CA_{TCRP}) at 1 and 3 months postoperatively

ANALYSIS AND CONCLUSIONS

Temporal CCIs created with LenSx® induce corneal astigmatism with respect to anterior corneal curvature and total corneal refractive power, but can be considered astigmatically neutral in eyes with against-the-rule CA_{TCRP} based on lack of statistical significance observed in this study.

The investigators recommended that further studies with a larger sample size be conducted to help determine which corneal curvature measurement should be used to plan corneal incisions; such studies should compare not only different femtosecond laser-created incision sizes but also planning methods.

STUDY RESULTS

TOMOGRAPHIC ANALYSIS

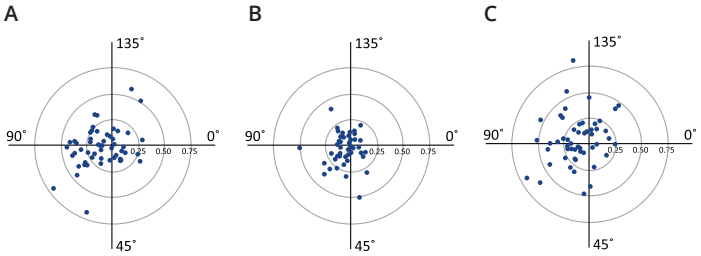
- Mean CA_{TCRP} values at 1 month and 3 months postoperatively were significantly higher compared with the mean preoperative value (P<.0001, P=0.008, respectively) (**Table 1**)
- Similar findings were observed for preoperative mean CA_{ant} compared with values at 1 month and 3 months (P<0.001, P=0.015, respectively)
- Mean CA_{post} was not significantly higher after 1 month (P=0.279), but it was significantly higher after 3 months (P=0.007)
- CA_{post} and CA_{TCRP} were significantly lower compared with the limit of 0.50 D (P<0.001, P=0.01, respectively), whereas CA_{ant} was not (P= 0.11)
- The mean SIA of CA_{ant}, CA_{post}, and CA_{TCRP} was 0.25 D ± 0.15 (SD), 0.16 ± 0.11 D, and 0.28 ± 0.17 D, respectively; **Figure 1** shows SIA_{ant}, SIA_{post}, and SIA_{TCRP} at 3 months postoperatively
- The angle of error for CA_{ant}, CA_{post}, and CA_{TCRP} was high (-1.98 ± 52.95 degrees, 1.64 ± 51.27 degrees, and -1.72 ± 48.79 degrees, respectively)
- Subgroup analyses showed that astigmatic postoperative changes were statistically significant on the anterior corneal curvature (P=0.005) and TCRP (P=0.004) in with-the-rule eyes, whereas there were no significant changes in against-the-rule eyes (P=0.964, P=1.0, respectively)

Table 1. Corneal astigmatism over time in eyes that had temporal clear corneal incisions with LenSx® surgery. Adapted from Kohnen et al. *J Cataract Refract Surg.* 2019;45:1602-1611.

Examination	CA_{ant} (D)		CA_{post} (D)		CA_{TCRP} (D)	
	Mean ± SD	P-value	Mean ± SD	P-value	Mean ± SD	P-value
Preoperative	0.31 ± 0.11	--	0.24 ± 0.12	--	0.33 ± 0.13	--
1 month postop	0.55 ± 0.25	<0.001*	0.26 ± 0.12	0.279	0.50 ± 0.24	<0.001*
3 months postop	0.46 ± 0.23	0.015*	0.28 ± 0.13	0.007*	0.42 ± 0.24	0.008*

CA_{ant}, anterior corneal curvature astigmatism; CA_{post}, posterior corneal curvature astigmatism; CA_{TCRP}, total corneal refractive power astigmatism.
**Statistically significant compared with preoperative value.*

Figure 1. Double-angle plot of the SIA 3 months after temporal clear corneal incisions with LenSx® surgery: (**A**) SIA_{ant}, (**B**) SIA_{post}, and (**C**) and SIA_{TCRP}.



SIA_{ant}, surgically induced astigmatism anterior corneal curvature; SIA_{post}, surgically induced astigmatism posterior corneal curvature; SIA_{TCRP}, surgically induced astigmatism total corneal refractive power.

Two Femtosecond Laser LASIK Platforms: Comparison of Evolution of Visual Acuity, Flap Thickness, and Stromal Optical Density

Surgical Outcomes

Visual Acuity

Parafita-Fernández et al. *Cornea.* 2019;38:98-104

OVERVIEW

STUDY DESIGN

Prospective case series to compare postoperative evolution of visual acuity, flap thickness, and stromal optical density during the first 3 months after femtosecond laser in situ keratomileusis surgery for correction of myopia using two different laser platforms

STUDY SITE(S)

Single center in Spain

PATIENTS

Seventy-seven (77) consecutive eyes; 39 eyes in the IntraLase iFS 150 kHz femtosecond laser group (mean age 34.0 years, range: 20 to 55 years), 38 refraction-matched eyes in the LenSx® femtosecond laser group (mean age of 32.2 years, range: 25-49 years)

SURGICAL METHODOLOGY

Femtosecond laser in situ keratomileusis (FS-LASIK)

SURGICAL TECHNOLOGY

One femtosecond laser with curved interface (LenSx® [Alcon Laboratories, Inc.] and one femtosecond laser with a flat interface (IntraLase iFS 150 kHz [Johnson & Johnson Vision])

KEY ENDPOINT(S)

Visual outcomes, flap morphology, and optical density of the stroma (in both flap and residual stromal bed) assessed at 4 visits during a three-month follow-up period

ANALYSIS AND CONCLUSIONS

This study found that both the iFS 150 kHz and LenSx® femtosecond laser platforms provided satisfactory visual outcomes for correction of myopia.

However, laps made with the iFS 150 kHz laser were thinner, more uniform, transparent, and accurate compared with those obtained with LenSx® platform.

STUDY RESULTS

VISUAL ACUITY

- No significant differences were found in mean uncorrected distance visual acuity (UDVA, decimal notation) at 1 day (1.06 vs. 1.08), 1 week (1.10 vs. 1.10), 1 month (1.11 vs. 1.09), and 3 months (1.10 vs. 1.14) postoperatively for the iFS 150 kHz and LenSx® systems, respectively
- No statistically significant correlation was found between postoperative UDVA and changes in flap parameters (including optical density)

SURGICAL OUTCOMES

- Flaps created with the iFS 150 kHz femtosecond laser were closer to the intended thickness (110 µm) in every postoperative comparison vs. LenSx® (1 day 108.6 vs. 124.3; 1 week 107.6 vs. 123.6; 1 month 110.4 vs. 126.8; 3 months 116.2 vs. 126.5 µm; P<0.0001)
- There was a trend toward smaller dispersion of values and smaller standard deviation in total flap thickness in favor of iFS 150 kHz flaps (ie, iFS 150 kHz flaps were thinner, more homogeneous, and more predictable than those obtained with LenSx® flaps) **(Figure 1)**
- In the iFS 150 kHz group, there was a significant progressive increase in the mean optical density of the stroma of the flap from the first postoperative day (134.5 gray scale unit [GSU]) to 3 months postoperatively (148.2 GSU) (P=0.02), whereas in the LenSx® group there was a significant progressive decrease (from 158.9 GSU to 146.2 GSU, P=0.02) **(Figure 2)**
- Residual stromal bed optical density was higher in the LenSx® group at all postoperative visits, and the differences reached significance at 1 week postoperatively (121.9 vs. 135.4 GSU; P=0.03) **(Figure 2)**
- No intraoperative or postoperative flap-related complications such as corneal haze, wrinkles, or microstriae were detected in any case during the follow-up period

Figure 1. Postoperative evolution of the mean total flap thickness of the flaps created with the iFS 150 kHz and LenSx® femtosecond lasers.

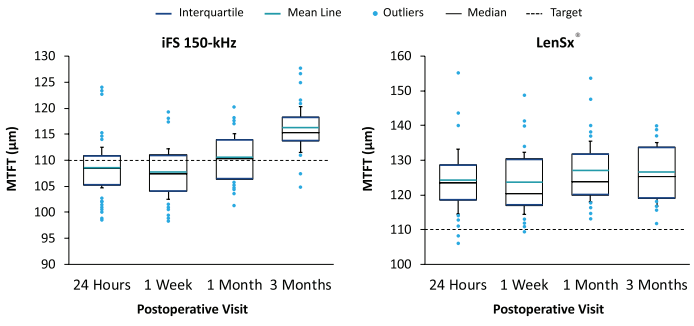
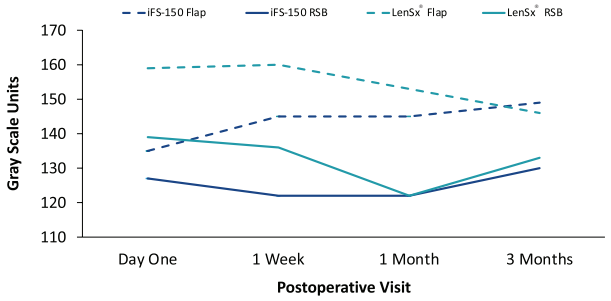


Figure 2. Postoperative evolution of the optical density of both flap and residual stromal bed of the eyes treated with the iFS 150 kHz and LenSx® femtosecond lasers.



Correction of Myopia and Myopic Astigmatism by Femtosecond Laser In Situ Keratomileusis

Řeháková et al. *Cesk Slov Oftalmol.* 2019;75:65-71

Surgical Outcomes
Surgical Complications
Visual Acuity
Refractive Outcomes
Patient-Reported Outcomes

OVERVIEW

STUDY DESIGN
Retrospective study to analyze one-year refractive results and incidence of complications in patients with low-to-high myopia or myopic astigmatism corrected with femtosecond LASIK

STUDY SITE(S)
Single center in Czechia

PATIENTS
One hundred and seventy-one (171) eyes of 87 patients who underwent correction of myopia and myopic astigmatism; mean age of 29.3 years (range of 18 to 46 years)

SURGICAL METHODOLOGY
Femtosecond laser in situ keratomileusis (FS-LASIK)

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.), AMARIS® 500E excimer laser (SCHWIND eye-tech-solutions)

KEY ENDPOINT(S)
Uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA), subjective refraction, central corneal thickness (CCT) at the thinnest point, patients satisfaction, and incidence of complications over 1 year

ANALYSIS AND CONCLUSIONS

This retrospective study demonstrated that FS-LASIK with LenSx® and AMARIS® 500E lasers is an effective, relatively safe and predictable method for correcting low-to-high myopia or myopic astigmatism.

The authors concluded that the basic prerequisite for good postoperative results and patient satisfaction is a thorough and comprehensive preoperative examination with respect to the indication criteria for these laser platforms.

STUDY RESULTS

OVERALL OUTCOMES

- Average preoperative UCVA (decimal value) was 0.06 ± 0.08 (range of 0.02 to 0.8), which improved to 1.12 ± 0.17 (0.8 to 1.5) at the end of the observation period (1 year); no significant differences were observed for BCVA (**Figure 1**)
- Mean preoperative subjective refraction for sphere was -4.14 ± 1.43 D (-8.5 to -1 D) and for cylinder was -0.57 ± 0.58 D (3 to 0 D); after 1 year, subjective refraction for sphere significantly decreased to -0.02 ± 0.16 D (-0.1 to 0.75 D) and for cylinder to -0.01 ± 0.1 D (-0.5 to 0.5 D) (**Figure 2**)
- Overall, manifest spherical equivalent up to ± 0.5 D was achieved in 97.1% of eyes, and manifest spherical equivalent up to ± 1.0 D was achieved in 100% of eyes
- No statistically significant changes were observed for CCT; the mean value preoperatively was 554.76 ± 30.07 µm (485 to 660 µm); this decreased to 494.06 ± 34.99 µm (421 to 594 µm) after 6 months and to 492.92 ± 34.55 µm (411 to 592 µm) after 1 year
- Perioperative complications were observed in 3 eyes, in all cases due to sudden eye movement that produced loss of femtosecond laser suction and interruption of the procedure
- The average patient satisfaction score at the end of the observation period was 1.04 (on a scale in which 1 is very satisfied, 5 is very dissatisfied)
- The most comment subjective complaints were a feeling of dry eye in 10 patients (11.5%), followed by blurred vision during computer work, under dim lighting or with increased fatigue in 6 patients (6.9%)

Figure 1. Average values for UCVA and BCVA surgery and during the course of the postoperative follow-up examinations. Statistically significant improvement was seen for UCVA starting at one day after surgery, but no statistically differences were observed for BCVA at any point during follow-up.

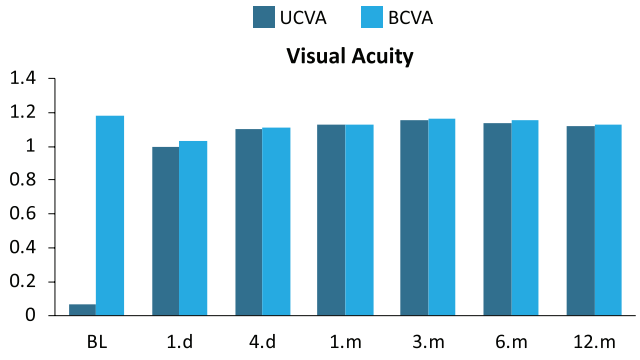
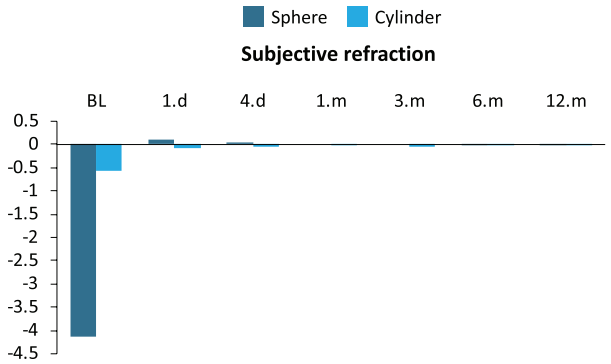


Figure 2. Mean values for subjective refraction preoperatively and during the follow-up period. Statistically significant improvement was observed starting at one day after surgery, with stable results through 1 year.



Effect of Femtosecond Laser-Assisted Lens Surgery on the Optic Nerve Head and the Macula

Reñones de Abajo et al. *Int J Ophthalmol.* 2019;12:961-966

OVERVIEW

STUDY DESIGN
Prospective longitudinal study to evaluate the effect of femtosecond laser-assisted lens surgery (FLALS; cataract surgery or refractive lens exchange) on the structure of the optic nerve head and the macula

STUDY SITE(S)
Single center in Spain

PATIENTS
Eighty-seven (87) healthy eyes of 46 patients; mean age of 65.7 years

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and refractive lens exchange

SURGICAL TECHNOLOGY
LenSx® Laser, CENTURION® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Retinal nerve fiber layer (RNFL), Bruch's membrane opening-minimum rim width (BMO-MRW) and macular thickness (MT) 1 and 6 months after surgery

ANALYSIS AND CONCLUSIONS

This study showed FLALS (cataract surgery or refractive lens exchange) does not seem to cause any deterioration in the structural status of the optic nerve head in healthy eyes.

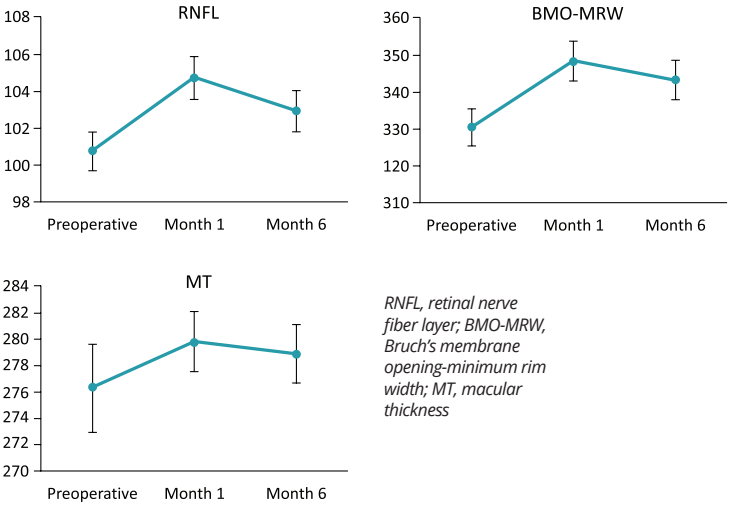
The investigators concluded that, since the postoperative values of RNFL, BMO-MRW and MT in this study were slightly superior to preoperative values, new baseline measurements should be acquired after FLALS in order to continue the follow-up in an accurate manner.

STUDY RESULTS

EFFECTS ON OPTIC NERVE HEAD AND MACULA

- A slight increase in all parameters was observed after surgery, and this increase was greater at one month after surgery than at six months (**Figure 1**)
- Preoperative RNFL was 100.77±10.39 and increased to 104.74±11.55 one month after surgery (3.93% increase) and to 102.93±11.17 six months after surgery (2.14% increase) (P<0.001)
- Preoperative BMO-MRW was 330.31±49.99 and increased to 348.32±54.05 one month after surgery (5.4% increase) and to 343.11±53.4 six months after surgery (3.87% increase) (P<0.001)
- Preoperative MT was 276.30±33.39 and increased to 279.83±22.65 one month after surgery (1.27% increase) and to 278.90±22.19 six months after surgery (0.94% increase); this change was not statistically significant (P=0.26)
- Bonferroni corrections were performed for those parameters that showed a P-value smaller than 0.05; significant differences were observed for RNFL and BMO-MRW for comparisons of 1 month postop vs preop, 6 months postop vs preop, and 6 months postop vs 1 month postop (**Table 1**)

Figure 1. Changes in RNFL, BMO-MRW and MT 1 month and 6 months after surgery (mean ± SD, µm).



RNFL, retinal nerve fiber layer; BMO-MRW, Bruch's membrane opening-minimum rim width; MT, macular thickness

Table 1. Percentage difference between preoperative and postoperative values of RNFL, BMO-MRW and MT.

Groups	Eyes (n)	Nd:YAG (n)	Nd:YAG Rate (%)	Odds Ratio (95% CI)
RNFL				
1 mo postop–preop	3.97	0.29	0.92	<0.001
6 mo postop–preop	2.16	0.29	0.92	<0.001
6 mo postop–1 mo postop	-1.80	0.29	0.92	<0.001
BMO-MRW				
1 mo postop–preop	18.01	0.92	15.85 to 20.17	<0.001
6 mo postop–preop	12.80	0.92	10.64 to 14.96	<0.001
6 mo postop–1 mo postop	-5.21	0.92	-7.37 to -3.05	<0.001

A Randomized Controlled Trial Comparing Femtosecond Laser-Assisted Cataract Surgery Versus Conventional Phacoemulsification Surgery

Roberts et al. *J Cataract Refract Surg.* 2019;45:11-20*

Surgical Outcomes

Visual Acuity

Refractive Outcomes

Patient-Reported Outcomes

OVERVIEW

STUDY DESIGN
Single-center prospective randomized interventional case-controlled trial to compare the clinical results of conventional phacoemulsification surgery with femtosecond laser-assisted cataract surgery

STUDY SITE(S)
Single center in the United Kingdom

PATIENTS
Four hundred eyes (400) of 400 patients (mean age 70.2 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional phacoemulsification surgery (CPS)

SURGICAL TECHNOLOGY
LenSx® Laser, INFINITI® Vision System, AcrySof® SA60AT intraocular lens (IOL) (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Surgical outcomes, uncorrected distance visual acuity (UDVA), refractive outcomes, patient-reported outcomes (EuroQOL 5 dimensions questionnaire [EQ-5D] and cataract surgery patient-reported outcome measures questionnaire [Cat-PROM5])

ANALYSIS AND CONCLUSIONS

This study confirmed the nonsignificant differences between LenSx® and CPS in terms of visual, refractive, and a range of other clinical and patient-reported outcomes.

Results from the study suggest that femtosecond laser–assisted cataract surgery with LenSx® might reduce the risk for posterior capsular rupture compared with CPS.

*This study was financially supported by Alcon.

STUDY RESULTS

VISUAL ACUITY AND REFRACTIVE OUTCOMES

- The mean uncorrected distance visual acuity (logarithm of the minimum angle of resolution [logMAR]) 0.15 ± 0.21 (SD) and 0.15 ± 0.19 logMAR after CPS and LenSx®, respectively (P=1.0); the pinhole-corrected visual acuity was 0.04 ± 0.12 and 0.04 ± 0.12, respectively (P=1.0) **(Table 1)**
- The manifest refraction spherical equivalent error was -0.14 ± 0.60 D after CPS and -0.12 ± 0.60 D after LenSx® (P=0.74); the proportion of eyes within ±0.5 D and ±1.0 D were similar between both groups **(Figure 1)**

SURGICAL OUTCOMES/COMPLICATIONS

- The increase in central corneal thickness was 13 ± 19 µm and 15 ± 25 µm after CPS and LenSx®, respectively (P=0.5); and the endothelial cell loss was 9.7 ± 13.7 % and 10.2% ± 13.7, respectively (P=0.76) **(Table 1)**
- The mean change in central foveal thickness was 9 ± 35 µm and 6 ± 35 µm, respectively (P=0.55) **(Table 1)**
- There were no differences in total rates of intraoperative or postoperative complications; the rate of posterior capsule rupture was significantly higher in the CPS group (P=0.03)

PATIENT-REPORTED OUTCOMES

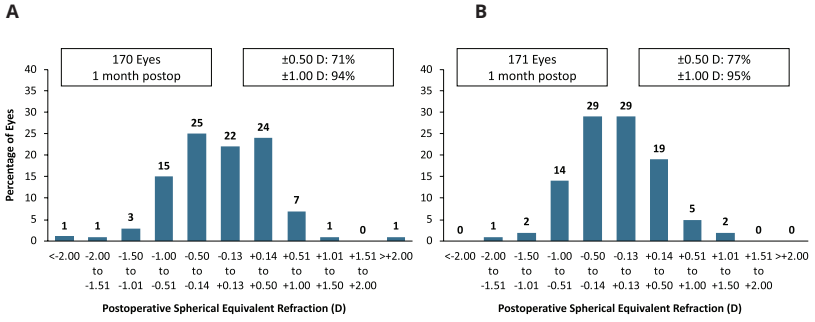
- The Cat-PROM5 demonstrated a substantial shift between preoperative to postoperative completions, signaling a significant self-reported reduction in visual difficulty after surgery that was similar in the two groups **(Table 1)**
- The EQ-5D summary index similarly reflected an improved score that was similar in the two groups; the visual analogue score was unchanged in the LenSx® group but increased in the CPS group **(Table 1)**

Table 1. Postoperative results in the LenSx® and CPS treatment arms. Adapted from Roberts et al. *J Cataract Refract Surg.* 2019;45:11-20.

Parameter (means ± SD)	LenSx®	CPS	P-value
UDVA (logMAR)	0.15 ± 0.19	0.15 ± 0.21	1.0
PHVA (logMAR))	0.04 ± 0.12	0.04 ± 0.12	1.0
Change in CCT (mm)	15 ± 25	13 ± 19	0.5
ECL (%)	10.2 ± 13.7	9.7 ± 13.7	0.76
Change in CFT (µm)	6 ± 35	9 ± 35	0.55
Absolute SE refractive error from target refraction (D)	0.42 ± 0.40	0.40 ± 0.46	0.65
SE refraction within ±0.5 D of intended (%)	67.3	72.3	0.32
Change in Cat-PROM5 calibrated score	-2.44 ± 3.13	-2.22 ± 2.89	0.49
Change in EQ-5D-3L index score	0.03 ± 0.17	0.03 ± 0.16	1.0
Change in EQ-5D visual analogue scale	0.71 ± 13.61	4.18 ± 13.91	0.02*

*Cat-PROM5, cataract surgery patient-reported outcome measures questionnaire; CCT, central corneal thickness; CFT, central foveal thickness; ECL, endothelial cell loss; logMAR, logarithm of the minimum angle of resolution; PHVA, pinhole visual acuity; SE, spherical equivalent; UDVA, uncorrected distance visual acuity. *Statistically significant.*

Figure 1. Spherical equivalent refractive accuracy at 1 month after LenSx® **(A)** and CPS **(B)**.



Comparison of Cumulative Dispersed Energy (CDE) in Femtosecond Laser-Assisted Cataract Surgery (FLACS) and Conventional Phacoemulsification

Saeedi et al. *Int Ophthalmol.* 2019;39:1761-1766

OVERVIEW

STUDY DESIGN
Prospective cohort study to compare the amount of phacoemulsification ultrasound energy used between eyes undergoing femtosecond laser-assisted cataract surgery and conventional phacoemulsification

STUDY SITE(S)
Single center in the United States

PATIENTS
One (1) eye of consecutive patients (mean age of 70.6 years) from 1159 surgeries conducted by 3 surgeons

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional phacoemulsification

SURGICAL TECHNOLOGY
LenSx®
Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Exposure and cumulative dispersed energy (CDE); age, surgeon, eye side, and eye sequence (first versus second eye) were covariates

ANALYSIS AND CONCLUSIONS

Femtosecond laser-assisted cataract surgery with LenSx® results in a modest reduction of phacoemulsification energy as compared to conventional phacoemulsification, most notably in specific surgical situations.

While this modest reduction was statistically significant overall in this large series, it may not be clinically significant; further study accounting for surgical approach, surgical technique, lens density, and laser settings is required to better understand when LenSx® may be most effective in lowering CDE.

STUDY RESULTS

SURGICAL OUTCOMES

- Assessment for confounding was conducted by determining the change in the β coefficient (a measure of the strength of effect) when adjusting for each covariate
- Age, surgeon, and eye sequence showed a significant association with both types of surgery and log CDE and resulted in a greater than 10% change in calculated β coefficient
- After adding these variables sequentially to the crude model, surgeon and age resulted in a greater than 10% change in calculated β coefficient, but eye sequence did not
- The final model showed that LenSx® resulted in significantly lower CDE as compared to conventional phacoemulsification (β = 0.89, 95% CI 0.83, 0.95) **(Table 1)**
- When stratified by eye side, a β coefficient of 0.92 (95% CI 0.84, 1.03) was observed for the right eye and 0.85 (95% CI 0.76, 0.94) for the left eye; this indicates that the use of LenSx® results in a statistically significant decrease in CDE in left eyes but not in right eyes
- When stratified by eye side and surgeon while controlling for age, LenSx® performed on left eyes operated on by surgeon 1 resulted in lower CDE as compared to conventional phacoemulsification (β = 0.76, 95% CI 0.66, 0.87), but not for right eyes operated on by surgeon 1 (β = 0.92, 95% CI 0.79, 1.07) or for eyes operated on by surgeons 2 or 3 **(Table 2)**

Table 1. Overall effect of LenSx® on CDE accounting for age and surgeon.

	β	95% CI
LenSx® (n=364)	0.89	(0.83, 0.95)
Surgeon 1 (n=590) 2 (n=169) 3 (n=400)	 1.46 2.61 1	 (1.36, 1.58) (2.36, 2.92) (REF)
Age, years	1.03	(1.02, 1.03)

CDE, cumulative dispersed energy; CI, confidence interval.

Table 2. β Coefficient for LenSx® stratified by surgeon and eye side.

	Right eye (n = 582)		Left eye (n = 577)	
	β	95% CI	β	95% CI
Surgeon 1	0.92	(0.79, 1.07)	0.76	(0.66, 0.87)
Surgeon 2	0.92	(0.73, 1.19)	0.95	(0.77, 1.16)
Surgeon 3	0.94	(0.78, 1.12)	0.98	(0.79, 1.21)

CI, confidence interval.

Long-Term Intraocular Pressure Changes After Femtosecond Laser-Assisted Cataract Surgery in Healthy Eyes and Glaucomatous Eyes

Shah et al. *J Cataract Refract Surg.* 2019;45:181-187*

OVERVIEW

STUDY DESIGN
Retrospective case series to examine the long-term effect of femtosecond laser-assisted cataract surgery on intraocular pressure (IOP) in healthy (control) and glaucomatous eyes

STUDY SITE(S)
Two centers in the United States

PATIENTS
Five hundred and four (504) eyes; 111 in glaucoma group (mean age of 70.7 years), 167 in glaucoma group (mean age of 68.6 years), and 226 in the control group (mean age of 67.0 years)

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery

SURGICAL TECHNOLOGY
LenSx®
Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Change in mean IOP from baseline to postoperatively

ANALYSIS AND CONCLUSIONS

Control eyes and eyes with glaucoma had an initial mean IOP rise 1 day after LenSx® surgery; this was followed by a significant decrease starting at 1 month, and this reduction was sustained through 3 years in the glaucoma group.

The IOP reduction at 1 year was proportional to preoperative IOP and of a similar magnitude seen in previous studies of conventional phacoemulsification.

*Dr. Seibold receives research support from Alcon Laboratories, Inc.

STUDY RESULTS

CHANGES IN INTRAOCULAR PRESSURE

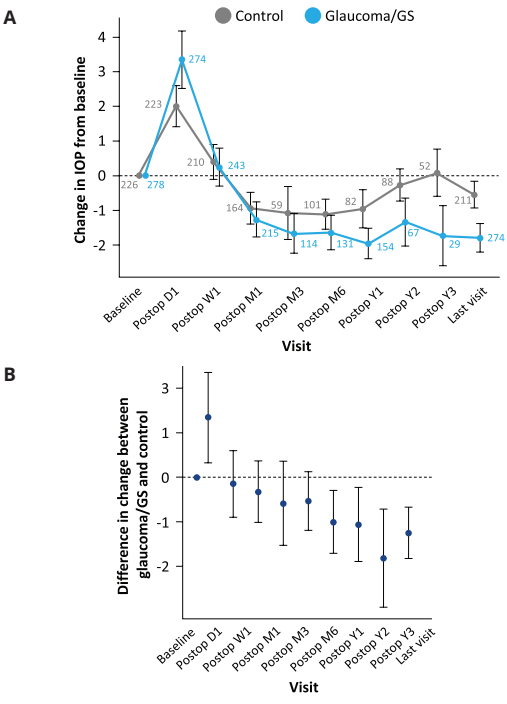
- Both the control group and glaucoma/glaucoma suspect group had an initial mean increase in IOP one day after surgery (control: +2.0 mm Hg; 95% CI, 1.4-2.6; glaucoma/glaucoma suspect: +3.4 mm Hg; 95% CI, 2.5-4.2) (both P<0.001) (**Figure 1**)
- One week postoperatively, there was no significant difference in IOP from baseline in either group; starting at month 1, both groups had a significant decrease in IOP that persisted until year 1 in the control group and through all timepoints to year 3 in the glaucoma group (**Figure 1**)
- Compared to the control group, the IOP in the glaucoma/.5
- At the other timepoints in between, there was no significant difference in IOP change between the two groups (**Figure 1**)
- The IOP change from baseline was similar at all timepoints between the glaucoma subgroup and the glaucoma suspect subgroup
- In both groups, the lowest IOP change was in eyes with the lowest preoperative IOP, while the highest IOP reduction was in eyes with the highest preoperative IOP (**Table 1**)

Table 1. Change in IOP at 1 year by level of preoperative IOP.

	Baseline IOP (mm Hg)				
Groups	**9-14**	**15-17**	**18-19**	**≥20**	**p-value**
Control Eyes (n) Mean ΔIOP (%)	52 +0.538 (+4)	18 -3.111 (-20)	7 -3.857 (-21)	5 -5.000 (-24)	<0.001
Glaucoma/GS Eyes (n) Mean ΔIOP (%)	77 -0.286 (-2)	36 -2.583 (-16)	21 -1.952 (-11)	19 -6.947 (-32)	<0.001

Δ, change by 1 year postoperatively; GS, glaucoma suspect; IOP, intraocular pressure.

Figure 1. (**A**) Mean change in IOP (mm Hg) from baseline in control and glaucoma/glaucoma suspect groups at each postoperative timepoint. Bars indicate 95% confidence intervals (n values indicated adjacent to each plotted value). Values adjusted for age, sex, and baseline IOP. (**B**) Difference in mean IOP between groups (glaucoma/glaucoma suspect – control), adjusting for baseline difference.



GS, glaucoma suspect; IOP, intraocular pressure.

Comparative Evaluation of Femtosecond Laser-Assisted Cataract Surgery and Conventional Phacoemulsification in Eyes with a Shallow Anterior Chamber

Surgical Outcomes

Visual Acuity

Vasavada et al. *J Cataract Refract Surg.* 2019;45:547-552

OVERVIEW

STUDY DESIGN

Prospective randomized masked clinical study to compare intraoperative performance and postoperative outcomes between femtosecond laser-assisted cataract surgery and conventional phacoemulsification in eyes with a shallow anterior chamber

STUDY SITE(S)

Single center in India

PATIENTS

Ninety-one (91) eyes in the LenSx® group (mean age of 67.2 years) and 91 eyes in the conventional phacoemulsification group (mean age of 63.7 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser, CENTURION® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Primary outcome: central corneal thickness (CCT); secondary outcomes: corneal clarity, anterior chamber cells and flare, endothelial cell density (ECD), coefficient of variance, hexagonality, and uncorrected distance visual acuity (UDVA) up to 6 months

ANALYSIS AND CONCLUSIONS

This study found that in eyes with shallow anterior chambers, LenSx® maintained clearer corneas, showed less increase in CCT, lower anterior chamber inflammation, and better UDVA in the early postoperative period compared with conventional phacoemulsification.

The authors concluded that these favorable results suggest LenSx® could be considered as a favorable alternative to conventional phacoemulsification in eyes with shallow anterior chambers.

STUDY RESULTS

PRIMARY OUTCOME

- An increase in CCT compared with baseline was observed in both the LenSx® and conventional phacoemulsification groups at 1 day and 1 week postoperatively (**Table 1**)
- Mean CCT was significantly lower with LenSx® vs conventional phacoemulsification (540.40 µm± 49.40 [SD] vs 556±12.5 µm, P=0.03) at 1 day and 1 week (535.5±44.3 µm vs 551±40.8 µm, P=0.04), returning to baseline at 1 month in both groups (**Table 1**)

SECONDARY OUTCOMES

- Cumulative dissipative energy was lower in the LenSx® group (P<0.05)
- A statistically significant higher percentage of eyes had clearer corneas on day 1 with LenSx® (79.12%) compared with conventional phacoemulsification (63.73%) (P<0.005)
- Significantly fewer eyes had higher than grade 2 anterior chamber cells and flare with LenSx® at 1 day and 1 week; there were no detectable cells or flare in any eyes in either group by 1 month
- At 6 months, the reduction in ECD was lower in the LenSx® group; the difference was not statistically significant
- At 6 months, the mean percentage reduction in ECD was 7.55% in the LenSx® group versus 8.20% in the conventional phacoemulsification group; the difference was not statistically significant
- At 1 week, UDVA was better with LenSx® (0.089 ± 0.31 logarithm of the minimum angle of resolution [logMAR] vs 0.178 ± 0.65 logMAR) (P=0.042) (**Table 2**)

Table 1. Postoperative central corneal thickness between LenSx® and conventional phacoemulsification at different timepoints.

	Mean CCT (µm) ± SD			
Parameter	Preop	1 Day Postop	1 Week Postop	1 Month Postop
LenSx®	531.2 ± 42.6	540.0 ± 49.40	535.0 ± 44.30	532.3 ± 40.90
Conventional	528.6 ± 39.2	556 ± 12.5	551 ± 40.8	530.1 ± 39.6
P-value	0.55	0.03	0.04	0.66

CCT, central corneal thickness.

Table 2. Comparison of UDVA between LenSx® and conventional phacoemulsification at different timepoints.

	Mean UDVA (logMAR) ± SD			
Parameter	Preop	1 Week Postop	1 Month Postop	3 Months Postop
LenSx®	0.67 ± 0.05	0.18 ± 0.31	0.14 ± 0.10	0.10 ± 0.09
Conventional	0.72 ± 0.67	0.27 ± 0.65	0.12 ± 0.09	0.09 ± 0.11
P-value	0.56	0.042	0.67	0.74

logMAR, logarithm of the minimum angle of resolution; UDVA, uncorrected distance visual acuity.

Ocular Cyclorotation and Corneal Axial Misalignment in Femtosecond Laser-Assisted Cataract Surgery

Xiang et al. *Curr Eye Res.* 2019;44:1313-1318

OVERVIEW

STUDY DESIGN
Retrospective study to explore ocular cyclorotation and the source of corneal axial misalignment during femtosecond laser-assisted cataract surgery

STUDY SITE(S)
China (study centers not specified)

PATIENTS
Fifty (50) eyes of 45 sequential patients; mean age of 59.2 years, range: 26-88 years

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Ocular cyclorotation, crystalline lens tilt, real angle between primary incision and secondary incision (RAPS), theoretic angle between the primary and secondary incisions (TAPS)

ANALYSIS AND CONCLUSIONS

Ocular cyclorotation commonly occurred during cataract surgery with LenSx®; increased axial length was associated with less ocular cyclorotation and increased crystalline lens tilt was related to more ocular cyclorotation.

The authors emphasized that machinery systemic errors during corneal astigmatism correction by arcuate incision with LenSx® should be taken into consideration.

STUDY RESULTS

SURGICAL COMPLICATIONS

- The average ocular cyclorotation occurring with LenSx® was 8.03 degrees, indicating a 28% undercorrection when treating corneal astigmatism with arcuate incisions
- The maximum ocular cyclorotation was 19.1 degrees, which can lead to a 65% undercorrection in astigmatism
- Overall, 40% of eyes (20/50) showed cyclorotation greater than 9 degrees **(Figure 1)**
- Crystalline lens tilt was 3.30 ± 1.44 degrees (0.93-6.44 degrees)
- Ocular cyclorotation positively correlated with crystalline lens tilt (r = 0.37, P=0.008), but negatively correlated with axial length (r = −0.29, P=0.038) **(Figure 2)**
- No significant correlation was found between ocular cyclorotation and LogMAR visual acuity (r = 0.01, P=0.971), corneal diameter (r = −0.03, P=0.860) or age (r = 0.13, P=0.377)
- Results for TAPS and RAPS were inconsistent (TAPS was 89.78 ± 1.45 degrees and RAPS was 85.68 ± 2.04 degrees); the approximate 4 degree difference can result in a 14% undercorrection of astigmatism
- The angle error was 4.11 ± 1.28 degrees (0 to 6.1 degrees) and showed significant difference (P<0.001)

Figure 1. Frequency of cyclorotation in LenSx® patients.

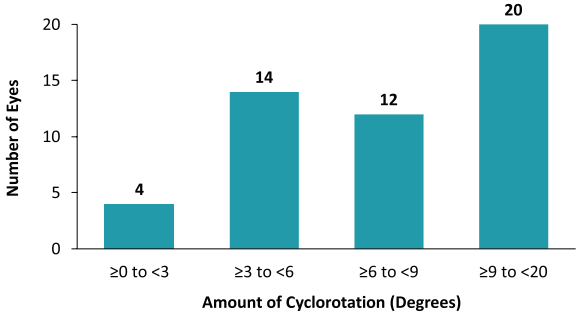
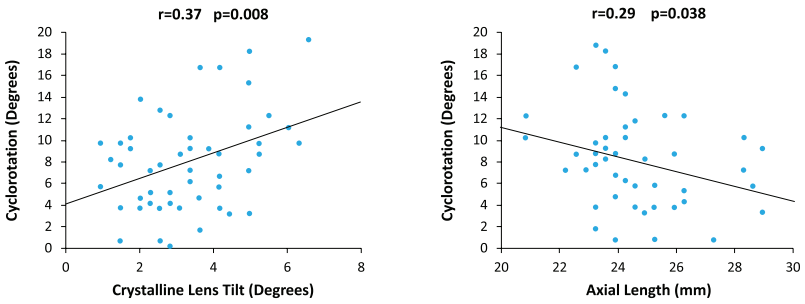


Figure 2. Correlations with ocular cyclorotation and crystalline lens tilt. A positive correlation was found between ocular cyclorotation and crystalline lens tilt, while a negative correlation was found between ocular cyclorotation and axial length.



Lens Capsule-Related Complications of Femtosecond Laser-Assisted Capsulotomy Versus Manual Capsulorhexis for White Cataracts

Zhu et al. *J Cataract Refract Surg.* 2019;45:337-342

OVERVIEW

STUDY DESIGN
Prospective consecutive nonrandomized comparative cohort study to compare lens capsule-related complications resulting from femtosecond laser-assisted capsulotomy and manual capsulorhexis in patients with white cataracts.

STUDY SITE(S)
Single center in China

PATIENTS
One hundred and thirty-two (132) eyes of 132 patients with white cataract; mean age of 69.4 years in the femtosecond laser group, 66.3 years in the manual group

SURGICAL METHODOLOGY
Femtosecond laser-assisted capsulotomy and manual capsulorhexis

SURGICAL TECHNOLOGY
LenSx® Laser with SoftFit™ Patient Interface (Alcon Laboratories, Inc.); Stellaris® (Bausch & Lomb)

KEY ENDPOINT(S)
Lens capsule-related events, including anterior capsule tears, posterior capsule ruptures (PCRs), incomplete capsulotomies, and irregular capsulorhexes were recorded; surgical parameters, postoperative visual acuities, intraocular lens (IOL) decentrations

ANALYSIS AND CONCLUSIONS

The authors concluded that LenSx® is a good choice for patients with white cataract because it decreases the incidence of anterior capsule tears in type I white cataracts, while also allowing for a precise capsulotomy and a well-centered IOL.

One caveat in this conclusion is that the incidence of incomplete capsulotomy can be increased with the use a femtosecond laser for white cataracts; the investigators advised that surgeons observe the residual region carefully after using a laser, with trypan blue being particularly useful in this regard.

STUDY RESULTS

LENS CAPSULE-RELATED EVENTS

- No cases of anterior capsule tears were observed in the LenSx® group (0/66 eyes), compared with an incidence of 8/66 eyes (12.1%) in the manual phacoemulsification group (P=0.007) (**Table 1**)
- When white cataract cases were classified as type I or type II, and the incidence of anterior capsule tears were compared by the different types with different surgical methods, the difference was significant in type I cases but insignificant in type II cases (P=0.006)
- All 8 anterior capsule tear cases and 5 PCR cases were in type I eyes
- The incidence of PCR was higher in the manual group, although without statistical significance (1 eye [1.5%] in the LenSx® group versus 4 eyes [6.1%] in the manual group) (P=0.362) (**Table 1**)
- There was also no statistically significant difference in vitreous loss between the LenSx® and manual groups (P=0.118)

OTHER OUTCOMES

- The mean ultrasound power, absolute phacoemulsification time, and effective phacoemulsification time were similar in both groups (**Table 2**)
- Aside from 4 cases with retinal disease, uncorrected and corrected distance visual acuity measured at 1 week and 1 month were similar between the LenSx® group and the manual group
- IOL centration was significantly better in the LenSx® group after 1 week (P=0.003); in addition, the circularity index was closer to 1 (P<0.001); the diameter of the capsulorhexis seemed closer to 5.0 mm (P=0.026), and the stability of capsulorhexis diameters was better (P=0.009) in the LenSx® group

Table 1. Comparison of surgical events between different surgical methods (LenSx® and manual phacoemulsification) and different types of white cataracts (type I and type II).

Parameter	LenSx®	Manual	(P-value)
Total			
Anterior capsule tear, n (%)	0 (0)	8 (12.1)	0.007
Posterior capsule rupture, n (%)	1 (1.5)	4 (6.1)	0.362
Vitreous loss, n (%)	0 (0)	4 (11.4)	0.118
Type I white cataract, n	37	35	--
Anterior capsule tear, n (%)	0 (0)	8 (22.9)	0.006
Posterior capsule rupture, n (%)	1 (2.7)	4 (11.4)	0.321
Vitreous loss, n (%)	0 (0)	4 (11.4)	0.118
Type II white cataract, n	29	31	--
Anterior capsule tear, n (%)	0 (0)	0 (0)	--
Posterior capsule rupture, n (%)	0 (0)	0 (0)	--
Vitreous loss, n (%)	0 (0)	0 (0)	--

Table 2. Comparison of surgical data between LenSx® and manual phacoemulsification groups.

Parameter	LenSx®	Manual	(P-value)
Mean US power (%) ± SD	16.98 ± 8.33	14.80 ± 7.50	0.084
Mean absolute phaco time (s) ± SD	66.86 ± 42.52	83.73 ± 52.77	0.138
Mean effective phaco time (s) ± SD	13.29 ± 9.64	13.31 ± 11.39	0.691
IOL implantation in ciliary sulcus, n (%)	0 (0)	4 (11.4)	0.118

Cataract Surgery: A Retrospective, Observational Study From an Outpatient Clinic in France

Charles Crozafon et al. *Eur J Ophthalmol.* 2020;1120672120925766*

Surgical Outcomes

Surgical Complications

Visual Acuity

OVERVIEW

STUDY DESIGN

Retrospective observational study to compare real-world safety and efficacy outcomes of cataract surgery performed with femtosecond laser-assisted cataract surgery or manual phacoemulsification cataract surgery procedures

STUDY SITE(S)

Electronic medical record database, France

PATIENTS

One thousand three hundred and seven (1307) patients; 496 patients in the femtosecond laser group (mean age of 71.7 years), 811 patients in the manual phacoemulsification group (mean age of 72.2 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser, VERION™ Image Guided System, INFINITI® Vision System, CENTURION® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Primary endpoint: cumulative dissipated energy (CDE); additional endpoints: proportion of eyes reaching emmetropia, best-corrected distance visual acuity (BCDVA), proportion of eyes with post-surgical complications, including corneal edema and posterior capsule opacification

ANALYSIS AND CONCLUSIONS

This retrospective study found that LenSx® surgery was associated with significantly lower cumulative dissipated energy when compared to manual phacoemulsification cataract surgery.

The investigators noted that these results support the hypothesis that LenSx® surgery involves less mechanical trauma than manual surgery, which might lead to more consistent refractive and safety outcomes, though such outcomes were found to be comparable in this study.

*This study was supported by Alcon Vision LLC.

STUDY RESULTS

CUMULATIVE DISSIPATED ENERGY

- Mean CDE (the primary endpoint) was significantly lower for cataract surgery with LenSx® (6.5 percent-seconds) than for that with manual phacoemulsification (14.3 percent-seconds; adjusted difference (95% CI: 7.79 [7.13–8.45]; P< 0.0001), representing a 55% reduction in effective CDE with LenSx® (**Table 1**)
- Similar reductions in mean CDE were observed for LenSx® compared with manual phacoemulsification when analyzed by the individual vision system used (INFINITI® or CENTURION®); the differences were still significant when adjusting for multiple comparisons

OTHER OUTCOMES

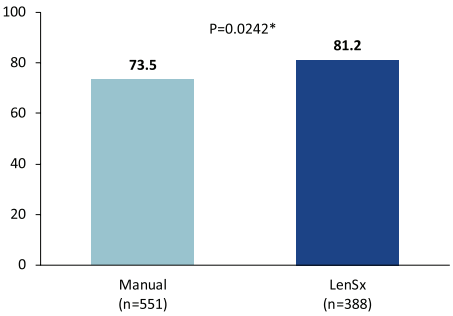
- A greater proportion of eyes reached emmetropia ± ≤0.5 D with LenSx® (81.2%) than with manual phacoemulsification (73.5%); adjusted odds ratio (OR) (95% CI): 0.65 (0.45–0.95); P=0.024 (**Figure 1**)
- However, there was no difference when using the greater threshold ± ≤1.0 D for emmetropia (88.7% vs 86.4%); adjusted OR (95% CI): 0.84 (0.54–1.29); P=0.46
- Mean change in BCDVA was similar for LenSx® (−0.17 LogMAR change from baseline) compared with manual phacoemulsification (−0.16 LogMAR change from baseline) 6 months after surgery (P=0.33); changes were slightly better for LenSx® at 1 week (−0.14 vs −0.12, P=0.03) and 1 month (−0.17 vs −0.15, P=0.12), but these earlier time points were not adjusted for multiple comparisons
- Mean change in the proportion of eyes with corneal edema, posterior capsule opacification or other complications were not significantly different between cohorts when adjusted for multiple comparisons
- Uncontrolled intraocular pressure within 1 week after surgery was less frequent with LenSx® (1.0%) compared with manual surgery (3.2%) (P=0.02)

Table 1. Adjusted mean cumulative dissipated energy in the manual phacoemulsification and LenSx® cohorts.

Parameter	LenSx® Percent-seconds (N)	Manual Percent-seconds (N)	P-value
Overall study population	6.5 (493)	14.3 (743)	<0.0001*
CENTURION® Vision System	6.8 (458)	15.0 (109)	<0.0001*
INFINITI® Vision System	6.9 (35)	14.0 (634)	<0.0001*

**P-value and adjusted means calculated using generalized estimating equations that adjusted for cataract grade and allowed correlation of outcomes for patients with multiple study eyes.*

Figure 1. Proportion of eyes reaching emmetropia in the manual phacoemulsification and LenSx® cohorts.



**P-value not significant when adjusted for multiple comparisons; P-value calculated using generalized estimating equations that adjusted for lens type (toric, multifocal and non-toric monofocal) and allowed correlation of outcomes for patients with multiple study eyes.*

Visual and Refractive Outcomes and Complications in Femtosecond Laser-Assisted Versus Conventional Phacoemulsification Cataract Surgery: Findings From a Randomised, Controlled Clinical Trial

Surgical Outcomes

Visual Acuity

Refractive Outcomes

Dzhaber et al. *Br J Ophthalmol.* 2020 [published online ahead of print, 2020 February 17]

OVERVIEW

STUDY DESIGN

Secondary analysis of an intraindividual, randomized, controlled clinical trial to compare visual and refractive outcomes, changes in intraocular pressure (IOP), and complications of femtosecond laser-assisted cataract surgery to conventional phacoemulsification surgery in paired eyes from the same patients

STUDY SITE(S)

Single center in the United States

PATIENTS

One hundred and ten (110) paired eyes from 55 patients; mean age of 68 years (range: 33 to 85 years)

SURGICAL METHODOLOGY

Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY

LenSx® Laser, INFINITI® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Primary outcomes: uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction and mean absolute refractive error over 3-month follow-up period; secondary outcomes: IOP, intraoperative and postoperative complications

ANALYSIS AND CONCLUSIONS

This study showed that in paired eyes from the same patients managed with either LenSx® or manual phacoemulsification, the 3-month postoperative refractive and visual outcomes were similar between the two procedures.

Intraocular pressure was also comparable between the two groups after postoperative day 1; the authors recommended that further investigations be conducted to assess the effect of LenSx® on postoperative changes in IOP and development of other complications.

STUDY RESULTS

VISUAL ACUITY

- UDVA and CDVA were not statistically different between the LenSx® and manual phacoemulsification groups over the postoperative follow-up period (**Table 1**)
- At month 3, a UDVA of 20/20 or better was achieved by 56.6% of eyes in the LenSx® group and 63.3% of eyes in the manual phacoemulsification group (P=0.48), while a CDVA of 20/20 or better was achieved by 86.1% of eyes in the LenSx® group and 88.9% of eyes in the manual phacoemulsification group (P=0.56)

REFRACTIVE OUTCOMES

- Manifest refraction parameters were not statistically different between the LenSx® and manual phacoemulsification groups over the postoperative follow-up period (**Table 2**)
- In addition, mean absolute refractive error was not significantly different between the two groups at postoperative month 1 (0.3±0.2 D for LenSx® vs 0.4±0.3 D for manual phacoemulsification, P=0.18) and month 3 (0.3±0.3 D for LenSx® vs 0.3±0.3 D for manual phacoemulsification, P=0.71)
- There was no statistically significant difference between FLACS and manual cataract surgery for total surgery time (WMD, 1.25; 95% CI, -0.08 to 2.59; P=0.07), capsulotomy circularity using a second formula (WMD, 0.05; 95% CI, -0.01 to 0.12; P=0.10), and corneal endothelial cell count (WMD, 73.39; 95% CI, -6.28 to 153.07; P=0.07)
- As well, there was a significantly higher concentration of prostaglandins after FLACS relative to manual cataract surgery (WMD, 198.34; 95% CI, 129.99-266.69; P<0.001)

SURGICAL COMPLICATIONS

- IOP was statistically higher in the LenSx® group on postoperative day 1 (20.6±5.7 mm Hg for LenSx® and 18.0±4.9 mm Hg for manual phacoemulsification, P=0.01), but there were no statistically significant differences for the remainder of the study
- Intraoperatively, one case of posterior capsular block syndrome was observed in the LenSx® group, resulting in a posterior capsular rupture, anterior vitrectomy and implantation of the IOL in the sulcus
- Postoperatively, one case of newly developed glaucoma was observed in the LenSx® group and one case of retinal tears in the manual phacoemulsification group

Table 1. Postoperative visual outcomes logMAR (mean ± SD).

Parameter	LenSx®	Manual	P-value*
UDVA			
1 Day	0.3±0.2	0.3±0.2	0.86
1 Week	0.1±0.2	0.1±0.2	0.65
1 Month	0.1±0.1	0.1±0.2	0.79
3 Months	0.1±0.1	0.06±0.1	0.07
CDVA			
1 Month	0.03±0.08	0.02±0.07	0.38
3 Months	0.05±0.07	−0.008±0.06	0.23

**Wilcoxon signed-ranks test. CDVA, corrected distance visual acuity; CPS, conventional phacoemulsification surgery; logMAR, logarithm of the minimum angle of resolution; UDVA, uncorrected distance visual acuity.*

Table 1. Postoperative refractive findings: sphere, cylinder and spherical equivalent (D) for patients aimed for emmetropia (mean ± SD).

Parameter	LenSx®	Manual	P-value*
Sphere			
1 Month	−0.7±0.5	−0.6±0.5	0.30
3 Months	−0.6±0.5	−0.7±0.5	0.72
Cylinder			
1 Month	0.7±0.5	0.6±0.3	0.36
3 Months	1.0±0.4	1.1±0.6	0.29*
Spherical equivalent			
1 Month	−0.2±0.4	−0.2±0.4	0.65
3 Months	−0.1±0.3	−0.1±0.3	0.22

**Wilcoxon signed-ranks test.*

Comparison of Changes in Corneal Endothelial Cell Density and Central Corneal Thickness Between Conventional and Femtosecond Laser-Assisted Cataract Surgery: A Randomised, Controlled Clinical Trial

Dzhaber et al. *Br J Ophthalmol.* 2020;104:225-229

OVERVIEW

STUDY DESIGN
Intraindividual randomized, controlled clinical trial to identify changes in endothelial cell density (ECD) and central corneal thickness (CCT) in eyes undergoing femtosecond laser-assisted cataract surgery compared with conventional phacoemulsification surgery (CPS)

STUDY SITE(S)
Single center in the United States

PATIENTS
One hundred and thirty-four (134) paired eyes from 67 patients

SURGICAL METHODOLOGY
Femtosecond laser-assisted cataract surgery and conventional (manual) phacoemulsification

SURGICAL TECHNOLOGY
LenSx® Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Changes in postoperative ECD and CCT. Secondary outcomes targeted intraoperative parameters and included EPT, CDE, amount of BSS use and OR time, as well as intraoperative complications.

ANALYSIS AND CONCLUSIONS

Postoperative corneal ECD and CCT were comparable between LenSx® and CPS during the 3-months follow-up period.

The authors hypothesize that the creation of corneal incisions by the LenSx® Laser might be implicated in an additional injury to endothelial cells, resulting in an overall ECL rate that is similar to that in CPS.

STUDY RESULTS

SURGICAL OUTCOMES

- ECD was not significantly different between the two groups preoperatively or at Month 1 or Month 3 postoperatively (postoperative month 1, P=0.18; postoperative month 3, P=0.19) (**Table 1**)
- No significant difference was observed in the mean CCT values between the two groups over the follow-up period (P>0.05) (**Table 2**)
- However, the mean relative change in CCT tended to be higher in the CPS group, but the difference was not statistically significant at postoperative Month 1 or Month 3.

PREDICTORS OF POSTOPERATIVE OUTCOMES

- In the LenSx® group, each of NS grade, BSS use, CDE and EPT were negatively correlated with ECD at POM3 (**Table 3**)
- A positive, statistically significant correlation was noted between CCT and each of CDE, BSS use and EPT at POM3.
- In the CPS group, the CDE was negatively correlated with ECD at POM3 (**Table 3**)
- CDE correlated with the NS grade in both LenSx® and CPS groups (r=0.37 with P=0.007 and r=0.48 with P<0.001, respectively) (**Table 3**)

Table 1. Mean (±SD) corneal endothelial cell density (cells/mm^2) and percentage of endothelial cell loss (%) between the LenSx® and CPS groups at each follow-up point.

	ECD (cells/mm^2)			ECL (%)		
Exam	LenSx® Group	CPS Group	P Value*	LenSx® Group	CPS Group	P Value*
Preoperative	2645 ± 275	2644 ± 309	0.37			
POM1	2370 ± 580	2467 ± 564	0.18	10.7 ± 20.0	6.8 ± 18.0	0.18
POM3	2374 ± 527	2433 ± 526	0.19	11.2 ± 17.9	8.0 ± 18.5	0.10

**Wilcoxon signed-rank test.*
CPS, conventional phacoemulsification surgery; ECD, endothelial cell density; ECL, endothelial cell loss; FLACS, femtosecond laser-assisted cataract surgery; POM1, postoperative month 1; POM3, postoperative month 3.

Table 2. Central corneal thickness (µm) and mean relative change in central corneal thickness (%) between the LenSx® and CPS groups at each follow-up point (mean±SD).

	CCT (µm)			Mean relative change in CCT (%)		
Exam	LenSx® Group	CPS Group	P Value	LenSx® Group	CPS Group	P Value
Preoperative	581 ± 45	579 ± 49	0.59			
POD1	607 ± 59	574 ± 45	0.08	8.4 ± 9.1	3.9 ± 8.0	0.25
POW1	595 ± 63	604 ± 57	0.29	3.7 ± 8.0	6.9 ± 8.2	0.10
POM1	593 ± 50	590 ± 57	0.27*	2.4 ± 8.4	3.0 ± 9.2	0.84*
POM3	578 ± 52	578 ± 48	0.99	0.2 ± 5.8	0.8 ± 7.1	0.63

**Wilcoxon signed-rank test.*
CCT, central corneal thickness; CPS, conventional phacoemulsification surgery; FLACS, femtosecond laser-assisted cataract surgery; POD1, postoperative day 1; POM1, postoperative month 1; POM3, postoperative month 3; POW1, postoperative week 1.

Table 3. Correlation coefficients (r) for intraoperative and postoperative outcomes.

Exam	LenSx® Group	CPS Group	P Value	LenSx® Group
CDE and NS	0.37	**0.007**	0.48	**<0.001**
ECD (POM3) and:				
NS	-0.15	0.26	-0.11	0.40
BSS use	-0.33	0.02	-0.04	0.80
CDE	-0.26	0.07	-0.34	0.01
EPT	-0.28	0.06	-0.04	0.80
CCT (POM3) and:				
CDE	0.41	0.03	0.1	0.61
BSS use*	0.49	0.007	0.06	0.75
EPT	0.38	0.04	-0.18	0.37

*Bold values indicate significance. *Pearson's correlation.*
BSS, balanced salt solution; CCT, central corneal thickness; CDE, cumulative dissipated energy; CPS, conventional phacoemulsification surgery; ECD, endothelial cell density; EPT, effective phacoemulsification time; FLACS, femtosecond laser-assisted cataract surgery; NS, nuclear sclerosis; POM3, postoperative month 3.

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LENSX® LASER IMPORTANT PRODUCT INFORMATION FOR CATARACT SURGERY, CORNEAL FLAP AND CORNEAL POCKETS & TUNNEL INCISIONS

CAUTION: Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

INDICATIONS FOR THE LENSX® LASER:

Cataract Surgery Indication

In the creation of corneal cuts/incisions (single-plane, multi-plane and arcuate) anterior capsulotomy and laser phacofragmentation during cataract surgery in adult patients. Each of these procedures may be performed either individually or consecutively during the same surgery.

Corneal Flap Indication

For use in the creation of a corneal flap in adult patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

Corneal Pockets and Tunnels

In adult patients, for the creation of corneal pockets for placement/insertion of a corneal inlay device; and for creation of corneal tunnels for the placement of corneal rings

RESTRICTIONS:

- Patients must be able to lie flat and motionless in a supine position.
- Patient must be able to understand and give an informed consent.
- Patients must be able to tolerate local or topical anesthesia.
- Patients with elevated IOP should use topical steroids only under close medical supervision.

CONTRAINDICATIONS:

Cataract Surgery Contraindications

- Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetocele with impending corneal rupture
- Presence of blood or other material in the anterior chamber
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy
- Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
- Corneal thickness requirements that are beyond the range of the system
- Corneal opacity that would interfere with the laser beam
- Hypotony, glaucoma* or the presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- History of lens or zonular instability
- Any contraindication to cataract or keratoplasty
- This device is not intended for use in pediatric surgery.

*Glaucoma is not a contraindication when these procedures are performed using the LenSx® Laser SoftFit® Patient Interface Accessory

Corneal Surgery (Flaps, Pockets, Tunnels) Contraindications

- Corneal lesions
- Corneal edema
- Hypotony
- Glaucoma
- Existing corneal implant
- Keratoconus
- This device is not intended for use in pediatric surgery.

Flap creation, tunnels, pockets and cataract procedures cannot be combined into a single treatment.

WARNINGS:

The LenSx® Laser System should only be operated by a physician trained in its use.

The LenSx® Laser delivery system employs one sterile disposable Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

PRECAUTIONS:

- Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser.
- Discard used Patient Interfaces as medical waste.

COMPLICATIONS:

Cataract Surgery AEs/Complications

- Corneal edema
- Capsulotomy, phacofragmentation, or cut or incision decentration
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tear
- Corneal abrasion or defect
- Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse
- Elevated pressure to the eye

Corneal Surgery (Flaps, Pockets & Tunnels) AEs/Complications

- Corneal edema
- Corneal or eye pain
- Corneal haze
- Epithelial in-growth
- Corneal abrasion or epithelial defect
- Infection/keratitis
- Corneal ectasia or endothelial perforation
- Decentered flap or pattern; uneven flap bed
- Incomplete dissection/inability to complete procedure
- Flap tearing or incomplete lift-off
- Free cap or buttonhole
- Elevated pressure to the eye

ATTENTION: Refer to the LenSx® Laser Operator's Manual for a complete listing of indications, warnings and precautions.

Notes

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Alcon