Surgical Outcomes and Safety of Femtosecond Laser Cataract Surgery

A Prospective Study of 1500 Consecutive Cases

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Objective: To report the surgical outcomes and safety of femtosecond (FS) laser cataract surgery (LCS) with greater surgeon experience, modified techniques, and improved technology.

Design: Prospective, interventional case series.

Participants: Fifteen hundred consecutive eyes undergoing FS laser cataract and refractive lens exchange surgery in a single group private practice.

Intervention: Femtosecond LCS.

Methods: All eyes undergoing LCS between April 2011 and March 2012 were included in the study. Cases underwent anterior capsulotomy, lens fragmentation, and corneal incisions with the Alcon/LenSx FS laser (Alcon/LenSx, Aliso Viejo, CA). The procedure was completed by phacoemulsification and insertion of an intraocular lens. The cases were divided into 2 groups: Group 1, initial experience consisting of the first 200 cases; and group 2, the subsequent 1300 cases performed by the same surgeons.

Main Outcome Measures: Intraoperative complication rates and comparison between groups.

Results: Both groups were comparable for baseline demographic parameters. Anterior capsule tears occurred in 4% and 0.31% of eyes, posterior capsule tears in 3.5% and 0.31% of eyes, and posterior lens dislocation in 2% and 0% of eyes in groups 1 group 2, respectively ($P<0.001$ for all comparisons). Number of docking attempts per case (1.5 vs 1.05), incidence of post-laser pupillary constriction (9.5% vs 1.23%), and anterior capsular tags (10.5% vs 1.61%) were significantly lower in group 2 ($P<0.001$ for all comparisons).

Conclusions: In the authors' experience, the surgical outcomes and safety of LCS improved significantly with greater surgeon experience, development of modified techniques, and improved technology.

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Cataract surgery is the most commonly performed ophthalmic procedure worldwide. Key steps of phacoemulsification surgery that impact safety and refractive outcomes are currently performed manually. The quality of the anterior capsulotomy influences the rate of complications and the refractive outcomes of surgery, but is also one of the most difficult steps for trainees and inexperienced surgeons to master.[1–3] Newer manual phacoemulsification techniques to fragment and remove the lens nucleus reduce ultrasonic energy requirements, but are technically challenging.[4] Clear corneal incisions offer speed of recovery and improved visual outcomes, but can undergo mechanical deformation and leakage.[5–7]

Femtosecond (FS) lasers deliver ultrashort pulses of energy at near infrared wavelengths and have been used in ophthalmology for many years, most commonly to create corneal flaps during LASIK corneal refractive surgery.[8] Technology integrating high-resolution anterior segment imaging with an FS laser capable of treating tissue significantly deeper in the eye now offers a system with the capacity of creating main, side-port, and astigmatic corneal incisions, the anterior capsulotomy and fragmenting or softening of the nucleus with automated, computer-guided laser precision with minimal collateral tissue damage.[9–11] There has been substantial progress in software development and surgical experience since the introduction of first-generation FS cataract lasers with emerging evidence of reduced phacoemulsification time, better wound architecture, greater precision and accuracy of the anterior capsulotomy, and more stable and predictable positioning of the intraocular lens.[12–16]

Because of this, the application of FS lasers has the potential to improve patient outcomes and allow surgeons of different experience and skill levels to perform better cataract surgery. The disruptive effect of this new technology on refractive and visual outcomes, complication rates, patient safety, other technologies related to cataract surgery, economics, and cost-effectiveness for patients, health insurance organizations, and day surgeries has generated much interest and discussion amongst ophthalmologists.[17–19]

We have reported our early experience with laser cataract surgery (LCS).[20–22] Although the FS laser increased the ease and predictability of the steps involved in cataract surgery, there was a definite learning curve associated with

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Table 1. Treatment Parameters for LenSx Femtosecond Laser

	Primary Incision	Side-port Incision	Anterior Capsulotomy	Nuclear Fragmentation
Energy (μJ)	6.2	6.2	13–14	15
Configuration	3-plane reverse trapezoid	Single-plane	4.9-mm diameter	4-segment cross, 2.5/5.0-mm diameter cylinders
Spot/layer	6/6	6/6	4/3	8/7
Length (mm)	1.8	1.2	—	—
Delta value (μm)	—	—	200 (anterior) 300 (posterior)	700 (anterior) 800 (posterior)

an initial high rate of complications. The purpose of this follow-up study is to evaluate the rate of complications in a large, prospective series performed by surgeons experienced with the FS laser for cataract surgery and to compare the complication rate with the initial learning curve cohort performed by the same surgeons.

Patients and Methods

This was a single-center, prospective, consecutive cohort study. Ethics approval was obtained from the local human research ethics committee for the evaluation of the safety and success of the LenSx laser system (Alcon, Fort Worth, TX). The study was a part of a prospective, multicenter, nonrandomized, postmarket evaluation undertaken after local regulatory approval was obtained for clinical use of the LenSx system. An in-depth discussion about the risks and benefits of the procedure was followed by informed written consent. All procedures were performed at Vision Eye Institute between April 2011 and March 2012.

All patients underwent a detailed preoperative assessment, including slit-lamp biomicroscopy, tonometry, measurement of uncorrected and corrected distance visual acuity, manifest refraction, and corrected near visual acuity. Cataract investigations included measurement of axial length and biometry (IOLMaster V.5, Carl Zeiss Meditech Inc, Jena, Germany); pachymetry, corneal topography, and lens densitometry (Allegro Oculyzer, Wavelight AG, Erlangen, Germany); specular microscopy (EM-3000, Tomey, Phoenix, AZ); and optical coherence tomography (OCT; Stratus OCT, Carl Zeiss Meditech Inc) for macular thickness. Patients with corneal opacities or poorly dilating pupils (<5 mm) limiting visualization of the anterior segment and anterior capsule; advanced glaucoma; hypotony or narrow palpebral fissures; and nystagmus or hemofacial spasm preventing placement of the docking ring were excluded from the study.

Operative Technique

All procedures were performed with the LenSx laser under topical anesthesia with 0.4% oxybuprocaine. Standard preoperative medications were ketorolac tromethamine (Acular, Allergan Inc, Irvine, CA) 4 times daily for 3 days before surgery; 1% tropicamide, 10% phenylephrine, and 1% cyclopentolate (Minims, Chauvin Pharmaceuticals, Kingston-Upon-Thames, UK) 1 hour before surgery for pupillary dilation. The disposable patient interface was docked to the eye and the individual patient treatment programmed into the laser. The anterior capsulotomy, nuclear-fragmentation, primary and side-port corneal incisions, and corneal relaxing incisions (if required) were then created with the FS laser under OCT image control. Treatment parameters for the LenSx FS laser were based on surgeon experience and are summarized in Table 1.

After completion of the laser procedure, the patient was transferred to the operating room. The laser-cut main corneal incision was opened with a Slade spatula (Asico, Westmont, IL) or directly with the phaco tip. The anterior capsular button was removed either with Utrata forceps (Katena Products Inc, Denville, NJ) or using suction with the phaco hand piece. Some surgeons performed hydrodissection, whereas others omitted this step as the laser-generated gas had created a "pneumo-dissection" wave resulting in adequate mobilization of the nucleus. The laser cut lens segments were divided either with an Akahoshi chopper (Katena Products Inc) or by using a direct "chop" technique. The surgery was then completed with standard phacoemulsification procedure using the Infiniti Vision System Unit (Alcon Inc), automated irrigation/aspiration to remove the cortex, and implantation of an intraocular lens (IOL) in the capsular bag.

The standard postoperative regimen included 1 drop each of 0.3% ciprofloxacin (Ciloxan, Alcon Inc), ketorolac tromethamine (Acular, Allergan Inc), and 0.1% dexamethasone ophthalmic suspension (Maxidex, Alcon Inc) 4 times a day for 2 weeks, then dexamethasone drops twice a day for another week. Each patient was followed at days 1 and 14, and weeks 6 and 12 after surgery.

As per protocol, all subjects were monitored intraoperatively for the presence (or absence) of complications, which were recorded for future analysis. Complications noted at the FS laser stage included suction break (before or during laser ablation) and redocking attempts. During the operating room procedure, the need to create corneal incisions manually with a keratome, the presence of anterior capsular tags, anterior radial capsular tears, posterior capsular rupture (with or without vitreous loss) and posterior lens dislocations were noted after each surgery.

Statistical Analysis

For comparison, surgeries were divided into 2 groups: group 1 comprising the first 200 cases, and group 2 the subsequent 1300 cases. The primary outcome measures were the incidence of intraoperative complications in cases across the total cohort; and comparison of complication rates between groups. Statistical analysis was performed with SPSS version (v 19.0 IBM SPSS, Chicago, IL). The Mann–Whitney test was used to compare incidence of variables across the 2 groups. The level of significance was set at $P<0.05$ across all parameters.

Results

A total of 1500 consecutive cataract/refractive lens exchange surgeries performed with the LenSx FS laser were included in the study. Baseline and demographic parameters were comparable between the 2 groups (Table 2). A comparison of complications between the 2 groups is listed in Table 3. In summary, the incidence of major complications (anterior capsule tears, posterior capsule tears, and posterior lens dislocation) in group 2 was statistically lower compared with the initial group (0.31% vs 4%, 0.31% vs 3.5%, and 0% vs 2%, respectively; $P<0.001$ for all comparisons).

Table 2. Baseline Demographic Characteristics of All Patients

	Group 1 (n = 200)		Group 2 (n = 1300)		
	Mean ± SD	*Range*	*Mean ± SD*	*Range*	**P (1 vs 2)**
Age (yrs)	69.2±9.8	52 to 85	70.1±10.6	41 to 91	0.678
Axial Length (mm)	23.85±1.22	20.93 to 27.77	23.71±2.16	20.96 to 33.20	0.694
Average Ks (D)	43.64±1.56	40.75 to 48.13	44.32±1.61	40.28 to 49.30	0.074
Preop SE (Ds)	0.04±3.56	−18.0 to +5.5	−0.26±4.13	−25.5 to 10.63	0.647

D = keratometric diopters; Ds = diopters; K = keratometry; SD = standard deviation; SE = spherical equivalent.

Group 1 (n = 200)

The results have been reported in detail elsewhere.[21] In summary, the mean age of the patients was 69.2±9.8 years and 74.5% of eyes underwent a complete procedure of laser capsulotomy, lens fragmentation, and corneal incisions. Five eyes (2.5%) had suction breaks during the laser procedure, and 21(10.5%) eyes had anterior capsular tags. The incidence of capsular complications (anterior and posterior tears) was 7.5 % (15/200); and that of posterior lens dislocation was 2% (4/200). The mean number of docking attempts was 1.5 per case.

Group 2 (n = 1300)

The mean age of the patients was 70.1±10.6 years. A complete consecutive sequence of capsulotomy, lens segmentation, and main and side-port corneal incisions was successfully completed with the FS laser in 1280 eyes (98.5%). In addition to routine preoperative dilating drops, all patients received 1 drop of 10% phenylephrine immediately after the laser procedure. No eyes received atropine drops to prevent pupil constriction. After the patients were transferred to the operating room, the pupil was noted to have constricted in 16 (1.23%) eyes. Twenty-five eyes (1.92%) required manual creation of the corneal incisions with a keratome, because either the corneal incisions could not be created with the laser owing to suction breaks/ air meniscus (n = 17); or the laser-cut corneal incisions could not be opened easily (n = 8). The mean number of docking attempts was 1.05 per case. Three eyes had white cataract and only underwent laser capsulotomy and creation of corneal incisions. In these cases, the anterior capsule was stained with a vital dye in the operating room and a complete circular capsulotomy was confirmed with no capsular tags or radial tears. In 17 eyes (1.31%), the procedure could not be completed either because of a suction break during laser delivery (n = 8; 0.61%) or an air meniscus obstructing the view of the peripheral cornea through the patient interface (n = 9; 0.69%). In these cases, the laser delivery was stopped immediately; the suction ring was not reapplied, and the patients were transferred to the operating room where the rest of the procedure was performed manually. Four eyes post penetrating keratoplasty and 5 eyes post trabeculectomy underwent technically successful capsulotomy, lens fragmentation, and corneal incisions.

Ease of removal of the capsular button was rated ≥8 out of 10 in 100% of cases (score of 1 indicating great difficulty and 10 indicating free-floating capsulotomies). A free-floating capsulotomy or "postage-stamp" configuration (small areas of nonperforation not impacting on complete removal of the capsule button) were present in 96% of cases. The capsular button could be easily removed in the cases of postage-stamp configuration with forceps, cystitome needle, or suction. The anterior capsulotomy button was incomplete in 52 cases (4%) and a manual capsulorrhexis was required to complete the capsulotomy. In 1 case, the capsulotomy was incomplete with 6 clock-hours of nonperforation and radial tears extending to the equator. The anterior capsular flap was left in situ; the case was managed successfully without vitreous loss and an IOL was implanted in the sulcus. Anterior capsular tags were seen in 21(1.62%) eyes after removal of the capsulotomy button. In 4 eyes (0.31%), capsular tags led to extension and formation of radial anterior capsular tears. These tears extended to the posterior capsule in 2 eyes with 1 requiring anterior vitrectomy. The overall incidence of posterior capsular tears was 0.31% (4/ 1300) with 2 cases occurring during the phacoemulsification procedure. Three cases of vitreous loss were successfully managed with bimanual anterior vitrectomy and sulcus IOL implantation. There were no cases of posterior lens dislocation or capsular block syndrome. No difference in the rate of anterior capsule tears, posterior capsule tears, or posterior lens dislocation was observed between surgeons with and without prior use of a refractive FS laser (P = 0.860, 0.237, and 0.998, respectively).

Table 3. Comparison of Intraoperative Complications between Groups

Complications	Group 1 (n = 200), n (%)	Group 2 (n = 1300), n (%)	*P* value
Suction breaks	5 (2.5)	8 (0.61)	0.023
Manual corneal incisions	26 (13)	25 (1.92)	<0.001
Pupillary constriction	19 (9.5)	16 (1.23)	<0.001
Anterior capsule tags	21 (10.5)	21 (1.62)	<0.001
Anterior radial tears	8 (4)	4 (0.31)	<0.001
Posterior capsule tears	7 (3.5)	4 (0.31)	<0.001
Posterior lens dislocation	4 (2)	0 (0)	<0.001

Discussion

This prospective, single-center study evaluates safety and surgical outcomes of FS LCS performed after the initial learning curve. We found a significantly lower rate of complications once the surgeons became familiar with the technology. The rate of major capsular complications (anterior and posterior tears) decreased from 7.5% to 0.62% with no cases of dropped nuclei or capsular block syndrome.

Preoperative demographic and clinical parameters were comparable between the 2 groups with no difference in patient age, axial length, keratometry, or spherical equivalent refraction to explain the difference in surgical results. The contribution of procedures by surgeons ranged between 0% and 35.5% in the initial cohort and 4.7% and 28.1% in the second group. The relative contribution for each surgeon was consistent between cohorts. Pre- and postoperative medication regimens were standardized for both groups.

Table 4. Published Rates of Major Complications Reported with Cataract Surgery

<table>
<tr><th>Authors</th><th>Study Design and Population</th><th>Surgery</th><th>AC Tear (%)</th><th>PC Tear without Vitreous Loss (%)</th><th>PC Tear with Vitreous Loss (%)</th><th>Posterior Lens Dislocation (%)</th></tr>
<tr><td>Gimbel et al 2001[23]</td><td>Retrospective (n = 18 470)</td><td>MCS</td><td>—</td><td>0.24</td><td>0.20</td><td>0</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">0.45</td><td></td></tr>
<tr><td>Tan et al 2002[24]</td><td>Retrospective (n = 2538)</td><td>MCS</td><td>—</td><td>—</td><td>3.6</td><td>—</td></tr>
<tr><td>Androudi et al 2004[25]</td><td>Retrospective (n = 543)</td><td>MCS</td><td>—</td><td>3.50</td><td>4.05</td><td>0</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">7.55</td><td></td></tr>
<tr><td>Muhtaseb et al 2004[26]</td><td>Prospective (n = 1441)</td><td>MCS</td><td>2.8</td><td>—</td><td>1.7</td><td>0.4</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">2.2</td><td></td></tr>
<tr><td>Hyams et al 2005[27]</td><td>Retrospective (n = 1501)</td><td>MCS</td><td>—</td><td>0.99</td><td>1.93</td><td>—</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">2.9</td><td></td></tr>
<tr><td>Misra et al 2005[28]</td><td>Prospective (n = 1883)</td><td>MCS</td><td>—</td><td>0.16</td><td>0.53</td><td>0.11</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">0.69</td><td></td></tr>
<tr><td>Ang et al 2006[29]</td><td>Retrospective (n = 2727)</td><td>MCS</td><td>—</td><td colspan="2">1.7</td><td>—</td></tr>
<tr><td>Chan et al 2006[30]</td><td>Retrospective (n = 8230)</td><td>MCS</td><td>—</td><td colspan="2">1.9</td><td>—</td></tr>
<tr><td>Marques et al 2006[1]</td><td>Retrospective (n = 2646)</td><td>MCS</td><td>0.79</td><td colspan="2">—</td><td>—</td></tr>
<tr><td>Unal et al 2006[31]</td><td>Prospective comparative (n = 296)</td><td>MCS</td><td>5.1</td><td>4.05</td><td>6.4</td><td>2.4</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">10.4</td><td></td></tr>
<tr><td>Olali et al 2007[32]</td><td>Interventional case series (n = 358)</td><td>MCS</td><td>5.6</td><td>—</td><td>—</td><td>—</td></tr>
<tr><td>Zaidi et al 2007[33]</td><td>Prospective and retrospective (n = 1000)</td><td>MCS</td><td>—</td><td>0.4</td><td>1.1</td><td>0.1</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">1.5</td><td></td></tr>
<tr><td>Mearza et al 2009[34]</td><td>Retrospective (n = 1614)</td><td>MCS</td><td>—</td><td>—</td><td>2.66</td><td>—</td></tr>
<tr><td>Agrawal et al 2009[35]</td><td>Prospective (n = 2984)</td><td>MCS</td><td>—</td><td colspan="2">1.46</td><td>—</td></tr>
<tr><td>Narendran et al 2009[36]</td><td>Retrospective (n = 55 567)</td><td>MCS</td><td>—</td><td colspan="2">1.92</td><td>0.18</td></tr>
<tr><td>Greenberg et al 2011[37]</td><td>Retrospective (n = 45 082)</td><td>MCS</td><td>—</td><td colspan="2">3.5</td><td>—</td></tr>
<tr><td>Clark et al 2011[38]</td><td>Population-based study (n = 129 982)</td><td>MCS</td><td>—</td><td>—</td><td>—</td><td>0.12</td></tr>
<tr><td>Lundstrom et al 2011[39]</td><td>Retrospective (n = 602 553)</td><td>MCS</td><td>—</td><td colspan="2">2.09</td><td>—</td></tr>
<tr><td>Bali et al 2012[21]</td><td>Prospective (n = 200)</td><td>LCS</td><td>4</td><td>0.5</td><td>3</td><td>2</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">3.5</td><td></td></tr>
<tr><td>Roberts et al 2012 (Current study)</td><td>Prospective (n = 1300)</td><td>LCS</td><td>0.32</td><td>0.08</td><td>0.23</td><td>0</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2">0.31</td><td></td></tr>
</table>

AC = anterior capsule; LCS = laser cataract surgery; MCS = manual cataract surgery; PC = posterior capsule.

The variables during the study were surgeon experience with the FS laser, the addition of 1 drop of 10% phenylephrine immediately after the LenSx procedure, and technical enhancements of the LenSx system.

The most serious intraoperative complications of manual cataract surgery (MCS) are capsular tears and dropped nuclei. To identify published reports of complication rates with MCS we performed a search of available databases (MEDLINE, EMBASE, CINAHL, and Google Scholar) using key words "cataract surgery complications," "phacoemulsification complications," "capsule rupture," "lens dislocation," and "femtosecond cataract surgery," without time limits or restriction to language, and have summarized the results of the peer-reviewed literature in Table 4. These studies report a rate of capsular complications ranging from 0.5% to 8% with several large health service database audits suggesting that a 1.9% to 3.5% rate reflects normal clinical practice. However, the reported complication rate depends on the experience of the surgeon and whether the series was single surgeon, multisurgeon or multicenter. Recent evidence-based guidelines for cataract surgery suggest a capsule complication frequency of <2% should be possible and desirable to achieve.[40]

The results from our group practice reflect a range of experience and cataract surgical volume and we believe would be indicative of the likely surgical outcomes with LCS over time in normal clinical practice. The selection criteria were the same for all 1500 cases and in our study a small number of difficult cases, such as very small pupils, were excluded and did not undergo LCS. A direct comparison, therefore, with the reported complication rates of MCS cannot be made. Although this study was not specifically designed to compare major surgical complication rates between manual and FS LCS, many complex cases were performed with LCS (floppy iris syndrome, pseudoexfoliation, posttrabeculectomy and postpenetrating keratoplasty eyes, traumatic zonulopathies, white cataract, mild-to-moderate corneal opacities). Because the selection criteria were constant, the number of patients with more difficult and hard to manage cataracts was numerically greater in group 2 than group 1, yet the complication rate was significantly lower. The percentage of cases performed with the FS laser increased from 87% in the initial 200 cases to 95% in the subsequent 1300 cases. With experience, improved technology and better operative techniques, our complication rate with LCS in normal clinical practice was comparable with the best reported rates with MCS.

We report a total capsular complication (anterior and posterior tear) rate of 0.62% in group 2 compared with 7.5% during our early experience. Four cases developed an anterior capsular tear (0.31%) that extended to the posterior capsule in 2 of the cases. One of these cases required an anterior vitrectomy and both were successfully managed with a sulcus IOL. Friedman et al[16] have shown that a laser-created capsulotomy may be more than twice as strong as a capsulorhexis created manually, suggesting that normal manipulation and stretching of the capsulotomy during phacoemulsification would be unlikely to tear the capsulotomy. Our impression is that anterior capsular tears are more likely to result from a microtag being stretched and torn during intracapsular manipulation and we recommend inspecting the edge of the laser cut capsulotomy for a capsular tag under higher magnification before phacoemulsification.

Posterior capsular tears occurred in 0.31% of cases (n = 4). There were no cases of capsular block syndrome or dropped nuclei observed in the 1300 cases performed after the learning curve. During the course of the study, the surgeons became proficient in managing the different operative environment by releasing gas and decompressing the capsular bag before commencing phacoemulsification; mobilizing the nuclear segments; and modifying the irrigation–aspiration technique for removal of the lens cortex. Each surgeon developed a slightly different technique with some hydrodissecting before, and others after, releasing the gas. In some cases, hydrodissection was eliminated and the nuclear segments mobilized by utilizing the laser-generated gas cleavage plane between the nucleus and cortex ("pneumodissection") and the irrigating effect of the phacoemulsification infusion fluid. Difficulty in adapting to the consistently smaller size of the laser-cut capsulotomy has been suggested as a possible explanation for the increased difficulty removing cortex after FS laser.[17] We found no greater difficulty accessing the peripheral cortical material and our clinical impression is that the altered irrigation/aspiration behavior is owing to laser-induced changes in cortical material, altered hydrodissection effect, or a combination of both.

Various surgical and technical factors explain the improvements observed during the course of the study. Initial difficult docking and suboptimal positioning of the patient had a cascade effect leading to poor alignment, significant eye tilt, longer laser treatment times, incomplete capsulotomies, and peripheral suction loss. Tilting the face away from the operated eye ensured that the patient's nose did not obstruct the patient interface; having the patient fixate on the red target light improved alignment of the capsulotomy with the visual axis. Modified suction software and improved placement of the patient interface reduced the incidence of leaks with fewer cases of peripheral suction loss. The number of docking attempts decreased from 1.5 per case to 1.05 and the rate of suction breaks precluding laser corneal incisions improved significantly compared with the early experience group (0.61% vs 2.5%). In group 2, a peripheral air meniscus developed in 9 eyes (0.69%). This obscured the peripheral corneal view on the live image and FS laser corneal incisions were unable to be made through the air/fluid interface. In these cases, adequate suction and central visualization were maintained, allowing completion of capsulotomy and laser lens fragmentation. The patients were transferred to the operating room and manual main and side-port incisions were successfully created with a metal keratome. In our initial article,[21] an incidental finding was that the learning curve in the first 100 cases was flatter with surgeons who had previously used a refractive FS laser. No difference in complication rates, however, was seen after the first 100 cases in the early study and in the subsequent 1300 cases reported in this study.

Technical enhancements of the LenSx system improved the capacity to pre-position the laser treatment patterns. Main, side-port, and astigmatic relaxing corneal incisions were able to be placed on any desired axis and the laser repetition rate has been increased. This in turn reduced the overall procedure time and allowed more efficient scanning patterns that minimized the delivered energy. We believe these technical factors combined with the instillation of 10% phenylephrine immediately after the laser treatment explains the decrease in pupillary constriction after the laser procedure from 9.5% to 1.2%. Laser treatment times also decreased substantially. The quality of the capsulotomy improved with the incidence of anterior tags decreasing from 10.5% to 1.61%. Additional pattern configurations allowed greater flexibility in creating the corneal incisions (including reverse trapezoidal incisions) and performing lens fragmentation. Several additional hardware and software improvements are still under way. Planned enhancements of the suction interface device, laser delivery, and imaging systems will further expand patient selection and treatment options. A proposed reduction in the outer diameter of the patient interface should allow docking in patients with smaller orbits and narrower palpebral fissures. Expanding the available cut diameter will allow treatments up to 12.5 mm and an increase in the OCT resolution should further enhance live imaging.

Evidence of the precision, reproducibility, and refractive benefits of FS laser created capsulotomies is emerging in the literature. Kránitz et al[12] showed that creating the capsulotomy with an FS laser leads to less postoperative IOL decentration and tilt compared with a manual capsulorrhexis. They found that manifest refraction values at 1 month and 1 year after surgery correlated significantly with total IOL decentration and corrected distance visual acuity correlated with IOL vertical tilt. In another study comparing sizing and positioning parameters of FS laser capsulotomy with manual capsulorrhexis, the same group found more precise capsulotomy sizing and centering with the FS laser.[14] The type of capsulorrhexis and capsule overlap were significant predictors of IOL horizontal decentration. These findings suggest that a properly sized, shaped, and centered FS laser capsulotomy results in better overlap parameters, offering more stable and predictable positioning of the IOL.

In another study,[20] we analyzed the visual and refractive results of all eyes in the initial 113 cases receiving an aspheric monofocal implant (Acrysof SN60WF, Alcon Laboratories Inc) and compared the results with a control group consisting of a retrospective consecutive cohort who had undergone manual phacoemulsification surgery immediately before LenSx installation. The absolute mean difference from the intended spherical equivalent correction was 0.29 ± 0.25 diopters (D) for the LCS group and 0.31 ± 0.24 D for the manual group ($P = 0.512$). Over 80% of both groups fell within ±0.5 D of the intended correction and over 90% of both groups achieved uncorrected visual acuity of ≥20/40 after surgery. These early results with LCS are encouraging. Despite the significant learning curve, the use of nonpersonalized A-constants for IOL calculations, and nonstandardized operative techniques, the refractive and visual results were as good with LCS as with refined manual surgery.

In conclusion, this prospective, single-center study documents the continuing evolution of LCS and highlights the true safety aspects of this procedure. Greater surgeon experience, development of modified techniques, and improved technology were associated with a significant reduction in complications. In our experience, most complications are now predictable and largely preventable; the complication rate is comparable with the best published reports of manual phacoemulsification surgery. The level of uptake of this new technology will ultimately be determined by clinical results, published peer-reviewed evidence, and cost-effectiveness data. We await the results of additional comparative studies to evaluate the impact FS lasers will have on the quality of cataract surgery and patient outcomes.

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