Cataract surgery is one of the most commonly performed surgical procedures worldwide. Between 2000 and 2020, the number of people aged 65 or over is projected to increase from 425 million to 677 million worldwide. This is likely to be accompanied by a corresponding increase in the incidence of cataracts and it has been estimated that by 2020, 32 million cataract surgeries will be performed annually (see Figure 1).

Phacoemulsification, the most commonly performed type of cataract surgery, requires manual creation of an opening in the anterior lens capsule, fragmentation and evacuation of the lens tissue with an ultrasound probe, and implantation of a plastic intraocular lens (IOL) into the remaining capsular bag. Femtosecond laser technology was approved by the US Food and Drug Administration (FDA) in 2010 for use in cataract surgery including the creation of surgical incisions in the cornea, formation of the capsulotomy, and lens fragmentation following incision into the remaining capsular bag. Femtosecond laser-assisted cataract surgery (FLACS) is particularly advantageous in difficult cases, including hypermature and white cataracts. However, it is still not known how technical advantages translate into functional benefits. Over the past 2 years, four unique laser platforms have been introduced. This article summarizes current literature relating to the efficacy and safety of FLACS and compares currently available laser platforms.

**Abstract**

Despite improvements in surgical technique, certain aspects of manual cataract surgery are performed with limited precision. Femtosecond laser technology enables precise incisions in the cornea and minimizes manipulations and energy required to fragment and emulsify the lens, resulting in less damage to surrounding tissues compared with manual techniques. The technique also results in superior geometric precision and centration, with reported better capsule strength compared with manual capsulotomy. Femtosecond laser-assisted cataract surgery (FLACS) is particularly advantageous in difficult cases, including hypermature and white cataracts. However, it is still not known how technical advantages translate into functional benefits. Over the past 2 years, four unique laser platforms have been introduced. This article summarizes current literature relating to the efficacy and safety of FLACS and compares currently available laser platforms.

**Keywords**

Cataract, cornea, femtosecond laser-assisted cataract surgery, phacoemulsification

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Table 1: Summary of Major Studies Demonstrating the Efficacy of Femtosecond-assisted Laser Cataract Surgery

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Number of Eyes</th>
<th>Laser Platform Used</th>
<th>Findings</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central corneal thickness/endothelial cell loss</td>
<td>76</td>
<td>LenSx® Laser</td>
<td>Central corneal thickness was significantly higher in the phaco group than in the FLACS group (607±91 μm versus 580±42 μm) on day 1, but there was no significant difference at 1 week and 1 month. Volume stress index at day 1 was significantly lower in the FLACS group than in the phaco group (p&lt;0.05) but did not differ significantly at 1 month.</td>
<td>42</td>
</tr>
<tr>
<td>Central corneal thickness</td>
<td>146</td>
<td>Catalys®</td>
<td>Mean relative change in corneal thickness from the preoperative values was –0.0±1.9 % at 1 day, 2.8±1.8 % at 1 week, and 3.3±1.7 % at 3 months in the study group and –0.9±2.3 %, 2.4±1.5 %, and 3.2±1.4 %, respectively, in the manual group. Mean ECL was 7.9±7.8 % SD 1 week postoperatively and 8.1±8.1 % 3 months postoperatively in the study group and 12.1±7.3 % and 13.7±8.4 %, respectively, in the control group.</td>
<td>34</td>
</tr>
<tr>
<td>Anterior chamber inflammation</td>
<td>176</td>
<td>Catalys®</td>
<td>Postoperative aqueous flare was significantly greater in the manual cataract surgery group versus FLACS at 1 day (p=0.0089) and at 4 weeks (p=0.003).</td>
<td>45</td>
</tr>
<tr>
<td>Capsulotomy strength</td>
<td>10</td>
<td>Victus®</td>
<td>Observed mean rupture force (i.e., maximum amount of force measured immediately before tissue rupture) was 113 mN ± 12 SD in FLACS and 73±22 mN in the manual procedure (p&lt;0.05). The stretching ratios were 1.6±0.10 (femtosecond) and 1.35±0.04 (manual) (p&lt;0.05).</td>
<td>10</td>
</tr>
<tr>
<td>Capsulotomy precision</td>
<td>20</td>
<td>LenSx® Laser (pre SoftFit™)</td>
<td>Vertical diameter of manual was statistically significantly higher in the first week and month. Horizontal IOL decentration was statistically significantly higher in the manual group over 1 year. There was a significant difference 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).</td>
<td>22</td>
</tr>
<tr>
<td>Capsulotomy precision</td>
<td>45</td>
<td>LenSx® Laser (pre SoftFit™)</td>
<td>Horizontal and vertical tilt were significantly lower in the FLACS group compared with manual (p=0.007 and p=0.001, respectively). Lenses implanted after manual procedures showed greater horizontal total decentration (p=0.034 and p=0.022, respectively).</td>
<td>27</td>
</tr>
<tr>
<td>Capsulotomy precision</td>
<td>99</td>
<td>LenSx® Laser (pre SoftFit™)</td>
<td>The FLACS group had significantly lower values of intraocular vertical tilt (–0.05±0.36 versus 0.27±0.57) and coma (–0.03±0.11 versus 0.1±0.15), and significantly higher Strehl ratios (0.02±0.02 versus 0.01±0.01) and MTF values at all measured cycles per degree compared with the manual group.</td>
<td>28</td>
</tr>
<tr>
<td>Capsulotomy precision</td>
<td>17</td>
<td>LenSx® Laser (pre SoftFit™)</td>
<td>Vertical and horizontal tilt were significantly higher in the 6.0 mm group than in the 5.5 mm group (p=0.014 and p=0.015, respectively).</td>
<td>32</td>
</tr>
<tr>
<td>Capsulotomy precision and strength</td>
<td>39</td>
<td>Catalys®</td>
<td>Deviation from intended diameter of the resected capsule disk was 29±26 μm and 337±258 μm for the FLACS and manual groups, respectively. Mean deviation from circularity was 6 % and 20 %, respectively. Capsulotomy center was within 77±47 μm of the intended position. Capsulotomy strength (porcine subgroup) decreased with increasing pulse energy: 152±21 mN for 3 μJ, 121±16 mN for 6 μJ, and 113±23 mN for 10 μJ.</td>
<td>11</td>
</tr>
<tr>
<td>Capsulotomy precision</td>
<td>111</td>
<td>LenSx® Laser (pre SoftFit™)</td>
<td>Circularity values were significantly better in the FLACS group (p=0.032). Incomplete overlap of capsulotomies in 28 % of eyes in the manual group and 11 % in the FLACS group (p=0.033).</td>
<td>21</td>
</tr>
<tr>
<td>Capsulorhexis geometry and strength</td>
<td>60</td>
<td>LENSAR®</td>
<td>Capsulorhexes obtained with FLACS at all energy settings were perfectly circular with negligible deformation. The manual group showed a significantly higher thickness of the capsulorhexis edge than the other groups (p&lt;0.001). There was also a statistically significant correlation between the degree of irregularity and increasing energy (p&lt;0.001).</td>
<td>25</td>
</tr>
<tr>
<td>Anterior capsule integrity</td>
<td>1626</td>
<td>Catalys®</td>
<td>There was a significantly increased rate of anterior capsule tears in the FLACS group (1.87 %) compared with the manual group (0.12 %; p=0.0002).</td>
<td>18</td>
</tr>
<tr>
<td>Phacoemulsification time</td>
<td>24</td>
<td>LenSx® Laser (pre SoftFit™)</td>
<td>Compared with control porcine eyes, FLACS resulted in a 43 % reduction in phacoemulsification power and a 51 % decrease in phacoemulsification time.</td>
<td>2</td>
</tr>
<tr>
<td>EPT</td>
<td>109</td>
<td>Catalys®</td>
<td>In the FLACS group, the mean laser treatment time was 54.9 seconds and the EPT was 0.1e±0.21 seconds compared with 4.07±3.14 seconds in the standard group.</td>
<td>37</td>
</tr>
<tr>
<td>EPT</td>
<td>212</td>
<td>Catalys®</td>
<td>Mean EPT was reduced by 83.6 % in the femtosecond pretreatment group (p&lt;0.0001) compared with controls, with 30 % having zero EPT (p&lt;0.0001).</td>
<td>36</td>
</tr>
</tbody>
</table>
Cataract

Table 1: Cont.

<table>
<thead>
<tr>
<th>Parameter</th>
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<tbody>
<tr>
<td>EPT</td>
<td>119</td>
<td>Victus*</td>
<td>Mean EPT was significantly lower in the laser group than in the manual group (5.2±5.7 versus 7.7±6.0 seconds) (p=0.025). There was a significant difference in the mean phaco energy between the two groups (13.8±10.3 % in laser group; 20.3±8.1 % in manual group) (p&lt;0.001). There were no significant between-group differences in the ease of phacoemulsification, mean phaco time, or balanced salt solution volume. Laser-assisted capsulotomies were significantly more accurate and precise (intended diameter, circularity, centration) (p=0.01).</td>
<td>35</td>
</tr>
</tbody>
</table>

Capsulotomy Accuracy and Precision

Capsulotomies using FLACS are more precise than manual capsulorhexes. The unpredictable diameter observed in manual capsulorhexis may lead to an irregularly shaped capsulotomy and influence the position of the implanted IOL, which may cause a decrease in visual quality. Capsulotomies created during FLACS were more regularly shaped than those in manual capsulorhexes, with better centration, and better IOL/capsule overlap compared with manual capsulorhexis. Smooth, regular edges may offer superior capsular strength and resistance to capsular tears, although the significance of capsular edge smoothness is not fully understood. Two recent studies used SEM to determine capsulorhexis cut quality at different energy settings and evaluated differences between laser and manual technique (see Figure 2). Both studies found the cut surface was smoother in the laser group. In FLACS, the degree of irregularity was higher with increased energy settings. In a study to evaluate cell death and ultrastructural morphology of capsulotomies, cut edge surfaces were found to be smoother and there was a lower level of cell death when laser pulse energy was reduced to 5 μJ—this level of smoothness was similar to the levels observed in manual capsulorhexis. A separate study comparing FLACS platforms and manual techniques noted a marked improvement in capsular edge smoothness with upgrades in all laser platforms (see Figure 2). Unlike previous studies the improvement in smoothness of FLACS capsulotomy edge was confirmed using objective criteria such as coefficient of variation (CoV) and gray level co-occurrence matrix (GLCM) analysis. The latter examined the inter-pixel changes in grayness of the scanning electron microscopy (SEM) images of the capsulotomy edge. The study noted that some FLACS platforms approached manual capsulorhexis when using CoV and were statistically no different when examining GLCM analysis.

FLACS is also associated with less lens tilt, and fewer internal aberrations, which may result in improved optical quality therefore improving postoperative visual acuity and quality of vision. Tilting of the lens induces a considerable amount of ocular coma-like aberrations. In fact, poor positioning of an IOL is one of the main indications for removal, exchange, or repositioning of a posterior chamber IOL. A study demonstrated a significantly better predictability of IOL power calculation than conventional phacoemulsification surgery. However, in this study, the results from the manual group were inferior to those published in other papers, potentially inflating the comparative outcomes. As surgical experience increases, it is becoming apparent that different parameters may influence visual outcomes: in a comparison of 6.0 mm versus 5.5 mm capsulotomies, vertical
and horizontal tilt were significantly higher in the 6.0 mm group than in the 5.5 mm group. Such subtle refinements were not possible before FLACS.

In a study investigating the visual and refractive outcomes in 61 eyes undergoing FLACS with implantation of a diffractive multifocal IOL, outcomes did not differ statistically from those in the manual phacoemulsification group. However, the manual group had exceptionally good outcomes that were difficult to improve upon, and this was an early study of FLACS, illustrating the difficulty of interpreting clinical studies.

**Effective Phacoemulsification Time**

Another major advantage of FLACS is a reduction in the time and energy required for the fragmentation of the cataract, resulting in decreased effective phacoemulsification time (EPT) compared with ultrasound procedures. This may lead to decreased corneal endothelial cell loss (ECL) and corneal edema in the early postoperative phase, resulting in faster visual recovery. The use of phaco energy may be avoided in some cases: a comparative study of manual and FLACS procedures found that mean EPT was reduced by 83.6% in the FLACS pretreatment group (p<0.0001) compared with controls, with zero EPT in 30% (p<0.0001). EPT was reduced by 28.6% within the FLACS group using improved lens fragmentation algorithms, and a further 72.8% reduction was achieved with a 20-gauge phacoemulsification tip. Overall, there was a 96.2% reduction in EPT between controls and the optimized FLACS group, which was associated with a 36.1% reduction in ECL in the femtosecond group. Reductions of 39% and 51% EPT have also been reported. A more recent study reported an EPT of 0.16±0.21 seconds compared with 4.07±3.14 seconds in the control group. Other studies have examined the effect of different fragmentation softening grids: a 350 μm grid softening led to a statistically significant lower EPT than the 500 μm grid (mean EPT 0.03±0.05 seconds versus 0.21±0.26 seconds).

The level of EPT required also depends on the degree of cataract severity. A recent retrospective, nonrandomized, consecutive case series found that overall mean EPT was significantly lower in FLACS (1.58±1.02 seconds) compared with 4.17±2.06 seconds in group 2 (p=0.001), and that EPT correlated positively with preoperative lens opacity.

**Safety**

Numerous studies support the safety of the FLACS procedure and a prospective study of 1,500 consecutive cases, from a group practice, found that surgical outcomes are equal to or better than best practice in terms of complications. FLACS is associated with less corneal swelling in the immediate postoperative period and less trauma to corneal endothelial cells compared with ultrasound phacoemulsification procedures, as shown by central corneal thickness (CCT), ECL, and volume stress index. However, in one study, statistical significance was only achieved by central corneal thickness (CCT), ECL, and volume stress index. It may therefore be beneficial in eyes with low preoperative endothelial cell values such as cases of cornea guttata. A small study of cadaver eyes was the first to demonstrate one of the most important potential benefits of FLACS: incisions offer added stability and reproducibility in corneal wound construction, reducing the potential for deformation and leakage. FLACS is associated with laser exposure well within retinal injury thresholds.

FLACS is associated with less anterior chamber inflammation compared with manual cataract surgery, a result of the reduction in phacoemulsification energy. An early study of 20 eyes suggested that FLACS does not significantly differ in postoperative macular thickness compared with standard ultrasound phacoemulsification. More recently, FLACS has been associated with an increase in outer zone thickness as measured by optical coherence tomography (OCT); however, several studies report superior surgical outcomes with FLACS compared with conventional phacoemulsification procedures. A case-control study found retinal thickening in both groups at 4 and 8 weeks postoperatively, but a lower degree of swelling in the outer nuclear layer after FLACS compared with ultrasound phacoemulsification. This same study also showed significantly lower macular thickness in the inner retinal ring in the FLACS group after adjusting for age and preoperative thickness across the time course, compared with a control group.

Adverse effects have been reported. In a recent study, five eyes (two in the FLACS group; three in the control group) developed significant cystoid macular edema (CME) following cataract surgery. Recent data suggest that levels of prostaglandins rise immediately after FLACS and suggest that anti-inflammatory drugs may be prescribed to maintain mydriasis before undergoing the procedure.

Patient movement during surgery may lead to complications: a case report described suction loss during FLACS caused by the patient moving abruptly during lens fragmentation. An IOL was implanted without complications, but 6 weeks after surgery the misaligned cuts on the cornea were still visible.

**Surgical Experience**

As with the introduction of any new technology, the procedure involves a learning curve. Early studies found that surgeons with prior experience with femtosecond lasers experienced fewer complications during initial cases. However, following software and hardware upgrades plus a better understanding of the training required, the learning curve has dramatically decreased. Intraoperative capsular block syndrome was reported in initial cases. However, this condition is now rarely encountered and preventable as a result of awareness of the changed intraocular environment following laser lens fragmentation. In a prospective case series that reviewed surgical outcomes of 1,500 consecutive eyes undergoing FLACS, it was found that surgical outcomes improved significantly with increased surgical experience. The cases were divided into two groups: group 1 comprised the first 200 cases performed by surgeons; group 2 the subsequent 1,300
Cataract

Figure 3: Comparison of Femtosecond Laser Platforms—Coefficient of Variation of Capsulotomy Edges

Use of Femtosecond Laser Technology in Difficult Clinical Cases

Cataract surgery in white or hypermature cataracts has been associated with increased risk for incomplete capsulorhexis and posterior capsule rupture. FLACS has been successfully employed in traumatic cataract following penetrating eye injury, and also after blunt trauma resulting in anterior segment imaging technology. LenSx® Laser utilizes Circle Scan technology and its OCT has 8.5 mm depth.

Comparison of Different Laser Platforms

Comparison of Interfaces

Different interfaces are associated with various benefits and drawbacks. A curved interface that approximately matches the curvature of the anterior cornea reduces globe deformation and the corresponding rise in intraocular pressure (IOP). The LOI reduces eye deformation by placing a layer of fluid between the cornea and an optical window. Mechanical attachment involves a suction ring outside the limbus. However, in order to accommodate the suction ring, the LOI also requires a larger aperture, which may prove disadvantageous for smaller orbits, such as those seen in Asian populations. Contact systems tend to have a smaller diameter and fit a smaller orbit better. Another drawback in LOIs is the need to precisely identify the anterior corneal surface necessary for placement of corneal incisions or a corneal flap, requiring sophisticated imaging techniques. Contact systems provide a separate reference plane for anterior incisions.

Capsulotomy Edges

A recent study aimed to perform a morphological comparison of capsulotomy edges between five femtosecond laser platforms (LenSx® Laser pre-SoftFit®, LenSx® Laser post-SoftFit®, Catalys®, Victus® 1, and Victus® 2) and manual surgery. The study involved 54 capsules from 49 patients (laser platforms: 10 each except Victus® 1 that had only four; manual: 10). Smoothness was assessed by quantitative analysis of the 2D image: the CLM. Results showed that the LenSx® Laser SoftFit™ PI in terms of COV and homogeneity gave capsulotomy edges closest to that of the manual method (see Figures 2 and 3). Qualitative assessment of the incidence of tags and other anomalies was also performed. Laser platforms with liquid interfaces appeared to have capsules with anomalous perforations: Catalys® (4/10), Victus® 1 (0/4), and Victus® 2 (4/10). The use of solid
approaching manual capsulorhexis and improvements in lasers and PIs are insufficient to result in significant complications. It is not known if US Ophtha 19/09/2014   12:20

Summary and Concluding Remarks
Femtosecond laser cataract surgery is performed in only a minority of cataract procedures worldwide; however, a growing body of literature supports the observations of improvements in corneal incisions, less harm to the corneal endothelium, less anterior chamber inflammation, improved capsulorhexis, and more precise IOL positioning. Most studies have been limited by a lack of randomization and masking; however, numerous studies have reached similar conclusions. Early studies are also affected by the learning curve. As surgeons gain experience and as technological upgrades are made available to surgeons quickly, it is likely that improved surgical outcomes will be reported. However, additional studies are required to assess the long-term efficacy and safety of FLACS.

The available laser platforms differ substantially in terms of docking. The LenSx® Laser SoftFIt™ PI offers advantages over other interfaces in terms of smoothness of capsulorhexis.

Concerns persist as to whether the clinical value of FLACS justifies the substantial costs involved. However, the technique may offer significant advantages for patients undergoing cataract surgery and may be valuable in difficult cases, including hypermature and white cataracts. Femtosecond laser technology is evolving rapidly and its performance potential has yet to be fully explored.
Cataract

LenSx® Laser Important Product Information

Caution
United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

Indication
The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacoemulsification, and the creation of single-plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

Restrictions
- Patients must be able to lie flat and motionless in a supine position.
- Patients must be able to understand and give informed consent.

Contraindications
- Presence of blood or other material in the anterior chamber
- Poorly distensible, 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
- Hyphema 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

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 LenSx® Laser Patient Interface consisting of an application lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

Precautions
- Do not use cell phones or pages of any kind in the same room as the LenSx® Laser.
- Discard used Patient Interfaces as medical waste.

Adverse/Complications
- Capsulotomy, phacoemulsification, or cut or incision dehiscence
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision
- Capsular tear
- Corneal abrasion or deficit
- Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse
- Elevated pressure to the eye

Attention
Refer to the LenSx® Laser Operator’s Manual for a complete listing of indications, warnings, and precautions.

September 2014/LX14006AR

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IMPORTANT PRODUCT INFORMATION ABOUT THE LENS® LASER CAN BE FOUND ON PAGE 88.

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