White Paper

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Femtosecond-laser Assisted Cataract Surgery – A Clinical Perspective

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Approximately 3.6 million cataract surgeries were performed in the USA and more than 20 million worldwide in 2015.1 Using established surgical techniques, the natural lens is removed and replaced with an intraocular lens. This is among the most common procedures performed by ophthalmic surgeons.

Femtosecond-laser assisted cataract surgery, with imaging guidance, is a modern technique enabling several essential elements of effective surgery: 1) well-centered capsulotomies with consistent diameter to build a strong foundation for stable IOL fixation, 2) consistent and accurately placed corneal incisions for resistance to wound leakage and astigmatism management and 3) performance of key steps including capsulotomy, lens pre-fragmentation and corneal incisions in the pre-operative environment for greater OR efficiency.

In The Operating Room - Need for Consistency and Efficiency

Both patients and healthcare systems expect good to excellent visual outcomes following cataract surgery.[2] Great strides towards meeting these expectations are being made to improve consistency and efficiency of cataract surgery. To obtain optimal predictable visual outcomes, there are several critical elements for the surgeon as summarized in Table 1.

Surgical Element	Clinical Significance
Well-centered continuous circular capsulorhexis of consistent diameter	• Minimization of risk associated with sharp angles that can extend into catastrophic outward leading tears during surgical manipulation and phacoemulsification. Such tears can significantly increase surgical time as the surgeon aims to avoid further extension of the tear or drop of the lens posteriorly. • Establish a strong foundation for stable IOL fixation by achieving a complete 360 degree IOL-capsulorhexis overlap that minimizes the risk of IOL tilt and decentration. This is particularly needed for premium IOLs with advanced optical designs.
Consistent and accurately placed corneal incisions (primary, secondary, arcuate incisions or LRIs)	• Minimization of risk associated with primary and secondary incisions, such as internal gaping corneal wounds or Descemet's membrane detachment. This will increase resistance of wound leakage for penetrating incisions. • To manage corneal astigmatism with well-placed arcuate incisions.
Operating Room (OR) Efficiency	• OR time is among the most expensive components of cataract surgery. A reduction in the complexity of the procedure achieved through pre-operative planning activities enables greater efficiency in the OR, and thus potentially decreased procedure time and increased number of daily procedures.

Table 1. List of important attributes that contribute to consistency and efficiency in the OR.

This white paper describes a solution that addresses each of the listed surgical elements. Continuing to read will equip the reader with knowledge on how to achieve consistency and efficiency during cataract surgery using femtosecond-laser assisted technology.

Femtosecond Laser Assisted Cataract Surgery

The femtosecond laser assisted cataract surgery (FLACS), also called "bladeless" cataract surgery, replaces manual incisions and the continuous curvilinear capsulorhexis (CCC). In addition, FLACS is also able to pre-fragment the lens. FLACS uses a near-infrared laser that separates tissues based on the principle of photodisruption. One fundamental benefit of FLACS is the image guidance that allows for visualization and specific placement of incisions in the cornea, anterior capsule and lens. Generally, a 3D optical coherence tomography (OCT) or a 3D spectral confocal structural illumination (CSI) is being used to visualize key anatomical landmarks of the eye in a cross-sectional fashion.

The size, centration and circularity of the CCC are important determinants for the final position of the intraocular lens (IOL) and may affect the visual outcome of the patient. CCCs that are constructed too small, too large, and/or decentered can cause hyperopic or myopic shifts, IOL decentration or tilt. Achieving a well-sized, centered and circular capsulorhexis manually requires a lot of practice as the lens capsule is extremely thin and sharp angles can result in unwanted tears. The femtosecond laser assists in minimizing intra- and inter-surgeon variation of the capsulorhexis by constructing a capsulotomy of consistent size, centration and circularity based on the image taken by the OCT or CSI (Figure 1).[3] The laser also automatically considers the corneal magnification (the cornea magnifies the anterior capsule approximately 1.15 times) and adjusts for it.

Lens pre-fragmentation, placed accurately with the help of image guidance, significantly softens the lens and aids with ease of cataract extraction. Removing the nucleus and cortex faster reduces effective phacoemulsification time (EPT), cumulative dissipated energy (CDE) and minimizes postoperative corneal thickness as well as endothelial cell loss,[4,5] which are especially critical for difficult cases, such as white or very dense cataracts.

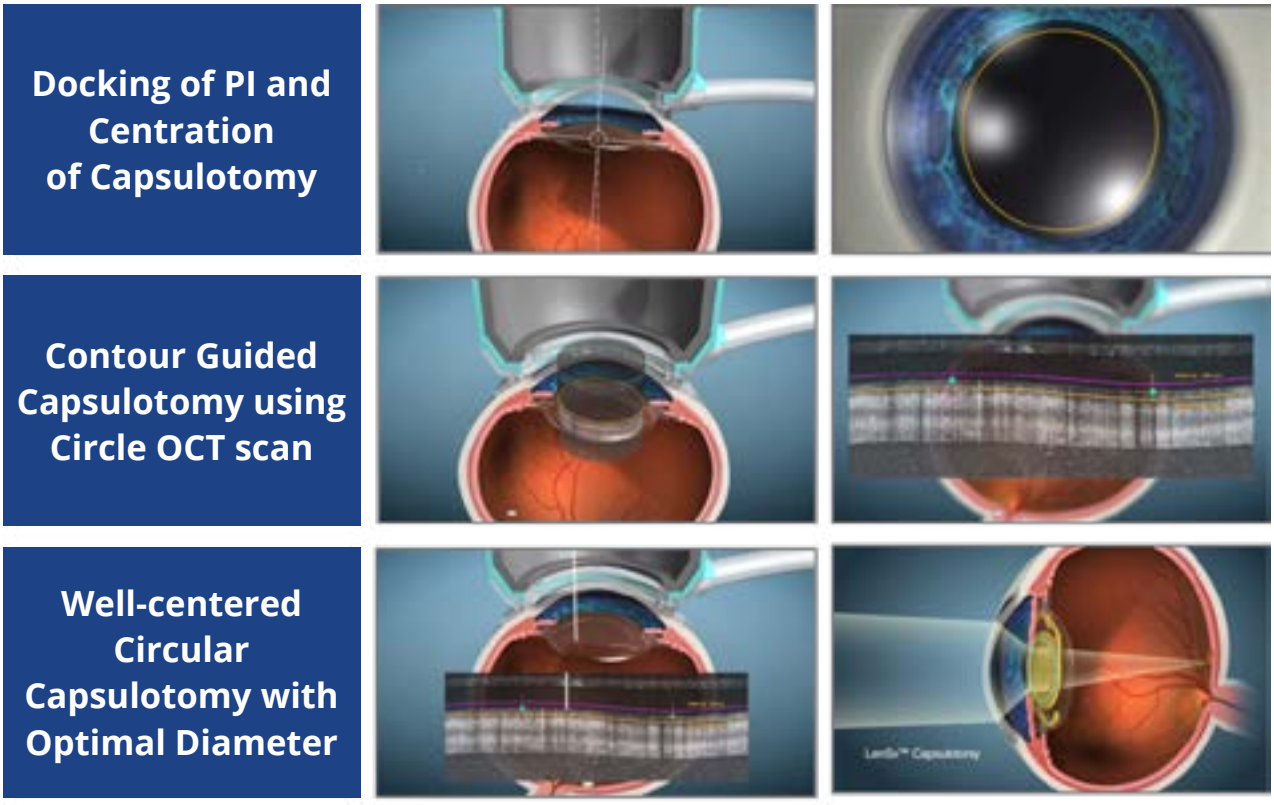


Figure 1. Capsulotomy with the LenSx® femtosecond laser. Following docking of the patient interface (PI) to the patient's eye, the circle OCT scan guides the user in adjusting the capsulotomy to the contour of the anterior capsule. The femtosecond laser creates a well-centered circular capsulotomy with an optimal diameter that minimizes IOL tilt and decentration.

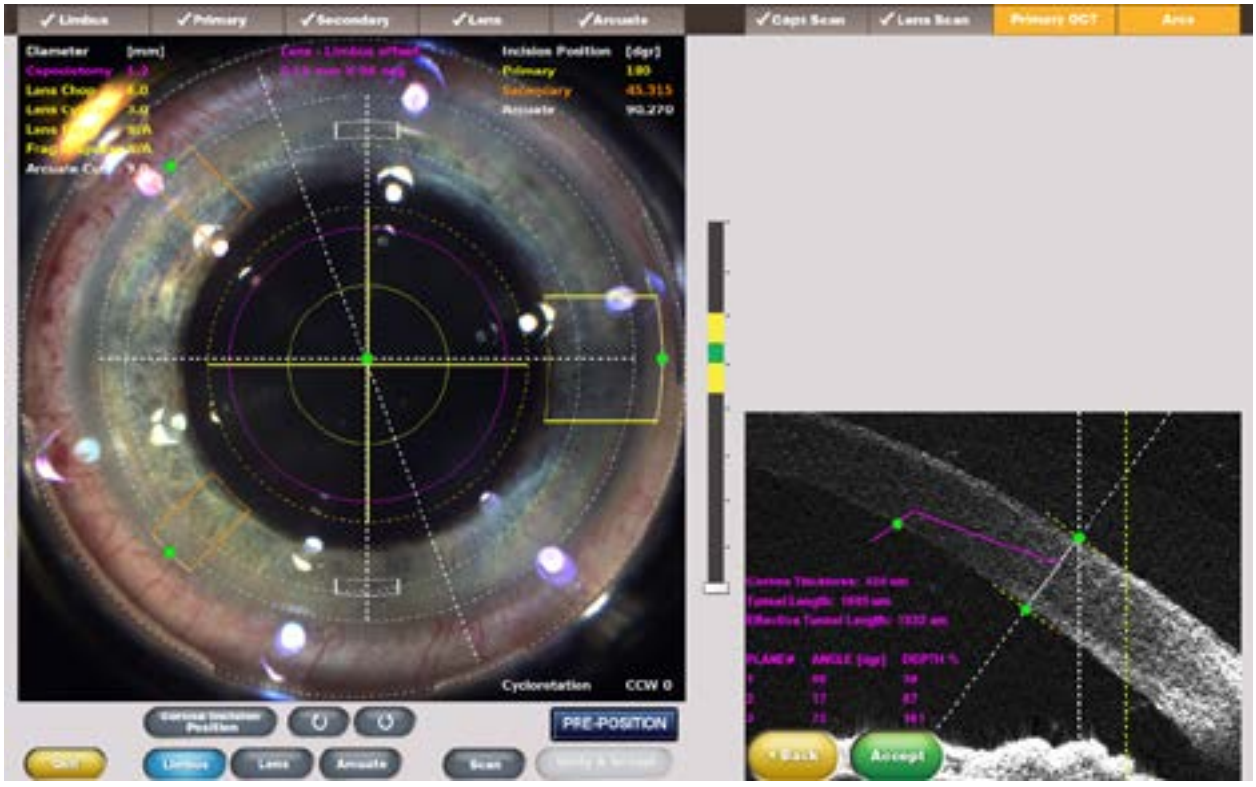


Figure 2. Three-planar primary corneal incision with the LenSx® femtosecond laser. Image left: The primary incision can be placed adjacent to the limbus (up to 12mm) as shown with yellow box. Image right: The primary corneal incision can be planned with a three-planar self-sealing architecture.

Femtosecond laser assisted corneal incisions can be constructed as multi-planar self-sealing incisions that prevent wound leakage with much higher precision than any blade-created incisions. Single, or rectangular patterns. Again, the images taken with the image guided system allow for precise positioning and sizing of the primary and secondary incisions as well as consistent depth, location and size of arcuate incisions.

Completing these crucial planning steps outside the sterile environment of the OR may help save expensive OR cost or, depending on the configuration of the surgery center, perhaps allow for additional patients to be treated in a day (see Figure 3). Efficiency of the OR may even be further improved by changing the set up model of the surgery center from a 1 OR : 1 Laser to a model in which a laser serves 2, 3 or more ORs.

Fine-tuning of workflow elements related to the laser requires time and corporation from the surgical staff. While the laser incision planning requires additional time outside the OR, once the workflow is in place and initial learning curve is overcome, significant efficiency and consistency advantages may be achieved in the OR.

In a minority of cases, FLACS may not be an option and conventional cataract surgery may still be necessary. The femtosecond laser necessitates a clear cornea and a well-dilated pupil to optimally image and plan for surgery. Any corneal diseases that result in corneal scarring or opacities interfere with the completeness of the laser application and cuts may not be complete. However, these are generally cases that are being identified before the surgery day by careful pre-operative assessments of the patient's eye and recording into the patient's chart.

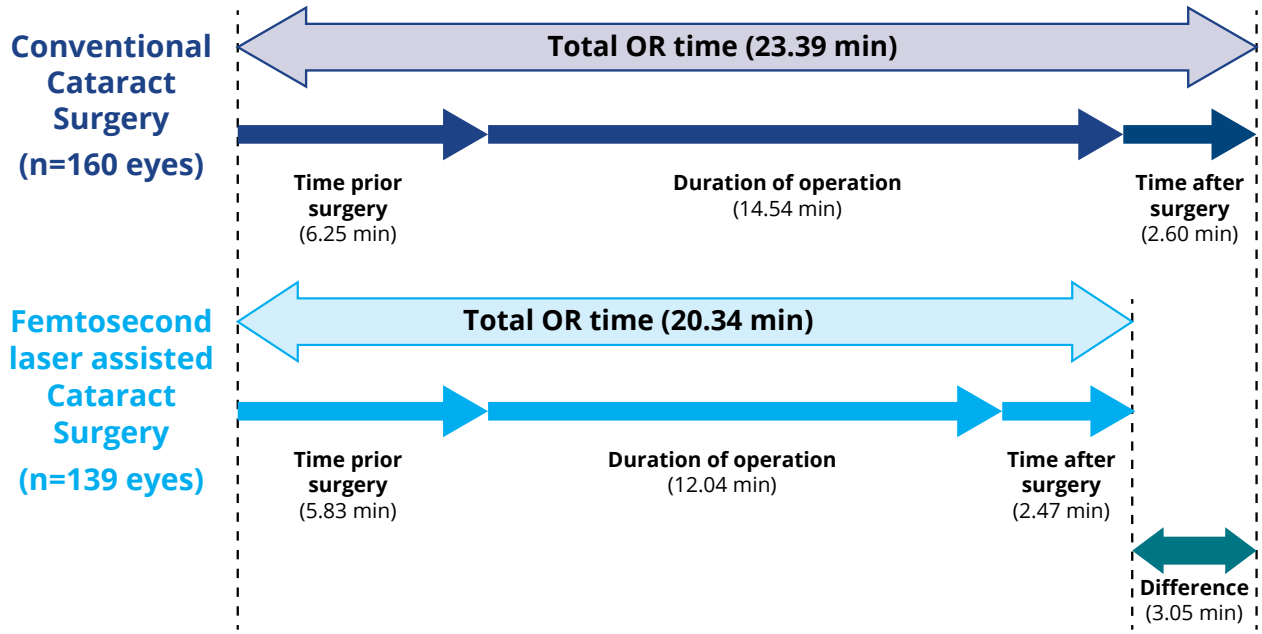


Figure 3. Example comparison of OR timings (in minutes) between femtosecond laser assisted cataract surgery using LenSx® laser and conventional surgery. Data has been recreated from Roberts et al Br J Ophthalmol 2018 (Epub ahead of print).

Alcon LenSx® Femtosecond Laser Technology

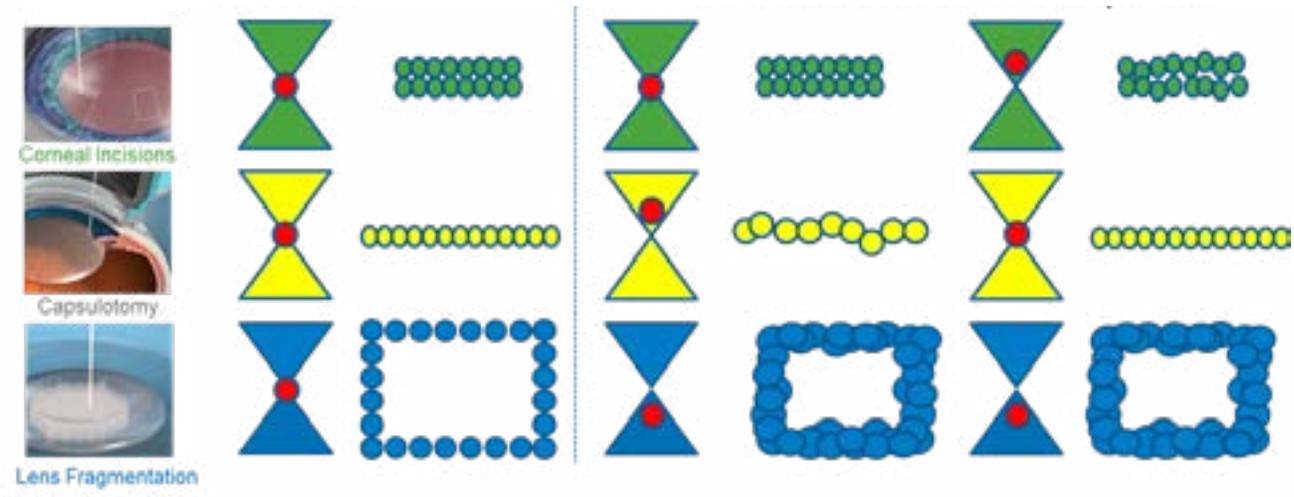
The LenSx® laser is Alcon's femtosecond laser platform for cataract surgery. The high-definition 3D spectral domain OCT is unique amongst other platforms on the market as it provides a 360-degree circle scan in addition to line scans along all meridians. A full view of anatomical landmarks of the eye is obtained in seconds without missing data or the need of stitching several images together which is critical to identify unwanted tilt of the eye and for precise planning of incisions. The new update to the LenSx® laser (to be released in April 2018) enables the user to clearly identify the limbus by de-magnifying the OCT image. Like in no other system, primary and secondary corneal incisions can be placed adjacent to the limbus (up to 12mm) to have close access to the iris plane and therefore establishing greater mobility in the capsular bag during lens removal.

The LenSx® laser is the only cataract femtosecond laser platform to use a non-liquid based docking system; a curved applanation patient interface with the LenSx® SoftFit™ insert. Hard surface interfaces produce posterior corneal folds during the docking procedure. These folds alter the laser beam energy delivered to the anterior capsule and result in capsular tags. Alternative interfaces, such as the liquid based docking systems, have been introduced to reduce the occurrence of folds. Liquid based docking systems compress liquid that was added into the patient interface. The compressed liquid does not, however, compensate for heart and breathing movements of the patient resulting in up to 200 microns movements of the eye. To counteract the movement, more laser pulses and energy are needed to achieve incisions and lens fragmentation patterns. The LenSx® laser patient interface with a surgical field of view of 12.5 mm utilizes a proprietary soft hydrogel contact lens insert (SoftFit™) to minimize corneal distortion with lower IOP increase of 16 mmHg and to permit treatment of patients with glaucoma (except ocular hypotony in glaucoma). The SoftFit™ closely mimics the natural curvature of the eye and is available in several curvatures to accommodate for exceptionally flat corneas (less than 41D), normal corneas (41D to 46D) and exceptionally steep corneas (greater than 46D). An essential feature is also the live high-definition circle OCT as it assists the user in easier docking and avoiding tilt of the eye.

The LenSx® laser is the only laser today with the patented variable numeric aperture technology (see Figure 3). The variable numeric aperture allows the laser to focus precisely on each tissue and to set optimal laser settings for each tissue. The XYZ-focusing ability together with the SoftFit™ patient interface enables the laser pulses to be placed evenly for optimal tissue bridge creation. These tissue bridges can be opened at any time during surgery or later when managing corneal astigmatism using arcuate incisions.

Creating a linear laser pulse pattern is particularly important when creating a capsulotomy. Manual construction of a capsulorhexis has an anterior capsular tear complication rate that varies widely from 0.79 to 5.6%.[6] Capsular tags that occur with the femtosecond laser created caspulotomies can result in a capsular tear. In a recent report of 3355 eyes, however, the anterior capsule tear rate with the LenSx® laser was 0.21%.6 The rate was even less (0.08%) when only eyes with the SoftFit™ patient interface were analyzed.

The LenSx® laser has a wide variety of fragmentation patterns ranging from chop, cylinder to cubes to help soften the cataract. Fragmentation patterns can be combined based on surgeon's preference. For example, the LenSx® laser is the one laser in which the cube or "French fries" pattern can be combined with the chop pattern. Resulting benefits of pre-softening the lens are easier removal of the cataract and reduction in EPT, CDE, postoperative corneal thickness and endothelial cell loss as well as surgical OR time.[4,5,7]



Compared to some other femtosecond lasers, the LenSx® laser has a non-fixed patient bed which can provide additional time saving as the patient does not need to be transferred from the gurney to the laser bed and back.

In summary, femtosecond laser cataract surgery provides a well matched tool to meet the technical and workflow needs for cataract surgery today. The femtosecond laser with its integrated imaging capabilities enables the surgeon to visualize key anatomical landmarks to plan for a targeted treatment with greater efficiency during cataract surgery.

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