A Review of Femtosecond Laser Assisted Cataract Surgery for Hawai‘i

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Abstract

Hawai‘i has had the first US Food and Drug Administration approved femtosecond laser (LenSx as shown in figure) for cataract surgery since early 2012, a brand new laser technology for modern cataract surgery in Hawai‘i. This article intends to evaluate the cost, safety, efficacy, advantages, and limitations of femtosecond laser-assisted cataract surgery through a review of the literature for the public of Hawai‘i. A search was conducted using keywords to screen and select articles from PubMed. In addition, recent published peer reviewed articles pertinent to the femtosecond laser-assisted cataract surgery were selected and reviewed. Safety and efficacy of femtosecond laser-assisted cataract surgery were demonstrated in the literature, with improvements in anterior capsulotomy, phacofragmentation, and corneal incision. However, there were limitations within these studies which included small sample size and short-term follow-up. In addition, cost-benefit analysis has not yet been addressed. Long-term studies to compare the complication rate and visual outcome between the laser and conventional cataract surgery are warranted.

Keywords

Capsulorhexis, Capsulotomy, Cataract, Cataract Laser Extraction, Clear Corneal Incision, Femtosecond, Femtosecond-Assisted cataract surgery, Fragmentation, Laser, LenSx, OptiMedica, LensAR, Optical Coherence Tomography, Phacoemulsification, Phacofragmentation, Refractive Cataract Surgery

Introduction

Lasers have been utilized in cataract surgery since the 1970s, when Krasnov reported a laser modality for phacopuncture.[1] Subsequently, in 1987, Peyman and Katoh focused an Erbium: YAG laser on the lens nucleus, inducing photoablation.[2] Currently, there are three lasers; OptiMedica (Santa Clara, CA), LenSx (recently acquired by Alcon, Fort Worth, TX), and LensAR (Winter Park, FL) that have studies in the literature for review. LenSx is the laser available in Hawai‘i. The birth of LenSx laser cataract surgery can be dated to 2009, when Zoltan Z. Nagy, MD, of Semmelweis University in Budapest, evaluated and described the ability of the LenSx femtosecond laser system (LenSx Lasers Inc, and Alcon Laboratories Inc) to perform anterior capsulotomy, lens fragmentation and to create self-sealing corneal incisions.[3,4] Today, over 61,000 procedures have been performed with this laser and over 300 units are available worldwide. Since premium intraocular lenses (IOLs) are getting more popular for near perfect vision, methods to increase accuracy and precision in cataract surgery are being investigated.[5-7] Femtosecond Laser assisted cataract surgery (FLACS) may be the answer to the investigation. Although FLACS can be a promising surgical modality, there are questions of its widespread utility and accessibility.

The laser system of LenSx is an all-solid-state laser source that produces a kHz pulse train of femtosecond pulses. An optical coherence tomography (OCT) imaging device and a video camera microscope (VM) are used to localize specific targets and to view the patient’s eye. Its intended uses in cataract surgery include anterior capsulotomy, phacofragmentation and 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. The LenSx Laser focuses a beam of low energy pulses of infrared light into the eye. Each pulse of energy creates photodisruption of a micro-volume of tissue at the focus of the beam. When scanned, the beam places individual photodisruption sites in a contiguous pattern to form continuous incisions. A typical incision consists of several tens of thousands micro-disruptions. By programming the size, shape and location of the scanning pattern, incisions are created. An anterior capsulotomy incision consists of a cylindrical cut starting from below the surface of the anterior capsule and continuing through the capsule a few microns into the anterior chamber. A lens phacofragmentation incision consists of two or more vertically oriented elliptical- shaped planes that intersect at the center of the lens.[1,2] This article intends to evaluate the safety, efficacy, advantages and limitations of femtosecond laser-assisted cataract surgery through a review of the literature.

Method

A PubMed electronic search in September 2012 was conducted using the following key words: Capsulorhexis, Capsulotomy, Cataract, Cataract Laser Extraction, Clear Corneal Incision, Femtosecond, Femtosecond-Assisted cataract surgery, Fragmentation, Laser, LenSx, OptiMedica, LensAR, Optical Coherence Tomography, Phacoemulsification, Phacofragmentation, Refractive Cataract Surgery.

Inclusion criteria for this search:
- All peer reviewed published articles or abstracts in the program of major ophthalmological meetings that investigated and demonstrated the benefits and limitations of femtosecond laser assisted cataract surgery.

The exclusion criteria:
- Studies were not pertinent on the topic of the benefit and limitation of femtosecond assisted cataract surgery.

Twenty eight papers were selected from one hundred forty five search results using the key words and those results were reviewed as following.

Results

Palanker, et al, studied 59 eyes of 50 patients who underwent FLACS using the OptiMedica platform in one eye, with the other eye receiving traditional cataract surgery. Postoperatively, 38% of laser treated eyes compared to 70% of eyes subjected to traditional cataract surgery experienced corneal edema. Best corrected visual acuity (BCVA) showed a gain of 4.3±3.8 lines in the laser group eyes (n=29) and a gain of 3.5±2.1 lines in the traditional group eyes (n=30). The authors also tested 12 rabbit eyes to assess retinal safety using maximal laser settings of 6 μJ and 100 kHz. With fluorescein angiography and fundoscopic imaging at 1 hour, and then at 3 days, they observed no retinal or other damage.[8]

Slade described 50 eyes treated with LenSx, and showed the corneal incisions self-sealed were reproducible and architecturally sound. The author showed less induced coma and astigmatism, manipulation, and phacoemulsification time. There was also less variation in lens position. He reported 100% of eyes achieved 20/30 or better BCVA after one week.[9]

However, Edwards, et al, performed a study with conventional versus LensAR FLACS, which included 60 FSL (Femtosecond laser)-treated eyes and 45 conventionally treated eyes. There were no significant differences in the outcomes of BCVA, IOP (intraocular pressure), or corneal thickness between the two groups. No major complications were reported in either group.[10]

The clear corneal incision (CCI) has been associated with an increased risk of postoperative endophthalmitis.[11] A recent study utilized anterior segment OCT after cataract surgery to show that a majority of eyes had an internally gaping corneal wound and detachment of Descemet's membrane after CCI.[12] It is hypothesized that these detected wounds can increase the risk of postoperative endophthalmitis. FSL may allow for more square architecture, which has proven more resistant to leakage.[13] Masket, et al, conducted a cadaver eye study in which they showed decreased leakage, added stability, and reproducibility at various IOPs after FSL-guided corneal incision.[14] Additionally, Palanker, et al, observed they could create an incision using the FSL that formed a one-way, self-sealing, and water-tight valve under normal IOP.[8] Nevertheless, currently no published comparative studies on endophthalmitis between standard keratome and FSL-guided incisions are available.

FSL systems are capable of delivering cuts to precise depths and lengths on cornea without touching the epithelium for limbal relaxation incision (LRI) and these LRIs may be more accurate, safe and adjustable when compared to manual techniques.

Trivedi, et al, demonstrated that smooth, regular edges may offer superior capsular strength and resistance to capsular tears.[15] In addition; the unpredictable diameter observed in manual capsulorhexis can have effects on IOL centration, with subsequent poor refractive outcomes, unpredictable anterior chamber depths, and increased rates of posterior capsular opacification.[16-18] The FSL is able to deliver a more circular, precisely planned capsulorhexis. Nagy, et al, performed anterior capsulotomies in 54 eyes, comparing the LenSx laser to manual capsulorhexis 1 week after cataract surgery. In the FSL group, the authors observed a higher degree of circularity, fewer patients with incomplete capsulorhexis-IOL overlap (11% of laser patients compared to 28% of manual capsulorhexis patients), and better IOL centration. Using the OptiMedica FSL platform, two studies similarly demonstrated a statistical advantage for the FSL-assisted capsulotomy in terms of precision, accuracy, and reproducibility in human eyes.[8,19] Kránitz, et al, studied the LenSx platform and compared manual capsulorhexis to FSL-assisted capsulorhexis with 1 year of follow-up. The authors observed greater capsulorhexis-IOL overlap in the FSL group and greater amounts of horizontal IOL decentration in the manual capsulorhexis group. This study suggested that decentration of the IOL was six times more likely to occur in the setting of manual capsulorhexis.[20] Friedman, et al, and Nagy, et al, showed greater strength in FSL-guided capsulotomies in porcine eyes.[19,21]

Early studies have shown that FSL systems reduced ultrasound energy necessary for all grades of cataract.[22,23] Nagy, et al, showed that the FSL reduced phacoemulsification power by 43% and operative time by 51% in a porcine eye study.[21] Two studies have compared human eyes receiving FSL-assisted capsulorhexis and phacofragmentation to fellow eyes receiving traditional cataract surgery. Both show easier phacoemulsification in the FSL group.[8,23] In one of these studies, Palanker, et al, observed a decrease in the perceived hardness of nuclear sclerotic cataract after the laser-assisted procedure, estimated by the surgeon to decrease from grade four to grade two. A 39% average reduction in dispersed energy for phacoemulsification was also observed in the FSL group.[8] Furthermore, Uy showed that with grade three or higher cataracts, FSL-assisted lens fragmentation also reduced the amount of energy.[24] Ultrasound phacoemulsification carries the risk of corneal injury. Using rabbit eyes, Murano, et al, studied the effect of ultrasound oscillations in the anterior chamber. The authors observed oxidative stress and cellular necrosis after ultrasound, and concluded that the corneal endothelial cell damage was caused by free radicals.[25] Similarly, Shin, et al, showed that increasing ultrasound time and energy had a direct relationship to cell injury.[26] With consideration to a reduction in ultrasound energy and instrumentation, FSLs may show improved safety and decreased complications. A more recent study also demonstrated that IOL power calculations were more predictable with laser assisted cataract surgery.[27]

Figure: Photo of LenSx

Table 1. Current Evidences on Benefits of Laser Assisted Cataract Surgery to Reduce Complication from Phacoemulsification	
Benefits	**Reasons**
Less Cornea edema and less damage to eye	Less phaco time, less damage to endothelium
Better Wound healing	More precise wound, more square wound
Better capsulorhexis	Precise, round and strong capsulorhexis
Better LRI (limbal relaxation incision) for astigmatism without perforation	Precise depth ,width and adjustable
Better IOL power prediction and centration with better vision outcome	Due to near perfect capsulorhexis
Better prevention of endophthalmitis	Due to better wound healing
No retina damage	Study by Palanker, et al

Discussion

Even though current studies support the safety and efficacy of FLACS,[8,10,21] the small patient population (between 40 to 60 eyes) and short-term follow-up (one hour to one year) of these studies limit the ability to adequately assess such safety factors. Even though the reoccurrence of cataract is not an issue, the posterior capsule haziness rates after surgery need to be compared between the laser group and the traditional group. Future studies will need to elucidate if there truly are superior visual outcomes in long-term follow-up of laser-assisted cataract surgery and if there is less endophthalmitis compare to conventional cataract surgery. A learning curve will be needed to master laser operation techniques to ensure the best outcomes. Complications may occur during the learning process such as rupture of the posterior capsule and dropped nucleus.[28]

FLACS may be difficult to apply to those patients who have deep set orbits or those with tremors or dementia or too deep sedation, since the initial docking of the lens requires patient cooperation. In addition, patients with posterior synechiae, intraoperative floppy iris syndrome or poor dilated pupil, small eye lid fissure and ocular motor paralysis may be poor candidates for FLACS.

The laser system is expensive to purchase (cost about three hundred thousand dollars) and to maintain (cost about forty thousand dollars a year) and the cost-benefit analysis has not yet been established. Surgical time usually is longer since it involves two surgeries. The cost of these laser machines plus the cost of PI (patient interface)(cost 325 dollars) will add considerable cost to the currently conventional procedure. The extra costs to the surgical center are incurred from a bigger space required to accommodate the laser and greater number of staff needed to assist in the procedure. This may be the main reason why the laser has had difficulty in achieving widespread utility and accessibility.

Conclusion

FLACS appears safe with many benefits (Table 1) in providing better outcomes for cataract surgery compared to conventional surgery. FLACS may be surgically indicated in some risky cataract cases such as hard nucleus and zonulopathy. However, continuous long term clinical studies of the outcomes of this laser surgery will provide data for cost-benefit analysis and the confirmation of its superiority over conventional surgery.

List of acronyms
FLACS: Femtosecond Laser Assisted Cataract Surgery
OCT: Optical Coherence Tomography
VM: Video Microscope
BCVA: Best Corrected Visual Acuity
FSL :Femtosecond Laser
IOP: Intra Ocular Pressure
CCI: Clear Corneal Incision
LRI: Limbal Relaxation Incision
IOL: Intra Ocular Lens

Disclosure and Conflict of Interest

The author reports no financial interest in any of the products in this article. The author reports no conflict of interest.

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Editor's Commentary

A main purpose of the *Hawai'i Journal of Medicine & Public Health* is education applicable to the medical and public health communities of Hawai'i and the Pacific Islands. Such education needs to be clearly separated from the "marketing" which often accompanies any new procedure, technique, or conclusion. Dr. Chen's even handed article has begun that task.

In a time of decreasing medical resources, there needs to be clear and unequivocal demonstration of net benefit to the patient and society rather than simple "non-inferiority." Multiple articles in the juried literature support this new laser technology yet some (*cf*. Femtosecond Laser for Cataract Surgery causes debate. *New Zealand Optics*, July 2012) raise issues of safety and cost.

We look forward to continued evaluation of the technique by the author with particular attention to statistically valid long term results.

Michael J. Meagher MD, Co-Editor
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