Femtosecond laser-assisted cataract surgery (FLACS) involves the use of laser energy to create precise incisions previously accomplished manually. The use of FLACS also softens the lens and reduces the amount of ultrasound energy applied to the eye.

Based on limited studies, FLACS appears to be safe; however, improvements in clinical outcomes over conventional surgery have yet to be demonstrated.

FLACS is substantially more expensive than conventional surgery, and it is likely to impose significant additional costs on either the health care system or on patients, or both, if implemented.

The Technology

A cataract forms when proteins in the lens of the eye clump together. Over time, the cataract can grow in size, making the lens increasingly cloudy and thus impairing vision. Cataracts are most commonly age-related, but they may also be congenital or secondary to other disease processes (e.g., diabetes) or trauma. In addition to age and diabetes, smoking and ultraviolet (UV) light exposure are known risk factors.

Femtosecond lasers have been used in refractive surgery, such as the correction of nearsightedness or farsightedness, for more than a decade. They have also been used to make precise corneal incisions for correcting astigmatism and for corneal transplant. Attention has turned to the potential application of femtosecond lasers in cataract surgery, and this technology is now commercially available.

Femtosecond lasers produce ultrashort pulses of light energy at near-infrared wavelengths. Although sufficient peak energy is created to essentially vaporize the targeted tissue, the ultrashort pulse duration minimizes energy transfer to adjacent tissue, thereby minimizing associated damage. In addition, the near-infrared wavelength is not absorbed by optically clear tissue, thus allowing the laser to be precisely targeted at various depths within the cornea, anterior chamber, and lens, the main areas of interest in cataract surgery.

Key steps in conventional cataract surgery, including corneal incisions and the formation of an opening in the front of the lens capsule (i.e., capsulotomy), are performed manually, relying on a surgeon’s skill and visual reference points. Then, the lens itself is broken up (phacoemulsified) using ultrasonic energy and removed from the eye. This ultrasonic energy produces free radicals and can damage the fragile corneal endothelium. In some cases, a diamond knife may be employed to incise the cornea in order to reduce pre-existing astigmatism. In femtosecond laser-assisted cataract surgery (FLACS), a computer-guided laser linked to an optical imaging system performs the corneal incision, capsulotomy, and lens fragmentation steps, thus changing the requirements associated with traditional techniques — removing the requirement for blade incisions and reducing phacoemulsification (ultrasound) time and energy. The potential gains in precision associated with FLACS may facilitate improved safety and clinical outcomes.

At least four FLACS platforms are commercially available, three of which are licensed in Canada. The platforms show some variation in docking systems (i.e., the approach to immobilizing the eye for imaging and laser treatment), imaging systems, and other features, but they all use a femtosecond laser to perform key incisions and to soften the cataract for extraction. Worldwide, it is estimated there are 300 sites offering FLACS, and more than 61,000 procedures have been performed.
Regulatory Status

Three FLACS platforms have been licensed by Health Canada, all as Class III medical devices. The following are the device names, manufacturers, and licensing dates:

- LenSx; Alcon LenSx Incorporated; April 17, 2012
- VICTUS Femtosecond Laser Platform; Technolas Perfect Vision GmbH; June 17, 2013
- CATALYS Precision Laser System; OptiMedica Corporation; July 8, 2013.

These devices, plus one additional device (the LENSAR Laser System, LENSAR Incorporated), have obtained US Food and Drug Administration (FDA) and CE (European conformity) mark approval.6

Patient Group

No large population eye health studies have been conducted in Canada; hence, cataract prevalence data are limited. As well, reported prevalence estimates can vary, as some studies assess symptomatic patient populations (e.g., those with vision loss), while others consider the broader population with eye disease regardless of vision loss.

In a chart-based review, Maberley et al.7 identified patients with visual impairment (n = 962) and captured a variety of data, including diagnosis. They concluded that the age-standardized prevalence of low vision and blindness in Canada ranged from 35.6 to 71.2 in 10,000, depending on the definition of low vision. Cataracts were identified as the leading cause of low vision and blindness (29.9%).7

Two additional studies provide Canadian prevalence estimates based on population studies conducted in other countries. One study focusing on visual impairment concluded that the prevalence of vision loss attributable to cataracts is 0.4% (133,836 Canadians in 2007).1 The other study addressed eye disease independent of vision loss. It estimated that in 2006 there were 2.7 million Canadians over the age of 40 with cataracts.8 Both studies projected that the prevalence of vision loss and cataracts will double by 2032.

While FLACS may be applied across a broad spectrum of patients requiring cataract surgery, those receiving premium intraocular lenses (IOL) — for example, multifocal, toric, and accommodative lenses — may be more likely to benefit, as the precise capsulotomy reportedly achievable with FLACS may be important to the performance of such lenses. However, this benefit of combining FLACS with premium lenses has yet to be demonstrated. Relative contraindications to FLACS reportedly include pediatric age, small pupils, existing corneal implants, previous corneal incisions, and other corneal abnormalities or diseases that may interfere with the laser penetration.9,10

Current Practice

Canadian guidelines specify that surgery is appropriate when cataracts interfere with activities of daily living or, in the absence of functional symptoms, when visual acuity falls below mandated requirements for some activities such as driving.11 Rarely must cataracts be removed to prevent damage to the eye; for example, when intraocular pressure increases or inflammation is caused by the maturing cataract. Cataract surgery is thus largely an elective, non-urgent procedure.

The major steps in conventional cataract surgery are the same as in FLACS, but most are accomplished manually. Incisions are made in the cornea to access the anterior chamber of the eye. The surgeon then tears a circular opening in the front of the capsular bag containing the lens. Creation of the capsulotomy is challenging to learn and regarded as the most technically difficult aspect of the surgery for surgical residents.12 Ideally, the capsulotomy is centred, perfectly circular, and sized to overlap the IOL by 0.5 mm for 360 degrees, as this minimizes the potential for the IOL to tilt, rotate, or decentrate.13 The contents of the capsular bag are emulsified using ultrasound (phacoemulsification) and aspirated. A synthetic IOL is subsequently inserted into the capsular bag.

Conventional cataract surgery is the most commonly performed surgery in the world, with an estimated 19 million procedures completed annually.8 In Canada, 255,800 cataract surgeries were performed in 2007/2008.14 Conventional cataract surgery is widely acknowledged as safe and effective.4

Methods

A peer-reviewed literature search was conducted using the following bibliographic databases: MEDLINE, PubMed, Embase, the University of York Centre for Reviews and Dissemination, and The Cochrane Library.
Incorporated remainder used the LenSx platform (Alcon LenSx surgeon. 17 were not independent trials in distinct patient groups. publication dates, raising the possibility that these substantial overlap equipment manufacturers. Three studies reported conventional cataract surgery. results regarding visual acuity following FLACS or

Five studies were identified that reported comparative studies regarding visual acuity following FLACS or conventional cataract surgery. 4,15-18 All of the studies reported financial or other relationships with equipment manufacturers. Three studies reported substantial overlap in authorship and submission for publication dates, raising the possibility that these were not independent trials in distinct patient groups. 15- 17 In two studies, all surgeries were completed by one surgeon. 15,16 One study 4 used the CATALYS Precision Laser System (OptiMedica Corporation), while the remainder used the LenSx platform (Alcon LenSx Incorporated).

Length of follow-up was undefined in one study, 4 six months or less in three studies, 15,17,18 and 12 months or less in the final study. 16 

Palanker et al. 4 reported their experience with 50 patients who underwent FLACS, a subset of which were included in a comparative study (n = 30). The method for selection of this subset was not reported. One eye was randomly assigned to FLACS, with the other eye receiving conventional surgery and serving as a matched control. The authors reported that the mean gain in visual acuity for the FLACS group was 4.3 ± 3.8 lines versus 3.5 ± 2.1 lines for the control group. The difference was not statistically significant.

Miháltz et al. 15 conducted a prospective controlled study to examine the impact of FLACS on internal aberrations and optical quality. FLACS was performed on 48 eyes (43 patients) and conventional surgery was performed on 51 eyes (58 patients), the latter serving as a control group. No statistically significant differences were found between the FLACS and conventional surgery groups for uncorrected distance visual acuity (UDVA — visual acuity at a distance without the additional aid of corrective lenses; 0.86 ± 0.15 versus 0.88 ± 0.08; \( P > 0.05 \)) or corrected distance visual acuity (CDVA — visual acuity at a distance with the aid of corrective lenses; 0.97 ± 0.08 versus 0.97 ± 0.06; \( P > 0.05 \)). Although the differences in UDVA and CDVA were not statistically significant, the authors found statistically significant reductions in intraocular vertical tilt and coma aberrations, which may suggest better image quality in the FLACS-treated eyes.

Kránitz et al. 16 conducted a prospective, randomized study to examine IOL tilt and decentration following FLACS or conventional surgery. FLACS was performed on 20 eyes (20 patients) and conventional surgery was performed on 25 eyes (25 patients). No difference was found in UDVA at any follow-up point. CDVA was not significantly different ( \( P > 0.05 \)) between the FLACS and conventional groups at the one-week follow-up point but significantly favoured the FLACS group at the one month (0.94 ± 0.11 versus 0.84 ± 0.16; \( P = 0.031 \)) and one year (0.97 ± 0.06 versus 0.92 ± 0.09; \( P = 0.038 \)) follow-up points. Further analysis showed a significant correlation between IOL vertical tilt and CDVA (\( R^2 = 0.17 \), beta = −0.41, 95% confidence interval [CI]: −0.69 to −0.13).

Filkorn et al. 17 examined IOL power calculation and refractive outcome in a randomized controlled trial. FLACS was performed on 77 eyes (77 patients) and conventional surgery was performed on 57 eyes (57 patients). Mean absolute error (MAE), the difference between predicted and achieved refraction, was used to analyze refractive outcome, and multivariable regression analysis was used to compare the groups. MAE was significantly lower in the FLACS group than in the conventional group (0.38 ± 0.28 dioptres versus 0.50 ± 0.38; \( P = 0.04 \)). After adjusting for the effect of axial length and IOL type, multivariable modelling showed that the type of surgery had a significant impact on MAE (\( P = 0.04 \)).

Roberts et al. 18 compared 113 consecutive FLACS-treated eyes to a retrospective consecutive cohort of 105 eyes treated with conventional surgery. No significant difference was found between the FLACS and conventional groups in the absolute mean difference from intended correction (0.29 ± 0.25 dioptres versus 0.31 ± 0.24; \( P = 0.512 \)).
Adverse Effects

The identified literature did not report any adverse events unique to FLACS, or a higher incidence of complications. Some studies have reported the occurrence of anterior capsular tears that have progressed to posterior capsular tears and concomitant loss of lens material into the vitreous due to the incomplete nature of capsulotomies performed using FLACS, but subsequent reports have supported the view that these were attributable to a learning curve. More recently, Abell et al. reported a higher rate of anterior capsule tears persisting beyond the expected learning curve. Based on the scanning of electron microscopy examination of lens capsules, they hypothesized that capsulotomy integrity is compromised by postage stamp-like perforations and misplaced laser pits possibly caused by eye movement. They also noted that variation across laser platforms cannot be ruled out.

Administration and Cost

The Canadian list price of the Alcon LenSx laser system is $550,000 (Mark Smithyes, Head, Government Affairs and Market Access, Alcon Canada, Mississauga, Ontario: personal communication, 2014 Feb 28). Costs associated with other laser systems were requested but were not provided by the respective manufacturers. Reports in the published literature indicate capital costs for such systems in the range of US$300,000 to US$600,000, with annual maintenance costs of US$40,000 to US$50,000. Consumables are estimated at US$150 to US$500 per procedure. The Canadian list price for the Alcon SoftFit Patient Interface (which positions the eye beneath the laser) is $4,500 for a box of 10 (Mark Smithyes: personal communication, 2014 Feb 28).

FLACS is substantially more expensive than conventional surgery. Lauschke et al. noted that a bent 27-gauge needle, the traditional instrumentation for accomplishing a capsulotomy, costs US$0.13. Abell and Votz estimated the incremental cost-effectiveness ratio for FLACS to be AUD$92,861 per quality-adjusted life-year. They concluded that FLACS costs would need to decline by 50% to 70% to be cost-effective.

Concurrent Developments

No competing technologies are known to be in development.

Rate of Technology Diffusion

Cost will likely be an impediment but not an absolute barrier to FLACS diffusion. At least four CATALYS Precision Laser Systems have been sold in Canada in the roughly five months following it being licensed in July 2013, and nine LenSx systems have been sold in Canada (Mark Smithyes: personal communication, 2014 Feb 28). Information on the sales of the VICTUS Femtosecond Laser Platform was not available. Published analysis suggests the break-even point could be as low as 19 procedures per month over five years, given an incremental patient charge of US$859 per case. These numbers might be further reduced for multi-purpose platforms such as the VICTUS, which is uniquely designed for use in both refractive (e.g., in situ keratomileusis [LASIK]) and cataract surgery. The Southern Alberta Eye Center is introducing FLACS technology in Western Canada and will reportedly charge each patient approximately $650 per eye.

It is estimated that FLACS will account for about 4% to 5% of total cataract surgery volume in the US by the end of 2013 and rise to approximately 30% in five to ten years. A number of considerations may challenge this diffusion projection. Cataract surgery is increasingly seen as refractive surgery, and surgeons and patients alike may seek the presumed benefits of FLACS technology, especially for premium IOLs or astigmatism correction. It is also important to note that almost 50% of FLACS procedures currently completed in the US involve non-premium lenses, thus suggesting the potential for more general use of the technology.

Implementation Issues

Although it appears FLACS is safe and brings increased precision to key steps in cataract surgery, improvements in clinical outcomes over conventional surgery have yet to be proven. In the absence of significant cost reductions, implementation of FLACS is likely to impose significant additional costs on either the healthcare system or on patients, or both. Combining Canadian cataract volumes (255,800 in 2007-2008), the user fee applied in Calgary ($650), and peak FLACS penetration projected for the US (30%) suggests potential incremental costs over conventional surgery of
approximately $50 million, with uncertain improvement on outcomes.

The introduction of FLACS may also require major changes to the organization of cataract services. Given the cost of the technology, each unit would need to support multiple surgeons. Laser treatment might occur in one suite and feed into multiple operating rooms where other surgeons would complete the manual portions of the procedure. One report suggested that case processing times could increase by 20% to 30%, based on experience with surgeons beginning to use the procedure, but no time estimates for experienced surgeons were identified. Given the need for 500 to 600 FLACS cases to support the acquisition of the laser technology, it might also be the case that smaller centres would cease offering cataract surgery, which could adversely impact the distribution of ophthalmologists and give rise to new equity or access issues for patients.

References


Cite as: Murtagh J. Femtosecond Laser-Assisted Cataract Surgery (FLACS) [Issues in emerging health technologies, Issue 126]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2014.

A clinical expert in ophthalmology was consulted by CADTH in preparing this report.

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Issues in Emerging Health Technologies is a series of concise bulletins describing drug and non-drug technologies that are not yet used (or widely diffused) in Canada. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

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