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Horizon Scanning Technology Prioritising Summaries

The IntraLase® femtosecond laser

September 2006



ASERNIP(S)

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**



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This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

**Name of Technology:**

IntraLase® femtosecond laser

Purpose and Target Group:

The IntraLase femtosecond laser was developed to create corneal flaps required for laser in situ keratomileusis (LASIK).

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged

IntraLase is currently available in Australia and hence is registered in the Australian Register of Therapeutic Goods (ARTG number: 107191 and 124974, Product number: 186270 and 208204).

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States			✓
Europe			✓

Impact Summary:***Background***

Laser in situ keratomileusis (LASIK) has emerged to become the most common refractive surgical procedures for correcting myopia, hyperopia and astigmatism since its introduction in the early 1990s. The LASIK procedure is essentially a two-step process, the first step requires the surgeon to create a flap of corneal tissue which is folded back to prepare the eye for the second step. The second step involves the use of an excimer laser which reshapes the inner cornea to correct the vision of the patient (IntraLase Corp. 2006). Despite the high success rates of LASIK there are some potential risks when this procedure is utilised. Studies have revealed that most major vision-threatening complications (e.g. epithelial defects, incomplete flaps, decentered flaps) are linked to the creation of the corneal flap (Binder 2006). Since the introduction of LASIK, various mechanical microkeratomes have been developed to create the corneal flap. However, despite the improvements which have been



made towards the design of microkeratomes, there are several complications which have not been adequately addressed. Flap dimensions created with existing microkeratome technology continues to produce unpredictable ranges of flap thickness that are unrelated to attempted flap thickness. This complication has the potential to place the laser ablation deeper than intended and therefore increasing the risk of corneal ectasia (progressive corneal thinning and bulging). In addition to this, several studies have revealed that current microkeratome systems create thinner flaps when the preoperative corneal thickness is thin and/or when the preoperative corneal curvature exceeds 46 diopters (D) (Binder 2006).

The femtosecond laser is the first alternative to mechanical microkeratomes and the IntraLase is the first femtosecond laser approved by the Food and Drugs Administration in the United States. The IntraLase system employs the precision of a computer-guided laser to create the corneal flap and therefore claims to be more precise compared to hand-held microkeratomes. It utilises an infrared beam of light to separate tissue via a process known as photodisruption. Photodisruption is the process whereby focused laser pulses divide material at the molecular level without the transfer of heat or impact to the surrounding tissue. Unlike mechanical microkeratomes, IntraLase creates the flap below the surface of the cornea using an 'inside-out' process. Each pulse of the laser creates a tiny bubble (2 to 3 microns) of carbon dioxide and water vapour. The laser essentially moves back and forth across the eye, creating a uniform layer of bubbles beneath the corneal surface. Bubbles are then stacked along the edge of the flap up to the corneal surface, thus completing the flap. This level of accuracy is the main reason for the purported safety of IntraLase compared to microkeratomes (IntraLase Corp. 2006). In addition to corneal flap creation, recent studies (Sikder and Snyder 2006, Terry *et al.* 2005) have examined the possibility of utilising IntraLase as a means of obtaining smooth donor cornea for corneal transplantation. However, corneal transplantation is beyond the scope of the current summary and the low-level evidence (*in vitro* and cadaver studies) currently available hinders its inclusion in the following discussion.

Clinical Need and Burden of Disease

The 2001 National Health Survey reported that 22% (~ 4 million) of Australians are hyperopic while 5% (~ 1 million) experience astigmatism (AIHW 2004). Most individuals afflicted by hyperopia and astigmatism would be satisfied with corrections using prescription glasses or contact lenses. However, some of these individuals may opt to undergo LASIK surgery to achieve permanent vision correction.

Previous studies have revealed that corneal flap-related complications occur in as many as 5% of LASIK cases and includes decentered flaps, free flaps, irregular flap edges and stromal bed surfaces, epithelial abrasions, buttonholes and flap lacerations. These complications can result in delayed recovery of visual acuity while severe cases may lead to permanent vision loss (Lim *et al.* 2006).



Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

In Australia, IntraLase has been approved by the TGA and is currently used for corneal flap creation for LASIK procedures. However, the extent of use of this technology in Australia is not documented. The IntraLase laser was approved by the FDA for laser assisted creation of the corneal flap in 2002 and has been used extensively in the United States with approximately 500,000 procedures as of October 2005. In addition to this, IntraLase has received the CE mark of approval in Europe with approximately 30 sites utilising this technology (Centre for sight 2006).

Existing Comparators

The main comparators to IntraLase are the current mechanical microkeratomes. However it is important to note that Ziemer Ophthalmic Systems AG (Switzerland) had developed the Da Vinci femtosecond surgical laser, but clinical studies are limited at the time of writing (Ziemer Ophthalmics 2006).

Estimated Cost Impact

LASIK surgery with IntraLase typically costs more than conventional LASIK with a microkeratome. The cost increases by approximately US\$250 to US\$500 per eye, averaging US\$344 (Segre and Thompson 2006). In Australia, the average cost increase of using IntraLase during LASIK surgery is approximately \$400 (Lasik Vision 2006).

Efficacy and Safety Issues

List of Studies Found

Total number of studies	17
Randomised controlled trials	1
Non-randomised comparative studies	2
Case series studies	12
Case reports	2

The studies included in this summary are highlighted in bold in the reference list. One randomised controlled trial, two non-randomised comparative studies and one case series were included in this summary. The case series by Binder (2006) was selected for inclusion above other case series studies due to the sheer number of corneal flaps created (n = 1000) which offers substantial insight to the efficacy and safety of IntraLase.



Safety

Achieving accurate corneal flap thickness is a key safety consideration for the prevention of ectasia following LASIK surgery. Compared to mechanical microkeratomes, IntraLase achieved a mean flap thickness 16 μm less than programmed, meanwhile the Carriazo-Barraquer (CB) microkeratome achieved a mean flap thickness that was 23 μm thicker than plate* thickness and the Hansatome achieved a mean 24 μm thinner than plate thickness. Mean flap thickness was significantly thinner ($p < 0.001$) and the variance of flap thickness was significantly better ($P < 0.001$) with IntraLase compared to the mechanical microkeratomes. In addition to this, no eye in the IntraLase group experienced loose epithelium. In comparison, loose epithelium was evident in 1 quadrant in 5.5% of eyes and 2 quadrants in 4.1% of eyes in the CB group, resulting in an overall rate of 9.6% ($p = 0.001$, compared to the IntraLase group). Meanwhile in Hansatome eyes, loose epithelium in 1 quadrant was seen in 5.1% of eyes and loose epithelium in 2 quadrants was reported in 2.6% of eyes for a total of 7.7% ($p = 0.001$, compared to the IntraLase group). There were no incidences of buttonholes, transacted flaps or other sight-threatening complications. Similar rates of best spectacle-corrected visual acuity (BSCVA) loss were documented for all three devices (IntraLase, CB, Hansatome) (Kerizian and Stonecipher 2004).

Eyes with corneal flaps created with IntraLase exhibited more post-operative inflammation compared to the mechanical keratome group in the study conducted by Lim *et al.* (2006); however the degree of inflammation was not quantified. In one eye, a mechanical failure caused the inadvertent release of the vacuum during flap creation. This required the suction ring to be remounted and the flap was created successfully on the second pass on the laser (Lim *et al.* 2006).

Binder (2006) documented several operative complications over the course of 1000 consecutive IntraLase corneal flaps. Six eyes experienced a loss of suction that precluded the completion of the operation on the same surgical day. Two incomplete laser passes due to suction loss were reoperated on the same day. Two flaps (in the 90 μm attempted thickness group) tore at the hinge due to excessive tension on the flap caused by the mechanical lift. No flap suffered from epithelial defects, but the peripheral host epithelium of three eyes experienced focal defects at the end of the procedure which was due to trauma at flap lift. No incidences of free, button hole, or decentered flaps were reported even when a previous mechanical microkeratome flap button hole case was reoperated. There were no incidences of visually significant interface inflammation (diffuse lamellar keratitis, DLK) on the first post-operative day, however 50 eyes had minor peripheral interface inflammation (Grade 1 or trace) and were treated with hourly topical prednisone acetate (1%) and cleared in 1 to 3 days. Four eyes had visually significant folds in the Bowman's layer (microstriae), while several eyes (exact numbers not stated) which had no visual symptoms developed a granular,

* A depth plate in microkeratomes determines the planned thickness for the flap resection.



peau d'orange appearance on the interface approximately 3 months post-surgery. Moderate to severe photophobia was documented in 5 patients 4 to 8 weeks following surgery with no loss of best spectacle-corrected visual acuity, no internal or external inflammation was detected in these eyes. Photophobia was resolved with constant topical steroid treatment for 1 to 2 weeks (Binder 2006).

Prior to the software update for IntraLase in 2004, Binder (2006) reported that the mean achieved flap thickness for IntraLase (at the 90 μm setting) exceeded the intended thickness by 15 μm to 30 μm . However, after the software update the mean achieved flap thickness improved substantially and was within 3 μm to 5 μm of the attempted flap thickness. Binder (2006) claims that the standard deviation of flap thickness remained consistent for almost all the intended flap thicknesses in IntraLase eyes, and the range of flap thickness was smaller compared to data reported with mechanical microkeratomes. However, no data was presented to support this statement. Mechanical microkeratomes has the tendency to create thicker flaps when operating on thicker corneas. In comparison, IntraLase results from this study revealed no difference in the achieved flap thickness (for attempted flap thickness of 90 μm and 100 μm) when comparing preoperative central corneal thickness of less than 500 μm with those greater than 576 μm . Another disadvantage of mechanical microkeratomes is the increased risk of creating thinner flaps when preoperative corneal curvature is greater than 46 D, Binder (2006) reported no difference in achieved flap thickness with the IntraLase despite preoperative mean corneal curvatures of less than 42 D or greater than 46 D (Binder 2006). Meanwhile the study by Tran *et al.* (2005) did not report of any safety issues throughout the study period. These results therefore indicate that IntraLase appears to be capable of producing consistent flap thickness regardless of pre-operative corneal thickness or curvature.

Efficacy

The randomised controlled trial by Tran *et al.* (2005) attempted to identify the potential advantages of IntraLase compared to a mechanical microkeratome, Hansatome, in wavefront-guided LASIK procedures. One of the key differences in wavefront-guided LASIK ablations compared to conventional LASIK is that the primary data input for ablation is objective data obtained from an aberrometer while conventional ablation utilises subjective refraction data. Due to the fact that aberrometer measurements are done prior to flap creation, any refractive changes that occur after flap creation cannot be programmed into the excimer laser. Therefore it would be advantageous to ensure that flap creation does not introduce any changes that may affect the accuracy of wavefront-guided LASIK. Nine patients with myopia or myopic astigmatism underwent a 2-step procedure with excimer laser treatment 10 weeks after initial flap creation. One eye in each patient was randomised to Hansatome keratectomy and the other eye to IntraLase. Tran *et al.* (2005) showed that 10 weeks after flap creation, statistically significant changes in defocus wavefront aberrations



were observed after IntraLase (baseline: 3.5 RMS, 10 weeks post-flap: ~3.2 RMS, $p = 0.008$) and Hansatome (baseline: 3.5 RMS, 10 weeks post-flap: ~2.7 RMS, $p = 0.004$) flap creation. A hyperopic shift in manifest refraction was seen in the Hansatome group after the creation of the corneal flap ($p = 0.04$), however no statistically significant change in manifest refraction was observed in the IntraLase group. In the Hansatome group, statistically significant increases of higher-order aberrations (trefoil and quadrafoil Zernicke terms) were noted after flap creation ($p = 0.02$). Conversely, no significant changes in higher-order aberrations were observed in the IntraLase group. Differential wavefront maps indicated that eyes with Hansatome-created flaps had significant aberrations while nearly flat wavefront changes were observed in the fellow eyes of the same patients which had IntraLase-created flaps (Tran *et al.* 2005).

A retrospective case study evaluated one surgeon's use of mechanical microkeratomes in 2002, using Carriazo-Barraquer (CB) ($n = 126$ eyes in 126 patients) or Hansatome ($n = 146$ eyes in 143 patients), compared with his use of IntraLase ($n = 106$ eyes in 106 patients) in 3 months in 2003. (Kerizian and Stonecipher 2004). 20/20 uncorrected visual acuity (UCVA) rates at day 1 post-surgery was slightly lower in the IntraLase group (45%) compared to CB (57%) and Hansatome (51%), but this was not statistically significant (p -value not stated). Similarly, when the 20/40 UCVA rate was considered, all groups achieved comparable results (IntraLase: 98%, CB: 99%, Hansatome: 99%) (Kerizian *et al.* 2004). Mean acuity for all groups was similar at day 1. Three months after surgery, 20/20 UCVA rates remained comparable in all three groups; 67% for IntraLase, 71% for CB and 66% for Hansatome. Meanwhile 20/40 rates 3 months post-surgery ranged from 98% to 99% (IntraLase: 98%, CB: 99%, Hansatome: 99%). Refractive predictability was significantly better for the IntraLase eyes, with 91% (95% CI, 88% to 94%) achieving a manifest refractive spheroequivalent (MRSE) of ± 0.50 D, while the MRSE ± 0.50 D rates for CB and Hansatome was 73% (95% CI, 69.4% to 77.4%; $p < 0.01$) and 74% (95% CI, 69.9% to 77.3%; $p < 0.01$) respectively. Meanwhile, all three groups achieved similar rate of MRSE ± 1.00 D; IntraLase 99%, CB 99% and Hansatome 95%. Linear regression analysis of the attempted MRSE versus the achieved MRSE revealed that IntraLase eyes had significantly better correlation compared to the CB group ($p < 0.05$) but not for the Hansatome group ($p = 0.14$). Surgically induced astigmatism in spherical corrections is a common occurrence in LASIK surgery. In this study, Kerizian and Stonecipher (2004) reported that IntraLase flaps induced significantly less astigmatism compared to flaps created with CB and Hansatome ($p < 0.01$). The standard deviation of postoperative cylinder in eyes that had spherical corrections (i.e. no cylinder treated) was 0.22 D for IntraLase, 0.32 D for CB and 0.40 D for Hansatome eyes ($p < 0.01$ for IntraLase vs CB and Hansatome). The authors proposed that the lack of procedure-induced astigmatism is due to the circular (rather than truncated) shape of the IntraLase flap. Other potential contributors include the programmed edge angle and constant flap thickness; however further investigation is necessary (Kerizian and Stonecipher 2004).



Lim *et al.* (2006) compared LASIK outcomes when the corneal flap was created with IntraLase (n = 28 eyes in 14 patients) or Hansatome (n = 27 eyes in 16 patients). Patients were allocated to either procedure according to their choice. Pre-operative spherical error for IntraLase eyes was -5.6 ± 2.3 D (range -2.5 to -10.75 D) while Hansatome eyes was -4.9 ± 1.6 D (range from -2.5 to -7.75 D). Meanwhile, pre-operative cylindrical error was 0.8 ± 0.9 D (range 0 to 2.5 D) in the IntraLase group and 0.6 ± 0.5 D (range 0 to 1.35 D) in the Hansatome group. Overall, pre-operative refractive errors were similar between both groups ($p > 0.05$). One month post-surgery, mean spherical error was comparable for both groups, with mean \pm SD of -0.40 ± 0.5 D for IntraLase eyes and -0.40 ± 0.6 D for Hansatome eyes. In the same way, post-operative mean cylindrical error at one month post-surgery was comparable between both groups as well, with a mean of 0.20 ± 0.4 D for the IntraLase group and 0.30 ± 0.5 D for the Hansatome group. The similarity between IntraLase and Hansatome eyes for spherical and cylindrical errors was maintained up to 3 months post-surgery (Table 2), indicating that the level of procedure-induced astigmatism was similar between both groups. These results were contradictory to Kerizian and Stonecipher (2004) where procedure-induced astigmatism was significantly lower for IntraLase eyes compared to eyes with flaps created by microkeratomes.

Table 2: Post-operative spherical and cylindrical errors for IntraLase and Hansatome groups (Lim *et al.* 2006).

Error	Hansatome group (n = 27)		IntraLase group (n = 28)	
	1 month	3 months	1 month	3 months
Spherical error < 0.5 D	19 (70.4%)	20 (74.1%)	17 (60.7%)	18 (64.3%)
Spherical error \geq 0.5 D	8 (29.6%)	7 (25.9%)	11 (39.3%)	10 (35.6%)
Cylindrical error < 0.5 D	17 (63.0%)	19 (70.4%)	23 (82.1%)	21 (75.0%)
Cylindrical error \geq 0.5 D	10 (37%)	8 (29.6%)	5 (17.9%)	7 (25.0%)

* Expressed as number of eyes (%)

Graphical representation of the relationship between achieved correction versus intended correction revealed that IntraLase showed a tendency towards undercorrection in myopia < 6 D. Lim *et al.* (2006) reported no loss of BCVA in either group after surgery. In addition, no statistically significant difference was noted in term of postoperative visual acuity between the two groups ($p > 0.05$) (Table 3).



Table 3: Postoperative uncorrected visual acuity for IntraLase and Hansatome groups (Lim *et al.* 2006)

Uncorrected visual acuity	>20/15	20/20	<20/25
Intralase (n = 28)			
1 month	2 (7.1%)	21 (75%)	5 (17.9%)
3 months	4 (14.3%)	18 (64.3%)	6 (21.4%)
Hansatome (n = 27)			
1 month	1 (3.7%)	19 (70.4%)	7 (25.9%)
3 months	2 (7.4%)	20 (74.2%)	5 (18.5%)
* Expressed as number of eyes (%)			

It is a generally accepted fact that after LASIK surgery, higher order aberrations increase due to the procedure. In this study, root mean square of higher-order aberrations (HO-RMS) increased from a preoperative value of $0.314 \pm 0.230 \mu\text{m}$ to $0.371 \pm 0.225 \mu\text{m}$ 3 months post-surgery in the IntraLase group, while the Hansatome eyes documented an increase from $0.305 \pm 0.171 \mu\text{m}$ to $0.430 \pm 0.222 \mu\text{m}$ 3 months post-surgery, therefore a significant increase of HO-RMS was noted in both groups ($p < 0.05$ for both groups). Previous studies have inferred that this event was due to the use of microkeratomes; however in the current comparative study by Lim *et al.* (2006), the increase of higher order aberrations were similar between both groups ($p > 0.05$), an outcome which is contradictory to the randomised control trial by Tran *et al.* (2005). However there was one exception, significantly higher spherical aberrations were reported in the Hansatome group compared to the IntraLase group ($p < 0.05$), an attribute which the authors believe was due to the flap configuration (square-shaped edge) of IntraLase. Post-operative contrast sensitivity was similar for both groups under photopic conditions. Yet under mesopic conditions, contrast sensitivity increased in both groups, with significant improvements in IntraLase eyes at high spatial frequencies (12 and 18 cycles per degree) ($p \leq 0.05$). This result was unexpected as previous studies reported decreases in contrast sensitivity after LASIK. With regards to corneal sensitivity, the evaluation of 10 eyes from each group revealed decreased sensitivity post-surgery. Both groups exhibited significantly slower improvement of corneal sensitivity at the central area compared to the peripheral areas ($p \leq 0.05$). However, the recovery of corneal sensitivity was significantly faster in IntraLase eyes for the central and inferior corneal areas ($p < 0.05$) (Lim *et al.* 2006).

Ethical Issues

No issues were identified from the retrieved material.

Cultural or Religious Considerations

No issues were identified from the retrieved material.



Other Issues

Preliminary investigations on the utility of the IntraLase laser in corneal transplantation reveals that it is capable of generating thin donor buttons for transplantation of corneal endothelium. However, Sikder and Snyder (2006) reported that IntraLase caused collateral damage to endothelial cells, indicating that further research is required to optimise endothelial cell survival before IntraLase can be used successfully in corneal transplantation procedures. In an earlier cadaver study, Terry *et al.* (2005) reported that the histology of the IntraLase-formed stromal dissections did not appear substantially better compared to manual deep lamellar endothelial keratoplasty dissections in both recipient and donor tissues. Therefore, additional research is required to examine and fine-tune the potential use of IntraLase in corneal transplantation surgery.

Recommendation

Current studies demonstrate that IntraLase is capable of producing predictable flap thickness, increased post-operative flap stability and decreased epithelial injury (Binder 2006, Kerizian and Stonecipher 2004). However, there are contentious results with regards to the benefits of IntraLase towards improving postoperative refractive errors (Kerizian and Stonecipher 2004, Lim *et al.* 2006), while improvements in clinical outcomes such as visual acuities and total higher-order aberrations were not apparent in the studies discussed. The potential of utilising IntraLase in corneal transplantation is of significant interest, however the issues identified in the current early-stage studies reveals that further research is required before IntraLase can be utilised in clinical corneal transplantation. Based on the evidence available, it is recommended that IntraLase is monitored for further developments in corneal transplantation.

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| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

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Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network of Agencies for



Health Technology Assessment, relevant online journals and the Internet was conducted in July 2006.

Search terms used were: 'IntraLase', 'femtosecond laser', 'laser cornea\$ flap', 'laser LASIK', 'cornea\$ flap creation'.

This Horizon Scanning Prioritising Summary was prepared by Mr. Irving Lee from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).