



Australian Government
Department of Health and Ageing



Horizon Scanning Technology Prioritising Summary

VISX CustomVue™ for hyperopia, hyperopic
astigmatism and mixed astigmatism

December 2005



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



**Royal Australasian
College of Surgeons**

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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

Horizon Scanning Technology Prioritising Summary

Name of Technology:

VISX CustomVue™

Purpose and Target Group:

The CustomVue™ laser vision correction procedure was originally approved by the FDA for the treatment of myopia and myopic astigmatism. Following the results of clinical trials, the indications for this procedure has been expanded for the treatment of hyperopia and hyperopic astigmatism in December 2004. Later (March 2005), the procedure was approved for the treatment of mixed astigmatism as well. This summary will focus on the use CustomVue™ for the treatment of hyperopia, hyperopic astigmatism and mixed astigmatism.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

Note: Although CustomVue™ is established in Australia, an ARTG number was not found for it. This summary will be updated when we receive a response from the TGA.

International Utilisation:

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

Impact Summary:

Background

Hyperopia or long sightedness is a very common condition and is characterised by difficulty in focusing on close objects (blurred vision) while distant objects can be seen clearly. This visual disturbance results from a shortened eyeball, which causes light to focus behind the retina. Astigmatism is a condition which also causes visual distortion; this is attributed to the cornea being oblong instead of spherical. As a result of this, light rays entering the eye do not meet at a single focal point, resulting in a distorted image.

Astigmatism is hereditary and may worsen over time; other causes include corneal scarring (due to injury), eye surgery and keratoconus (Lee & Bailey 2005).

Both astigmatism and hyperopia can be corrected using prescription glasses or contact lenses. A more advanced treatment would be laser in situ keratomileusis (LASIK). The LASIK procedure involves the use of a microkeratome or laser to create a thin circular flap in the cornea. This flap is then folded out of the way and an excimer laser is used to remove the corneal tissue underneath. This laser uses a cool ultraviolet light to ablate the corneal tissue and therefore reshape the cornea. If the procedure is successful, the reshaped cornea enables light to be focus appropriately onto the retina, thus improving vision.

The CustomVue™ procedure is a relatively new form of LASIK and involves the use of the VISX STAR S4 IR™ Excimer laser with Variable Spot Scanning (VSS™) and the WaveScan WaveFront® System. The WaveScan WaveFront® System is the key component in this procedure; it provides an accurate measurement and visual representation of optical aberrations of an eye based on the behaviour of light waves. It does this by comparing the light passing through the patient's eye to the light pattern from a perfect, aberration-free optical system. This information is then used to produce the WavePrint® map which captures the eye's imperfections as detected by WaveScan®. WaveScan® has been touted to be able to measure and correct imperfections with 25 times greater precision in a patient's eye compared with conventional measurements used to produce prescription glasses and contact lenses. The information is then relayed and utilised to calibrate the VISX STAR S4™ laser to maximise precision and accuracy.

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.

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

The Food and Drug Administration (FDA) granted marketing approved the CustomVue™ laser vision correction procedure for the treatment of hyperopia and hyperopic astigmatism on December 2004. In March 2005, CustomVue™ was approved for the treated of mixed astigmatism as well. If this procedure proves to be more effective than other forms of LASIK, it would be expected to gain widespread acceptance in Australia. At the time of writing, the CustomVue™ procedure is available in Australia for the treatment of myopia. However, the extent of utilisation of this procedure to treat hyperopia, hyperopic astigmatism and mixed astigmatism in Australia is not known.

Existing Comparators

- CustomCornea/LADARVision® System (Alcon Laboratories Inc.)
- Technolas 217A Excimer Laser/Zioptix (Bausch & Lomb)
- Navex Quest (NIDEK Co., Ltd)
- Allegretto (Wavelight Laser Technologie AG)
- Conventional LASIK
- Conventional Photorefractive Keratectomy (PRK)
- Automated lamellar keratoplasty (ALK)
- Conductive Keratoplasty (CK)
- Radial Keratotomy (RK)
- Contact lenses
- Prescription glasses

Note: Both CustomCornea and Technolas are wavefront guided LASIK systems.

Estimated Cost Impact

The cost of the CustomVue™ procedure in Australia is approximately AUD\$2400 (Sydney laser and vision centre 2005). Conventional LASIK (without wavefront technology) costs ~AUD\$1900 (NewVision Clinics 2004). The extra cost for CustomVue™ treatment is attributed to the increased cost of the laser devices.

Laser refractive surgery is not covered under the Medicare Benefits Schedule although prescription glasses and fitting of contact lenses are covered.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	2
Case series	2

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from two case series were selected for inclusion in this summary. These studies were selected as they were the key studies which resulted in the approval of CustomVue™ for the treatment of hyperopia, hyperopic astigmatism and mixed astigmatism by the FDA.

Hyperopia and hyperopic astigmatism

The safety and efficacy of the CustomVue™ system in treating hyperopia with and without astigmatism was examined in a clinical study which involved 74 patients (144 eyes). Of all the eyes treated, 134 were evaluated for effectiveness with 98.5% accountability at 3 months, 131 eyes with 97% accountability at 6 months, 118 eyes with 90.8% accountability at 9 months and 27 eyes with 87.1% accountability at 12 months. The results revealed that of the 131 eyes that were examined at 6 months post-treatment for uncorrected visual acuity (UCVA), 97.3% were corrected to 20/40 or better, and 66.2% were corrected to 20/20 or better in 74 spherical hyperopic eyes. Meanwhile, 93% were corrected to 20/40 or better and 56.1% were corrected to 20/20 or better in 57 astigmatic hyperopic eyes. With regards to stability of the treatment, the study showed that at 6 months follow-up there was no loss of ≥ 2 lines of best corrected vision that was obtained with the use of spectacles in both the astigmatic hyperopic eyes (63 eyes) and spherical hyperopic eyes (74 eyes). In addition to this, neither of the astigmatic hyperopic eyes or spherical hyperopic eyes had a best spectacle corrected visual acuity (BSCVA) worse than 20/25. However, one astigmatic hyperopic eye (1/63 eyes, 1.6%) lost > 2 lines of BSCVA at 1 month while none of the spherical hyperopic eyes lost > 2 BSCVA lines or had a BSCVA worse than 20/40 throughout the duration of the study.

The CustomVue™ system was proven to be sufficiently accurate with 58% (76/131 eyes) of eyes within 0.5D and 88.5% (116/131 eyes) were within 1.0D of the attempted sphere correction. With regards to eyes of the astigmatic group, 68.4% (39/57 eyes) were within 0.5D and 94.7% (54/57) were within 1.0D of attempted cylindrical correction at 6 months follow-up. In addition to this, 65% (85/131) of eyes were within ± 0.5 D and 91% (119/131) were within ± 1.0 D of attempted MRSE correction at 6 months post-treatment. Stability of treatment was satisfactory; with over 98% of eyes experiencing ≤ 1.00 D change in MRSE between 3 months and 9 months post-treatment.

Adverse events or complications occurred in at least 1% of the 144 eyes treated at any point of time up to 6 months post-treatment. This includes cell growth under the flap (2.1%), foreign body sensation in the eye (1.4%), diplopia (ghost images) (11.3%) and peripheral corneal epithelial defect (2.1%). Questionnaires completed by patients after the treatment revealed that there was an increase of various symptoms post-treatment. When comparing 6 months post-treatment eyes (131 eyes) to pre-treatment eyes (136 eyes) under symptoms that were rated to occur 'often', there was an increase in: dryness

(17% vs 6%), fluctuation of vision (13% vs 6%), halos (9% vs 7%) and ghost images (7% vs 2%).

One device failure was reported in this study where the laser stopped firing during treatment. The patient completed the procedure despite this setback. This failure was not reported in any other centres and hence no further action was required. The faulty device was examined and the relevant components were replaced by VISX field service (VISX STAR S4 IR™ Excimer laser with Variable Spot Scanning (VSS™) and the WaveScan WaveFront® System, Summary of Safety and Effectiveness Data, FDA 2004).

Mixed Astigmatism

The effectiveness of the CustomVue™ system in treating naturally occurring mixed astigmatism was evaluated in a clinical trial of 86 eyes. UCVA analysis at 3 months revealed that 95.3% were corrected to 20/40 or better, 91.9% were corrected to 20/32 or better, and 61.6% were corrected to 20/20 or better. One eye experienced a temporary loss of 2 BSCVA lines at 1 month follow-up but this was resolved at 6 months where no eyes had BSCVA worse than 20/40.

Refractive stability was achieved at 3 months post-treatment and was confirmed at 6 months post-treatment. All eyes experienced a change in cylinder of $\leq 1.00\text{D}$ up to 9 months post-treatment. With regards to accuracy of treatment, results at 3 months revealed that 94.2% (81/86) of eyes were within 1.0D of the attempted sphere correction while 88.4% (76/86).

Adverse events and complications occurred in at least 1% of the 86 eyes up to the third post-operative month. The incidents reported are: miscreated flap (1.2%), epithelium in the interface (4.7%), diplopia (8.1%) and retinal vascular accidents (1.3%). Patient questionnaires point towards an increase in dryness (22% vs 6%) and halos (20% vs 13%) three months after the procedure (VISX STAR S4 IR™ Excimer laser with Variable Spot Scanning (VSS™) and the WaveScan WaveFront® System, Summary of Safety and Effectiveness Data, FDA 2005).

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

No issues were identified from the retrieved material.

Recommendation:

No studies comparing CustomVue™ with conventional LASIK for the treatment of hyperopia and astigmatism were located. The two studies currently available indicate that CustomVue™ is capable of performing accurate and lasting corrections to these defects. At the time of writing, no studies have been conducted to compare CustomVue™ against other wavefront guided procedures for the treatment of hyperopia and astigmatism. Based on the available information, it is recommended the following be conducted:

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

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Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in July 2005.

Search terms used were: 'CustomVue', 'wavefront LASIK', and 'Visx wavefront'.

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).