Australian Government
Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network
ANZHSN
AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

National Horizon Scanning Unit
Horizon scanning prioritising summary

Volume 7, Number 10:

Implantable collamer lens: For the correction of myopic vision.

October 2004

AHTA
Adelaide
Health Technology
Assessment

Electronic copies can be obtained from http://www.horizonscanning.gov.au

Enquiries about the content of this summary should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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 Linda Mundy from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Department of Public Health, Mail Drop 511, University of Adelaide, South Australia, 5005.

PRIORITISING SUMMARY

REGISTER ID: **000135**

NAME OF TECHNOLOGY: **IMPLANTABLE COLLAMER LENS**

PURPOSE AND TARGET GROUP: **TO CORRECT MYOPIC VISION IN PEOPLE WHO ARE NOT SUITABLE CANDIDATES FOR LASER SURGERY**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☒	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number	
☒	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia		✓	
Finland	✓		
United States	✓		
France	✓		
Spain	✓		

IMPACT SUMMARY:

Two companies, Ophtec USA Incorporated and STAAR Surgical Company, manufacture implantable or intraocular contact lenses (ICL) for visual correction in people with moderate to high myopia. Ophtec USA Inc manufactures the Verisyse or Artisan ICL, which was given approval from the United States Food and Drug Administration (FDA) in September 2004. The STAAR Surgical ICL does not have FDA approval, and neither device has approval from the Australian Therapeutic Goods Administration. However, the STAAR Surgical ICL is currently being trialled in Australia, and is distributed by Concept Vision Pty Ltd. It is available under the TGA's Special Access Scheme, the Individual Patient Use (IPU) scheme, which allows access to unapproved medical devices (personal communication, Concept Vision Australia).

BACKGROUND

Implantable contact lenses are designed for patients with moderate to severe myopia (shortsightedness) who are not candidates for laser surgery due to the curvature of their corneas. The differences in vision are measured in diopters (D), which represents the reciprocal of the focal length, in metres, of a lens. A normal eye falls within the diopter range

of - 0.50 to +0.50, whereas severe myopia would be ≤ -10.0 D and hyperopia (farsightedness) has a range of +0.75 to +4.00 D (Tyson 2004).

The eye's lens and cornea normally focus light into an image on the retina. In the myopic eye, light is focussed in front of the retina and so the image of distant objects is blurred (Figure 1). ICLs such as the Artisan are inserted under paraocular anaesthesia, through an incision made posterior to the cornea and are fixated to the peripheral iris. The foldable STAAR Surgical ICL is inserted through a small incision between the iris and the crystalline lens. The procedure takes approximately 30 minutes. Unlike intraocular lenses implanted during cataract surgery, ICLs do not replace the eye's natural lens, but are inserted in front of it (Maloney et al 2002). ICLs have a diopter range between –5.0 to –20.0.

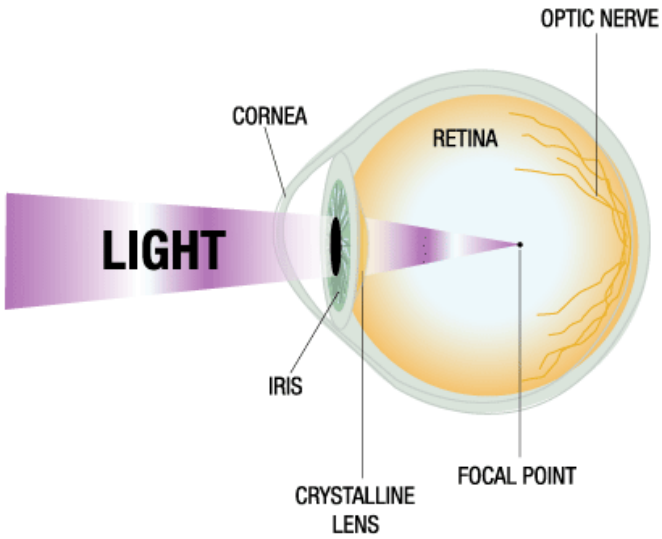

Figure 1 The myopic eye (Printed with permission, Advanced Medical Optics 2004)

Adverse events caused by the implantation of ICLs may include retinal detachment, corneal swelling, the development of cataracts due to contact with the crystalline lens, glaucoma, displacement of the iris and loss of endothelial cells from the cornea. It is recommended that ICLs are used on patients with a dense corneal endothelium, capable of withstanding loss of volume over time (FDA 2004; Maloney et al 2002).

Clinical Need and Burden of Disease

Myopia is a very common condition in Australia with approximately 15 per cent of the population affected. Myopia usually develops during the teenage years and may worsen over time (Optometrists Association Australia 2004). Implantable contact lenses are primarily for patients with high levels of myopia, i.e. greater than what can ideally be treated by changing corneal curvature with laser surgery (laser). Therefore the market size in Australia for this product is small, although in the Asian population the incidence of severe myopia would be much higher (personal communication, Concept Vision Australia).

There is currently a lack of reliable incidence and prevalence data for severe myopia in Australia. However, a cross-sectional study conducted in the Blue Mountains area of Australia reported the visual acuity status of 3,647 persons who were ≥ 49 years of age. Visual impairment was found in 170/3647 (4.7%) participants. Of these, mild visual impairment (Snellen equivalent 20/40 to 20/60 in the better eye) was found in 3.4%, moderate visual impairment (20/80 to 20/160 in the better eye) in 0.6%, and severe visual impairment or blindness (20/200 or worse in the better eye) in 0.7%. Visual impairment increased with

age from 0.8% of persons 49 to 54 years of age to 42% of persons 85 years of age or older (Attebo et al 1996).

DIFFUSION

Concept Vision are in the process of conducting a controlled roll-out of the STAAR Surgical ICL, in Australia, involving the training of ophthalmologists in the technique used for implanting the lens. To date in Australia, approximately 350 STAAR Surgical ICLs have been implanted in patients with between –2.0 and –6.0 diopters (D) of myopia (personal communication, Concept Vision Australia).

COMPARATORS

Myopia is usually treated with prescribed spectacles or contact lenses. Refractive or laser surgery to reshape the front surface of the eye may also correct vision in some people with between -1.0 and –6.0 D of myopia. Refractive surgery involves irreversible alterations to the cornea, which are designed to change its curvature and therefore reducing the refractive error (Optometrists Association Australia 2004).

EFFECTIVENESS AND SAFETY ISSUES

Malecaze et al (2002) conducted a randomised controlled trial (level II evidence), comparing the insertion of the Artisan ICL in one eye, to refractive or laser surgery in the other eye. Allocation of eyes was randomised and the same surgeon performed both procedures. Twenty-five patients with stable bilateral myopia between –8.0 and –12.0 D were enrolled and followed-up for one year. At one year, the refractive outcome or mean spherical equivalent refraction was –0.74 ± 0.67 D for laser treated eyes and –0.95 ± 0.45 D for the ICL treated eyes. Laser treated eyes had a significant improvement in mean spherical equivalent refraction at one month, -0.28 ± 0.71 D compared to –1.07 ± 0.59 D for ICL treated eyes (p<0.01), however this difference was no longer evident at three months. At one year, 80 per cent of eyes treated with laser and 60 per cent of eyes treated with an ICL had an uncorrected visual acuity of 20/40 or better (see Appendix). The two techniques showed no statistical difference in efficacy, defined as the mean post-operative uncorrected visual acuity to the mean pre-operative best spectacle-corrected visual acuity. Visual acuity was evaluated in terms of losing the ability to read two lines or more from the Snellen eye chart. There was no loss of lines with eyes treated with the Artisan ICL, however three eyes lost two lines or more after laser surgery. Endothelial cell loss was 0.21 ± 12.3% at three months and 0.42 ± 11.95% at one year for laser treated eyes, compared to 0.96 ±13.45% and 1.76 ± 12.05%, respectively for the ICL treated eyes at the same time points.

A case series (level IV evidence) conducted by Maloney et al (2002) assessed the safety and effectiveness of the Artisan ICL for submission to the FDA. Results were reported on 155 eyes of 155 patients with myopia ranging from –5.5 to –22.5 D. Due to rolling enrolment, only 84 eyes were available to be followed up at six months. The mean pre-operative spherical equivalent refraction was –12.69 ± 3.8 D. The mean post-operative spherical equivalent refraction at day one was –0.39 ± 1.04 D and –0.54 ± 0.7 D at six months. At six months 85% of eyes had 20/40 or better uncorrected visual acuity. Endothelial cell counts were unchanged at six months. An irregular pupil was reported in 1/84 (1.2%) eyes, glare and halo effect in 5/84 (6.0%) eyes and asymptomatic vacuoles on the crystalline lens in 2/84 (2.4%) eyes.

Finally, a case series (level of evidence IV) conducted by Sanders et al (2002) also assessed the safety and effectiveness of the STAAR Surgical ICL for submission to the FDA. Resuklts were reported on 526 eyes of 294 patients with myopia ranging from –3.0 to –20 D, with a three year follow-up. Uncorrected visual acuity at three years was 20/20 or better in 41 per cent of eyes and 20/40 or better in 81 per cent of eyes. Cumulative endothelial cell loss over

the first three post-operative years ranged from 8.4% to 9.7%, depending on the method of analysis. Loss of two lines or more when reading from the Snellen chart was reported in 5/526 (1.0%) eyes. Safety issues reported include repositioning of the ICL in 4/526 (0.8%) eyes, replacement followed by removal of ICL in 1/526 (0.2%), replacement of ICL in 8/526 (1.5%) eyes, cataract development in 7/526 (1.3%) eyes and retinal detachment in 3/526 (0.6%) eyes.

COST IMPACT

The STAAR Surgical ICL costs approximately A$1000 per eye (personal communication, Concept Vision Australia). The Medicare Benefits Schedule provides rebates for optometric consultations. Item numbers 10900, 10905, 10912, 10913, 10914 and 10915 have an MBS fee of $59, and item numbers 10907 and 10916 have a $29.55 fee. In addition, the MBS provide two item numbers (10821 and 10921) for the fitting of contact lenses for people with myopia of 5.0 diopters or greater. Medicare benefits are not available for refractive surgery, consultations in preparation for the surgery or consultations in the aftercare period. Medicare benefits are not provided for lens insertion for correction of refractive error. The Eye Institute, Victoria, routinely perform laser surgery to correct myopic vision for $2,850 per eye. The cost of prescription lenses for severe myopia may range from A$100 to A$450, with frames ranging from A$250 to A$550 (personal communication Laubman & Pank, Optometrists).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

All papers by Sanders et al were supported and funded by the STAAR Surgical Company.

CONCLUSION:

There is limited but good quality evidence (level II) currently available implantable for intraocular contact lenses (ICL) for visual correction in people with moderate to high myopia. It is expected that there would be high demand for this technology in the Australian population.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

Advanced Medical Optics (2004). *What is nearsightedness?* [Internet]. Advanced Medical Optics. Available from: http://www.visioninfocus.com/220.asp [Accessed 12th October 2004].

Alexander, L., John, M. et al (2000). 'U.S. clinical investigation of the Artisan myopia lens for the correction of high myopia in phakic eyes. Report of the results of phases 1 and 2, and interim phase 3', *Optometry*, 71 (10), 630-642.

Attebo, K., Mitchell, P. & Smith, W. (1996). 'Visual acuity and the causes of visual loss in Australia. The Blue Mountains Eye Study', *Ophthalmology*, 103 (3), 357-364.

FDA (2004). *FDA Approves Implanted Lens to Correct Nearsightedness* [Internet]. United States Food and Drug Administration. Available from: http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01313.html [Accessed 11th October 2004].

Guell, J. L., Vazquez, M. et al (2003). 'Artisan toric phakic intraocular lens for the correction of high astigmatism', *Am J Ophthalmol*, 136 (3), 442-447.

Malecaze, F. J., Hulin, H. et al (2002). 'A randomized paired eye comparison of two techniques for treating moderately high myopia: LASIK and artisan phakic lens', *Ophthalmology*, 109 (9), 1622-1630.

Maloney, R. K., Nguyen, L. H. & John, M. E. (2002). 'Artisan phakic intraocular lens for myopia:short-term results of a prospective, multicenter study', *Ophthalmology*, 109 (9), 1631-1641.

Mastropasqua, L., Toto, L. et al (2004). 'Long-term complications of bilateral posterior chamber phakic intraocular lens implantation', *J Cataract Refract Surg*, 30 (4), 901-904.

Moshirfar, M., Barsam, C. A. & Parker, J. W. (2004). 'Implantation of an Artisan phakic intraocular lens for the correction of high myopia after penetrating keratoplasty', *J Cataract Refract Surg*, 30 (7), 1578-1581.

Optometrists Association Australia (2004). *Myopia* [Internet]. Optometrists Association Australia. Available from: http://www.optometrists.asn.au/eyevision/disorders/referrors/myopia [Accessed 12th October 2004].

Optometrist Australia (2004). [Internet]. Available from http://www.optometrist.com.au [Accessed 27th July, 2004].

Sanders, D. R. (2003). 'Postoperative inflammation after implantation of the implantable contact lens', *Ophthalmology*, 110 (12), 2335-2341.

Sanders, D. R., Brown, D. C. et al (1998). 'Implantable contact lens for moderate to high myopia: phase 1 FDA clinical study with 6 month follow-up', *J Cataract Refract Surg*, 24 (5), 607-611.

Sanders, D. R., Doney, K. & Poco, M. (2004). 'United States Food and Drug Administration clinical trial of the Implantable Collamer Lens (ICL) for moderate to high myopia: three-year follow-up', *Ophthalmology*, 111 (9), 1683-1692.

Sanders, D. R., Vukich, J. A. et al (2003). 'U.S. Food and Drug Administration clinical trial of the Implantable Contact Lens for moderate to high myopia', *Ophthalmology*, 110 (2), 255-266.

Tyson, J. (2004). *How LASIK works* [Internet]. How Stuff Works. Available from: http://health.howstuffworks.com/lasik5.htm [Accessed 12th October 2004].

Uusitalo, R. J., Aine, E. et al (2002). 'Implantable contact lens for high myopia', *J Cataract Refract Surg*, 28 (1), 29-36.

SEARCH CRITERIA TO BE USED:

Anterior Chamber/*surgery
Contact Lenses
Endothelium, Corneal/pathology
Myopia
Prosthesis Design/Implantation
Keratoplasty, Penetrating
Lens Implantation, Intraocular
Lens, Crystalline/*physiology
Lenses, Intraocular
Visual Acuity

APPENDIX

20/20 vision is a term used to describe normal distance vision. The ‘20’ represents a distance of 20 feet, the standard testing distance used by optometrists. In metric countries such as Australia vision may be described as 6/6, where the six represents 6 metres. If an individual is described as having 20/40 vision, then that person must stand at 20 feet to see what a person with normal vision can see at 40 feet. 20/200 vision is the cut off for legal blindness.

Conversely, an individual with 20/10 vision has above normal vision (Optometrist Australia, 2003).