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Australia and New Zealand Horizon Scanning Network

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# National Horizon Scanning Unit
# Horizon scanning prioritising summary

## Update Number 4

# Implantable Collamer lens for the correction of myopic vision

## June 2006

AHTA

Adelaide Health Technology Assessment

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# UPDATE 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 | 96278 |
| ☐ | No | | |
| ☐ | Not applicable | | |

**INTERNATIONAL UTILISATION:**

| COUNTRY | LEVEL OF USE | | |
|---|---|---|---|
| | Trials Underway or Completed | Limited Use | Widely Diffused |
| Australia | | ✓ | |
| Europe | | ✓ | |
| 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 Philip Stoney, 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.

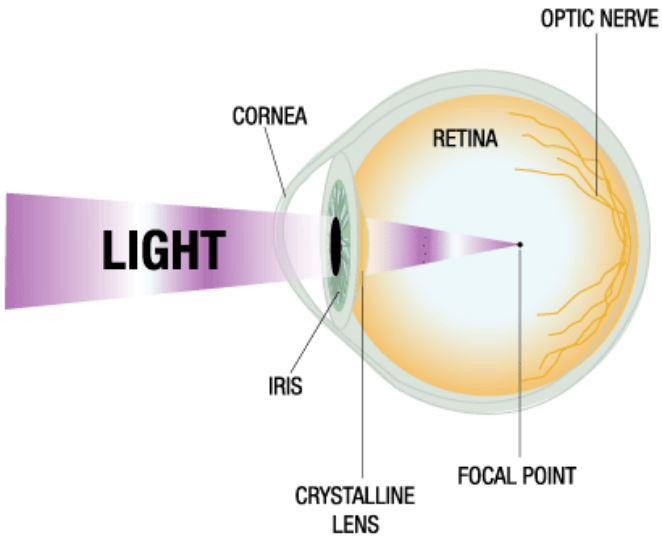


Figure 1 The myopic eye (Advanced Medical Optics 2004)

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 Philip Stoney, 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 Philip Stoney, 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 IV evidence) conducted by Sanders et al (2002) also assessed the safety and effectiveness of the STAAR Surgical ICL for submission to the FDA. Results 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 Philip Stoney, 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. 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.

### OCTOBER 2004 - CONCLUSION:

Based on the limited but good quality evidence (level II) currently available and the apparent demand for this technology in the Australian population, it is recommended that the technology be monitored.

### OCTOBER 2004 - 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
Prosthesis Implantation
Keratoplasty, Penetrating
Lens Implantation, Intraocular
Lens, Crystalline/*physiology
Lenses, Intraocular
Visual Acuity
Astigmatism/*surgery

**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).

**NOTE:**
A normal eye falls within the diopter (D) 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). ICLs have a diopter range between –5.0 to –20.0.

**JUNE 2006 UPDATE - EFFECTIVENESS AND SAFETY ISSUES**

Since October 2004 when the original Prioritising Summary was submitted, a number of studies evaluating the safety and effectiveness of ICLs have been published. A case series by Benedetti et al (2005) (level IV intervention evidence) investigated the effectiveness of the Artisan ICL in 60 patients (93 eyes total) with moderate to severe myopia over a period of 24 months. In the study, patients were divided into one of two groups according to myopia severity. Group one contained patients with preoperative spherical equivalent (SE) refractions between -6.75 and -15.50 D (68 eyes), whereas group two contained patients with preoperative SE refractions between -16.0 to -23.0 D (25 eyes). After four months, 84 per cent of group one eyes and 68 per cent of group two eyes had achieved an uncorrected visual acuity of 20/40 or better. Also at four months, 69 per cent of group one eyes and 52 per cent of group two eyes had achieved the desired level of SE refraction (within ± 1 D). Postoperative complications reported during the study period included iris atrophy (11/93 eyes), lens decentration (5/93 eyes) and night glare (6/93 eyes). Cumulative endothelial cell loss over the 24 month period was estimated to be 5.4 per cent.

Dick et al (2004) assessed changes in contrast sensitivity following implantation of the Artisan ICL in 18 patients with myopia and astigmatism (level IV intervention evidence). According to the authors, contrast sensitivity may provide a better measure of functional eyesight than standard clinical tests of visual acuity (eg Snellen testing chart) which use high contrast, black on white letters. In the study, the mean SE refraction and mean astigmatism of the patients was -9.14 D and -3.57 D respectively prior to implantation. Three months after implantation, mean contrast sensitivity had increased from 3.2 to 4.4 at 6 cycles per degree ($p = 0.03$), and from 2.4 to 3.7 at 12 cycles per degree ($p = 0.032$). No improvements were found however at spatial frequencies of 3 and 18 cycles per degree (low and high spatial frequencies).

A case series (level IV intervention evidence) conducted by Lackner et al (2004) assessed the incidence and progression of lens opacification following implantation of the STAAR Surgical ICL V4 into 76 myopic eyes (mean preoperative SE refraction of -16.5 D). Patient follow-up occurred at 1, 3, 6, 12, 24, and 36 months following implantation. During the follow-up period, lens opacification was discovered in a total of 11 eyes (14.5%). Patients who developed opacifications were significantly older ($p<0.001$) and had lower endothelial cell density after 36 months ($p<0.05$). After the onset of lens opacification, six eyes (55%) reported a stable best corrected visual acuity within ± 0.5 lines, while the remaining five eyes had progressive opacification (45%), losing between 0.5 lines and 3.5 lines of best corrected visual acuity. Interestingly, four of the five patients with progressive opacification also experienced trauma during the implantation of the lens.

Long-term safety results of the Phase III trial by Sanders et al (2002) (level IV intervention evidence) have more recently been reported by Edelhauser et al (2004). In the study, the safety and effectiveness of the STAAR Surgical ICL V4 was investigated in a group of 294 patients (526 eyes) with myopia. Endothelial cell density was obtained prior to surgery (212 eyes measured), and at 3 (221 eyes), 12 (257 eyes), 24 (234 eyes), 36 (205 eyes) and in some cases 48 months (67 eyes) following surgery. The cumulative endothelial cell loss over the first 36 months of follow-up was estimated to be between 8.4 and 8.9 per cent. Between three and four years, however, endothelial cell density increased by 0.1 per cent, suggesting that the surgical procedure is not associated with ongoing endothelial remodelling.

**JUNE 2006 UPDATE - DIFFUSION**

Emagin Pty Ltd is the Australian distributor for Ophtec USA Incorporated. The Verisyse ICL is reported to have received TGA approval in 2004 for the treatment of myopia, however only an anterior chamber intraocular lens was listed on the TGA site.

**JUNE 2006 – CONCLUSION:**

Long term follow-up of patients surgically implanted with intraocular contact lenses has provided convincing evidence for the safety of the device. However, given the low prevalence of severe myopia and the presence of alternative treatment options such as laser surgery and external contact lenses, it is likely that uptake of the technology will be limited.

**JUNE 2006 - HEALTHPACT ACTION:**

Given that the uptake of this technology would be low, it is recommended that this technology be archived.

**JUNE 2006 - SOURCES OF FURTHER INFORMATION:**

Benedetti, S., Casamenti, V. et al (2005). 'Correction of myopia of 7 to 24 diopters with the Artisan phakic intraocular lens: two-year follow-up', *J Refract Surg*, 21 (2), 116-126.

Dick, H. B., Tehrani, M. & Aliyeva, S. (2004). 'Contrast sensitivity after implantation of toric iris-claw lenses in phakic eyes', *J Cataract Refract Surg*, 30 (11), 2284-2289.

Edelhauser, H. F., Sanders, D. R. et al (2004). 'Corneal endothelial assessment after ICL implantation', *J Cataract Refract Surg*, 30 (3), 576-583.

Lackner, B., Pieh, S. et al (2004). 'Long-term results of implantation of phakic posterior chamber intraocular lenses', *J Cataract Refract Surg*, 30 (11), 2269-2276.

**LIST OF STUDIES INCLUDED IN UPDATE**

| | |
|---|---|
| Total number of studies | |
| Level IV intervention evidence | 4 |