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# **National Horizon Scanning Unit Horizon scanning prioritising summary**

## **Volume 6, Number 3:**

### **CrystaLens™ : An accommodating intraocular lens replacement for patients with cataracts.**

## **August 2004**



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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.

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# PRIORITISING SUMMARY

**REGISTER ID:** 000107

**NAME OF TECHNOLOGY:** CRYSTALENS™

**PURPOSE AND TARGET GROUP:** AN ACCOMMODATING INTRAOCULAR LENS  
REPLACEMENT FOR PATIENTS WITH CATARACTS

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |  |   |
|--|---|
| <input type="checkbox"/> Yet to emerge                 | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental                  | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational               | <input type="checkbox"/> Should be taken out of use   |
| <input checked="" type="checkbox"/> Nearly established |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |   |   |       |
|---|---|-------|
| <input checked="" type="checkbox"/> Yes | ARTG number                             | 96278 |
| <input type="checkbox"/> No             | <input type="checkbox"/> Not applicable |       |

The CrystaLens™ device is listed on the Australian Register of Therapeutic Goods and received approval from the United States Food and Drug Administration in November 2003.

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Germany	✓		
United States	✓		

## IMPACT SUMMARY:

CrystaLens™ is manufactured by eyeonics incorporated and is distributed by Concept Vision Australia Pty Ltd. CrystaLens™ is an intraocular lens (IOL) intended for visual correction in patients in whom a cataractous lens has been removed. It is a multi-focal IOL, intended to provide near, intermediate and distant vision without the aid of spectacles. The technology is available through ophthalmologists in public and private practice.

## BACKGROUND

The lens is responsible for focusing light and producing clear, sharp images. It is contained in a capsule and as old cells die they accumulate in the capsule, causing the lens to cloud (a cataract), making images blurred (Figure 1).

Cataracts may affect individuals of any age, however they usually occur as a part of the natural ageing process and predominantly occur in people over 50 years of age. Cataracts may occur in one or both eyes and can develop as a result of injury or eye disease, or may occur as a complication of other diseases such as diabetes. Exposure to cigarette smoking and sunlight increase the risk of developing cataracts (Royal Australian and New Zealand College of Ophthalmologists 2004).

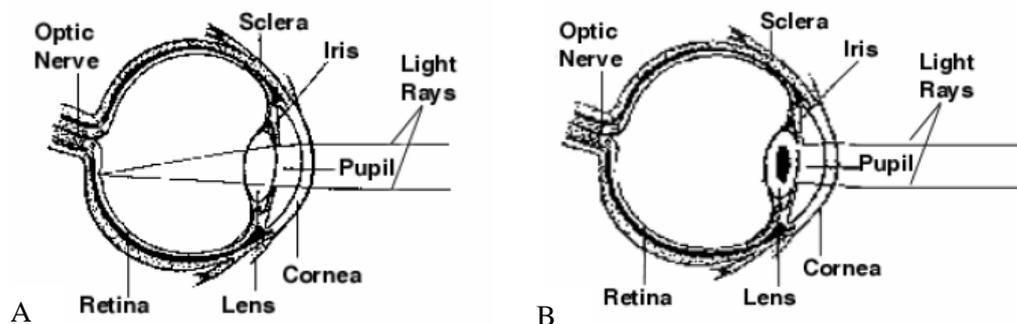


Figure 1 A: In a normal eye the cornea and the lens focus light rays onto the retina  
 B: Lens with a cataract, blocking the light rays so the eyesight is reduced  
 (Printed with permission, The Children's Hospital at Westmead, Sydney Children's Hospital, Randwick & Kaleidoscope Hunter Children's Health Network)

Mild cataracts may be treated with a change in prescription glasses, however more serious symptoms need to be treated by the surgical removal of the cataract and the implantation of either a mono- or multi-focal intra-ocular lens (Royal Australian and New Zealand College of Ophthalmologists 2004).

The Crsytalens™ is manufactured from high-refractive, non-reflective silicone, which contains a UV filter. The lens consists of a hinged plate with a relatively small biconvex optic and is fixed to the capsular bag by polyimide loops (Figure 2). The hinged plate enables maximum posterior positioning of the lens in the capsular bag, allowing for greater forward movement of the lens when the ciliary body<sup>1</sup> constricts. Anteroposterior movement of the lens along the axis of the eye provides near, intermediate and distant vision. The total length of the lens is 11.5 mm from loop-to-loop, while the length measured from the ends of the plate haptics is 10.5 mm (Breen et al 2001; Cumming et al 2001). The use of CrystaLens™ may be contraindicated in patients whose pupils widely dilate in low levels of illumination due to the small size of the biconvex optic (Colvard 2004).

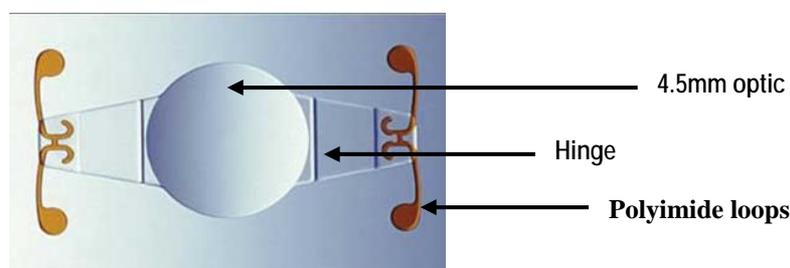


Figure 2 The CrystaLens™ AT-45 accommodating intraocular lens (Printed with permission, eyeonics)

### CLINICAL NEED AND BURDEN OF DISEASE

In Australia, there are 36,000 people with vision impairment due to cataract (Vision Australia Foundation 2004) and cataracts account for approximately eight per cent of blindness (Lions Eye Institute 2003). The rate of cataract surgery doubles with each decade of life, from approximately 0.5 per cent of individuals aged 40 years to approximately 50 per cent of those in their 90s (Vision Australia Foundation 2004). The Australian Institute of Health and Welfare reports that the total number of Australian public hospital separations for senile cataracts and other cataracts (AR-DRG numbers H25 and H27) were 137,662 and 352, 678

<sup>1</sup> The ciliary body is the thickened part of the vascular portion of the eye, which lies between the iris and the choroid. It produces the aqueous humour, which circulates in the chambers of the eye (Merck, Sharp and Dohme 2004).

respectively during the year 2001-02 (AIHW 2004). Approximately 60% of these separations were female, which may reflect the gender imbalance in the ageing population.

## **DIFFUSION**

Concept Vision are in the process of conducting a controlled roll-out of their product, CrystaLens™, in Australia. This involves training ophthalmologists in patient selection, as well as in to the technique used for implanting the lens. Currently 250 CrystaLens™ lenses have been implanted in Australia. There have been approximately 25,000 CrystaLens™ lenses implanted in Europe and 10,000 implanted in the USA since FDA approval in November 2003 (personal communication, Concept Vision Australia).

## **COMPARATORS**

Cataracts causing only mild symptoms may not need treatment. Some individuals may experience changes in their eyesight due to the presence of cataracts, which may be remedied by the provision of a new prescription for glasses. If the symptoms of cataracts are more serious, then the only option is the surgical removal of the cataract followed by the implantation of an either a monofocal or multifocal IOL. Monofocal IOLs have a fixed refractive power and therefore a fixed focal length, meaning that most patients will require reading glasses for near vision. Multifocal IOLs may give a two to three fold increase in the depth of field but this is achieved at the expense of an approximate 50 per cent reduction in the contrast of the retinal image. Multifocal IOLs are effective at improving near vision compared to monofocal IOLs and may give independence from spectacles, however a number of adverse effects are associated with multifocal IOLs, such as haloes, or rings around lights (Leyland & Zinicola 2002).

## **EFFECTIVENESS AND SAFETY ISSUES**

A pre-clinical case series study (Level IV evidence) of the CrystaLens™ device was conducted by eyeonics inc for submission to the United States FDA. Pre-implantation visual acuity values were not reported for patients enrolled in this study, only visual acuity values post-implantation with CrystaLens™, therefore it is impossible to determine the effectiveness of this procedure. A further study, conducted by eyeonics inc compared patients implanted with the CrystaLens™ (n=126) to those implanted with a variety of standard IOLs (n=64). No pre-implantation visual acuity scores were reported for patients in either group, however the number of adverse events in the group implanted with CrystaLens™ was reported. Adverse events included persistent iritis (<1.0%), persistent cystoid macular oedema (<1.0%) and cumulative cystoid macular oedema (3.7%) (FDA 2004a).

Cumming et al (2001) reported the results of a case series (level IV evidence) of 48 patients who were implanted unilaterally with CrystaLens™. Results for this study were presented as 20/25 visual acuity after one-month follow-up, rather than the standard 20/20 measurement, making comparison with alternative studies difficult (see Appendix). Pre-operative uncorrected distance visual acuity values were 20/40 in 10/48 (21%) patients and in 42/48 (88%) patients post-operatively. Uncorrected near visual acuity was 20/30 in 3/48 (6%) of patients pre-operatively and in 46/48 (96%) of patients post-operatively. No adverse events or complications were reported at one-month follow-up.

## **COST IMPACT**

The cost of a single CrystaLens™ in Australia is currently \$920, with reimbursement possible through several private medical insurance companies (personal communication, Concept Vision Australia). The removal of a cataractous lens *and* the insertion of an artificial lens is covered by the Medicare Benefits Schedule item number 42702, with a fee of \$748.05.

The current cost of multifocal or monofocal IOLs is approximately \$200 and \$180, respectively (personal communication, Advanced Medical Optics Australia Pty Ltd).

#### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

#### **OTHER ISSUES**

The authors of the White paper and the authors of the paper '*Clinical evaluation of the model AT-45 silicone accommodating intraocular lens: results of feasibility and the initial phase of a Food and Drug Administration clinical trial*', all have commercial interests in the CrystaLens intraocular lens.

#### **CONCLUSION:**

There is limited case series evidence currently available and reported results lack standardisation.

#### **HEALTHPACT ACTION:**

Therefore it is recommended that this technology be archived.

#### **SOURCES OF FURTHER INFORMATION:**

Breen, M. J., Cumming, J. S. & Kramsky, P. S. (2001). *The C&C vision CrystaLens (TM) model AT-45 silicone multipiece intraocular lens. (White paper)*, C & C Vision, California.

Colvard, M. (2004). *Moving forward with the CrystaLens* [Internet]. Review of Ophthalmology. Available from: [http://www.revophth.com/index.asp?page=1\\_453.htm](http://www.revophth.com/index.asp?page=1_453.htm) [Accessed 26th July 2004].

Cumming, J. S., Slade, S. G. & Chayet, A. (2001). 'Clinical evaluation of the model AT-45 silicone accommodating intraocular lens: results of feasibility and the initial phase of a Food and Drug Administration clinical trial', *Ophthalmology*, 108 (11), 2005-2009; discussion 2010.

EyeWorld, The American Society of Cataract and refractive Surgery (2002). *Accommodative IOLs coming a long way* [Internet]. Available from:

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Food and Drug Administration (2004a). *Summary of safety and effectiveness data-CrystaLens™* [Internet]. Available from: <http://www.fda.gov/cdrh/pdf3/P030002b.pdf> [Accessed 26th July 2004].

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Sydney Children's Hospital (2004). *Congenital Cataracts Fact Sheet* [Internet]. Available from: [http://www.chw.edu.au/parents/factsheets/pdf/congenital\\_cataracts.pdf](http://www.chw.edu.au/parents/factsheets/pdf/congenital_cataracts.pdf) [Accessed 26th July 2004].

Vision Australia Foundation (2004). *How common is cataract?* [Internet]. Available from: <http://www.visionaustralia.org.au/index.asp?inc=&parentnav=vision&childnav=cataract&subsection=common&topnav=cataract&float=> [Accessed 26<sup>th</sup> July 2004].

**SEARCH CRITERIA TO BE USED:**

Lasers/diagnostic use

\*Lens Implantation, Intraocular

\*Lenses, Intraocular

Presbyopia/surgery

Prosthesis Design

Pseudophakia

Phacoemulsification

\*Silicone Elastomers

Visual Acuity/physiology

**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).