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Australia and New Zealand Horizon Scanning Network

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AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summaries

AcrySof® ReSTOR® Multifocal Intraocular Lens

March 2006



ASERNIP/S

**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).

Name of Technology:

AcrySof® ReSTOR® Multifocal Intraocular Lens (IOL) (Alcon, Inc., Fort Worth, TX, USA).

Purpose and Target Group:

The ReSTOR IOL is designed to treat aphakia, or absence of the natural lens of the eye, which usually results from surgical removal of a cataractous lens. ReSTOR lenses are indicated for adults with or without long-sightedness (presbyopia) who wish to reduce their dependence on glasses (Austin Eye Clinic 2006).

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 in Australia

The AcrySof ReSTOR Multifocal IOL is registered in the Australian Register of Therapeutic Goods (ARTG number: 92318, Product ID: 162927).

International Utilisation:

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

Impact Summary:

Background

Cataracts are cloudy areas of accumulated protein that form on the lens of the eye. They cause vision impairment by limiting the amount of light which is able to reach the retina (eMedicine.com 2005). Symptoms of cataract formation typically include blurred and reduced vision, faded colour perception, glare, light sensitivity and impaired night vision(AIHW 2005).

Advancing age is the leading risk factor for the development of cataracts, although factors such as smoking, diabetic complications, prolonged sunlight exposure, eye trauma or chronic inflammation, family history and congenital factors (such as infection in pregnant women), arthritis, short-sightedness, certain blood pressure medications and prolonged steroid use are

also thought to play a causative role (Better Health Channel 2002; Viva! Communications 2005).

Medical and surgical treatments are the primary means of tackling the condition. Mild cataracts, where vision is not significantly impaired, either require no treatment or are managed conservatively by prescribing glasses (Leyland and Zinicola 2003). In severe cases, surgery to remove the cataractous lens may be required. In developed countries, an IOL is implanted at the time of cataract surgery to replace the natural lens and help regain some of the focussing ability of the eye (Better Health Channel 2002; eMedicine.com 2005).

Traditionally, IOL implants have been monofocal in design and only capable of restoring a patient's distance vision (Access Media Group 2005). As a result, recipients still required reading glasses to achieve good near vision. Multifocal IOLs were developed to overcome the restrictions of monofocal IOLs and restore near and distance vision in recipients (Access Media Group 2005).

Early generation multifocal IOLs, such as Crystalens® by Eyeonics, Inc. (Aliso Viejo, CA, USA), achieved near and distance vision by relying on the mechanical action of the ciliary muscle to adjust the lens by a process of accommodation, similar to the movement of natural lenses. This approach, however, requires a period of time for re-training and adjustment of the eye musculature and places added pressure on the ciliary muscle, which naturally deteriorates over time (The Medical Management Services Group 2005). ReSTOR lenses, on the other hand, do not rely on the ciliary muscle. Instead, they use adaption technology (a gradual layering of diffractive gradations radiating from the centre of the lens) to appropriately distribute light to the near and distant focal points of the retina without the need for any mechanical movement of the lens (The Medical Management Services Group 2005). The result is a simultaneous improvement in both near and distance vision that is not dependent on the mechanical movement of the eye musculature and a reduction in the dependence on glasses or contact lenses. Once the natural lens of the eye is removed, it cannot be replaced. However ReSTOR lenses can be removed, if need be, and replaced with monofocal, bifocal or other multifocal IOLs (Austin Eye Clinic 2006).

Clinical Need and Burden of Disease

In 2004 it was estimated that there was approximately 1.5 million Australians aged 55 or over living with untreated cataracts (AIHW 2005). Advancing age accounts for significant increases in cataract prevalence, rising from about 2.5% in middle-aged cohorts to as much as 99% prevalence in those aged 90 years and over (AIHW 2005; Better Health Channel 2002). As a result, cataract surgery is one of the most commonly performed surgical procedures (Better Health Channel 2002; Viva! Communications 2005). In 1999, as many as 120,000 cataract procedures were performed in Australia (Better Health Channel 2002).

While the majority of patients with mild cataracts are not bothered by the need to wear glasses, some patients prefer the convenience of unaided near and distance vision (Leyland and Zinicola 2003). In addition, patients suffering from more severe cataracts may benefit substantially from a multifocal IOL implant.

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

The United States Food and Drug Administration (FDA) granted approval for the commercial distribution of the AcrySof ReSTOR Multifocal IOL on March 21, 2005. In Europe the ReSTOR lens has already received the Conformité Européenne (CE) Mark and has been commercially available since April 4, 2003 (Austin Eye Clinic 2006). Although the ReSTOR lens is currently available in Australia, the extent of its use is currently not known.

Existing Comparators

- ReZoom™ (Advanced Medical Optics, Inc., Santa Ana, CA, USA)
- Crystalens® (Eyeonics, Inc., Aliso Viejo, CA, USA)

Estimated Cost Impact

The fee for the implantation of ReSTOR lenses has been reported at US\$4600 per eye (inclusive of surgeon fee, ReSTOR lens, operating room fee and IOL adjustment) (Austin Eye Clinic 2006). Implantation of ReSTOR lenses is not regarded as a medical necessity, so most insurance companies do not cover the costs. In some cases the cataract surgery may be covered, but not the insertion of the lens (Austin Eye Clinic 2006). In Australia, the cost of implanting ReSTOR lenses in June 2004 was approximately AU\$3500, inclusive of some Medicare reimbursement (The Sydney Morning Herald 2005).

The Medicare Benefits Schedule item numbers, reimbursements and number of claims between July 2004 and June 2005 for treatments associated with the extraction of the natural lens, insertion and removal of artificial lens are outlined in Table 1.

Table 1 Year 2006 Medical Benefits Schedule of Fees for cataract surgery and lens replacement

Category	Item Number	Benefit	Number of Claims July 2004 to June 2005
Lens extraction and insertion of an artificial lens	42702	\$779.05	105,320
Insertion of an artificial lens into the posterior chamber	42703	\$495.10	101
Artificial lens removal and replacement with a lens inserted into the posterior chamber	42710	\$780.95	58

Efficacy and Safety Issues

List of Studies Found

Total number of studies	3
Non-randomised comparative studies	2
Case series studies	1

The studies included in this summary are highlighted in bold in the reference list. One of the non-randomised comparative studies consisted of unpublished data submitted to the FDA in 2004 by Alcon, Inc. as part of a Premarket Approval Application. Data from the case series study by Oliveira *et al.* (2005) were derived from the English abstract since the full text was published in Portuguese.

Visual Acuity

The data presented to the FDA were obtained from clinical trials conducted in Europe and the United States. Of the 802 participants, 760 were evaluated after one year. In these 760 patients, 566 received a ReSTOR implant in one eye (monocular) and 194 patients received a monocular monofocal lens implant (control group). Of these, 549 of the 566 monocular ReSTOR recipients received an implant in the second eye, while 181 of the 194 monocular monofocal lens recipients also had an implant placed in the second eye, resulting in 730 binocular implantations.

For monocular implantation, ReSTOR recipients exhibited significantly lower (P value not stated) uncorrected and best corrected distance acuity, compared to the control group. Six months after surgery, binocular ReSTOR lens recipients achieved similar distance vision acuity to patients who had monofocal lenses implanted in both eyes. However, no 12-month data were available for patients with binocular implants.

Photopic near visual acuity (uncorrected, distance corrected and best corrected) for monocular implants at 6 and 12 months post-surgery was better in ReSTOR lens recipients, compared to the control group. This was also true for binocular implants at 6 months post-implantation.

Intermediate photopic visual acuity data at 6 months post-implantation were only available for a subset of patients receiving binocular implants (n = 34 ReSTOR group; n = 27 control group). The uncorrected and distance corrected intermediate visual acuity was measured in ReSTOR and monofocal lens recipients. Overall, the percentage of recipients who achieved 20/40 vision at 50, 60 and 70 cm was greater in the ReSTOR patient group. More specifically, uncorrected visual acuity results revealed that at a distance of 50 cm significantly more (P < 0.05) ReSTOR recipients achieved 20/40 vision (or better) than monofocal lens recipients.

Contrast Acuity

The FDA trial showed that ReSTOR recipients had contrast acuity that was clinically equivalent to the control group under various lighting conditions. The limited data available in the abstract of Oliveira *et al.* (2005) stated that patients with binocular ReSTOR implants achieved contrast sensitivity and stereopsis results congruent with those of phakic and pseudophakic patients.

Frequency of Spectacle Wear

Data regarding the effect of ReSTOR lenses on the frequency of spectacle wear in patients with binocular implants revealed that over 90% of patients no longer required spectacles for distance vision, compared to 62% of monofocal control lens recipients. The difference in spectacle requirement for near vision was even more dramatic. Over 80% of ReSTOR recipients no longer used spectacles for near vision as opposed to only 7.7% in the control group.

Visual Quality and Disturbances

Visual disturbance results from the FDA trial demonstrated that patients with monocular ReSTOR implants experienced night vision problems, including glare, flare and presence of halos, more often (P < 0.05) than patients with the monofocal control lens implant. However, the degree of visual disturbance was similar between the groups for binocular implants.

A prospective non-randomised comparative study of four different types of IOL implants (including ReSTOR) measured differences in visual quality (Rocha *et al.* 2005). The study revealed that ReSTOR lens recipients experienced significantly (P < 0.05) less spherical, mean total and mean high order aberrations than patients receiving the monofocal IOLs.

Safety Issues and Contraindications

Data from clinical trials show that insertion of ReSTOR lenses poses no safety concerns for recipients. Patients involved in clinical trials presented to the FDA reported no occurrences of any persistent adverse events associated with the implantation of ReSTOR lenses. There are no known contraindications for ReSTOR lenses.

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

Although no contraindications were identified in the literature retrieved, the manufacturer has outlined warnings and precautions for the use of the lenses in the Brief Product Statement. In addition, patient selection has been identified as a key factor influencing the degree of success, suggesting that this product may not be suitable for all patients.

Recommendation:

No published studies comparing ReSTOR lenses and other multifocal IOLs were located. The largest data set available on the ReSTOR lens comes from unpublished data submitted to the FDA. The limited evidence indicates that the ReSTOR IOL improves distance and near vision acuity and reduces dependency on spectacles for near and distance vision, compared to monofocal lens implants. Based on the information available, it is recommended the following be conducted:

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

Note: At the time of writing there are no cost-effectiveness data regarding the ReSTOR lenses. ReSTOR lenses are significantly more expensive compared to other lenses and unless the additional cost is justified it is difficult to recommend the use of this lens above other alternatives.

References:

- Access Media Group. Cataract News. Access Media Group. Last updated 2005. http://www.allaboutvision.com/conditions/cataracts_news.htm [Accessed January 2006].
- AIHW. Vision problems in older Australians. Australian Institute of Health and Welfare. Last updated July 2005. <http://www.aihw.gov.au/publications/aus/bulletin27/bulletin27.pdf>
- Austin Eye Clinic. Crystalens, ReSTOR lens & other surgical options to correct presbyopia. Austin Eye Clinic. Last updated 2006. <http://www.austin-eye.com/restor.htm> [Accessed January 2006].
- Better Health Channel. Cataracts explained. Better Health Channel. Last updated November 2002. http://www.betterhealth.vic.gov.au/bhvc2/bhcarticles.nsf/pages/Cataracts_explained [Accessed January 2006].
- eMedicine.com. Cataracts. eMedicine.com, Inc. Last updated January 2005. <http://www.emedicinehealth.com/articles/1439-1.asp> [Accessed January 2006].
- US Food and Drug Administration - P040020 AcrySoft ReSTOR apodized diffractive optic posterior chamber intraocular lenses, model MA60D3 and SA60D3. Last updated 2005. <http://www.fda.gov/crdh/pdf4/p040020b.pdf> [Accessed February 2006]**
- Leyland M and Zinicola E. Multifocal versus monofocal intraocular lenses after cataract extraction. *The Cochrane Database of Systematic Reviews* 2003;1.
- Medicare Australia. Last update 2006. <http://www9.health.gov.au/mbs/> [Accessed January 2006].
- Oliviera F, Mucciolo C, Silva LM, Soriano ES, Souza CE, Belfort R. Contrast sensitivity and stereopsis in pseudophakic patients with multifocal intraocular lens. *Arquivos Brasileiros De Oftalmologia* 2005;68(4):439-443.**
- Rocha KM, Chalita MR, Souza CEB, Soriano ES, Freital LL, Muccioli C, Belfort R. Postoperative wavefront analysis and contrast sensitivity of a multifocal apodized diffractive IOL (ReSTOR) and three monofocal IOLs. *Journal of Refractive Surgery* 2005; 21(6)**
- The Medical Management Services Group. ReSTOR, Crystalens & ReZoom lens replacement surgery. The Medical Management Services Group, L.L.C. Last updated 2005. <http://www.seewithlasik.com/docs/crystalens-restor-lens.shtml> [Accessed January 2006].
- The Sydney Morning Herald. Lens removes cataracts and glasses. Last updated December 2005. <http://www.smh.com.au> [Accessed January 2006].
- Viva! Communications. VNR Media alert: Revolutionary all-in-one lens set to restore full range of vision for people living with cataracts. Viva! Communications. Last

updated 2005. <http://www.vivacommunications.com.au/cataracts/> [Accessed January 2006].

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 January 2006.

Search terms used were:

'ReSTOR', 'intraocular lens', 'multifocal apodized diffractive IOL', 'multifocal posterior chamber intraocular lens', 'hydrophobic intraocular lens', and 'Acrysof ReSTOR.'

This Horizon Scanning Prioritising Summary was prepared by Mr. Luis Zamora 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).