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National Horizon Scanning Unit
Horizon scanning prioritising summary

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AlphaCor™, artificial cornea: Corneal replacement in patients considered at high risk for conventional keratoplasty

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AHTA

Adelaide Health Technology Assessment

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PRIORITISING SUMMARY

REGISTER ID: **0000059**

NAME OF TECHNOLOGY: **ALPHACOR™, ARTIFICIAL CORNEA**

PURPOSE AND TARGET GROUP: **CORNEAL REPLACEMENT IN PATIENTS CONSIDERED AT HIGH RISK FOR CONVENTIONAL KERATOPLASTY**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	83042
☐	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia	✓		

IMPACT SUMMARY:

Argus Biomedical Pty Ltd is an Australian based company that manufactures AlphaCor™, an artificial cornea with the aim of replacing damaged or diseased corneas in patients. The technology is currently available through private practice in either public or private hospitals.

AlphaCor™ is indicated for patients who are not suitable candidates for donor grafts. Possible reasons for excluding a donor graft option include poor ocular surface quality, degree of deep vascularisation, number of previously failed grafts, previous glaucoma and lens status. In some cases the physical fitness of the patient is an indication for excluding the donor option as they may not tolerate the ongoing immunosuppressant medication required following graft surgery. AlphaCor™ is synthetic, so patients do not require long term systemic immunosuppressants.

The surgical procedure involves removing part of the diseased cornea and inserting the AlphaCor™ lens. AlphaCor™ is a curved flexible plastic disc with a transparent central part that acts like a lens. The patients own tissues grow into the rim of the disc thereby securing it into place. The procedure is completed by the formation of a flap of tissue from the conjunctiva that is used to cover the surface of the front of the eye and allows the AlphaCor™ to heal in place. This tissue is removed approximately three months after the initial surgery. The device has been trialled in several studies by its developers since 1998.

The first phase I human clinical trial (level IV evidence) assessed preliminary safety (retention, incidence of serious complications) and performance (visual acuity, comfort, appearance) in

fourteen consecutive patients (Crawford et al 2002). The device was retained in 93% of patients, for up to 2.5 years. All but one patient maintained or improved their pre-operative level of visual acuity.

One published study (level IV evidence) describes outcomes of 38 patients who had the device implanted to November 2001, with follow up ranging from 2 weeks to 36 months (Hicks et al. 2003a). The percentage of patients who had previously received at least one donor graft prior to recruitment in this study was 85% (32) and the mean number of prior grafts was 1.6. The device had been retained in 83% (33) of patients, removed and replaced with donor tissue in 13% (5) and removed and replaced with a second AlphaCor™ in 5% (two) of cases. In this study 52% of the patients remained free of any complications requiring additional treatment. Pre-operative and best post-operative acuities (uncorrected and best-corrected) show that most patients displayed an improved visual acuity. Pre-operative visual acuity ranged from a perception of light (PL) to 6/60 (20/200) vision, whilst post-operative visual acuity ranged from PL to $6/6^{-1}$ ($20/20^{-2}$) vision.

The most common category (30%) of complication was that related to stromal melting adjacent or anterior to the device skirt and was strongly associated with a history of infection by ocular herpes simplex virus (HSV). The strong association between melt-related complications and device removals and history of ocular HSV is now considered a contraindication for AlphaCor™ surgery (Hicks et al 2003a).

The other main category of complication relates to optical surface spoilation or substance deposits within the hydrogel optic.This is attributed to patient use of topical medication and smoking, which discolours the optical surface and affects vision (Hicks et al 2003a).

The cost of corneal transplantation in Australia in 2003 for Medical Benefits Schedule item numbers 42653, 42656, 42659 was $1,112.35, $1,387.35 and $749.90. The number of major corneal, scleral and conjunctival procedures undertaken in public hospitals was 2,896 in 2001-02 (AIHW, 2004).

A total of 119 AlphaCor™ devices have been implanted to the end of January 2004. This total comprises 48 implanted in American patients and 71 in either Europe, Australia and Singapore. The USA total does not include implants used in clinical trials, whereas the latter includes devices used in trials in Australia. The cost of the device is currently $A11,922.73, excluding GST (AlphaCor™ 2004). Additional costs would include surgeon and anaesthetist fees. An AlphaCor™ marketing spokesperson indicated that several private health insurance companies in Australia cover the cost of this device (personal communication, Marketing Division AlphaCor™).

The AlphaCor™ device may serve a small proportion of the population who have no other alternative treatment. These patients are generally not suitable candidates for corneal transplants or may have religious beliefs that oppose donor transplants.

CONCLUSION:

This technology has minimal low evidence available sourced from one group which suggests it may be effective; it is likely to be used by only a small group of potential patients, who have no existing treatment alternatives; and at considerable cost.

HEALTHPACT ACTION:

It is therefore recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

Hicks, C. R. & Crawford, G. J. (2003). 'Melting after keratoprosthesis implantation: the effects of medroxyprogesterone', *Cornea,* 22 (6), 497-500.

Hicks, C. R., Crawford, G. J. et al (2003a). 'Corneal replacement using a synthetic hydrogel cornea, AlphaCor: device, preliminary outcomes and complications', *Eye,* 17 (3), 385-392.

Hicks, C. R., Crawford, G. J. et al (2003b). 'AlphaCor cases: comparative outcomes', *Cornea,* 22 (7), 583-590.

Hicks, C. R., Crawford, G. J. et al (2002). 'Outcomes of implantation of an artificial cornea, AlphaCor: effects of prior ocular herpes simplex infection', *Cornea,* 21 (7), 685-690.

Laibson, P. R. (2002). 'Current concepts and techniques in corneal transplantation', *Curr Opin Ophthalmol,* 13 (4), 220-223.

SEARCH CRITERIA TO BE USED:

Artificial Organs/adverse effects/contraindications
Cornea/surgery
Prostheses and Implants/adverse effects
Prosthesis Implantation
Hydrogel
Cornea
Corneal Diseases/physiopathology/surgery
Corneal Transplantation
Keratitis, Herpetic/physiopathology/surgery
Cataract Extraction/adverse effects