AlphaCor™: an introduction

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‘Chirila Keratoprosthesis’

The ideal characteristics of PHEMA led to the development of the prototype Chirila Keratoprosthesis.

Core - transparent homogenous PHEMA

Skirt - porous, opaque, PHEMA
- allows biointegration

Fusion by a sequential interpenetrating polymer network (IPN)
AlphaCor Design and Dimensions

Diameter: 7.0mm, Thickness: 0.6mm

• Standard and aphakic powers

• Allows implantation within the corneal plane

• Iridectomy, vitrectomy, lensectomy and muscle detachment not required
Patient Selection

• Appropriate selection of patients is crucial for success

• Indications for AlphaCor differ from those for traditional keratoprostheses

• AlphaCor exists between traditional keratoprostheses and human donor penetrating keratoplasty
Inclusion criteria

• Bilateral OR unilateral blindness, PL-20/200
• Graft or repeat graft too high risk to attempt
• Most recent graft > 12 months ago
• Evidence of functioning retina
• Normal IOP or glaucoma controlled on AlphaCor ‘safe’ topical medications
• Ocular surface optimised – lid position, blepharitis controlled, tear film optimised and reasonable
• No history ocular HSV
• No chronic/recurrent inflammation or progressive conjunctival scarring
Contraindications to AlphaCor

- History of HSV due to risk of reactivation/inflammation/stromal melting
- Dry eye or ongoing inflammation
- Stevens-Johnson Syndrome
- Pemphigoid
- Uncontrolled IOP
- Smoker unwilling to stop
- AlphaCor is NOT recommended for use in children; it has not been evaluated for safety or efficacy
AlphaCor surgery has 2 stages

Stage I

- Intralamellar pocket insertion
- Posterior lamella opening
- Optional conjunctival flap

Stage II

- Opening of tissue anterior to optic
Small or Large Incision

- **Standard large incision technique:** involves large incision and flap/pocket for access of skin-punch trephine

- **Small incision technique:** made possible with use of low-profile trephine and special scissors

- A Gunderson flap is recommended where the ocular surface is at risk. In other cases with a healthy limbus and good ocular surface, a bandage lens may be helpful.
Off-Label use

• Specific medications have never been specifically approved for marketing as an adjunct to any keratoprosthesis or synthetic cornea, including AlphaCor

• Specific contact lenses have not been specifically approved for marketing as an adjunct to any keratoprosthesis or synthetic cornea, including AlphaCor
Standard medications: post stage I

- Acetazolamide – 1-2 doses if required
- Systemic tetracyclines, starting pre-op
- Topical prednisolone 1% qid, reducing over ~ 1 month
- Topical guttae antibiotic eg Tobrex for 2 weeks
- Medroxyprogesterone (MPG) 1% qid – for long term
- Any previous anti-glaucoma therapy or consider adding a suitable topical drug in cases at increased risk of glaucoma
- Consider bandage lens
Standard medications: post stage II

- *Short* course of topical prednisolone
- Topical antibiotic FOR EVER eg Tobrex
- Continue MPG 1% qid FOR EVER (MPG 1% halted during trial by FDA)
  Continue systemic tetracyclines if tolerated
- Adequate lubrication – hydrogel contact lens safe
- Consider bandage contact lens
- Increased risk of optic staining/deposition after stage II – don’t co-administer topical steroids with beta-blockers
Post-op evaluation IOP

Digital assessment

Schiotz (over sclera)

Proview™ (Bausch & Lomb) (through-the-lid, phosphene endpoint)

TDG-01c (Envision) (through-the-lid, digital display)

Field test and disc exam possible after stage II
Contact lens use

- RGP
- Silicone-hydrogel, Permalens, Kontur or other bandage lens

• The higher the oxygen permeability, the better
• Disposable, monthly or less
• Rigid GP lenses may give better VA but may carry greater risk
• Spectacles may provide additional protection/cosmetic disguise
Principles of AlphaCor data collection and analysis

• Ensure data collected for every case, pre-operatively and prospectively
• Evaluate pre-op profiles for comparative purposes
• Plot survival curves
• Trend complication and survival rates
• Regression analysis for risk and protective factors
• Compare with alternative strategies for high risk cases e.g. re-grafts
• Ensure all surgeons have access to own data
• Facilitate peer-review
Outcomes classification

- Complications
- Device-related
  - Anatomical
    - Optic deposition
- Non device-related
- Visual acuity
- Device retention
- Quality of Life
Outcome data

- Returned through web-based system
- Data sets ‘frozen’ at each month’s end, stored and analysed
- Data for every patient
- This presentation will be based upon the latest complete data set available
Publications: Clinical Investigation Outcomes


Practicalities

- AlphaCor has been cleared for marketing in Australia (TGA), USA (FDA), and Europe (CE-Mark)
- Reimbursement available in some countries
- Accreditation is required prior to undertaking surgery
- Further product information: www.coopervisionsurgical.com

Clinical queries welcomed by Scientific Advisory Board: contact crhicks@cyllene.uwa.edu.au