

# Insertion of hydrogel keratoprosthesis

## 1 Guidance

- 1.1 Current evidence on the safety and efficacy of insertion of hydrogel keratoprosthesis does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake insertion of hydrogel keratoprosthesis should take the following actions.
  - Inform the clinical governance leads in their Trusts.
  - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
  - Audit and review clinical outcomes of all patients having insertion of hydrogel keratoprosthesis.
- 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty.
- 1.4 The manufacturer of the synthetic hydrogel cornea implant used in this procedure maintains a registry ([www.argusbiomedical.com.au](http://www.argusbiomedical.com.au)). The Institute may review the procedure upon publication of further evidence.

## 2 The procedure

### 2.1 Indications

- 2.1.1 The cornea is the transparent part of the coating of the eyeball, that covers the iris and pupil and admits light to the interior

of the eye. Injury or disease of the cornea can make it opaque, hindering the passage of light and resulting in loss of vision. Diseases that can cause the cornea to deteriorate include keratoconus, bullous keratopathy and herpetic eye disease.

- 2.1.2 A corneal transplant is the standard treatment when the cornea becomes damaged by injury or disease. This procedure involves the removal of a disc comprising the majority of the cornea using a trephine, and replacing it with a corresponding disc from the cornea of a donor eye. In penetrating keratoplasty, a disc the entire thickness of the cornea is removed and replaced with a disc of equivalent thickness. Some patients cannot undergo the standard procedure using donor tissue for several reasons, such as disease severity, severe involvement of the conjunctiva, objection to the use of donor tissue, failed past donor tissue transplants, or when measures required to prevent graft rejection are medically contraindicated. For these patients, penetrating keratoplasty using an artificial cornea or keratoprosthesis is an option.

### 2.2 Outline of the procedure

- 2.2.1 The implantation of a synthetic hydrogel cornea is a two-stage surgical procedure. The first stage involves making a partial thickness incision at the junction of the cornea and sclera, to allow an intralamellar pocket to be created within the cornea. The superficial flap is then reflected to allow a portion of the central part of the posterior lamella to be removed using a trephine, and the synthetic hydrogel cornea to be inserted into the intralamellar pocket. The superficial flap is repositioned and the incision closed. In most cases, the operation is completed by forming

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This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

a flap of tissue from the conjunctiva, which is used to cover the surface of the front of the eye. This may cause changes in the cosmetic appearance of the eye.

- 2.2.2 The second stage of the procedure is performed 12 weeks later, and involves removing the conjunctival cover and the superficial flap of the cornea, exposing the synthetic hydrogel cornea to light. The eye may still not appear completely 'normal' after this stage of the operation.

## 2.3 Efficacy

- 2.3.1 Evidence on the efficacy of this procedure was based on small, uncontrolled studies with short-term follow-up. Initial results indicated that visual acuity improved (although it was still poor) or remained the same in most patients. In a report of 41 patients with a mean preoperative visual acuity of hand movements, mean best corrected visual acuity for 21 patients at 12 months follow-up was 20/300. An improvement of this degree is likely to be valuable to patients. The authors of this report also stated that among the 41 patients undergoing implant of a synthetic cornea, 26 implants remained in situ (63%) at a mean follow-up of 16 months. However, patient selection criteria have changed since the first trial of this procedure, and it is unclear what impact this will have on efficacy outcomes. For more details, refer to the Sources of evidence (see right).

- 2.3.2 The Specialist Advisors considered that this procedure should be restricted to those individuals who cannot be treated with established procedures and who have no useful vision in the other eye.

## 2.4 Safety

- 2.4.1 Stromal melting is a frequent complication for all keratoprotheses and is common following this procedure. In a review of 41 non-herpetic patients, 42% (17 patients) developed a stromal melt. In this particular review, the number of patients requiring device removal as a result of this

complication was unclear; however, in another series, the same authors reported that 13% (5/40) implants were removed because of melting. Other complications included cellular depositions on the device itself (22%), development of retroprosthetic membranes (7%), and retinal detachment (5%). The literature seemed to suggest that certain patients were at increased risk of complications, namely patients with herpetic eye disease and smokers. For more details, refer to the Sources of evidence (see below).

- 2.4.2 The Specialist Advisors considered that the long-term complication rate of this procedure is still unknown. Although endophthalmitis is thought to be the most significant potential complication of any artificial cornea, the Advisors noted that this had not yet been reported following this procedure.

## 2.5 Other comments

- 2.5.1 Data were based on small numbers of patients.

Andrew Dillon  
Chief Executive  
June 2004

## Information for the Public

The Institute has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from [www.nice.org.uk/IPG069publicinfo](http://www.nice.org.uk/IPG069publicinfo)

## Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

*Interventional procedure overview of insertion of hydrogel keratoprosthesis*, October 2003

Available from: [www.nice.org.uk/ip225overview](http://www.nice.org.uk/ip225overview)

### Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0606. *Information for the Public* can be obtained by quoting reference number N0607 for the English version and N0608 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL [www.nice.org.uk/IPG069distributionlist](http://www.nice.org.uk/IPG069distributionlist)

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