NICE guidance

Insertion of hydrogel keratoprosthesis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg69

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 [link broken, Feb2012]. 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 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 section.

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 keratoprostheses 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 section.

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

3 Further information

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.

Information for the public

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

The guidance was considered for reassessment in June 2007 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please contact us.

27 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Your responsibility

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

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.