

Insertion of hydrogel keratoprosthesis

**Understanding NICE guidance –
information for people considering the
procedure, and for the public**

June 2004



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197

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Contents

About this information	4
About insertion of hydrogel keratoprosthesis	5
What has NICE decided?	8
What the decision means for you	9
Further information	10

About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called insertion of hydrogel keratoprosthesis. It is not a complete description of what is involved in the procedure – the patient’s healthcare team should describe it in detail.

NICE has looked at whether insertion of hydrogel keratoprosthesis is safe enough and works well enough for it to be used routinely for the treatment of injury to the cornea.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of insertion of hydrogel keratoprosthesis and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE’s work on ‘interventional procedures’ (see ‘Further information’ on page 10).

About insertion of hydrogel keratoprosthesis

A hydrogel keratoprosthesis is a type of artificial cornea (from here on, we'll call it the hydrogel cornea). The cornea is the transparent covering of the iris and pupil in the eye. If the cornea gets damaged because of injury or disease, it can get cloudy. This stops light getting into the eye, which affects the person's sight.

Normally, when this happens, the person has a corneal transplant. A donated cornea is used to replace the damaged one. But some people can't have a transplant because the operation isn't suitable for them for medical reasons, or they don't want to have a donated cornea, or because corneal transplants haven't worked for them in the past. An artificial cornea may be an option for these people.

The operation to have a hydrogel cornea has two stages. First, the hydrogel cornea is put into place in a pocket made in the front part of the eye. It is covered using a flap of the person's own cornea. Usually, a second flap, this time made out of the covering of the white of the eye, is used to cover the front of the eye to keep everything in place. The aim of this stage is to get the cornea into position so it attaches in the right place.

About 12 weeks later, the two flaps are removed so that light can reach the hydrogel cornea and it can start to work.

How well it works

What the studies said

There was not much information on how well the hydrogel cornea worked. In most patients, eyesight seemed to improve slightly or stay the same after the operation.

In one study, after around 16 months, the hydrogel corneas were still in place in 26 of the 41 patients who had the operation.

Since these studies were done, the types of patients who are thought to be suitable for the operation have changed – this may have an effect on the results of future studies.

What the experts said

The experts thought that this operation should only be used for people who couldn't have the usual transplant operation and who couldn't see out of their other eye.

Risks and possible problems

What the studies said

Having an artificial cornea put in can often cause something called a stromal melt, where the cells die in the deeper layer of the cornea. Sometimes, the new cornea has to be removed as a result. From the studies, stromal melt seemed to be common after the hydrogel cornea was put in – in one study, 17 patients out of 41 had a stromal melt. It wasn't clear how often this meant that the hydrogel cornea had to be removed, though 5 out of 40 implants had to be removed because of a stromal melt in another study.

Other problems were:

- cells from the eye collecting on the hydrogel cornea (affecting nearly a quarter of patients)
- structures growing in the wrong place, behind the cornea (this happened in 3 eyes in 41 patients)
- the retina (the inside back surface of the eyeball) coming away from its normal position (this happened in 2 eyes in 41 patients).

The studies seemed to show that people who smoked or who had eye problems due to herpes infection were more likely to have problems following the operation.

What the experts said

The experts said that the possible long-term problems with the hydrogel cornea weren't known about yet. One possibly serious problem that is found with artificial corneas is where the inside of the eye becomes infected, usually with bacteria. This is known as endophthalmitis. The experts said that this hadn't been reported for a person who'd had a hydrogel cornea.

What has NICE decided?

NICE has decided that, if a doctor wants to carry out an insertion of a hydrogel keratoprosthesis, he or she should make sure that the patient understands what is involved and that there are still uncertainties over the safety of the procedure and how well it works. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

NICE has also highlighted to doctors that the company that makes the hydrogel cornea is monitoring what happens in patients who have the operation. NICE may look at the operation again if new information becomes available.

Other comments from NICE

NICE has pointed out that the studies it looked at involved only a small number of patients, so they weren't very informative.

What the decision means for you

Your doctor may have offered you a hydrogel cornea. NICE has considered this operation because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of having a hydrogel keratoprosthesis inserted which you need to understand before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these benefits and risks may be described above.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on insertion of hydrogel keratoprosthesis is on the NICE website (www.nice.org.uk/IPG069guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0606. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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