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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating keratoconus with corneal implants

NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how corneal implants can be used to treat people with keratoconus in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe keratoconus or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 6.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

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What has NICE said?

This procedure can be offered routinely as a treatment option for people with keratoconus, provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

This procedure may not be the only possible treatment for keratoconus. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Corneal implants for keratoconus

The procedure is not described in detail here – please talk to your specialist for a full description.

Keratoconus is a progressive disease of the cornea (the clear covering of the eye) which affects its shape and causes blurred and distorted vision.

Usually, spectacles or contact lenses may help people with less severe keratoconus. Sometimes, special eye drops or surgery may be required. Eventually, some patients may need a corneal transplant.

This procedure is carried out under a local or general anaesthetic. Channels are made in the cornea with probes or a laser. Small plastic rings are then threaded into these channels to change the shape of the cornea, alter its focus on the retina and improve vision. If necessary, the implants can be surgically removed at a later date.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks corneal implants are a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to the procedure.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at eight studies on this procedure.

How well does the procedure work?

Most studies that NICE looked at followed patients' progress for up to 12 months after the procedure.

One study of 34 eyes showed that after the procedure, vision improved in 62% of eyes, remained unchanged in 32% of eyes and deteriorated in 6% of eyes. A second study of 74 eyes showed that vision improved in 45%, and a third study of 31 eyes showed that vision improved in 87% of eyes. A fourth study of 51 eyes also showed that the procedure worked.

A study of 13 eyes showed that the shape of the cornea improved for up to 6 months after the procedure, but this improvement was not sustained when patients were reviewed 3 years after the procedure. However, a different study of 100 eyes showed that the improvement in corneal shape was sustained when patients were reviewed 2 years after the procedure.

The study of 13 eyes showed that all patients who had been unable to wear contact lenses before the procedure were able to wear them afterwards.

The expert advisers said that the procedure is designed to improve vision and delay the need for corneal transplant for patients with keratoconus. However, they said that the effect of the procedure varies from patient to patient, and in some cases where there is advanced disease the benefits may be limited.

Risks and possible problems

A study of 57 eyes reported that there were no major problems during or immediately after the procedure. There was a feeling of discomfort in 2% of eyes treated, and in another study of 74 eyes, there were reports of feeling as though there was a foreign body in the eye in 4% of eyes, which led to the implants being removed. The most common visual problems after the procedure were seeing a halo around objects or difficulty in seeing in bright light (glare): these problems were reported in between 3 and 5% of eyes after the procedure.

The study of 74 eyes reported that there was a problem fitting the implant in 1 eye, but it was finally successfully fitted.

In four studies, part of the implant became displaced in between 0% and 20% of eyes. In the four studies, a bacterial infection occurred after the procedure in between 0% and 3% of eyes.

The expert advisers said that other potential problems could include damage to the eye during the procedure and that the effects of the procedure may not be long term.

More information about keratoconus

Your local Patient Advice and Liaison Service (PALS) may be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG227

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1299).

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