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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating short-sightedness 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 short-sightedness 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 vision problems 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.

What has NICE said?

There are uncertainties about how well this procedure works for treating short-sightedness. The safety of the procedure is also a concern for people whose vision could be treated by other means, such as spectacles, contact lenses or laser surgery. NICE has said that this procedure should only be used to treat vision problems due to a disease of the cornea (the clear covering of the eye) called keratoconus. NICE's guidance on corneal implants for keratoconus is available from www.nice.org.uk/IPG227

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

Corneal implants for short-sightedness

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

Short-sightedness is a common vision problem in which near objects are seen clearly but distant objects appear blurred. It usually happens because the eye is too long and images are focused in front of the retina, rather than on it. It can also happen because of a progressive condition called keratoconus, which affects the shape of the cornea, and causes blurred and distorted vision. Short-sightedness is usually corrected by spectacles, contact lenses or laser surgery.

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 should not be used to treat short-sightedness where spectacles, contact lenses or laser surgery could be used instead. It should only be used for visual problems that result from keratoconus. If your doctor thinks this procedure is 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 it.

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?

In one study, eyesight improved in 58 out of 77 eyes 3 months after the procedure. After 1 year, eyesight improved in 74% of eyes in a second study of 452 patients, and in 35 out of 79 eyes in a third study. In the third study, a greater fraction of people had improved vision 5 years after the procedure.

Two further studies of 42 and 16 eyes showed that the procedure was successful in 68 to 100% of cases.

A study of 159 eyes showed that vision was clearer between 1 and 3 months after the procedure, but the effect was slightly reduced when patients were reviewed 6 months to 1 year after the procedure.

Another study of 104 patients who were surveyed 1 year after the procedure showed that 47% of patients rated the result as ‘excellent’, 9% said it was ‘fair’ and 2% said it was ‘poor’.

One study, which looked at 76 eyes treated with implants and 126 eyes treated with laser surgery, appeared to show that the effects of the implant procedure reduced over time. When reviewed 3 months after the procedure, vision had worsened in 9% of eyes treated with implants, compared with only 1% of eyes treated with laser surgery. Another study of 138 eyes showed that vision worsened in 2 to 4% of eyes when patients were reviewed after 12 months.

One expert adviser said that the procedure has not been widely used because of the development of laser eye surgery. Another adviser commented that a potential problem may be that the positive effects of the procedure may not continue in the long term.

Risks and possible problems

Three studies reported a very small rate of the procedure damaging the cornea. This happened in between 0 and 2% of cases. There was also a case of an infection in 1 out of 452 patients treated.

The most common visual problems reported in the 452 patients were poor night vision in 5%, seeing a halo around objects in 1%, experiencing difficulty in seeing in bright light (glare) in 1%, and sensitivity to light in less than 1%. Another study of 104 patients reported similar results: two reported seeing halos, two reported glare and one reported sensitivity to light.

In one study, part of the implant became slightly displaced in one eye. The implant was removed.

The expert advisers said that other potential problems include a feeling that there is a foreign body in the eye or infection or damage to the eye during the procedure.

More information about visual problems

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also 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/IPG225

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1295).

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