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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Partial-thickness transplantation of the cornea (endothelial transplantation)

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how partial-thickness transplantation of the cornea (endothelial transplantation) can be used in the NHS. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. 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.

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 partial-thickness transplantation of the cornea (endothelial transplantation) in detail – a member of your healthcare team should also give you full information and advice about this. 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 the page 7.

What has NICE said?

This procedure can be offered routinely as a treatment option 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.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a central store of information at NHS Blood and Transplant (www.nhsbt.nhs.uk) so that the safety of the procedure and/or how well it works can be checked over time. NICE has encouraged more research (looking at long-term results) on this procedure. Partial-thickness transplantation of the cornea (endothelial transplantation) should only be done by surgeons with specific training in this procedure.

Other comments from NICE

There are several different techniques for this procedure, some of which are still developing. NICE also noted that procedures in the cornea are classified as having a medium risk of Creutzfeldt-Jakob disease (CJD).

Current information shows that graft survival is better after full-thickness corneal transplantation than this procedure. However, the difference in graft survival is narrowing with increased experience in the use of this procedure. In addition, this procedure can be repeated, whereas revision of a full-thickness corneal transplant is difficult. For this reason, NICE has said that that there is enough evidence for this procedure to be used in the NHS, provided that information about the procedure continues to be collected.

Partial-thickness transplantation of the cornea (endothelial transplantation)

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

The medical name for this procedure is ‘corneal endothelial transplantation’ or ‘endothelial keratoplasty’ (sometimes shortened to EK). The procedure is not described in detail here – please talk to your surgeon for a full description.

Some diseases can cause the clear section at the front of the eye (the cornea) to become cloudy, leading to blurred vision. Common causes are Fuchs’ dystrophy (a genetic disorder) and bullous keratopathy (a haziness of the cornea caused by ageing). Corneal endothelial transplantation (EK) is done with the patient under a local or general anaesthetic. The innermost layer of the cornea (the endothelium) is removed and replaced with a healthy section from a donor eye, leaving the rest of the cornea in place. Unlike the standard procedure (called ‘penetrating keratoplasty’ or PK), in which the full thickness of the cornea is replaced, EK does not usually require stitches (sutures) and is less invasive. Eye medication, which may include steroids, is often required after surgery.

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 it 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?

Summary of possible benefits and risks

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

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 a study of 28 eyes, the ability to see clearly and in detail (visual acuity) 6 months after the procedure was significantly improved in 13 eyes treated with EK but not in 15 eyes treated with PK.

In a study of 177 eyes, visual acuity 15 months after the procedure was significantly improved in 129 eyes treated with EK and 48 eyes treated with PK. This study also showed that astigmatism (irregular curvature of the cornea) was significantly lower after EK than it was after PK.

One study reported that in patients with Fuchs' dystrophy, the transplant was healthy 1 year after the procedure in 77% who had EK and 98% who had PK. In patients who developed bullous keratopathy following insertion of an artificial lens (pseudophakic bullous keratopathy) the transplant was still healthy in 79% who had EK and 88% who had PK.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the success of the procedure can be measured using visual acuity scores, quality of life scores, and by how fast visual clarity is regained.

Risks and possible problems

Three studies involving a total of 231 eyes reported that conversion from EK to PK was required in 16 eyes and in 13 eyes a second corneal endothelial transplantation procedure was needed.

In another study, rejection of the transplant within 2 years was less common in eyes treated with EK (15 out of 199 eyes) than in eyes treated with PK (92 out of 708 eyes).

In a study of 34 eyes treated with EK, the transplanted layer had thinned by 41% within 2 years.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that, in addition to the risk of transplant rejection, failure or dislocation, there is a risk of clouding where the transplant sits against the rest of the cornea. All of these problems can result in a worsening of vision.

More information about corneal transplantation

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information 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. This guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. 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 is about 'corneal endothelial transplantation'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG195

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1888 for the standard print version and N1893 for the large print version). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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