

Implantation of a corneal graft– keratoprosthesis for severe corneal opacity in wet blinking eyes

Information for the public
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What has NICE said?

Although there is evidence that implantation of a corneal graft–keratoprosthesis works well, a high number of serious complications were reported. NICE has decided that the procedure can be offered on the NHS to people with severe corneal opacity in wet blinking eyes because there are few options for people with this condition if a standard corneal transplant has failed or isn't appropriate.

What does this mean for me?

Your health professional should fully explain what is involved in having this procedure, and discuss the possible benefits and risks with you. There are risks of serious complications and your sight may get worse. You will also need to have regular checks in the long term, and some people find this to be a problem. You should be

provided with information in an appropriate format, and told how to find more information about the procedure. All of this should happen before you decide whether you want to have this procedure or not.

Other comments from NICE

NICE said that the procedure should only be done in people who have inadequate sight in both eyes. It also said that the procedure is usually only offered after a standard corneal transplant has failed.

NICE noted that there have been a lot of complications reported with the procedure, including loss of remaining sight. But, NICE felt that there are few alternatives for people with this condition, and the possible benefits may outweigh the risks.

Your healthcare team

A healthcare team experienced in managing blindness caused by corneal damage should decide who should be offered this procedure, and should follow them up in the long-term. The procedure should only be done in a specialist centre by a surgeon with special expertise in implantation of corneal graft–keratoprotheses.

The condition

The cornea is the clear outer layer at the front of the eyeball that acts as a window to the eye. Injury, surgery or

disease can make the cornea cloudy (corneal opacity), affecting vision. The standard treatment for significant corneal opacity is a corneal transplant, which is an operation to remove all or part of a damaged cornea and replace it with healthy donor tissue. Some people can't have a standard corneal transplant, for example, because of disease severity or a failed previous corneal transplant, or when medicines needed to prevent rejection of a donor cornea aren't suitable.

NICE has looked at implantation of a corneal graft–keratoprosthesis in people with reasonably intact blink and tear mechanisms (wet blinking eyes) as another treatment option.

NHS Choices (www.nhs.uk) may be a good place to find out more.

The procedure

A corneal graft–keratoprosthesis (type I) is an artificial cornea surrounded by a corneal graft from a human donor. It is inserted using a local or general anaesthetic. The centre of the person's opaque cornea and the natural lens, if in place, are removed. The corneal graft–keratoprosthesis, which is made to match the person's eye, is then inserted and secured with stitches. Finally, a

special soft contact lens is used to protect the eye while it heals.

After the operation, for the rest of their lives, people who have had the procedure have to wear a soft contact lens, use antibiotic drops and possibly topical steroid drops or ointment, and be monitored and followed up frequently.

Benefits and risks

When NICE looked at the evidence, it decided that it showed that implantation of a corneal graft–keratoprosthesis is safe enough and works well enough for use in the NHS. The 15 studies that NICE looked at involved a total of 1095 patients.

Generally, they showed the following benefits:

- improved sight in the affected eye – 70% of people were able to at least read the bottom line on an eye test chart at 6 months, compared with only 9% before surgery
- 84% of people still had the device in 2 years after surgery, and 67% still had it in at 7 years
- improved sight-related quality of life at an average of 16 months after the procedure.

The studies showed that significant complications are common with corneal graft–keratoprosthesis. Problems included infection, inflammation, ulceration, increased

pressure and bleeding in the eye, as well as loss of sight and the need to remove the eyeball. Around a third of corneal graft-keratoprotheses had been removed 7 years after the procedure because of complications such as leaks or the device moving out of position. Your doctor should make sure you clearly understand the balance of risks and benefits, including the possibility that your sight may not improve and may get worse.

If you want to know more about the studies, see the [guidance](#). Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- 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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

About this information

NICE interventional procedures guidance advises the NHS on the safety of a procedure and how well it works.

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