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**Understanding NICE guidance**

**Information for people who use NHS services**

National Institute for Health and Clinical Excellence

# Correcting refractive errors by inserting an artificial lens near to the natural lens

*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 inserting an artificial lens can be used in the NHS to correct refractive errors. 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.

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 refractive errors 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 7.

## What has NICE said?

NICE has said that there is a lot of good evidence on how safe this procedure is and how well it works in the short term. This procedure can be offered routinely as an option for correcting refractive errors 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.

If a doctor wants to use this procedure, they should make sure that extra steps are taken to ensure that patients understand the risks of having an artificial lens implanted instead of using glasses or contact lenses. They should explain that cataract, damage to the cornea (the clear covering over the front of the eye) or detachment of the retina (the inner part of the eye sensitive to light) may occur, and that there isn't much evidence about what happens in the long term. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. NICE has encouraged doctors and manufacturers to collect long-term data on people who have these artificial lenses fitted, and to publish their findings. NICE may review the procedure if more evidence becomes available.

## Correcting refractive errors by inserting an artificial lens near to the natural lens

*This procedure may not be the only possible treatment for refractive errors. 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 'intraocular lens insertion for correction of refractive error, with preservation of the natural lens'. It is not described in detail here – please talk to your specialist for a full description. The procedure is used to treat the type of eyesight problems that usually mean a person has to wear glasses or contact lenses. Other treatments include surgery, including laser surgery. The procedure may be offered to people with very bad short sight or those who find it difficult to wear spectacles, for example because of a disability or because of the needs of their job.

The procedure is usually carried out with the patient under local anaesthesia. The patient is given eye drops to widen the pupil and the artificial lens is inserted into the eye through a small cut made in the cornea; it can be placed in front of or behind the iris (the coloured part of the eye) depending on the design of the lens. Sometimes a small stitch is used to close the hole.

### Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE looked at 12 studies on this procedure.

## 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 implanting an artificial lens 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.

Your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

## 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?

## How well does the procedure work?

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

In a study of 50 eyes measuring clarity of vision, there was no difference between eyes that had been treated with the artificial lens and those that had laser treatment. In a larger study of 9239 eyes using the same test, it was unclear whether there was any difference in eyesight between the two different treatments. In another study, good correction of vision was more successful in eyes treated with the artificial lens (127 out of 184 eyes) than in those treated with laser (57 out of 100 eyes), 1 year after surgery. Sixty-two out of 231 eyes had 20/20 vision or better without contact lenses or glasses, 3 years after the procedure. No eyes (0 out of 622) had 20/20 vision before the procedure.

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 main success factors are improved vision with or without glasses or contact lenses, freedom from the need to wear glasses or contact lenses, and continuing good-quality vision.

## Risks and possible problems

The large study reported that several patients developed a detached retina after having surgery. Twelve out of 294 eyes that had the new artificial lens and 11 out of 3009 eyes that were treated with laser surgery had a detached retina after an average of about 2 years. Nine out of 5936 eyes treated with another type of laser had a detached retina after an average of about 4.5 years. Several patients developed cataract. This occurred in 258 out of 6338 eyes within a year of the new lens being inserted. In another study 1 patient out of 43 developed cataract within 2 years of surgery. In one study the new lens had to be removed from 3 out of 399 eyes because it had damaged the corneal endothelium (the layer of cells on the inner surface of the cornea). The

same study reported that the endothelium showed signs of damage 4 years after insertion of the new lens. Other symptoms included having problems with glare and seeing halos of light around things at night in 157 out of 263 treated eyes 1 year after surgery.

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 problems include glaucoma, poorer vision when using contact lenses or glasses, reduced ability to distinguish between light and dark, poor night vision and the need for more surgery.

## More information about visual problems

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 'intraocular lens insertion for correction of refractive error, with preservation of the natural lens'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG183*

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1801 for the standard print version and N1808 for the large print version). The NICE website has a facility called Browsealoud which gives you the option to access our guidance via a screen reader service. The software allows your computer to read aloud our website content. Click on the Browsealoud logo on the NICE website to access it.*

*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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