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Information for the public

Treating presbyopia by inserting an artificial lens in the cornea

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

This document is about when and how inserting an artificial lens in the cornea of an eye can be used in the NHS to treat people with age-related long-sightedness (presbyopia). It explains guidance (advice) from NICE (the National Institute for Health and Care 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 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 document 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 presbyopia or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document 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 8.

What has NICE said?

There is not much good evidence about how well or for how long this procedure works, or how safe it is. If a doctor wants to insert an artificial lens in the cornea to treat presbyopia, they should make sure that patients understand that this is mainly a cosmetic procedure that may reduce the need to wear glasses or contact lenses. Patients should be made aware of other management options and extra steps should be taken to explain the uncertainty about how well it works, and the potentially common risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this document and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure. NICE has encouraged further research into inserting an artificial lens in the cornea to treat presbyopia. This should include collecting details about complications with the procedure and how well people do in the long term. NICE may review the procedure if more evidence becomes available.

Other comments from NICE

NICE commented that presbyopia is a condition that tends to worsen over time and it is therefore important to have long-term evidence on how well it works and how safe it is.

NICE noted that there are a number of different types of artificial lenses available for this procedure and they may differ in how well they work and how safe they are.

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

Inserting an artificial lens into the cornea

The medical name for this procedure is 'corneal inlay implantation for correction of presbyopia'.

The cornea is the clear outer layer of the eye.

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

Presbyopia is the medical name for long-sightedness that develops because of age, usually in people over 40. Long-sightedness is when a person can see distant objects clearly but near objects are out of focus.

The lens in the eye can stiffen with age and this can make it difficult to focus on near objects. Presbyopia is usually corrected with glasses or contact lenses. In some patients laser surgery (LASIK) or surgery to replace a lens is considered.

Inserting an artificial lens in the cornea aims to improve near vision by changing the way in which light passes through the eye. The procedure is normally performed under local anaesthesia on the non-dominant (weaker) eye. A small flap or pocket is made in the centre of the cornea, using a laser or a surgical instrument called a microkeratome, and an artificial lens is placed inside with the help of a special tool. The flap or pocket seals itself and holds the artificial lens in place (stitches are not needed). Corticosteroids and antibiotic eye drops are normally prescribed immediately after the procedure for a short time. Artificial tears should be used for as long as needed. The artificial lens can be removed or replaced if necessary.

People who find it difficult to use glasses or contact lenses, such as those with limited dexterity, may especially benefit from this procedure.

What does this mean for me?

If your doctor has offered to insert an artificial lens in the cornea of your eye to treat presbyopia, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that 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 document, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

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 procedure?
- What happens if something goes wrong?

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 5 studies on this procedure.

How well does the procedure work?

Two studies (involving 32 and 39 patients) measured changes in vision after the procedure. Measurements were taken for up to 3 or 4 years after patients had the procedure. Overall, there was an improvement in near and intermediate vision, and a slight decrease in distance vision.

In the study of 32 patients, there was a decrease (improvement) in average reading distance from 48.1 cm to 38.9 cm. The 32 patients were also assessed on their reading speed. This improved from 142 to 149 words per minute, 2 years after the procedure.

Two of the studies (involving 32 and 24 patients) found patients were less reliant on using reading glasses after having the procedure. In the study of 32 patients, the percentage of patients using reading glasses all or most of the time decreased from 88% to 6%, 3 years after having the procedure. The study of 24 patients found they were moderately satisfied with the procedure 2 years after treatment, and with the extent to which their need to use reading glasses had reduced in bright light. Patients were less satisfied with how much this had reduced in dim light. Of these, 18 said they would have the procedure again, 5 were undecided and 1 would not have the procedure again.

As well as looking at these studies, NICE also asked expert advisers for their views. They said the main success factors were improved near or reading vision (without glasses or contact lenses) with no change in distance vision.

Risks and possible problems

In a study of 39 patients, the artificial lens had to be removed in 4 patients because of problems with the flap in which the artificial lens was placed, vision disturbances and halos of light and glare. Patients' vision returned to the way it was before the procedure after the lens was removed. In this study 5 patients developed cataracts in their treated eye needing surgical treatment.

The artificial lens moved out of the centre of the pocket and had to be put back in place in 2 out of 32 patients in 1 study. Both patients' vision improved afterwards. In the same study, a patient developed wrinkling of the surface of their cornea which needed treatment including stitching after 2 months.

Of the 32 patients, 14 lost some distance vision, 4 became more long-sighted and 4 became more near-sighted 3 years after the procedure.

Halos were also experienced in 20 patients in the study of 32 patients – most were moderate or mild, but in 1 patient these were severe. Three patients had experienced mild or moderate halos before the procedure. In the same study, 5 patients reported severe problems with night vision.

There was a decrease in contrast sensitivity (patients' ability to distinguish between light and dark) in well-lit conditions and at low light 1 year after treatment in a study of 508 patients.

In a study of 8 patients, very mild haze around the edge of the cornea was reported 2 years after the procedure in all patients.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that in theory, other problems could include infection, scarring, thinning, 'melting' (severe ulceration) and cloudiness of the cornea, difficulty measuring pressure in the eyeball, difficulties

adjusting to one eye being dominant for near vision, poorer long-distance vision, and seeing objects less clearly and in less detail than was achieved by wearing glasses before the procedure.

More information about presbyopia

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

For details of all NICE guidance on presbyopia, visit our website at www.nice.org.uk

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. HealthTech 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 document is about ‘Corneal inlay implantation for correction of presbyopia’. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG311

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on Accessibility at the bottom of the NICE homepage to use this service.

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

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