NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Treating advanced age-related macular degeneration using an artificial lens system

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

This leaflet is about when and how an artificial lens system can be used in the NHS to treat people with advanced age-related macular degeneration. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures 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 age-related macular degeneration 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 the back page.

Information about NICE interventional procedure guidance 272
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What has NICE said?

Evidence shows that this procedure can improve vision and quality of life in the short term. However, there is not much good long-term evidence about how well it works or how safe it is. If a doctor wants to use this procedure, they should make sure that extra steps are taken to explain how the patient will need to adapt to having an artificial lens system in their eye (for example, because of the different image size in each eye) and the risk of early complications. They should also explain the uncertainties about how well the procedure works and how safe it is 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 information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

This procedure should only be done on carefully selected patients.

Further information on the safety of artificial lenses and how well they work would be helpful, especially in gathering evidence about long-term results. NICE may look at this procedure again if more information becomes available.

Other comments from NICE

There are several different artificial lens systems available for this procedure, and the technique is developing.

Artificial lens systems for advanced age-related macular degeneration

The medical name for this procedure is 'implantation of miniature lens systems for advanced age-related macular degeneration'.

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

Age-related macular degeneration affects the central part of the retina, which is responsible for detailed distance and reading vision. Both eyes are usually affected, but not necessarily to the same extent. Age-related macular degeneration is the most common form of macular degeneration and occurs later in life.

The procedure is usually carried out under local anaesthesia, but general anaesthesia can be used where appropriate. The surgery is similar to a normal cataract and lens implant operation, but with a different lens device. The surgeon makes a small cut in the front area of the eye where the cornea (the clear film at the front of the eye) meets the sclera (the thick white coating of the eye). A small piece of the iris is also removed to prevent the normal flow of fluid through the eye becoming blocked. The surgeon then removes the eye's natural lens and replaces it with an artificial lens. Because the central vision is magnified, patients require a period of visual rehabilitation to benefit fully from this operation.

What does this mean for me?

If your doctor has offered you an artificial lens system for advanced age-related macular degeneration, he or she should tell you that NICE has decided that the benefits and risks are uncertain, especially in the long term. 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 information, including this leaflet, 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 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 five studies on this procedure.

How well does the procedure work?

In a study of 217 people, 128 said their distance vision had improved and 130 said their near (or reading) vision had improved in the eye that had the new lens, at 1-year follow-up.

Distance vision was worse in 2% (or 2 in 100) of eyes with the implant and in 9% of eyes without the implant, at 1-year follow-up. In another study, distance vision improved in all 35 patients after an average of 20 months.

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. They said that success of the procedure can be assessed by looking at near and distance vision, reading speed and the patient's ability to navigate unfamiliar surroundings.

Risks and possible problems

Two out of 217 patients developed severe corneal problems, which needed the artificial lens to be removed together with a corneal transplant more than a year after the initial surgery. A total of 23 patients (14 of 206 and 9 of 36) had problems with increased fluid in the cornea resulting in impaired vision; 57 out of 206 patients needed treatment because of a build up of pressure in the eye. Eleven procedures could not be completed because of problems such as bleeding during surgery. Three out of 253 patients had to have the implant removed because they were dissatisfied with it, four because of condensation in the artificial lens and one because of double vision.

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. They said that there is a risk of damaging the cells lining the cornea, and that patients could have other problems with the cornea, such as a build up of fluid. One adviser said that the procedure has more risks than standard cataract surgery.

More information about age-related macular degeneration

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. Interventional procedures 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 'implantation of miniature lens systems for advanced age-related macular degeneration'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IPG272

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1655 for the standard print version and N1679 for the large print version).

NICE has also produced an audio version of this leaflet. This is available at www.nice.org.uk/IPG272

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

National Institute for Health and Clinical Excellence
MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

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