

Treating wet age-related macular degeneration by repositioning part of the macula with a stitch

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 surgery to reposition part of the macula can be used in the NHS to treat people with wet age-related macular degeneration (AMD). 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 wet AMD 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?

Evidence shows that this procedure does not work in all patients, and that there is potential for serious problems as a result of the operation. If a doctor wants to use this procedure, they should make sure that extra steps are taken to explain the uncertainties about how well the procedure works and how safe it is. They should also explain the alternative treatments available to the patient. 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.

Other comments from NICE

Before surgery is offered, most patients with wet AMD are treated with drugs called antivascular endothelial growth factor agents, which block the growth of blood vessels in the eye. Evidence suggests if a patient does not respond to drug treatment, it is likely that this procedure will not improve their eyesight either.

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The medical name for this procedure is 'limited macular translocation for wet age-related macular degeneration'.

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

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

In the eye, the retina covers the back wall of the eyeball and is the layer of cells responsible for creating vision. Macular degeneration affects the area of the retina responsible for detailed vision (the macula). Because degeneration usually occurs in older people it is also known as 'age-related macular degeneration'. There are two types – 'dry' and 'wet'. The wet form is caused by bleeding at the back of the eye from new blood vessel growth, and the loss of vision can be quicker than the dry form.

The aim of this procedure is to improve vision by repositioning the macula so that it lies over a healthier part of the eyeball that has not been affected by new blood vessel growth. One way is to make a small cut in the retina and inject fluid under it so it becomes detached from the layer of tissue underneath. The surgeon then puts a 'tuck' into the outer layers of the eye and secures the tuck with a stitch. The result is that the affected part of the macula ends up lying over healthier tissue in the eye.

What does this mean for me?

If your doctor has offered you this procedure, he or she should tell you that NICE has decided that not all patients benefit from the procedure, and that serious complications can develop as a result of having the procedure. 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.

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?

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?

In 1 study, results after 1 year were available in 86 of 151 patients. In 69 of these patients, eyesight had improved. In a study of 65 patients, eyesight improved more in the patients who had the procedure, compared with patients who had a type of laser treatment called photodynamic therapy (PDT).

In the study of 101 patients, the procedure was successful, in terms of moving the macula as far as planned, in 52 of 86 eyes examined 12 months after the operation. In another study, the macula was moved as far as planned in 17 out of 25 patients.

In the study of 65 patients, regrowth of abnormal blood vessels in the area the macula was moved to was seen in 13 eyes when the patients' progress was checked at an average 4.8 months after 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 success factors are improved eyesight, reading speed, quality of life and whether there is further damage to the macula from recurrent disease.

Risks and possible problems

In the study of 65 patients, postoperative complications were reported in 36 patients, including deteriorating eyesight. Detachment of the retina was reported in 5 eyes among the 36 patients, and a second operation was needed to reattach the retina.

In the study of 151 patients, detachment of the retina became less common as surgical experience grew over time. Detachment of the

retina was reported in 25 of 153 eyes at a follow-up of 1 to 13 weeks (21 needed a second operation). A 'break' in the retina was reported in 13 eyes, but no further information was given.

In 1 study, double vision was reported in 14 of 250 patients treated by this procedure. In a smaller study, 1 of 2 patients experienced double vision, which resolved without further surgery when their progress was checked after 5 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. The advisers said that other possible problems include cataracts and a retinal fold in the macular area that persists over time. There may be a risk of infection of the inner layers of the eye (called endophthalmitis).

More information about age-related macular degeneration

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. For details of all NICE guidance on AMD, including the procedure in which the affected part of the retina is removed, completely rotated and then reattached, 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. 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 'limited macular translocation for wet age-related macular degeneration'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG215

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2148 for the standard print version and N2149 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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