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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Using keyhole surgery to repair damaged knee cartilage with a biodegradable implant

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

This document is about when and how a biodegradable implant can be used in the NHS to treat people with damaged knee cartilage. 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 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 damaged knee cartilage or the procedure in detail – a member of your healthcare team should also 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?

Although there are no major concerns about the safety of this procedure, there is not much evidence that it is better than standard surgery to relieve short-term symptoms or that it reduces further operations in the long term. If a doctor wants to use keyhole surgery to repair damaged knee cartilage using a biodegradable implant, they should make sure that extra steps are taken to explain the uncertainty about how well it works as well as the potential risks of the procedure and the time it takes to recover. 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.

The procedure should only be done by surgeons who are very experienced in knee cartilage surgery.

NICE has encouraged further research into keyhole surgery to repair damaged knee cartilage with a biodegradable implant. Further research should describe how patients are selected for the procedure and any additional treatments used. It should also assess symptom relief and how well the knee works in the short term, and the need for further treatment in the long term.

Other comments from NICE

NICE noted that it is not clear which patients should be offered this procedure. They also said that the needs of young active patients and older patients with worn knee cartilage and the results of the procedure in these patients may be different.

Using keyhole surgery to repair damaged knee cartilage with a biodegradable implant

This procedure may not be the only possible treatment for damaged knee cartilage. 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 'Partial replacement of the meniscus of the knee using a biodegradable scaffold'.

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

Inside the knee on both sides is a crescent-shaped piece of cartilage called the meniscus. The cartilage acts as a shock absorber between the long bones of the leg and can be damaged by injury or overuse, causing pain, swelling and locking of the knee. This damage may increase the risk of arthritis of the knee in the long term. Rest and physiotherapy is often successful in treating minor damage to the cartilage, but for some people an operation to remove or repair the damaged meniscus may be advised.

This procedure uses a biodegradable implant, which acts as a scaffold to allow the meniscus to regrow into it, helping to reduce pain and restore knee function. It is hoped that the procedure may reduce the risk of arthritis and the need for further operations.

The procedure is done with the patient under a local or general anaesthetic. Using keyhole surgery and a small camera called an arthroscope, the damaged part of the meniscus is removed and the implant stitched in its place. Sometimes extra incisions in the knee may be needed to carry out the procedure.

Rehabilitation after the procedure can be lengthy and it may take up to 6 months to return to unrestricted activity, including sport. For several weeks afterwards the patient may have to wear a leg brace to limit knee movement, and may be asked not to support their weight on the affected leg.

The types of implant available for this procedure include ones made of a synthetic plastic scaffold and implants made of collagen from animal sources. Your doctor may be able to offer you a synthetic alternative if you do not want to use an animal product.

What does this mean for me?

If your doctor has offered you keyhole surgery to repair damaged knee cartilage using a biodegradable implant, he or she should tell you that NICE has decided that although the procedure is safe there are uncertainties about how well it works. 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 how long it takes to recover, 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?
- 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 8 studies on this procedure.

How well does the procedure work?

Three studies (involving 311, 60 and 33 patients) asked patients about their knee pain, knee function and quality of life using a questionnaire, to determine how well the procedure worked. A study of 311 patients compared knee pain before and at an average of 59 months after surgery. The study was split into two groups depending on whether or not patients had surgery on their knee before. Patients in each of these groups then had either the procedure using a biodegradable implant, or a different type of surgery to remove part of the knee cartilage, but without using an implant. For patients who had not had any surgery before, 75 patients had slightly less pain in their knee after the procedure (average pain score was 16 out of 100, a lower score means less pain) compared with 82 patients who had the other type of surgery (average pain score was 21 out of 100). For the patients who had surgery on their knee before, there was no difference in knee pain regardless of which type of surgery they had (pain scores were the same for the 82 patients who had the implant fitted and the 69 patients who had the other type of surgery). For all patients in the study, 1 in 10 patients who had the implant and around 1 in 4 patients who had the other type of surgery needed more surgery within 5 years because of pain, swelling or instability in the knee.

The second study of 60 patients found that functional score (which measures for example, ability to bend the knee, ability to walk) improved (from 65 to 94 out of 100) in 23 out of 30 patients who had the implant together with a procedure to realign the knee joint, 8 to 18 months after the procedure.

The third study, which included 33 patients, scored quality of life. At an average of 11 years after surgery, 17 patients who had the procedure had better physical and mental health scores (54 and 55 out of 100) than 16 patients who had the other type of surgery (44 out of 100 for both scores).

A study of 52 patients reported that the procedure did not work in 9 patients. One patient had infection unrelated to the polyurethane implant and 8 patients needed further surgery between 1 week and 24 months after the procedure. Of the patients needing further surgery, in 3 patients this was not related to the implant. However in 3 patients the further surgery was needed because of the implant, in 1 patient it was possibly related to the implant and in a further patient the cause was unknown.

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 reduced pain, functional improvement (for example, ability to walk), reduced risk of further damage to the knee cartilage, and avoiding early failure of the implant (for example, recurring symptoms or need for more surgery).

Risks and possible problems

The study of 60 patients reported that in 1 patient who had the implant and a procedure to realign the knee, the implant moved out of position after surgery and was removed. The timing of this was not reported.

In another study, after 10 to 13 years the collagen implant no longer worked in 2 out of 25 patients because of mechanical failure or infection of the implant. An infection also developed within a week of the procedure in 1 patient in another study of 52 patients who had the procedure using a polyurethane implant. Although the implant did not cause the infection it was removed.

In the study of 311 patients, 4 patients who had the procedure and 1 patient who had partial removal of the knee cartilage but no implant, developed swelling, fluid retention and redness around the treated knee. In another study, swelling of the knee was reported in 7 out of 22 patients in a study of 25 patients who had the procedure. No further details were given in either study.

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 possible problems other than the usual risks of operations on the knee could include allergic reaction to the implant, infection or the cartilage not healing and then tearing or moving out of position.

More information about damaged knee cartilage

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 damaged knee cartilage, 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. 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 document is about 'Partial replacement of the meniscus of the knee using a biodegradable scaffold'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG430

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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