NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Focal resurfacing implants to treat articular cartilage damage in the knee

Articular cartilage protects the ends of the bones in the knee joint from friction during movement. Damage from injury or disease to a small (focal) area of the articular cartilage can cause pain, stiffness in the knee and reduced mobility. In this procedure, performed under general or regional anaesthesia, a surgeon makes a cut to access the knee joint. The damaged area of the cartilage and bone is removed and replaced with a small artificial implant that restores the smooth surface (resurfacing). The aim is to reduce symptoms, allow immediate weight bearing and preserve joint function. It also may reduce or delay the need for a later knee replacement.

NICE is looking at focal resurfacing implants to treat articular cartilage damage in the knee.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 14 April 2022

Target date for publication of guidance: August 2022

1 Draft recommendations

1.1 Evidence on the efficacy of focal resurfacing implants to treat articular cartilage damage in the knee is limited in quality and quantity. Short-term evidence on safety shows no major safety concerns, but long-term evidence is limited in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wanting to use focal resurfacing implants to treat articular cartilage damage in the knee should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes, including those in the long term, of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Enter details about everyone having focal resurfacing implants to treat articular cartilage damage in the knee into a suitable registry and review local clinical outcomes.
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Further research should report patient selection, including the site and size of the cartilage damage, and long-term outcomes, including the incidence of revision procedures and joint replacements.

1.5 Patient selection should be done by a multidisciplinary team experienced in managing the condition.

1.6 The procedure should only be done by surgeons experienced in focal articular cartilage resurfacing.

1.7 Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

2 The condition, current treatments and procedure

The condition

2.1 Cartilage covers the end of the bones comprising the knee joint. There are 2 types of cartilage in the knee – articular (or chondral) and meniscal. Damage because of injury or disease to a focal area of articular cartilage, particularly in the main weightbearing areas, can cause pain, stiffness, and reduced mobility. Cartilage tissue has very limited self-healing potential and, if left untreated, cartilage damage can progress to osteoarthritis.

Current treatments

2.2 Treatment for people with focal articular cartilage damage typically involves arthroplasty or biological treatment. Arthroplasties include total, bicompartmental, unicompartmental, and patellofemoral knee arthroplasties. Biological treatments include microfracture, osteochondral autograft transfer system, and autologous chondrocyte implantation.

The procedure

2.3 Focal articular resurfacing is aimed at people for whom biological treatments and arthroplasty may not be suitable due to age or other factors.

2.4 Before surgery, the articular cartilage damage is assessed using a pre-planned MRI, an arthroscopy, or both. Then, either the implant is custom-adapted to fit the damaged area, or an implant is selected from a catalogue to closely match the damaged area. Various implant brands, designs, and materials are used for the procedure. The procedure is done under regional (spinal) or general anaesthesia. An incision is made to access the damage site. The damaged area is prepared by removing the damaged bone and cartilage, and drilling a hole for the stem of the implant. The implant is then press-fitted into the damaged area with or without the use of bone cement. The surface of the implant is slightly recessed below the surrounding articular cartilage.

2.5 Rehabilitation after surgery depends on the person and implant. It typically includes either an immediate (as tolerated) or gradual return to full weight bearing and range of motion.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 2 registry analyses (1 of which was not published in a peer-reviewed journal), 1 cohort study, 3 before-and-after studies, and 1 case series. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in pain, improvement in quality of life, and reduced need for future joint surgery.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, infection, need for revision, and effect on future joint replacement.

3.4 A total of 7 commentaries from people who have had this procedure were discussed by the committee.

Committee comments

3.5 The technology used for this procedure is evolving.

3.6 The committee was informed that there is more than 1 device available to use for this procedure and some of these devices may be adapted to individual people based on 3D imaging.

3.7 This procedure is for treating focal articular cartilage damage and not for generalised osteoarthritis.

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Chair, interventional procedures advisory committee

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