



Focal resurfacing implants to treat articular cartilage damage in the knee

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 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 shows no major safety concerns, but long-term evidence on safety 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 <u>shared decision making</u>, including <u>NICE's information for</u> 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.
- 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 <u>Medicines and</u> 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 focal articular cartilage damage typically involves arthroplasty or biological treatment. Types of arthroplasty include total, bicompartmental, unicompartmental and patellofemoral. Types of biological treatment 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 because of age or other factors.
- 2.4 Before surgery, the articular cartilage damage is assessed using a preplanned MRI, an arthroscopy or both. Then, either the implant is customised 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 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.
- 2.6 The aim of this procedure is to alleviate pain, allow immediate weight bearing, preserve physiological joint function, slow progression to osteoarthritis, and reduce or delay the need for arthroplasty.

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 9 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, 4 before-and-after studies, and 1 case series. It is presented in the summary of key evidence section in the appendix of the 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.
- 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.
- The committee was informed that there is more than 1 device available to use for this procedure, and that some of these devices may be customised 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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

