NICE guidance

Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg727

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

1.1 For people with advanced disease for whom arthrodesis is indicated, evidence on the safety of synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus) shows no major safety concerns in the short term. But evidence on efficacy is limited in quantity and quality. Therefore, for these people, 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 For all other people with hallux rigidus, evidence on the safety of synthetic cartilage implant insertion for hallux rigidus shows no major safety concerns in the short term. But evidence on efficacy is inadequate in quantity and quality. Therefore, for these people, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.3 Clinicians wanting to do synthetic cartilage implant insertion for hallux rigidus for people with advanced disease for whom arthrodesis is otherwise indicated 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.

- Make sure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Enter details about all people having synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus) onto the British Orthopaedic Foot & Ankle Society (BOFAS) Registry and review local clinical outcomes.
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.4 Healthcare organisations should:

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

1.5 Further research should include suitably powered randomised controlled trials. These should report details of patient selection, including stage of osteoarthritis, and patient-reported outcomes such as pain, mobility and quality of life, and long-term outcomes related to the implant.

2 The condition, current treatments and procedure

The condition

2.1 Osteoarthritis is a common condition in which the surface of the joint becomes worn, and the adjacent bone thickens and forms osteophytes. It can affect the first metatarsophalangeal joint at the base of the big toe, which may become painful and stiff (hallux rigidus).

Current treatments

2.2 Conservative treatments include exercise, physiotherapy, orthotics,

analgesics, non-steroidal anti-inflammatory tablets and cream, and corticosteroid injections into the joint. Surgery may be needed if severe osteoarthritis of the first metatarsophalangeal joint does not respond to conservative treatments. If an osteophyte on the surface of the joint is the only problem, it can be trimmed (cheilectomy). The main surgical options for treating the whole joint are fusion (arthrodesis), osteotomy or joint replacement. Rarely, excision arthroplasty is offered.

The procedure

2.3 Synthetic cartilage implant insertion for hallux rigidus is usually done under general or regional anaesthesia. A moulded cylindrical implant made of polyvinyl alcohol (a soft plastic-like substance) and saline is used with specifically designed single-use instruments. A small incision is made over the top of the big toe joint and a drill is used to remove enough bone to make an appropriately sized hole for the implant. The implant is placed into the hole in the bone and left slightly raised, providing a smooth and slippery surface in the area of the cartilage defect. Once the implant is in place, the incision is closed with sutures. Weight bearing can typically resume immediately after the procedure. The aim is to reduce pain and improve the toe's 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 15 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (described in 2 papers), 4 non-randomised comparative studies, 7 case series, 1 case report and a review of adverse events from the US Food and Drug Administration Manufacturer and User Facility Device Experience database. It is presented in the summary of key evidence section in the interventional procedures overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: pain, mobility, quality of life and range of movement.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, infection and need for device removal.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee was informed that the procedure should not be used in people with inflammatory arthritis or diabetic peripheral neuropathy.

3.6 There was little evidence about the people for whom the procedure is most appropriate, particularly the stage of osteoarthritis at which it should be used.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation