NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Osteoarthritis in the big toe joint (the first metatarsophalangeal joint) can cause a condition called hallux rigidus. Cartilage in the joint wears away, causing pain and stiffness. In this procedure, which is done under general or regional anaesthesia, damaged cartilage is replaced with an artificial (synthetic) implant. A small cut is made over the top of the big toe joint, a hole is drilled into the bone and the implant is pressed into the hole. The aim is to reduce pain and improve mobility.

NICE is looking at synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus).

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.

Issue date: December 2021

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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 13 January 2022

Target date for publication of guidance: May 2022

1 Draft 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 people without advanced disease and for whom arthrodesis is not indicated, 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.

- Audit and review clinical outcomes of all people 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 all people having synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus) onto the 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 steroid injections into the joint. Severe first metatarsophalangeal joint osteoarthritis that does not respond to conservative measures may need surgery. 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.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
January 2021

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