NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

High tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis

In medial knee osteoarthritis the cartilage in the inner part of the knee joint wears away. The knee tilts and the lower leg bows, causing pain and reduced movement. In this procedure, a cut (osteotomy) is made at the top of 1 of the bones in the lower leg (tibia). An adjustable magnetic nail is inserted into the bone and screwed in place. After the operation the nail can be lengthened or shortened using an external controller, which adjusts the shape of the leg over time. When the bone is fully healed the nail is removed. The aim is to straighten the leg to relieve pain and maintain movement.

NICE is looking at high tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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

Issue date: July 2020

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 31 July 2020

Target date for publication of guidance: January 2021

1 Draft recommendations

1.1 Evidence on the safety and efficacy of high tibial osteotomy with adjustable magnetic nail insertion for symptomatic medial knee osteoarthritis is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.

1.2 Further research should preferably be in the form of randomised controlled trials and report details of patient selection, long-term outcomes, subsequent nail removal, adverse events and effect on further surgery.

2 The condition, current treatments and procedure

The condition

2.1 Medial knee osteoarthritis is the result of progressive deterioration of the articular cartilage and menisci of the joint. This can cause exposure of the bone surface with chronic and excessive joint loading during movement. Symptoms include joint pain, stiffness, local inflammation, limited movement and loss of knee function.

Medial knee osteoarthritis can lead to knee deformity and malalignment, including bowing.

Current treatments

2.2 Treatment for knee osteoarthritis depends on the severity of the condition. Current management includes lifestyle changes (such as losing weight and regular exercise), medicines (such as analgesics and corticosteroid injections), physiotherapy and prescribed exercise. When these options do not work or symptoms are severe, surgery may be indicated. Options include high tibial osteotomy, microfracture surgery, and unicompartmental or total knee replacement.

The procedure

2.3 The procedure is done using spinal or general anaesthesia. Following a high tibial osteotomy, a magnetic nail is inserted into the medullary canal of the tibia using image intensification and positioned below the tibial plateau. The nail is secured proximally and distally using multiple locking screws. After wound closure the position of the magnet inside the nail is identified and this is marked on the skin. The procedure takes about 2 hours.

2.4 During the post-operative phase, the magnetic nail can be gradually lengthened or shortened by placing the external remote controller over the marked skin to control the exact amount of the opening of the osteotomy. New bone forms in the wedge defect that is generated. The nail is removed when the desired alignment has been achieved and bony consolidation is complete, assessed radiologically. The aim is to correct the malalignment of the knee to reduce symptoms.

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 1 source, which was discussed by the committee. The evidence included 1 non-randomised comparative study. It is presented in table 2 of 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 symptoms including pain relief measured on a validated scale, quality of life and time to reintervention.

3.3 The professional experts and the committee considered the key safety outcomes to be: fracture, infection, delayed union and device failure.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that there is a UK knee osteotomy registry for this procedure.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
March 2020

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