NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Joint distraction for knee osteoarthritis without alignment correction

Osteoarthritis of the knee is caused by deterioration of the cartilage and underlying bone in the knee joint, resulting in stiffness, swelling, pain and difficulty in walking. In joint distraction for knee osteoarthritis without alignment correction, an operation is done to separate the bones on either side of the knee joint and an external frame is fixed to these bones to hold them apart and allow the damaged cartilage to heal.

The National Institute for Health and Care Excellence (NICE) is examining joint distraction for knee osteoarthritis without alignment correction and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about joint distraction for knee osteoarthritis without alignment correction.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.

- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 21 April 2015

Target date for publication of guidance: July 2015

1 Provisional recommendations

1.1 Current evidence on the safety and efficacy of joint distraction for knee osteoarthritis without alignment correction is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research into joint distraction for knee osteoarthritis without alignment correction should include comparative studies against existing forms of management. Studies should record patient selection, joint space measurements in the medium to long term,

functional outcomes, quality of life and complications. They should also report the nature and timing of any further surgery on the knee. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Osteoarthritis of the knee is the result of progressive deterioration of the articular cartilage and menisci of the joint. Articular cartilage deteriorates because of injury, or wear and tear. This leads to exposure of the bone surface. Symptoms include pain, stiffness, swelling and difficulty walking.

2.2 Treatment for knee osteoarthritis depends on the severity of the disease. Conservative treatments include analgesics and corticosteroid injections to relieve pain and inflammation, and physiotherapy and prescribed exercise to improve function and mobility. When symptoms are severe, surgery may be indicated. Options include upper tibial osteotomy, microfracture surgery, and unicompartmental or total knee replacement.

3 The procedure

3.1 Joint distraction for knee osteoarthritis without alignment correction aims to offload and modify the mechanical environment in osteoarthritic joints to allow cartilage regrowth. Intra-articular surgery (such as debridement) may be done before distraction to stimulate cartilage healing.

3.2 With the patient under spinal block or general anaesthesia, pins are drilled through the tibia and femur. A distraction frame is then fitted external to the leg, unloading the knee by gradually increasing the

distance between the cartilaginous surfaces of the knee (usually up to 5 mm) over a few days or weeks. The distraction is normally maintained for about 2–3 months before the frame is removed. During this time, the patient is able to walk. The continuous flow of synovial fluid through the joint (enhanced by the distraction) is claimed to support chondrocyte nutrition and regeneration of cartilage. However, the exact mechanisms that may lead to cartilage regeneration during distraction are not known.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 A case series of 20 patients with end-stage knee osteoarthritis treated by joint distraction reported significant improvements in Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores (range from 0 to 96, with lower scores indicating better outcomes) of 70% at 1-year follow-up and of 74% at 2-year follow-up ($p<0.001$ for both improvements from baseline). The individual components of the WOMAC score (pain, stiffness and function) all improved significantly compared against baseline ($p<0.005$ for all 3 subscales at each time point: 3, 6, 12, 18 and 24 months). A case series of 6 patients with knee osteoarthritis treated by joint distraction reported a significant increase in the mean Japan orthopaedic association score (range from 0 to 100, with higher scores indicating better function) from 56 (range 55–60) before the procedure to 81 (range 70–85) at the latest follow-up (mean 3-year follow-up, $p<0.001$).

4.2 A non-randomised comparative study of 61 patients treated by joint distraction and debridement (n=19) or debridement alone (n=42) reported a significant improvement in pain (measured on a 4-point Likert scale, with a higher score indicating more severe pain) within the joint distraction group, with none of the patients having no pain before the procedure and 58% (11/19) of patients having no pain 3–5 years after the procedure ($p<0.004$). In the debridement-only group, none of the patients had no pain before the procedure and 50% (21/42) of patients had no pain 3–5 years after the procedure ($p=0.163$). The case series of 20 patients reported a significant decrease in pain scores (measured on a 10-point visual analogue scale, with a higher score indicating more severe pain) of –58% at 1-year follow-up and of –61% at 2–year follow-up (both improvements from baseline were significant, $p<0.001$).

4.3 The non-randomised comparative study of 61 patients treated by joint distraction and debridement or debridement alone reported a significant increase in walking capacity in the joint distraction group from 10–35 minutes before the procedure to 32–51 minutes 3–5 years after the procedure ($p<0.001$). In the debridement-only group, the walking capacity range was 12–23 minutes before the procedure and 20–31 minutes 3–5 years after the procedure ($p=0.142$). The non-randomised comparative study of 61 patients treated by joint distraction and debridement or debridement alone also reported a significant improvement in stair climbing in both groups. In the joint distraction group, none of the patients (0/19) had no difficulty in ascending or descending stairs before the procedure and 74% (14/19) of patients had no difficulty in stair climbing 3–5 years after the procedure ($p<0.002$). In the debridement-only group, 33% (13/42) of patients had no difficulty in

stair climbing before the procedure and 67% (28/42) of patients had no difficulty in stair climbing 3–5 years after the procedure ($p<0.001$).

4.4 The case series of 20 patients reported a significant difference in mean cartilage thickness for the total subchondral bone area of the most affected compartment from baseline of 0.6 mm (95% confidence interval [CI] 0.24 mm to 1.22 mm) at 1-year follow-up ($p=0.002$) and of 0.4 mm (95% CI 0.06 mm to 0.83 mm) at 2-year follow-up ($p=0.03$) (no further details reported).

4.5 The non-randomised comparative study of 61 patients treated by joint distraction and debridement or debridement alone reported mean joint spaces on X-ray in the joint distraction group of 2.5 mm before the procedure and of 4.3 mm 3–5 years after the procedure ($p<0.001$); in the debridement-only group, mean joint spaces were 2.7 mm before the procedure and 2.4 mm 3–5 years after the procedure ($p=0.135$). The case series of 20 patients reported a significant difference in the minimum joint space width in the most affected compartment from baseline of 59% (0.57 mm, 95% CI 0.09 mm to 1.06 mm; $p=0.03$) after 2 years. The difference in mean joint space width in the most affected compartment from baseline was 21% (0.36 mm, 95% CI 0.13 mm to 0.85 mm; $p=0.11$) after 2 years.

4.6 The specialist advisers listed key efficacy outcomes as improvement in pain symptoms, improved function, increase in joint space and a delay in the need for joint replacement.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Deep vein thrombosis was reported in 11% (2/19) of patients treated by joint distraction in a non-randomised comparative study of 61 patients treated by joint distraction and debridement (n=19) or debridement alone (n=42); in 1 patient the thrombosis resolved after heparinisation and 1 patient developed a non-fatal pulmonary embolism (no further details provided). Pulmonary embolism was reported in 10% (2/20) of patients in a case series of 20 patients with end-stage knee osteoarthritis; both patients were treated by oral anticoagulants for 6 months (no further details provided).

5.2 Pin track infections were reported in 18% of patients (absolute number not given) treated by knee joint distraction in the non-randomised comparative study of 61 patients treated by joint distraction and debridement (n=19) or debridement alone (n=42); all patients responded completely to local cleaning and systemic antibiotics (no further details provided). Pin track infections were reported in 85% (17/20) of patients treated by knee joint distraction in the case series of 20 patients; all the infections were treated by oral antibiotics (flucloxacillin, no further details provided). Superficial skin infections around the insertion of the pin were reported in 33% (2/6) of patients treated by knee joint distraction in a case series of 6 patients with knee osteoarthritis (no further details provided).

5.3 Limited flexion immediately after treatment was reported in all patients (20/20) in the case series of 20 patients (mean –31.6º of flexion, 95% confidence interval [CI] –43.9º to –19.2º). Flexion improved at 6 months (mean –7.2º of flexion, 95% CI –15.2º to 1.1º) and flexion range fully normalised within 1 year (mean +2.9º of flexion, 95% CI –3.3º to 9.1º).

5.4 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not list any anecdotal adverse events. They considered that the following were theoretical adverse events: stress fracture at pin site, creation of deformity, pain, risk of worsening symptoms and failure to give benefit.

6 Further information

6.1 For related NICE guidance, see the NICE website.

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