NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Joint distraction for ankle osteoarthritis

Osteoarthritis of the ankle is caused by deterioration of the cartilage and underlying bone in the ankle joint, resulting in stiffness, swelling, pain and difficulty in walking. In joint distraction for ankle osteoarthritis, an operation is done to separate the bones on either side of the ankle 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 ankle osteoarthritis 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 ankle osteoarthritis.

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- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 27 July 2015

Target date for publication of guidance: November 2015

1 Provisional recommendations

1.1 Current evidence on the safety and efficacy of joint distraction for ankle osteoarthritis 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 ankle osteoarthritis should include comparative studies against the natural history of the disease and against other forms of management. Studies should record patient selection, pain relief, functional outcomes, complications, and quality of life in the long term. They should also report the nature and timing of any further surgery on the ankle. Minimising loss to follow-up is of particular importance. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Osteoarthritis of the ankle is the result of progressive deterioration of the articular cartilage 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 ankle 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 arthroscopic surgery (to remove loose bodies and bone spurs and to smooth the cartilage surfaces of the ankle joint), fusion surgery or total ankle replacement.

3 The procedure

3.1 Joint distraction for ankle osteoarthritis 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 with the aim of stimulating cartilage healing.

3.2 With the patient under spinal block or general anaesthesia, an external frame is fitted to the ankle. The frame is secured to the tibia and the foot with pins and wires. The ankle is distracted over several days, gradually increasing the distance between the cartilaginous surfaces of the joint (usually up to about 5 mm). Distraction is usually maintained for about 2–3 months before the frame is removed. During this time, the patient is able to walk. The distraction is thought to enhance continuous flow of synovial fluid through the joint and this 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 In a randomised controlled trial (RCT) of 36 patients treated by fixed distraction (n=18) or distraction with motion (n=18), the mean combined ankle osteoarthritis scale (AOS) scores (higher score indicates more pain and disability) were 62.8 in the fixed group and 63.1 in the motion group before the procedure (no difference between groups, p=0.93). At 52 weeks after fixator removal, the mean AOS scores were 54.5 in the fixed group and 33.1 in the motion group; at 104 weeks the mean AOS scores were 48.4 and 27.4 respectively (significant differences between groups, p<0.01 at 52 and 104 weeks). A case series of 22 patients treated by ankle joint distraction reported mean (± standard error) percentages of the maximum total AOS score before distraction of 69% (±4%) and 29% (±6%) at a minimum follow-up of 7 years after distraction (p<0.001). A case series of 25 patients treated by joint distraction reported mean American Orthopaedic Foot and Ankle Society (AOFAS) scores (0 to 100 from worst to best outcomes) of 55 (range 29 to 82) before the procedure and 74 (range 47 to 96) at a mean follow-up of 30.5 months (significant difference from baseline, p=0.005).

4.2 The case series of 22 patients reported mean (± standard error) percentages of the maximum score for pain measured by clinical evaluation before distraction of 78% (±3%), and of 30% (±5%) at a minimum follow-up of 7 years after distraction (n=16; p<0.0001). The same study reported mean percentages of the maximum score for AOS scores for pain of 67% (±6%) before distraction and of 25% (±6%) at a minimum follow-up of 7 years after distraction (n=16; p<0.002). A case series of 26 patients treated by ankle joint distraction reported AOS pain scores (mean percentage of the maximum score ± standard deviation) of 60% (±3%) at baseline, 35% (±4%) at 1-year follow-up and 35% (±5%) at 2-year follow-up (p<0.001 for all scores compared against baseline). The case series of 25 patients reported mean AOFAS pain scores of 15 (range 0 to 20) before the procedure and 31 (range 20 to 40) at a mean follow-up of 30.5 months; 91% (21/23) of patients reported a reduction in pain.

4.3 The case series of 22 patients reported mean (± standard error) percentages of the maximum score for functional ability measured by clinical evaluation of 20% (±4%) before distraction and 73% (±6%) at a minimum follow-up of 7 years after distraction (n=16; p<0.001). For the AOS scores for disability the same study reported mean percentages of the maximum score before distraction of 74% (±5%), and of 32% (±7%) at a minimum follow-up of 7 years after distraction (n=16; p<0.001). In a case series of 23 patients treated by ankle joint distraction, at a mean follow-up of 64 months after the procedure, 77% (14/18) of patients said that they walked for pleasure, 33% (6/18) of patients said that they could run, 22% (4/18) of patients used an assistive device to walk and 11% (2/18) of patients reported severe limitations (no further details provided). The case series of 26 patients reported AOS

disability scores (mean percentage of the maximum score ± standard deviation) of 67% (±2%) at baseline, 46% (±5%) at 1-year follow-up and 36% (±5%) at 2-year follow-up ($p<0.001$ for all scores compared against baseline). The case series of 25 patients reported ranges of motion before the procedure of 7º dorsiflexion (range –5º to 15º) and 32º plantarflexion (range 15º to 50º), and at a mean follow-up of 30.5 months of 4.3º dorsiflexion (range 0º to 10º) and 33º plantarflexion (range 20º to 40º); levels of significance were not stated.

4.4 In the RCT of 36 patients treated by fixed distraction or distraction with motion, the motion group had better SF-36 physical component summary scores than the fixed group at 26 weeks after fixator removal ($p=0.02$) and at 104 weeks after fixator removal ($p=0.05$), but not at 52 weeks after fixator removal ($p=0.49$).

4.5 In the case series of 23 patients, at a mean follow-up of 64 months, 61% (11/18) of patients were very satisfied or satisfied by the result of the procedure and 71% would recommend this procedure to a friend (absolute number not given), but 33% (6/18) were not satisfied with the outcome.

4.6 A case series of 57 patients treated by ankle joint distraction reported that 23% (13/57) of patients withdrew from the study because of persistent pain; 62% (8/13) of these patients withdrew within 1 year after distraction. All the patients who withdrew were treated by arthrodesis. A combined analysis of treatment failure in a case series of 75 patients treated by ankle joint distraction and in the RCT of 36 patients treated by fixed ankle distraction or distraction with motion, reported treatment failure in 17% (18/105) of patients still included in the studies within 2 years after ankle distraction (6 patients were lost to follow-up). Treatment failure was

defined as patients treated by arthrodesis, osteotomy or a second distraction, or patients who developed Sudeck's atrophy.

4.7 The case series of 25 patients reported that there was no change from baseline in ankle joint space measured on X-ray, at a mean follow-up of 30.5 months, in 91% (21/23) of patients.

4.8 The specialist advisers listed the following key efficacy outcomes: improvement in symptoms, reduced pain, improvement in function, preservation of the joint, avoiding or delaying the need for ankle fusion or arthroplasty, preservation or improvement of the range of ankle movement, long-term increase in joint space measured on X-ray, and reduced use of analgesics.

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 distal to the knee was reported in 1 patient treated by ankle joint distraction in a randomised controlled trial (RCT) of 36 patients treated by fixed distraction (n=18) or distraction with motion (n=18); this was treated by anticoagulation therapy (no further details provided).

5.2 Infection at the pin sites was reported in 28% (16/57) of patients treated by ankle joint distraction in a case series of 57 patients; this was treated by antibiotics (no further details provided). Pin track infection was reported on 43 occasions in 53% (19/36) of patients in the RCT of 36 patients treated by fixed distraction or distraction with motion. All infections were initially treated with oral antibiotics;

4 persisted and the pins were removed. Two of the 4 infections were treated by 6 weeks of intravenous antibiotics because acute osteomyelitis was suspected. Superficial pin site infection was reported in 100% (23/23) of patients with complete data in a case series of 25 patients treated by ankle joint distraction; all infections resolved following a single course of antibiotics.

5.3 Numbness in the distribution of the medial calcaneal branch of the tibial nerve and in the deep peroneal distribution onto the great toe, after the frame was fitted, was reported in 22% (8/36) of patients in the RCT of 36 patients treated by fixed distraction or distraction with motion. When numbness occurred in the context of distraction exceeding 5 mm on X-ray, the distraction was reduced to 5 mm; no other treatment was given. In 50% (4/8) of patients numbness resolved with the frame in place, 25% (2/8) resolved within 3 months after frame removal, and 25% (2/8) of patients were left with residual numbness.

5.4 Sudeck's atrophy (reflex sympathetic dystrophy) was reported in 2% (2/105) of patients treated by ankle joint distraction who were still in the study at 2-year follow-up, in a combined analysis of a case series of 75 patients treated by ankle joint distraction and the RCT of 36 patients treated by fixed ankle distraction or distraction with motion. Sudeck's atrophy was reported in 1 patient treated by ankle joint distraction in a case series of 22 patients; it was unclear if this was related to the procedure.

5.5 A broken pin through the forefoot, possibly caused by excessive strain during walking, was reported in 14% (8/57) of patients in the case series of 57 patients. Of these patients, 63% (5/8) had the broken pin removed and 38% (3/8) had the pin replaced; local infections were prevented or treated by antibiotics.

5.6 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 listed the following anecdotal adverse events: stiffness or clawing of the toes, pain during distraction, and difficulty tolerating the frame. They considered that the following were theoretical adverse events: neurovascular injury, tendon injury, creation of deformity, risk of worsening symptoms, septic arthritis, avascular necrosis of the talus, fracture, joint stiffness, complex regional pain syndrome, and ongoing pain after the frame is removed.

6 Committee comments

6.1 The Committee considered that many of the published studies on joint distraction for ankle osteoarthritis reported the grade and site of osteoarthritis poorly. It was also concerned that high rates of loss to follow-up reduced the value of the findings. These deficiencies contributed to the uncertainties about the efficacy of the procedure and the consequent recommendation for only using it in research.

7 Further information

7.1 For related NICE guidance, see the NICE website.

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