NICE guidance

Joint distraction for ankle osteoarthritis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg538

1 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. At 104-week follow-up, the mean AOS scores were 48.4 in the fixed group and 27.4 in the motion group (significant improvements from baseline in both groups, $p<0.01$ in the motion group and $p<0.02$ in the fixed group). 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 in walking ability (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. In a 5 to 10-year follow-up study of 29 patients from the RCT of 36 patients, conversion was reported in 45% (13/29) of patients; 28% (8/29) were treated by ankle arthrodesis and 17% (5/29) by total ankle arthroplasty. Of the 13 conversions, 2 were done within 1 year after ankle distraction, 3 in the second year, 1 in the third year, 1 in the fifth year, 3 in the sixth year, 2 in the seventh year and 1 in the eighth year.

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.

Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced information for the public explaining this guidance. Information about the evidence the guidance is based on is also available.

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Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their 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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation