NICE National Institute for Health and Care Excellence

NICE guidance

Sinus tarsi implant insertion for mobile flatfoot

HealthTech guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a 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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG305.

1 Recommendations

1.1 Current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot is inadequate in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake sinus tarsi implant insertion for mobile flatfoot should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and/or their parents/carers understand the uncertainty about the procedure's safety and efficacy in relation to symptom relief, quality of life, and long-term outcomes; that the success of the procedure may be dependent on the aetiology of their flatfoot; that there may be a need for adjunctive or subsequent procedures; and that the implant may need to be removed. Patients and parents or carers should be provided with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having sinus tarsi implant insertion for mobile flatfoot (see section 3.1).

1.3 Sinus tarsi implant insertion is not appropriate for most children with mobile flatfoot. The procedure may be used in selected children with persistent mobile flatfoot due to neuromuscular disorder, skeletal dysplasia or systemic ligamentous laxity, whose treatment is supervised by a multidisciplinary team. The procedure may be indicated rarely in highly selected adult patients.

1.4 NICE encourages further research into sinus tarsi implant insertion for mobile flatfoot. Research studies should define patient selection criteria, address uncertainties about using the procedure in children and in adults, include descriptions of adjunctive procedures, and provide long-term outcome data.

Studies comparing outcomes of the procedure with the natural history of mobile flatfoot would be useful. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 In people with mobile flatfoot, the foot arch is effaced only on weight bearing. Manipulation or standing on tiptoe can restore it to normal appearance.

- Most children go through a self-resolving phase of mobile flatfoot during growth.
- In some children, it can be permanent as a result of neuromuscular disorders, skeletal dysplasias or ligamentous laxity.
- In adults, mobile flatfoot is common and may be associated with posterior tibial tendon insufficiency.

2.1.2 The condition is usually asymptomatic, particularly in children, but some people may have foot pain.

2.1.3 Orthotics and physiotherapy are normally used to treat children and young adults. Depending on the underlying cause, treatments may include corticosteroid injections (in adults), surgical decompression, tendon augmentation, and osteotomy or lengthening of the calcaneum.

2.1.4 A number of different devices can be used for this procedure.

2.2 Outline of the procedure

2.2.1 The procedure (also known as subtalar arthroereisis) can be performed with the patient under general or local anaesthesia. Exact technique and instrumentation vary. The sinus tarsi (between the calcaneum and the talus) is accessed by a lateral incision. A trial implant may be used, with intraoperative imaging and simulated weight bearing, to direct appropriate placement and degree of correction before a sized implant is inserted. Adjunctive bone or soft tissue

procedures may also be carried out.

2.2.2 Compression dressing or plaster cast (particularly with adjunctive procedures) and modified footwear and/or orthotics may be used postoperatively.

2.2.3 The implant may need to be removed, particularly in children; exact timing for this varies.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 In a case series of 54 patients (68 feet), 24%, 42%, 27% and 6% of patients (or their parents) respectively reported '100%', '75%', '50%' and 'either 25% or no' resolution of symptoms (mean follow-up 2 years).

2.3.2 In a case series of 37 patients (65 feet), 59% (22 out of 37) reported pain before and 5% (2 out of 37) after the procedure (mean follow-up 26.5 months). In a case series of 23 patients (28 feet), the mean pain score decreased from 3.2 preoperatively to 1.6 postoperatively on a scale from 4 (severe pain) to 1 (no pain; $p<0.0001$; mean follow-up 44 months).

2.3.3 The Specialist Advisers listed key efficacy outcomes as quality of life, pain relief, X-ray angles, gait analysis, normal foot shape and footwear, clinical scoring scales and long-term correction.

2.4 Safety

2.4.1 In 7 case series, less than 1% (2 out of 234), 5% (4 out of 80), 5% (3 out of 65), 7% (3 out of 41), 36% (8 out of 22) and 39% (11 out of 28) of feet and 10% of patients (exact number not stated) required implant removal (follow-up from 3 months to 10 years).

2.4.2 In the case series of 23 patients, 1 patient had a fractured talus 6 years after implantation.

2.4.3 Further studies reported avascular necrosis in 1 foot 10 years after bilateral surgery; bilateral intraosseous talus cysts and osteophytes in 1 patient after 2.5 years; talus bony sclerosis in 1 patient at 4 years; and talus spur formation in 1 foot at 3 months.

2.4.4 The case series of 54 patients reported implant extrusion in 9% of feet after 1 year. A case series of 49 patients reported fragments in the sinus tarsi (unclear whether bone or implant) in 1 foot (follow-up not stated).

2.4.5 The Specialist Advisers considered theoretical or anecdotal adverse events to include sural nerve injury and complete loss of subtalar movement.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed audit support (which is for use at local discretion).

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 305 has been migrated to HealthTech guidance 196. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.