Issue date: July 2009

NHS
National Institute for Health and Clinical Excellence

Sinus tarsi implant insertion for mobile flatfoot

1 Guidance

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 patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG305publicinfo).
- 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.

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Interventional procedure guidance 305

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

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.

Sections 2.3 and 2.4 describe efficacy and 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 overview, available at www.nice.org.uk/IP101overview

2.3 Efficacy

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% (22/37) reported pain before and 5% (2/37) 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% (2/234), 5% (4/80), 5% (3/65), 7% (3/41), 36% (8/22) and 39% (11/28) 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 is developing audit support (which is for use at local discretion), which will be available when the guidance is published.

3.2 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/IPG305publicinfo

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Ordering printed copies
Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1902 for this guidance or N1903 for the 'Understanding NICE guidance'.

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ISBN 1-84629-993-4
N1902 1P 7k Jul 09