NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of sinus tarsi implant insertion for mobile flatfoot

Mobile flatfoot is a condition in which the foot becomes flattened when standing. It is a normal and usually self-resolving phase of growth in many otherwise fit children. It may be persistent in disabled children, and in adults it may be associated with tendon dysfunction. Although usually asymptomatic, it may be painful. This procedure involves surgery to insert an implant above the heel bone, in order to correct the condition and improve symptoms.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in January 2008.

Procedure name

- Sinus tarsi implant insertion for mobile flatfoot

Specialty societies

- British Orthopaedic Association
- British Orthopaedic Foot and Ankle Society
- The Chartered Society of Physiotherapy
- British Society for Children's Orthopaedic Surgery
- The Society of Chiropodists and Podiatrists (Feet for Life)

Description

Indications and current treatment

Flatfoot (also called pes planus or pes planovalgus) is characterised by a 'fallen' foot arch. Two main clinical variants exist: rigid and mobile (or flexible) flatfoot.

In people with rigid flatfoot, the flatfoot deformity is unaltered by weight-bearing: the foot is always flat. It is usually associated with problems in the bones of the feet. In people with mobile flatfoot, the deformity is accentuated when the foot is weight-bearing and is readily reversible by standing on tiptoe, manipulation of the foot or orthotic use. In these cases the basic bony structure of the foot is usually normal. This overview covers only mobile flatfoot.

In children, mobile flatfoot is usually part of growth and does not have a neurological cause. If mild, it will often resolve on its own. The usual cause of mobile flatfoot in adults is posterior tibial tendon insufficiency, which may have a number of causes including hindfoot valgus or trauma.

The condition may be asymptomatic, particularly in children. However some people may experience pain in the foot. .

Diagnosis of symptomatic mobile flatfoot is usually made by history and clinical examination. X-rays are often taken to assess the bones and joints. Magnetic resonance imaging (MRI) scanning can be used to assess the tibialis posterior tendon and either MRI or computed tomography (CT) scanning can be used to exclude bony abnormalities such as tarsal coalition. Foot pressure studies (pedobarography) or gait analysis has been used.

Current treatment/alternatives

Treatment for this condition depends on the patient's age. In children, the condition will usually resolve on its own with growth; simple orthotics and physiotherapy are usually all that is required. Very occasionally, if the condition is severe or an underlying cause is present, surgery may be required to either the tendons or bones of the foot.

In adults, treatment will also depend on age and cause. A younger adult may require only orthotics and physiotherapy for a mild condition. However, in older patients and where there is pathology of the tibialis posterior tendon, more aggressive treatment is often needed to prevent the condition progressively worsening, which will eventually lead to painful arthritis of the midfoot.

Inflammation of the tibialis posterior tendon may require injection of steroids. If this is unsuccessful, surgical decompression or augmentation of the tendon by transferring another tendon into it may be necessary.

If the cause is an abnormality of the bones of the foot causing hindfoot valgus, osteotomy of the calcaneum to move it medially or lengthening of the calcaneum (lateral column lengthening) may be undertaken. If the cause is a tight achilles tendon, this may be treated surgically.

What the procedure involves

The sinus tarsi is a conical opening on the outer side of the foot between the calcaneum (heel bone) and the talus (lower ankle bone). In mobile flatfoot the calcaneum rotates laterally under the talus and closes down the sinus tarsi. The aim of the procedure is to insert an implant into the sinus tarsi to hold it open artificially and correct the flatfoot. The procedure is sometimes referred to as a subtalar arthorereisis.

Implants can take the form of a self-locking wedge ('free floating'), an axis-altering device (to reduce calcaneal eversion), or an impact-blocking device.

The procedure is usually performed with the patient under general anaesthesia. Various techniques are used.

The sinus tarsi is accessed surgically using an incision on the outer side of the hindfoot. After intraoperative sizing of the sinus tarsi, a suitable size of implant is inserted (the exact technique and instrumentation for implant insertion may vary, depending on the implant). Intraoperatively, a trial implant and clinical (simulated weight-bearing) and imaging investigation may be used to ensure the appropriate placement and degree of deformity correction is achieved.

Adjunctive bone or soft-tissue procedures may also be carried out.

Postoperative care can include the use of a compression dressing, elastic bandage, or a plaster cast (particularly if other procedures are performed concomitantly). The patient may need to wear a surgical shoe, a soft-soled shoe and/or orthotics for some time after the operation.

In children, the implant may need to be removed at a later stage to allow for growth. There is no clear recommended time to remove the implant.

List of studies included in the overview

This overview is based on approximately 643 feet from eight case series and four case reports.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Efficacy

Patient-reported outcomes, such as resolution of pain and other functional impairment

A study reporting results from a patient questionnaire on 68 feet treated by arthorereisis reported that 24% of patients (or parents of patients) felt that the surgery completely relieved their symptoms; 42% felt that 75% of their symptoms were resolved; 27% felt that 50% of their symptoms were resolved and 6% felt either that there was no reduction in their symptoms or that there was only a 25% improvement [10]. Prolonged pain or disability was reported in 3% of feet (exact number not given).

The same study reported that 63% of respondents stated that they were able to walk normally within 7 days of surgery, 24% were able to walk normally 1–3 weeks after surgery and 2% were still limping at 3 weeks or when the questionnaire was taken. Follow-up for these patients ranged from 4 months to 4 years.

A case series of 65 feet (37 patients) treated by subtalar arthorereisis reported that 51% (19/37) of patients who were not originally able to participate in sports did so postoperatively, while 49% (18/37) did not [1]. Pain, which was reported in 59% (22/37) of patients preoperatively, decreased to 5% (2/37) of patients postoperatively. Persistent postoperative pain or discomfort after walking was reported in four feet (6%); the implant was removed from three feet and replaced with a larger implant in one foot (follow-up for these outcomes not stated).

A case series of 41 feet (23 patients) treated by subtalar arthorereisis reported that 95% of patients stated in a questionnaire that they were walking normally within 1 month of surgery. Ninety per cent of patients reported that they were satisfied and 85% said they would repeat their experience (exact patient numbers not given) [11].

A case series of 28 feet treated by subtalar arthorereisis reported average overall patient satisfaction (from a patient questionnaire) to be 8.3 out of 10. Patients reported that their average walking ability increased from 2.5 preoperatively to 1.6 postoperatively (scale of 1 to 3; 1 suggesting no difficulty in walking and 3 as extreme difficulty; $p < 0.0001$). Average pain was reported to have decreased from 3.2 to 1.6 postoperatively (scale 1–4 from no pain to severe pain; $p < 0.0001$) [4]. Postoperative pain was chronic without pathology in 42% (11/26) of feet.

A case series of 22 feet treated by subtalar arthorereisis reported significant pain in 73% (16/22) on follow-up (ranging from 6 month to 18 months). Implant removal was required in 36% (8/22) of these feet[13].

Clinical or physician-assessed outcomes

In the case series of 234 feet, clinical improvement was reported in all'cases'[12]. The authors stated that there was a 'normalisation' in the footprint of 56% (130/234) of feet and an improvement in 44% (102/234) of feet. However, there was no footprint change in two feet (follow-up not stated).

The case series of 96 feet reported 'good' results in 78% (70) of feet (denominator not stated), 'fair' results in 19% (number not stated) of feet and 'poor' results in 3% (3/96) of feet ('good': deformity reduced and symptoms resolved; 'fair': partial resolution of symptoms; 'poor': deformity recurrence)[3].

A case series of 80 feet (43 patients) reported 'good' results in 58% (25/43) of patients, 'fair' results in 30% (13/43) of patients and 'poor' results in 12% (5/43) of patients ('good', 'fair' and 'poor' were determined by the degree of change in various angles and whether or not manual correction was possible) [7].

The case series of 28 feet (23 patients) reported that American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot scores (a system used to score pain, function and alignment on an increasing 100-point scale) increased from 52 to 87 postoperatively ($p < 0.00001$) [4]. In the 11 feet that needed implant removal because of postoperative pain, AOFAS scores were 80 or better in 8 feet and less than 80 in 3 feet.

The case series of 65 feet reported that postoperative footprint was 'normal' in 59% (38/65) feet and first-degree flatfoot was reported in the remaining 42% (27/65) feet (follow-up not stated; details not provided on the other 4 feet). The study stated that there were no significant differences in footprint in the 38 feet that were also treated with Achilles tendon lengthening [1].

The case series of 22 feet reported clinical improvement in 32% (7/22) patients postoperatively. However, this improvement regressed to the preopereative position in most patients 3-6 months after surgery. The same study reported radiological improvement in 14% (3/22) of feet and improvement in pressure studies in 14% (3/22) of feet [13].

Safety

Fracture (bone or implant) or other bone or joint lesion development

In the case series of 96 feet, talar beaking (lifting of periosteum under the talar joint creating a bony growth) was reported in two 'cases' (the authors stated that this was likely to be because of talonavicular jamming before arthorereisis) [3]. Gradual flattening of the lateral talar process was also reported in two 'cases'. Another 'case' in this series had multiple fragments in the sinus tarsi of one foot (it is not reported whether this was fragments of bone or of the implant) but it was asymptomatic (follow-up not reported for these events).

In the case series of 68 feet, evidence of bony sclerosis was reported on the neck of the talus of one foot but not on the articular surfaces at 4-year follow-up [10].

The case series of 41 feet reported fracture of the lateral process of the talus in one foot following an inversion ankle injury recalcitrant to conservative treatment 6 years after the surgery. An operation to remove the implant could not be completed because of bone growth around it. However the implant did not show any signs of fracture or erosion. The patient was reported to be asymptomatic 6 months after the operation [11].

The case report of three patients with bilateral implants reported a small fracture inside the sinus tarsi of one foot, assumed to be sports-related, 3 months after implantation (it is not clear if the fragment was of bone or implant) [2]. The patient was treated with a cast and symptoms appear to have resolved 5 years after implantation.

The same report described a spur on the talus of another patient's foot 3 months after implantation. After removal, the implant was described as eroded and there were small fragments of polypropylene and giant cell reaction in the sinus tarsi. Fibrocartilage was also present on the anterior edge of the talus. No pain was reported 3 years after removal.

Spontaneous extrusion of implant into sinus tarsi

The case series describing responses to a questionnaire representing 68 feet reported extrusion to be the most frequent complication (9% of feet), usually because of subcutaneous lumps on the lateral part of the foot and usually within 1 year of follow-up (exact figure not stated) [10]. In these patients, a modification procedure to resecure the implant was successful (resulted in no further extrusions) after 1 year of follow-up.

The case report of three patients reported implant failure because of an injury while skating in one patient 6 months after surgery [2]. The implant was said to be eroded and there were multiple minute fragments of the implant with detritic synovitis and giant cell reaction in the talus. Fibrocartilate was also present.

Of the nine patients who reported pain, the case series of 13 feet reported extruded methyl methacrylate (bone cement used in the procedure) in the subtalar joint associated with lateral subluxation requiring removal in 22% (2/9) of feet (time of occurrence not reported) [9].

Requirement for additional procedure or removal

Implant removal (already reported in the safety section of this overview) was performed in less than 1% (2/234) [12], 5% (4/80) [7], 10% (exact number not stated) [10], 5% (3/65) [1], 7% (3/41) [11], 39% (11/28) [4], and 36% (8/22) [13] of feet in seven case series at follow-ups ranging from 3 months to 6 years (time of removal not stated in any). Four case reports described bilateral implant removal in seven patients at follow-ups ranging from 3 months to 10 years [2, 5, 6, 8].

Bone or joint infection

The case series of 41 feet reported one case of acute osteomyelitis of the calcaneus requiring removal of the implant (removal was performed by another doctor and the patient was unavailable for follow-up; time of removal not stated) [11].

The case series of 28 adult feet reported that one patient had persistent preoperative peroneal spasm, which mean the implant had to be removed and a triple arthrodesis performed 5 months after implantation [4].

A case report diagnosed avascular necrosis in one foot of a patient treated with bilateral implants 10 years after surgery [8]. Osteosclerosis, focal necrosis, focal remodelling, fibrotic stoma and fibrotic synovium was reported in both tali. The patient retained foot alignment 6 months after removal and was able to return to work without restrictions or limitations. Upon removal, the implants showed signs of wear, but were not fragmented.

A case report of a 15-year-old girl treated with a bilateral implant described bilateral intraosseous cysts in the talus and osteophytes in the anterior border of the subtalar joint 2.5 years after surgery. The implant was removed and some pain remained for 2 years afterwards. However, the alignment remained corrected [5].

A case report described foreign body synovitis with extensive granulomatous giant cell reaction to refractile polyethylene debris requiring removal in two children with bilateral implants 2 years after surgery [6].

Other

The case series of 234 feet reported postoperative superficial infection, usually related to intolerance of the suture material, in 8 ‘cases’, resolving spontaneously within a few days [12]. One patient had a deep infection requiring removal of the implant although correction was retained. The same study reported the following events, which were cured by inflammatory drugs or physical therapy: ischaemia caused by compression of the cast in one patient; swelling, limping and continuing pain in seven ‘cases’, and peroneal contracture in one ‘case’ (follow-up was not reported for these events).

The case series of 65 feet reported tibiotarsal sprain in two feet in the first 3 months after surgery [1].

The case series of 41 feet reported subtalar joint arthritis in two patients aged 7 years and 20 years. The first patient required implant removal and subsequent subtalar joint fusion (time of occurrence not stated) [11]. The second patient was an athlete, whose implant was removed 1 year after surgery because of chronic pain and stiffness in the sinus tarsi area; arthritis was evident at 6-year follow-up. The case series reports that the talar was broken, the posterior facet had narrowed, and there was sclerosis in the talonavicular joint. At the time of the report, the patient was still in pain and had swelling with increased activity.

Of the nine patients who reported pain, the case series of 13 feet reported abnormal calcaneal recession in 22% (2/9) of feet as a result of excessive resection of the dorsal calcaneus during surgery [9]. Revision was not performed because of excessive bone resection and because the symptoms were mild.

The same study reported loosening of the implant in three patients because of a gap between the bone and cement interface, which was identified by x-ray. This was revised surgically in one patient; the other two patients refused revision.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to sinus tarsi implant insertion for mobile flatfoot. Searches were conducted of the following databases, covering the period from their commencement to 01 April 2009: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy).

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with mobile flatfoot.
Intervention/test	Sinus tarsi implantation insertion.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Metatarsophalangeal joint replacement of the hallux. NICE interventional procedures guidance 140 (2005). Available from www.nice.org.uk/IPG140

Table 2 Summary of key efficacy and safety findings on sinus tarsi implant insertion for mobile flatfoot

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Viladot, A (1992)[12] Study type: **case series** Country: Spain Study period: 1970–1984 Study population: children with flatfoot n = **234 feet** Age range: 5–15 years (mean not stated) Sex: 58.6% male, 41.4% female Inclusion criteria: not stated Technique: internal and external incision, lever passed between incisions to supinate the foot (Achilles tendon or peroneal muscle retraction may be used too), insertion of a cup-like endo-orthosis with introducer device, suture and dressing; postoperative care includes dressing, followed by non-padded cast; rehabilitation starts within 1 month with insoles worn for 1 year after surgery. Follow-up: **not stated** Conflict of interest: not stated	***Overall clinical improvement (n = 234)*** Clinical improvement was reported in all 'cases'. The authors state that plantar arch raising was not spectacular initially after the procedure but there was progressive improvement. No functional disability reported, patients were 'able to practice any sport'. ***X-ray evidence of angle improvement (n not specified)*** Average improvement in the calcaneus-naviculo-metatarsal lateral angle by '14.1%'* (normal range between 120° and 130°). *The publication describes '%' but this may be a typographic error, instead of '°' Average improvement in the astragalus-calcaneus angle was 9.7° (normal angle between 15° and 125°). ***Footprint ('photopodogram' investigation, not otherwise defined) (n = 234)*** There was 'normalisation' in 55.6% (130 feet) and an improvement in 43.6% (102 feet). Two feet had no change (0.8%).	**Complications** Implant removal in two patients: -Deep infection requiring prosthesis removal in a patient. Despite removal, foot was said to be 'cured' once the complication was resolved. -Also, implant removal required in another patient (not possible to decipher whether reason was clinical). Ischaemia caused by cast compression in a patient (no further details on outcome provided). Swelling, limping and some pain over several months was reported in 7 'cases'. One patient developed 'peroneal contracture' (not otherwise qualified or described). Superficial infection resolving spontaneously within days in eight patients (attributed to 'intolerance of the suture material' in most of these patients).	Author states that surgical treatment of flatfoot in children was needed in 1.6% of all cases (in his practice). Length of follow-up not stated. Publication included illustrations of x-rays of some patients before the operation, and at 1 and 5 years post-operatively. Recruitment method was not described.

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Lundeen (1985)[3]

Study type: case series
Country: US
Study period: not stated

Study population: children with hypermobile pes planovalgus; all patients had foot flattening on weightbearing and no superstructural torsional abnormalities, average talocalcaneal (Kite's) angle 40°

n = 96 feet (49 patients)
Mean age: 8 years (range 3–19)
Sex: not stated

Inclusion criteria: not stated

Technique: insertion of STA peg (manufactured by Biomet, Inc, later taken over by Dow Corning Wright); bone cement is also used in this procedure
Some also had Achilles tendon lengthening (how many not stated); surgery was followed by long-term use of orthosis.

Mean follow-up: 46 months (range 19–76)
Conflict of interest: not stated</td>
<td>Operative success
Good results (pes planovalgus deformity reduced and symptoms resolved) in 78% of feet (70; denominator not stated).
Fair results (partial resolution of symptoms) in 19% of patients (failure to solve forefoot adductus in four and metatarsal breech in 10; one case of sustained supination resulting in synovial changes and relieved with lavage and lysis).
Poor results (pes planovalgus recurrence) in 3% (two from accidental trauma; one from implant loosening requiring additional surgery).
<table>
<tr><th>Radiographic measure of angle</th><th>Average preop score</th><th>Average postop score</th></tr>
<tr><td>Rearfoot varus</td><td>6.0°</td><td>5.6°</td></tr>
<tr><td>Forefoot varus*</td><td>7.4°</td><td>2.7°</td></tr>
<tr><td>Calcaneal stance</td><td>9.6°</td><td>2.7°</td></tr>
<tr><td>Eversion of subtalar joint</td><td>11°</td><td>2.7°</td></tr>
<tr><td>Total range of subtalar joint motion</td><td>43°</td><td>32°</td></tr>
<tr><td>Frontal plane motion**</td><td>45° inversion
15° eversion</td><td>'approximate ly the same'</td></tr>
<tr><td>Calcaneal inclination</td><td>28°</td><td>31°</td></tr>
<tr><td>Talar declination</td><td>33°</td><td>28°</td></tr>
</table>
*based on clinical criteria (all others based on radiological criteria); **data not available for all patients (exact number not given)
<table>
<tr><th>Mid-tarsal breeches</th><th>Preoperati ve</th><th>Postoperative</th></tr>
<tr><td></td><td>22% of patients:</td><td></td></tr>
<tr><td>- naviculocuneiform
- metatarsocuneiform
- talonavicular</td><td>78%
14%
7%</td><td>all reduced
80% reduced
36% reduced</td></tr>
</table>
</td>
<td>Long-term radiographic changes
'Multiple fragments' were discovered in the sinus tarsi of one 'case' but was asymptomatic (not stated if fragments were of bone or implant).
Postoperative talar beaking was reported in two 'cases' (lifting of periosteum under the talar joint creating a bony growth 'likely due to talonavicular jamming before arthorereisis').
Gradual flattening of the lateral talar process was reported in two 'cases'.
Disability following operation
This ranged from 1 to 7 weeks. With the use of short leg walking casts initially, disability lasted 6 weeks, but this was reduced to 4 weeks when casts were no longer used. Average disability increased to 7 weeks with concomitant Achilles tenotomy.
Other clinical complications
Of the six feet diagnosed with forefoot adductus before surgery, four remained asymptomatic after surgery (follow-up not stated).
Of those with 'good results' (see efficacy column), 17 had minor postoperative problems.
<table>
<tr><th>Adverse event</th><th># of patients</th></tr>
<tr><td>Leg cramp</td><td>5</td></tr>
<tr><td>Heel pain</td><td>2</td></tr>
<tr><td>Peroneal tendonitis</td><td>2</td></tr>
<tr><td>Awkward gait</td><td>2</td></tr>
<tr><td>Drainage from incision</td><td>1</td></tr>
<tr><td>Ankle pain</td><td>1</td></tr>
<tr><td>Accidental trauma after surgery*</td><td>4</td></tr>
</table>
(All were resolved with conservative care)
*Two remained symptomatic; exact time not stated.</td>
<td></td>
</tr>
</table>

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Scialpi (2006)[7]
Study type: case series
Country: Italy
Study period: Apr 2001–Jan 2004
Study population: idiopathic flatfoot Patients had symptoms of pain in the midfoot, contractures, 'unbalance' and unsteadiness of walking.
n = 80 feet (43 patients)
<u>Pisani talocalcaneal arthorereisis</u> (40 feet, 22 patients, 15 of whom male)
Mean age: 11 years (7.5–14.5)
Average follow-up: 23 months (5–38)
<u>Giannini endo-orthotic implant</u> (40 feet, 21 patients, 10 of whom male)
Mean age: 9.7 years (6–13.5)
Average follow-up: 41.2 months (11–118)
Inclusion criteria: patients with IV degree footprint (Viladot categories) and hindfoot ≥ 10°
Technique: under general anaesthesia. Pisani: a titan screw with a dome is inserted with an oblique angle dorso-plantar and 'proximal to distal in the heel', cast applied for 2 weeks after surgery; Giannini: a screw with expanding polyethylene prostheses inserted into lateral part of sinus tarsi, cast applied for 3 weeks after surgery
Conflict of interest: not stated</td>
<td>Operative success
According to the following criteria,
<table>
<tr><th></th><th>Costa-Bartani angle</th><th>Kite's angle</th><th>Valgus of hindfoot</th><th>Manual correction</th></tr>
<tr><td>Good</td><td>Normal or < 5°</td><td>Normal or < 5°</td><td>Normal or < 5°</td><td>possible</td></tr>
<tr><td>Fair</td><td>> 5° but < 10°</td><td>> 5° but < 10°</td><td>> 5° but < 10°</td><td>partial</td></tr>
<tr><td>Poor</td><td colspan="3">No enhancement after surgery</td><td>impossible</td></tr>
</table>
<u>Pisani</u>
59% (13) had 'good' results
32% (7) had 'fair' results
9% (2) had 'poor' results
<u>Giannini</u>
54.5% (12) had 'good' results
28.5% (6) had 'fair' results
17% (3) had 'poor' results
(percentages and figures as given by study)</td>
<td><u>Pisani</u>
Implant removal in two patients:
-In one patient, it was necessary to remove the titanium screw because of loosening ('early removal').
-In one patient, the implant was removed as it was considered to be 'undersized' and replaced 'at a later date'.

<u>Giannini</u>
Implant removal in two patients 4 and 9 years from surgery (no other details apparent; uncertain if this was planned removal).</td>
<td>The authors state that surgical correction of flatfoot in children is required in 2–3% of cases.
In the discussion the authors allude to 'per protocol' removal of the device, but no clear details are provided.
The authors stated that they planned to remove the Giannini endo-orthotic implant but the rule they proposed using is not clear; they stated that the Pisani device did not need to be removed unless there were complications.</td>
</tr>
</table>

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'

Study details	Key efficacy findings	Key safety findings	Comments

Smith, R (1983)[10]

Study type: **case series**

Country: US

Study period: Mar 1997–Dec 2000

Study population: idiopathic flatfoot deformity in children and adolescents

n = **68 feet (54 patients)**

Average age: not stated

Sex: not stated

Inclusion criteria: not stated

Technique: insertion of subtalar arthorereisis (Silastic plug). postoperative treatment involves a cast for 2 weeks, followed by a bandage.

Arthorereisis alone in 38%; arthorereisis + gastrocnemius recession and tendo Achilles lengthening in 54%; arthorereisis + medial supportive procedure (such as Young's, Kidner's or talonavicular desmoplasty) in 8%

Mean follow-up: **1.98 years (4 months–4 years)**

Conflict of interest: not stated

Subjective results

A retrospective questionnaire was sent to 54 patients/parents of patients who had this procedure (108 feet). Questionnaires were returned for 68 feet (54 patients) with the following results:

	% of respondents
Ability to walk normally:	
Within 4 days	24
4–7 days	39
1–3 weeks	24
Still limping at 3 weeks/now	2
How much has surgery helped the problem?	
100%	24.2
75%	42.4
50%	27.4
25%	3
none	3
Has the arch height increased?	
Yes	65.6
No	9.4
Slightly	25
Straightening of toes following surgery?	
No	60.6
Yes	39.4

Objective measurements/findings

Of these patients, 20 patients (40 feet) were examined and x-rayed postoperatively.

Results of preoperative and postoperative radiographs on weightbearing dorsoplantar and lateral views:

Angle type	Average angle change
Calcaneal inclination	3.2°
Talocalcaneal angle	7.6°
Declination of talus	7.8°
Lateral talocalcaneal angle	4.25°

Complications

Device extrusion in 9% of feet. This was stated to be the most frequent complication, usually because of subcutaneous lump formation on the lateral part of the foot (exact figure not stated). It usually occurred within 1 year and a modification procedure to better secure the implant resulted in no further extrusions or displacements after 1 year.

From the start of procedure, 10.3% of patients had the implant removed, in addition to the 9% whose implant extruded (exact figure not stated).

In two 'cases', implants removed at 4 and 14 months had no sign of wear or abrasion from removed 'plugs'.

One implant was removed because of overcorrection.

Compression from the cast usually requiring recasting was reported to be the second most common complication (exact number not reported).

In one case, there was some evidence of bony sclerosis of the neck of the talus at 4-year follow-up but not on articular surfaces.

Prolonged pain/disability was reported in 3%.

The authors stated that undercorrection was 'present more than could be documented' (as given by substantial heel valgus) and suggested that this was because of a tendency of the surgeon to under correct rather than overcorrect.

The authors state that there was little difference in pre and postoperative radiographs when arthorereisis was performed with concomitant procedures. They then state that gastrocnemius recession and Achilles lengthening are meant to alleviate pronatory forces.

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Gutierrez (2005)[1]
Study type: case series
Country: Spain, Study period: Mar 1997–Dec 2000
Study population: idiopathic flatfoot deformity in children and adolescents
n = 65 feet (37 patients, 22 of whom male, 15 female)
Average age: 9.4 years (5–14)
Inclusion criteria: 1) pain, fatigue or discomfort in medial arch 2) abnormal shoe wear 3) hindfoot valgus of > 10°, 4) no improvement after > 2 years of orthotic treatment or orthopaedic footwear 5) no improvement after > 6 months of exercises to stretch Achilles tendon 6) negative toe-raising test (Jack test) 7) no corrective response of heel in varus or appearance in tiptoe position 8) contracted Achilles tendon and 9) Viladot footprint type II, III or IV
Exclusion criteria: prior injury, fracture, inflammatory disorders, hereditary-degenerative problems, or spastic neurologic pathologies
Technique: 1.5–2 cm incision on lateral side of tarsi to insert appropriately sized Giannini expanding endo-orthotic implant, Achilles tendon lengthening if dorsiflexion of ankle impossible or subtalar joint inverted; postoperative care included either compression bandage or plaster cast
Mean follow-up: 26.5 months (13–51)
Conflict of interest: not stated</td>
<td>Medial longitudinal arch pain or discomfort/fatigue
Of the 37 patients, 22 (59%) reported pain preoperatively and 15 patients (27%) reported discomfort or fatigue. Pain was reported to have decreased to 6% (2 patients) postoperatively.
Participation of physical activity
19 (51.4%) patients who did not participate in sports did so postoperatively (for example, rhythmic gymnastics, cycling, martial arts, handball, hunting) while 18 (48.6%) did not.
Footprint
Postoperative 'footprint index' (minimal over maximal foot width observed on footprint) was normal in 38 feet (58.5%). First degree flatfoot occurred in the remaining 27 (41.5%) (this is defined as the minimal width remaining larger than half of the maximal width).
(Exact follow-up for this outcome not explicitly stated.)
However, there were no significant differences in footprint indices when those who had Achilles tendon lengthening were compared with those who did not (p = 0.11).

Radiographic outcomes (angles)
<table>
<tr><th>Angle type</th><th>Average preop angle</th><th>Average postop angle</th><th>Average degree change</th><th>p-value</th></tr>
<tr><td>Talar-first metatarsal</td><td>–17.6°</td><td>0.13°</td><td>+18°</td><td>p < 0.001</td></tr>
<tr><td>Costa-Bartani</td><td>146.1°</td><td>130.6°</td><td>–11°</td><td>p < 0.001</td></tr>
<tr><td>Calcaneal-pitch</td><td>8.9°</td><td>13.9°</td><td>+4°</td><td>p < 0.001</td></tr>
<tr><td>Talocalcaneal</td><td>26.0°</td><td>20.7°</td><td>–6°</td><td>p < 0.001</td></tr>
<tr><td>Giannestras</td><td>65.1°</td><td>83.7°</td><td>+18°</td><td>p < 0.001</td></tr>
</table>
However, there were no significant differences in radiographic measurements when those who had Achilles tendon lengthening were compared with those who did not (p = 0.08).</td>
<td>Complications
Pain leading to implant removal in two patients:
-Two patients (four feet, 6%) had persistent postoperative pain or discomfort after walking making it necessary to extract the implant in 3 feet and replace with a larger implant in the fourth foot.

Postoperative supination (not otherwise described or defined) was the most common complication. It was reported in 26.9% (17, denominator not stated) feet. It resolved spontaneously in 4 feet (6.1%) for 4 months, 7 feet (10.8%) for 3 months and in 6 feet (9.2%) for 1 month postoperatively.

Tibiotarsal sprain was reported in two feet in the first 3 postoperative months.</td>
<td>Authors state that paediatric and juvenile flatfoot is only considered to be 'pathologic' in 2.6% to 4% of all cases.
In the discussion, the authors state they removed the device in 7.5% of feet –this is inconsistent with what is stated in their results.
Achilles tenotomy was performed in 38 feet (58.5%).
Two patients (with bilateral implants) were lost to follow-up.
The authors state that the implant removal rate was similar to removal by Giannini (designer of implant).
The study originally included 39 patients (69 feet), but two were lost to follow-up.</td>
</tr>
</table>

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Tompkins (1993)[11]

Study type: case series
Country: US
Study period: not stated

Study population: hypermobile flatfoot

n = 41 feet (23 patients)
Mean age: 8.9 (5–16)
Sex: 43% male, 57% female

Inclusion criteria: calcaneal stance position > 8°, loss of arch on weightbearing, manually correctable, forefoot varus > 10°, midtarsal breach, anteroposterior kite angle > 30°, lateral kite angle > 40°, talonavicular joint articulation < 50°, anterior break of cyma line, talonavicular and/or naviculocuneiform breach (following Smith and Millar indications)

Exclusion criteria: patients having other procedures alongside arthorereisis

Technique: under general anaesthesia, 3–5cm incision, insertion of STA peg

Mean follow-up: 32.6 months (min: 12)
Conflict of interest: not stated</td>
<td>
Patient experience
95% of patients stated normal walking within less than 1 month of surgery (based on questionnaire of patients or parents).
90% stated that they were satisfied with the overall appearance and function of the foot and 85% stated that they would repeat their experiences.
Biomechanical results
<table>
<tr><th>Criteria</th><th colspan="3">Percentage</th></tr>
<tr><td>Pain/stiffness in sinus tarsi</td><td>Asymptomatic 95.1%</td><td>Symptomatic 4.9%</td><td></td></tr>
<tr><td>Calcaneal stance position</td><td>< 2° valgus: 70.7%</td><td>< 5° valgus: 19.6%</td><td>> 5° valgus: 9.7%</td></tr>
<tr><td>Arch appearance</td><td>Present: 75.6%</td><td>Moderate: 12.2%</td><td>Absent:12.2%</td></tr>
<tr><td>Radiographic findings</td><td>Mild: 41.4%</td><td>Moderate: 19.5%</td><td>Severe: 4.9%</td></tr>
</table>
Overall results:
<table>
<tr><th>Classification</th><th>Percentage</th></tr>
<tr><td>Optimum (asymptomatic, < 2° valgus, ROM > 30°)</td><td>58.4% (24/41)</td></tr>
<tr><td>Satisfactory (asymptomatic, < 5° valgus, ROM > 20°)</td><td>36.6% (15/41)</td></tr>
<tr><td>Unsatisfactory (persistent pain, no correction)</td><td>4.9% (2/41)</td></tr>
</table>
(Lack of correction was observed in one patient where calcaneal stance was greater than 7° everted. No arch was observed on weightbearing and pain recurrence occurred in the arch region.)
Radiographic results:
<table>
<tr><th>Angle type</th><th>Average Preoperative</th><th>Average Postoperative (on weightbearing)</th><th>Average degree change</th></tr>
<tr><td>Calcaneal inclination</td><td>16.26°</td><td>18.92°</td><td>+2.66°</td></tr>
<tr><td>Talar declination</td><td>41.73°</td><td>22.26°</td><td>–19.47°</td></tr>
<tr><td>Critical angle</td><td>105.58°</td><td>126.29°</td><td>+20.71°</td></tr>
<tr><td>Metatarsus-adductus angle</td><td>16.40°</td><td>15.43°</td><td>–0.97°</td></tr>
</table>
p values not stated; values for anteroposterior and lateral kite angle and cyma line values were said to have 'inconsistent data'
</td>
<td>
Complications
One case of acute osteomyelitis of calcaneus requiring implant removal (done by another doctor and patient was unavailable for follow-up evaluation).
One fracture secondary to inversion ankle injury recalcitrant to conservative treatment was reported 6 years after surgery (12-year-old female). Oedema and 'clicking' of sinus tarsi region was reported and fracture of the lateral process of talus (1.3 cm x 0.6 cm) was discovered 'floating' in the sinus tarsi. Removal could not be completed because of bone growth around the implant. The superior surface of the implant was visible with no signs of fracture or erosion. The patient was asymptomatic 6 months after the reoperation.
Two patients have developed subtalar joint arthritis. The first had implant removal and subsequent subtalar joint fusion (7-year-old male). The second (20-year-old college athlete) had implant removal 1 year after surgery because of chronic pain and stiffness in the sinus tarsi area. Arthritis, talar beaking, narrowing of posterior facet and sclerosis of talonavicular joint were evident at 6-year follow-up. Continuing pain and swelling with increased activity at the time of the report.
</td>
<td>
The patients in this study were reported not to have had other operations in addition to arthorereisis.

The author notes that while methylmethacrylate bone cement has been reported to have caused problems in previous studies, it has not been used in this study and should be used with awareness of the risks if used with a permanent prosthesis.
</td>
</tr>
</table>

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Needleman (2006)[4]
Study type: case series
Country: US
Study period: Feb 1998–Apr 2003
Study population: flexible flatfoot, symptomatic medially with tight gastrocnemius or soleus and Achilles tendon complex.
13 feet (12 patients) – stage II PTTD
1 foot (1 patient) – loss of integrity from soft-tissue stabilisers
1 foot (1 patient) – cerebral palsy
10 feet (7 patients) – congenital flexible flatfoot
3 feet (2 patients) – flexible flatfoot associated with accessory navicular
n = 28 feet (23 patients)
Mean age: 51 (28–74)
Sex: 65% female, 35% male
Inclusion criteria: nonoperative management failure and activity restriction, minimum 18 years old, patients with stage II PTTD had limited or no active inversion of the foot
Technique: 3 cm incision, insertion of MBA implant with Achilles lengthening or gastrocnemius recession (flexor digitorum longus tendon transfer and spring ligament reconstruction in all PTTD feet), short leg cast
Mean follow-up: 44 months (range 7–76)
Conflict of interest: not stated</td>
<td>Functional status from clinical evaluation
Average preoperative AOFAS hindfoot scores increased from 52 to 87 postoperatively (p < 0.00001.
After implant removal from 11 feet (see safety), AOFAS score was less than 80 in 3 feet (3 patients) and 80 or better in 8 feet (7 patients).

Patient-reported quality of life outcomes (from questionnaire)
<table>
<tr><th></th><th>Average preop scores</th><th>Average postop scores</th><th>p values</th></tr>
<tr><td>Walking distance (0 = bedridden, 1 = bed to chair, 2 = household, 3 = community, 4 = long distance, 5 = active athlete)</td><td>3.1</td><td>3.5</td><td>p = 0.076</td></tr>
<tr><td>Ability to walk (1 = no difficulty, 2 = some difficulty, 3 = extreme difficulty)</td><td>2.5</td><td>1.6</td><td>p < 0.0001</td></tr>
<tr><td>Amount of pain (1 = none, 2 = mild, 3 = moderate, 4 = severe)</td><td>3.2</td><td>1.6</td><td>p < 0.0001</td></tr>
<tr><td>Activity level (1 = no limitations, 2 = limited recreational/normal daily, 3 = limited recreational/daily, 4 = severe limit recreational/daily)</td><td>2.7</td><td>1.6</td><td>p = 0.00024</td></tr>
<tr><td>Footwear limitations (1 = fashionable, 2 = comfortable, 3 = modified shoes/braces)</td><td>2.2</td><td>1.9</td><td>p = 0.0065</td></tr>
<tr><td>Average overall satisfaction (scale of 0 to 10)</td><td colspan="3">8.3</td></tr>
<tr><td>Would have surgery again</td><td colspan="3">Yes – 78%
No – 18%
Not sure – 4%</td></tr>
</table>
(Statistically significant differences for all but walking distance.)</td>
<td>Pain
Postoperative pain in the sinus tarsi occurred in 46% (13/28) feet. Implant removal in occurred in 39% (11/28) of feet (10 patients) because of 'postoperative sinus tarsi pain'.

In nine feet, implant removal occurred 8 months or more after surgery. A patient had her implant removed 7 months after surgery because of a 'time miscalculation' (not otherwise described); another had implant removal at 5 months because of persistence of peroneal spasm requiring triple arthrodesis.
Two patients with postoperative sinus tarsi pain had pre-existing subtalar joint pathology (subtalar synovitis with peroneal spasm in one and periarticular subtalar bone cyst in the other).

Postoperative pain was chronic without pre-existing pathology in 42% (11/26) of feet.</td>
<td>The authors noted that a patient who had a failed Grice procedures (extra-articular subtalar arthrodeses) was included in the study.
Flexible flatfoot was defined as one with adequate subtalar and transverse movement and ability to be passively manipulated.
Diagnosis was confirmed by physical exam (standing and walking evaluation) and radiographic exam.
Distal adjunctive procedures were included.</td>
</tr>
</table>

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Black (2000)[13] Study type: **case series** Country: UK Study period: 1992–1995 Study population: Children with painless flatfeet with no improvement from orthotics or physiotherapy n = **22 feet (15 patients)** Age: from 5–14 Sex: 60% female, 40% male Inclusion criteria: not stated Technique: insertion of Viladot silastic implant as described by Viladot above; slivers of bone included in periosteal flap to promote bony union; tibialis posterior advancedment on medial side helping stabilisation of correction; postoperative therapy included immobilisation for 1 month, below knee plaster cast and rehabilitation with physiotherapy. Mean follow-up: **35 months (11 – 54)** Conflict of interest: not stated	***Clinical improvement*** There was clinical improvement in 32% (7/22) feet operated on. It was stated that these 7 feet later regressed after 3 to 6 months and did not maintain their correction. ***Radiological improvement*** There was radiological improvement in 14% (3/22) of feet to within normal values (calcaneo-naviculo-metatarsal angle from 120 to 130° and talo-calcaneal angle from 12 to 15°). The other 86% did not have significant differences in angles. (these were measured pre and postoperatively) ***Relief of pain*** 73% (16/22) of feet were reported to have significant pain on follow-up. No patients were pain-free. 9% of patients had little discomfort ***<u>Function</u>*** All parents reported deterioration in ability to participate in sports, run or walk. Most had reduced their use of footwear and had a reduction in the rate of their shoes breaking (requiring new shoes). ***Footprint*** 14% (3/22) of feet had an improvement in centre of pressure as measured by pedobarograph (these were measured 6 months, 1 month, 18 months after surgery).	***Complications*** 36% (8/22) of implants were removed because of pain (time of removal not stated) Postoperative pain was significant and limited activity in all but 2 feet.	

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Smith, DK (1990)[9] Study type: **case series** Country: US Study period: 3.5 years Study population: patients who had persistent pain following subtalar arthorereisis for flatfoot/pes planus deformity n = **13 feet (7 patients)** Mean age: 11 years (2–16) Sex: not stated Inclusion criteria: referred by podiatrists because of persistent pain which could not be explained by radiograph Technique: all patients had previously received a Silastic wedge implant into the sinus tarsi; evaluation was by CT scan Mean follow-up: not stated Conflict of interest: not stated	No efficacy outcomes were reported on.	**Complications** CT scans revealed 'normal' positioning in the four asymptomatic feet and the following in the nine painful feet: Lateral subluxation with respect to the talus: 44% (4/9); all were revised resulting in improvement or resolution of symptoms Loosening of implant as result of continuous lucency of bone/cement interface: 33% (3/9); aseptic loosening was confirmed in surgical revision in one 'case' (not further described) and the other two patients (two implants) refused revision. Extruded methyl methacrylate in subtalar joint associated with lateral subluxation: 22% (2/9); the extruded methyl methacrylate was removed (not further described). Abnormal calcaneal recession: 22% (2/9); this occurred in both feet of the same patient as a result of excessive resection of the dorsal calcaneus upon implantation. Suboptimal correction of the flatfoot deformity and mild, persistent subtalar pain were both noted and surgical revision was not recommended because of excessive bone resection and only mild symptoms.	This report focuses on the ability of CT scanning to determine the cause for pain in patients who have previously received subtalar arthorereisis.

Abbreviations used: 'STA, subtalar arthorereisis; ROM, range of motion; PTTD, posterior tibial tendon dysfunction; AOFAS, American Orthopaedic Foot and Ankle Society'

Study details	Key efficacy findings	Key safety findings	Comments
Siff (2000)[8] Kuwada (1988) [2] Rockett (1998) [5] Scher (2007) [6] Study type: four case reports n = **2 feet (1 patient)**[8] Follow-up: 5–10 years n = **6 feet (3 patients)**[2] Follow-up: 3–6 months n = **2 feet (1 patient)**[5] Follow-up: 18 months–2.5 years n = **4 feet (2 patients)**[6] Follow-up: 2 years Technique: subtalar arthorereisis	These case reports describe the following events : First report (1 patient)[8]: Pain on weightbearing 5 years after surgery and unattributed to trauma. After unsuccessful conservative management (including cast immobilisation), physical examination 10 years after surgery showed Achilles tendon contracture, plantar flexion contracture and pain on both plantar and dorsiflexion. Moderate planovalgus deformity, limited subtalar motion, and chronic synovitis in both feet. X-rays revealed osteosclerosis in both tali and MRI revealed avascular necrosis in the right talus. Both implants were removed and debrided. The implants were worn but not fragmented. Biopsies taken from the talar dome through the sinus tarsi revealed focal necrosis, focal remodelling, fibrotic stoma that contained both foreign body giant cells and refractile polarisable material. The synovium was also fibrotic and had irregular refractile polarisable material. Six months after the removal, the patient had no change in foot alignment and had improved range of motion in her hindfoot and was able to return to work without restrictions or limitations. Second report (3 patients)[2]: 1) Implant failure in one implant because of injury while skating required removal 6 months following surgery. Peroneal tendon spaticity and eroded peg; reactive or detritic synovitis secondary to multiple minute fragments of the peg with a giant cell reaction; eroded and compressed talus with evidence of fibrocartilage were reported. 2) Pain due to a small fracture was reported inside the sinus tarsi of one foot 3 months after implantation (fragment was inside the sinus tarsi – not clear if fragment was bone or implant). Authors state it is possibly sports-related. After 2 weeks in a cast, pain appeared to subside and appeared to resolve 5 years later. 3) Talus spur formation was reported in one foot 3 months after implantation requiring removal. Upon removal, the implant appeared eroded, fibrocartilage was present on the anterior edge of the talus and small fragments of polypropylene were detected with giant cell reaction. There was no pain 3 years after removal. Third report (1 patient)[5]: This is a case report of a 15 year old who had pain bilaterally 18 months from index procedure. One year later (2.5 years from original surgery) a radiograph revealed bilateral intraosseous cysts in the talus as well as osteophytes in the anterior border of the subtalar joint; STA peg was removed and demonstrated erosion. Two years after removal some pain with activity was reported but flatfoot correction from first surgery was retained. Fourth report (2 patients)[6]: This case reported of two children (7 and 10 years old) had bilateral implants removed two years after their procedure because of pain. Foreign body synovitis with extensive granulomatous giant cell reaction to refractile polyethylene debris was discovered on histological examination (the author concludes that arthorereisis should not be used in the treatment of painful flatfeet in children).		

Validity and generalisability of the studies

- The studies were all case series; no prospective comparative data was found in the literature.
- The retrieved evidence largely relates to paediatric patient populations. The overview only contains one case series of 23 patients (28 implants) reporting on the use of arthorereisis in adults. Aetiology may differ between adult and paediatric patients.
- Articles on hindfoot valgus have been excluded as this is not considered to be flexible flatfoot.
- The procedures described in the studies vary significantly, particularly in relation to design, size and instrumentation/insertion of the implant(s).
- A number of patients in the reviewed evidence also had concomitant Achilles tendon procedures. In at least one study, the authors suggested that arthorereisis should be performed alongside other procedures.
- The procedure can be done bilaterally or unilaterally – no analysis is presented in the evidence about the potential effect modification (of efficacy) that could result from bilateral implantation. Similarly, there is no analysis about the potential differential efficacy in relation to laterality (left/right implantation).
- The literature search picked up a number of relatively recent articles that involved using bioabsorbable/bioreabsorbable implants. These studies have not been included in this overview because of the likelihood of this type of implant having a significantly different impact on efficacy and/or safety.

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr John McKinley, Mr Andrew Robinson, Mr Paul Williams (British Orthopaedic Foot and Ankle Society), Mr Christopher Bradish, Mr Sunil Dhar, Mr Mark Flowers (British Society for Children's Orthopaedic Surgery), Mr Ralph Graham, Mr Stuart Metcalfe (The Society of Chiropodists and Podiatrists).

- Four Specialist Advisers have performed this procedure. Two stated that they perform it regularly, one has performed only two procedures, and another has performed fewer than 10 procedures in the last 6 years in both adult and paediatric populations. One Adviser only had experience in removing failed implants.
- One of the Advisers noted that indications for this procedure are different in paediatric and adult populations. Another highlighted that the procedure is more widely used in paediatric practice.
- Five Advisers considered the procedure to be novel and of uncertain efficacy and safety. The other three Advisers considered this procedure either to be established or a minor variation of an existing procedure, which is unlikely to alter the procedure's safety and efficacy. One Adviser added that many in the UK are sceptical about the procedure but that it is more widespread in other parts of Europe.
- The Advisers considered comparator procedures to include orthotic managements, soft tissue procedures or bone/joint realignment surgery with bone lengthening/arthrodesis and/or bone graft techniques (depending on patient selection and surgeon choice). One added that the decision about which procedure to use depends on the presentation of the condition. Another stated that treatment is usually not required in asymptomatic individuals (this is an important point of controversy).
- One Adviser commented that this procedure is often performed with other procedures.
- One Adviser commented that patient selection for this procedure is 'key'.
- All Advisers stated that minimal training is needed. One highlighted that surgeons who perform this procedure should have a background in orthopaedic surgery with an interest in either paediatric or foot and ankle surgery and should observe an experienced surgeon before performing the surgery themselves.
- With regard to the likely diffusion of this procedure, all Advisers stated that it has been around for many years. One stated that it hasn't been universally

taken up and another noted the increase in different implants, but these two Advisers both agreed that the potential impact on the NHS is minimal. One Adviser stated that there has been a large usage of this procedure, mostly by podiatric surgeons.

- Most of the Advisers acknowledged the controversy around this procedure and this was evident in their responses.

Efficacy

- Key efficacy outcomes that were considered by the Advisers included quality of life, pain relief, X-ray angles, gait analysis, normal foot shape and footwear, and clinical scoring scales (such as the AOFAS questionnaire, Child Health Questionnaire, Foot Health Status Questionnaire, or pedobarometric pressures studies pre- and post-surgery). Correction in the long-term was also important.
- One Adviser commented that there are no well-documented long-term reviews of the efficacy of this procedure. This Adviser also noted that various implants are available with no follow-up published and that all implants have slightly different design. The other Adviser also commented on the existence of controversy about whether or not there is adequate research on this procedure. This Adviser also noted that controversy exists around the use of biodegradable and non-biodegradable implants.
- One Adviser noted concerns around the efficacy of the procedure included whether it can reduce pain and correct the foot shape by clinical and radiological parameters.

Safety

- The Advisers considered theoretical adverse events to include infection, sural nerve injury, implant failure, intolerance or dislocation, wrongly positioning the device, breakage or extrusion, pain related to the implant, complete loss of subtalar movement, peroneal spasm, intraosseous cyst formation, and foreign

body granuloma formation with certain types of implants (such as biodegradable implants).

- Anecdotal adverse events included implant wear, persistent pain related to the implant and implant fracture, failure, ongoing pain, silicone synovitis (with silicone implants) and over-sizing of the implant causing complications and dislocation.
- One Adviser stated that the main concern with this procedure is the high number of patients suffering from long-term pain as a result of the procedure, which is sometimes alleviated with implant removal. Another stated that subtalar joint damage may develop into osteoarthritis.
- Another Adviser stated that adverse events related to older devices, such as the STA peg (which required bone cement and cutting into the calcaneus) and silicone-type implants, should be ignored. He stated that his advice is on the 'free-floating' device. He stated that the design of newer devices creates more stability and is less prone to adverse events.

Patient Commentary

NICE's Patient and Public Involvement Programme sent 6 questionnaires to 1 trust for distribution to patients who had the procedure (or their carers). NICE received 1 completed questionnaire.

The Patient Commentators' views on the procedure were consistent with the published evidence and the opinions of the Specialist Advisers.

Issues for consideration by IPAC

- One of the Advisers suggested that the title is changed to include: '…in both the adult and paediatric population' as indications may vary depending on the condition type.
- The selection of studies was made particularly difficult because of the large number of implants used for this procedure. It is unclear if the variations

between the different types of implants have a substantial impact on the safety or efficacy of the procedure.

- The use of this procedure in adults is likely to have significantly different efficacy and safety than on children whose feet are still growing. Some authors talk about the planned removal of implants in younger patients though the time at which this is done varies. A few authors have reported on foot alignment after removal of the implant.
- The literature that came back from the search spans a large period, reflecting the Specialist Adviser comments that this procedure has been around for a while.
- Some studies suggested 'per protocol' implant removal in at least some patients; some did not have a clear statement on this. Those studies that hinted at 'per protocol' implant removal at a later date did not give clear criteria/protocols for such removal.
- Postoperative care needs varied between studies.
- Some studies used bone cement (usually methyl methacrylate) to stabilise the implant. One Adviser mentioned that the STA peg, which is an older implant that required bone cement and cutting into the calcaneus, is no longer advocated. Of the studies in the overview, Lundeen et al. [3] described the use of bone concrete in the procedure, and extruded methyl methacrylate was described in Smith DK et al. [9]. At least one study [11] stated that cement was not used in their study because of earlier reports of extrusion of the cement.

References

1. Gutierrez PR and Lara MH. (2005) Giannini prosthesis for flatfoot. Foot & Ankle International 26:918-926.

2. Kuwada GT and Dockery GL. (1988) Complications following traumatic incidents with STA-peg procedures. Journal of Foot Surgery 27:236-239.

3. Lundeen RO. (1985) The Smith STA-peg operation for hypermobile pes planovalgus in children. Journal of the American Podiatric Medical Association 75:177-183.

4. Needleman RL. (2006) A surgical approach for flexible flatfeet in adults including a subtalar arthroereisis with the MBA sinus tarsi implant. Foot & Ankle International 27:9-18.

5. Rockett AK, Mangum G, and Mendicino SS. (1998) Bilateral intraosseous cystic formation in the talus: a complication of subtalar arthroeresis. [Review] [14 refs]. Journal of Foot & Ankle Surgery 37:421-425.

6. Scher DM, Bansal M, Handler-Matasar S et al. (2007) Extensive implant reaction in failed subtalar joint arthroereisis: report of two cases. Hss Journal 3:177-181.

7. Scialpi L, Mori C, Mori F et al. (2008) Arthroerisis with Giannini's endo-orthotic implant and Pisani's talocalcaneal arthroerisis. A comparison of surgical methods. Chirurgia Degli Organi di Movimento 92:61-65.

8. Siff TE and Granberry WM. (2000) Avascular necrosis of the talus following subtalar arthrorisis with a polyethylene endoprosthesis: a case report. [Review] [14 refs]. Foot & Ankle International 21:247-249.

9. Smith DK, Gilula LA, and Totty WG. (1990) Subtalar arthrorisis: Evaluation with CT. American Journal of Roentgenology 154:559-562.

10. Smith RD and Rappaport MJ. (1983) Subtalar arthroereisis. A four-year follow-up study. Journal of the American Podiatry Association 73:356-361.

11. Tompkins MH, Nigro JS, and Mendicino S. (1993) The Smith STA-peg: a 7-year retrospective study.[see comment]. Journal of Foot & Ankle Surgery 32:27-33.

12. Viladot A. (1992) Surgical treatment of the child's flatfoot. Clinical Orthopaedics & Related Research 34-38.

13. Black PRM, Betts RP, Duckworth T and Smith TWD. (2000) The Viladot Implant in Flatfooted Children. Foot & Ankle International 21:478–481.

Appendix A: Additional papers on Sinus tarsi implant insertion for mobile flatfoot

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Addante JB, Ioli JP, and Chin MW. (1982) Silastic sphere arthroereisis for surgical treatment of flexible flatfoot: a preliminary report. Journal of Foot Surgery 21:91–95	n = 2 feet (one 12 year old) Follow-up = 36 months	Ability to limit excessive pronation with no complications reported.	Larger studies of patients within this age group are included in table 2.
Addante JB, Chin MW, Loomis JC et al. (1992) Subtalar joint arthroereisis with SILASTIC silicone sphere: a retrospective study. Journal of Foot Surgery 31:47–51	n = 25 feet (15 patients, but 5 patients – 9 feet – lost to follow-up; in both adults and children) Mean follow-up = 54.5 months	7 had 'good' improvement in symptoms (no symptoms), 2 had 'fair' (occasional pain/discomfort), and one 'poor' (painful daily). Mean calcaneal inclination decreased from 16° to 12°; mean talar declination angle from 30.6° to 24.7°.	Larger studies of patients are included in table 2.
Adelman, V.R., J.A. Szczepanski, and R.P. Adelman, Radiographic evaluation of endoscopic gastrocnemius recession, subtalar joint arthroereisis, and flexor tendon transfer for surgical correction of stage II posterior tibial tendon dysfunction: a pilot study. J Foot Ankle Surg, 2008. 47(5): p. 400-8	n = 10 (mean age at time of surgery 56.9) Mean follow-up = not stated	This study measured the radiographic angles of patients who had previously undergone the procedure. 10% (1/10) required surgical removal for implant loosening. They reported sinus tarsitis in 4 patients (40%). This was transient in all but one which required removal (not clear if this was the same patient as above).	Larger studies of patients within this age group are included in table 2.
Bruyn JM, Cerniglia MW, and Chaney DM. (1999) Combination of Evans calcaneal osteotomy and STA-Peg arthroreisis for correction of the severe pes valgo planus deformity. Journal of Foot & Ankle Surgery 38:339–346.	n = 25 feet (20 patients in both adults and children) Mean follow-up = 25.6 months	Radiographs revealed improvement in angles, but 2 under corrected. Phone and mail questionnaire revealed 100% were satisfied/very satisfied. No reoperations required. Transient case of sinus tarsitis resolved with injection.	Larger studies of patients within this age group with longer follow-up are included in table 2.

Caranzza-Bencano A, Z|amora-Navas P, Fernandez-Velaquez JR. (1997) Viladot's operation in the treatment of the child's flatfoot. Foot & Ankle International 18(9):544–9.	n = 77 feet (43 patients aged 6–15 years). Mean follow-up = 6–14 years	75% (58) had 'normal' footprint; 5 overcorrection in younger patients. Results were classified as: 45 'excellent', 23 'good' and 9 as 'fair' or 'poor'. Wound dehiscence (6), deep infection requiring removal (2), prosthetic subluxation (1), prosthetic dislocation (1).	Outcomes are included in table 2.
Caranzza-Bencano A, Duque-Gimeno V, Gomez-Arroyo JA et al. (2000) Giannini's prosthesis in the treatment of juvenile flatfoot. Foot and Ankle Surgery 6:11-17.	n = 50 feet (50 patients aged 9 to 14) Mean follow-up = 6.4 years	At the final evaluation, results were the following in the cases: Excellent – 28% (14) Good – 4% (2) Fair – 62% (31) Poor – 6% (3)	Outcomes are included in table 2.
Cicchinelli LD, Huerta JP, Garcia Carmona FJ et al. (2008) Analysis of gastrocnemius recession and medial column procedures as adjuncts in arthroereisis for the correction of pediatric pes planovalgus: a radiographic retrospective study. Journal of Foot & Ankle Surgery 47:385–391.	n = 28 feet (20 patients, mean age 11.57) Mean follow-up = 35.9 weeks	Statistically significant differences in all angles measured.	Larger studies of patients within this age group with longer follow-up are included in table 2.
Cohen-Sobel E, Giorgini R, and Velez Z. (1995) Combined technique for surgical correction of pediatric severe flexible flatfoot. Journal of Foot & Ankle Surgery 34:183–194.	n = 1 foot (5-year old) Follow-up = 1 year	Mild pain in bad weather, can perform all physical activity. Mother rated results of operation 10/10.	Larger studies of patients within this age group are included in table 2.
Crawford AH, Kucharzyk D, Roy DR et al. (1990) Subtalar stabilization of the planovalgus foot by staple arthroereisis in young children who have neuromuscular problems. Journal of Bone and Joint Surgery – Series A 72:840–845.	n = 48 feet (30 patients, but 10 patients – 17 feet – lost to follow-up; aged 2–10) Mean follow-up = 4.1 years	Results in lateral talocalcaneal angle (radiologically and clinically) was satisfactory (excellent or good) in 84% (26) and unsatisfactory for 16% (5). Minor complications of infection, wound breakdown and neurovascular damage but none necessitated reoperation.	Larger studies of patients within this age group are included in table 2.
Forg P, Feldman K, Flake E et al. (2001) Flake-Austin modification of the STA-Peg arthroereisis: a retrospective study. Journal of the American Podiatric Medical	n = 40 feet (21 patients, mean age 9.7) Mean follow-up = 36 months	Subjective, objective and radiographic results were said to be positive. Complications included implant removal (2) because of an increase in symptoms, peroneal	Safety complications and larger studies of patients within this age group are included in table 2.

Association 91:394–405.		spasms after sports injury and recurring pain.	
Giannini S, Girolami M, and Ceccarelli F. (1985) The surgical treatment of infantile flat foot. A new expanding endo-orthotic implant. Italian Journal of Orthopaedics & Traumatology 11:315–322.	n = 32 cases (between 7 and 13 years old) Follow-up = 18 months minimum	Consistent and stable correction with some walking difficulty in some for 2–3 months after implantation. Planned removal in 6 and correction was maintained at 18-month follow-up.	Larger studies of patients within this age group are included in table 2.
Giorgini RJ, Schiraldi FG, and Hernandez PA. (1988) Subtalar arthroereisis: a combined technique. Journal of Foot Surgery 27:157–161.	n = 4 patients (not clear if unilateral or bilateral implants; from 2–12 years) Follow-up = 4 months to 6 years	Decrease in symptoms, hypermobility and increase function. Two extrusions (over 7-year period) and one case of superficial wound dehiscence.	Larger studies of patients within this age group are included in table 2.
Maxwell JR, Carro A, and Sun C. (1999) Use of the Maxwell-Brancheau arthroereisis implant for the correction of posterior tibial tendon dysfunction. Clinics in Podiatric Medicine & Surgery 16:479–490.	n = 1 adult Follow-up = 6 weeks	Foot alignment 'excellent' and reduction of inversion despite two falls postoperatively.	Larger studies of patients within this age group are included in table 2.
Nelson SC, Haycock DM, and Little ER. (2004) Flexible flatfoot treatment with arthroereisis: radiographic improvement and child health survey analysis. Journal of Foot & Ankle Surgery 43:144–155.	n = 67 feet (37 patients: 34 paediatric and 3 adult) Average follow-up = 18.4 months	Scores on patient questionnaire showed better results in role emotional behaviour, global behaviour and parent time than population norms. Loosening requiring reinsertion in 2 cases. Irritation requiring removal in 2 cases	Safety complications and studies with longer follow-up are included in table 2.

Oloff LM, Naylor BL, and Jacobs AM. (1987) Complications of subtalar arthroereisis. Journal of Foot Surgery 26:136–140.	n = 6 feet (3 patients aged 2, 11 and 13) Follow-up = not stated for each patient	1 case of medial displacement. 1 case of methylmethacrylate in sinus tarsi and detritic synovitis 3 months after surgery. 1 case of bulge over sinus tarsi indicating implant extrusion.	Safety complications and studies with longer follow-up are included in table 2.
Roth S, et al. (2007) Minimally invasive calcaneo-stop method for idiopathic, flexible pes planovalgus in children. Foot Ankle International 28(9): p. 991-5.	n = 94 procedures (48 patients from 8 to 14 years old) Follow-up = 5 years	Radiological and clinical improvement in heel valgus and longitudinal arch in all feet. All implants removed after 3 years per protocol.	Outcomes reported are already included in table 2.
Sanchez AA, Rathjen KE, Mubarak SJ. (1999) Subtalar stable arthroeresis for planovalgus foot deformity in children with neuromuscular disease. Journal of Pediatric Orthopaedics 19:34–38.	n = 34 feet (22 patients average 5 years old) Average follow-up = 5 years	Long-term results unpredictable. Revision required in 47% (16 feet) at an average of 39 months after surgery. 2 patients lost to follow-up.	Safety complications and larger studies of patients within this age group are included in table 2.
Smith SD and Millar EA. (1983) Arthrorisis by means of a subtalar polyethylene peg implant for correction of hindfoot pronation in children. Clinical Orthopaedics & Related Research 15–23	n = 53 feet (27 patients from 10 months to 17 years) Follow-up = 3–9 years	Appears to be effective at reducing excessive pronation. 17% (9) required additional mechanical support. Complications: pain and swelling (3), spontaneous remission (2), detritic synovitis following sports injury requiring revision (1), calcaneal fracture (1).	Safety complications and more recent studies of patients within this age group are included in table 2.
Smith SD and Wagreich CR. (1984) Review of postoperative results of the subtalar arthrorisis operation: a preliminary study. [Review] [26 refs]. Journal of Foot Surgery 23:253–260.	n = 20 feet (11 patients: 3–17 years) Follow-up = not clear in study	Significant differences in subtalar joint inversion and various angles. Noticeable subjective improvement in 10 of 11 patients. Reports only efficacy.	Larger studies of patients within this age group are included in table 2.
Solomon AD, Avery KB, and Weber RB. (2002) Surgical treatment of the pes planovalgus foot secondary to Ehlers-Danlos syndrome with the Maxwell-Brancheau subtalar arthroereisis. Foot 12:150–157.	n = 2 feet (1 patient, 15 years old) Follow-up = not stated	Stability was provided, avoiding the need for arthrodesis. There was a large amount of bleeding requiring overnight observation. Mild scar hypertrophy reported.	Larger studies of patients within this age group are included in table 2.
Subotnick SI. (1974)	n = 10 feet (10 children	Successful at limiting	Larger studies of

The subtalar joint lateral extra-articular arthroereisis: A preliminary report. J Am Podiatry Association: 64 (9): 701–711.	aged 2–17) Follow-up = 1 year	excessive movement. Incorrect placement of staple in a 2.5 year old requiring resurgery. Hip drop and weakness in 2 patients who had tendo Achilles lengthening as well.	patients within this age group are included in table 2.
Subotnick SI. (1977) The subtalar joint lateral extra-articular arthroereisis. J Am Podiatry Association: 67 (3): 157–171.	n = 14 feet (14 children aged 2–17) Follow-up = 1–3 years	Gait and joint function is improved. The same safety events were reported in the above publication by Subotnick.	Larger studies of patients within this age group are included in table 2.
Sullivan RW. (1985) Correction of the hypermobile flatfoot by the subtalar arthroeresis procedure. Military Medicine 150:546–548.	n = 2 feet (1 adult patient) Follow-up = 9 weeks	Improvement in stability and alignment. Asymptomatic 9 weeks after surgery. Calf stiffness and cramping 2 weeks following surgery.	Larger studies of patients within this age group are included in table 2.
Van Aman SE, Schon LC. (2006) Subtalar arthroereisis as adjunct treatment for type II posterior tibial tendon deficiency. Techniques in Foot and Ankle Surgery 5: 117–125.	n = 45 'cases' (not otherwise described) Follow-up = up to one year	Treatment benefit without additional risk of complications (no further detail on these patients provided).	Larger studies with longer follow-up and more information on outcomes are included in table 2.
Verheyden F, Vanlommel E, Van Der BJ et al. (1997) The sinus tarsi spacer in the operative treatment of flexible flat feet. Acta Orthopaedica Belgica 63:305–309.	n = 45 feet (29 patients, mean 9.8 years old) Mean follow-up = 34 months	Radiological improvement, but pain and functional impairment sustained after 5 months. Spacer dislocation frequent (22%, 10/45).	Outcomes reported and larger studies of patients within this age group are included in table 2.
Viladot R. (2003) Subtalar arthroereisis for posterior tibial tendon dysfunction: A preliminary report. Foot and Ankle International 24: 600–666.	n = 21 implants (21 patients, aged 20–78) Mean follow-up = 27.31 months	Average improvement of 47.3 to 81.6 AOFAS score and improvement of pain. 17/19 patients were satisfied or very satisfied. Removal required in 2 because of incorrect implant size.	Larger studies of patients within this age group are included in table 2.
Zaret DI and Myerson MS. (2003) Arthroerisis of the subtalar joint. [Review] [18 refs]. Foot & Ankle Clinics 8:605–617.	n = 43 (31 children, 12 adults) Follow-up = min 1 year	Difficult to determine if postoperative hindfoot motion was result of arthroereisis or adjunctive procedures. Postsurgical pain in 16% (7/43). Implant removal in 4 of these patients at mean 9 month follow-up (2 adults, 2 children).	Outcomes reported and larger studies of patients within this age group are included in table 2.

Zatti G, Teli M, Moalli S et al. (1998) Arthroresis in flexible flatfoot treatment: Comparative follow-up of two methods. Foot and Ankle Surgery 4:219–226.	n = 40 feet (25 patients, mean 11 years old) Average follow-up = 32 months	Improvement of symptoms in all feet and no recurrence of symptoms in 11 feet (7 patients) at 40 months follow-up. Pain requiring removal in one patient one year after implantation (one of bilateral implants). Broken talar screw requiring replacement was reported in 2 feet.	Safety complications and larger studies of patients within this age group are included in table 2.

Appendix B: Related NICE guidance for sinus tarsi implant insertion for mobile flatfoot

Guidance	Recommendations
Interventional procedures	**Metatarsophalangeal joint replacement of the hallux. NICE interventional procedures guidance 140 (2005)** 1.1 Current evidence on the safety and efficacy of metatarsophalangeal joint replacement of the hallux appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 Clinicians should ensure that patients fully understand the uncertainties about the place of this procedure in relation to alternative treatment options. Patients should be provided with clear written information and, in addition, use of the Institute's *Information for the public* is recommended. 1.3 Patient selection is important, and should take into consideration the likely intensity and duration of use of the joint based on the patient's activities and aspirations. 1.4 Further research will be useful in establishing the long-term outcomes of different types of prosthesis.

Appendix C: Literature search for sinus tarsi implant insertion for mobile flatfoot

Database	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	28/10/08	Issue 4, 2008	0
Database of Abstracts of Reviews of Effects – DARE (CRD website)	28/10/08	N/A	0
HTA database (CRD website)	28/10/08	N/A	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	28/10/08	Issue 4, 2008	1
MEDLINE (Ovid)	28/10/08	1950 to October Week 3 2008	120
MEDLINE In-Process (Ovid)	28/10/08	October 27, 2008	8
EMBASE (Ovid)	28/10/08	1980 to 2008 Week 43	157
CINAHL (Search 2.0, NLH)	28/10/08	1981 to present	39
BLIC (Dialog DataStar)	24/10/08	1993 to date	0
National Research Register (NRR) Archive	24/10/08	Nothing found	
UK Clinical Research Network (UKCRN) Portfolio Database	24/10/08	Nothing found	
Current Controlled Trials *meta*Register of Controlled Trials - *m*RCT	24/10/08	Nothing found	
Clinicaltrials.gov	24/10/08	Nothing found	

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Database: Medline - 1950 to October Week 3 200	
Search Strategy: ---------- 1 Subtalar Joint/su (301) 2 ((Subtalar$ or Subastragoid$) adj3 arthro$).tw. (384) 3 (Talocalcane$ adj3 arthro$).tw. (27) 4 (Sinus$ adj3 Tarsi$).tw. (120) 5 HyproCure.tw. (0) 6 Kalix.tw. (3) 7 Maxwell-Brancheau Arthroereisis.tw. (4) 8 Absorbable bioblock.tw. (0) 9 Conical subtalar implant.tw. (0) 10 Talar-fit.tw. (0)	

11	Horizon BioPro.tw. (0)
12	Endo-Orthotic Implant.tw. (3)
13	STA-peg.tw. (12)
14	Subtalar peg implant.tw. (0)
15	Giannini prosthesis.tw. (1)
16	or/1-15 (677)
17	Flatfoot/ (1439)
18	(Flat$ adj3 (foot$ or feet$)).tw. (526)
19	(Flatfoot$ or Flat-foot$ or Flatfeet$ or Flat-feet$).tw. (1034)
20	((Pes$ or Talipe$) adj3 Plan$).tw. (783)
21	(Fallen$ adj3 Arch$).tw. (7)
22	(Hyperpronat$ or Hyper-pronat$).tw. (33)
23	or/17-22 (2395)
24	16 and 23 (120)
25	Animals/ (4366113)
26	Humans/ (10754031)
27	25 not (25 and 26) (3277268)
28	24 not 27 (120)