National Institute for Health and Clinical Excellence

101– Sinus tarsi implant insertion for mobile flatfoot

Consultation Comments table

IPAC date: 15th May

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Specialist Advisor NHS Professional Consultant trauma and Orthopaedic surgeon	**1**	It would be worth mentioning that the overall alignment of the lower limb needs to be assessed, and on occasions corrected. As such this surgery should be undertaken in departments where surgery to the whole limb can be addressed, and preferable treated.	Thank you for your comment. No such evidence formed part of the reviewed studies.
2	Consultee 2 Specialist Advisor NHS Professional	**1**	1 I feel that the guidance should differentiate the proven benefits of the more modern devices compared with either the silicone or cemented devices.	Thank you for your comments. The IP programme does not compare the efficacy and safety of interventions against comparator interventions.
3	Consultee 2 Specialist Advisor NHS Professional		2 The decision as to which flat feet require treatment is not unique to arthroereisis. Â It will never be possible to see RCTs of treated v untreated matched groups over 50-60 years. Â NICE Â might wish to consider the impact of the alternative treatments for which there is equally little high level evidence. Â All of the alternative procedures are more complex, carry greater surgical risk and are not reversible in the same way the free-floating arthroereisis devices are. Â	The Committee encourages research into this procedure but the recommendations do not stipulate a specific study design.
4	Consultee 2 Specialist Advisor NHS Professional		3 Assuming treatment is deemed necessary which is judged on a case by case basis. Â Treatment is typically determined on a risk / benefit basis. Â Arthroereisis is the least invasive surgical option. Â Osteotomies, joint fusions, tendon transfers all represent more complex procedures.	Section 1.3 of the guidance has been changed to clearly state the patient group suitable for this procedure.

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5	Consultee 3 Private Sector Professional Bupa Employee	**1**	Essentially, Bupa agrees. Is it possible, given the current state of knowledge, to expand section 1.3? If it is not being categorised as research only some indication of the characteristics of suitably highly selected patients would be helpful.	Thank you for your comment. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated.
6	Consultee 4 Private Sector Professional	**1**	Specific detail of audit/outcome tool to be used. Advice please where surgeon not employed by local trust...private provider clinical governance department involvement	Thank you for your comment. Section 3.1 of the guidance states that NICE is producing audit criteria which will be published on the NICE website with the final guidance.
7	Consultee 5 NHS Professional	**1**	Mobile flat foot does not usually result from tendon damage in children. Â it is usually found to be a flattening of the medial arch that is evident on standing still but which is fully correctable when the child stands on tiptoes. Â It is in fact a feature of ligamentous laxity and does indeed tighten up over time. Â There are no studies that show that treatment of this type of fully correctable flat foot with orthotics is helpful or necessary. Â The condition in children is effectively a normal variant and does not warrant treatment other than reassurance. Where there is no correction on standing on tiptoes or where there is indeed pathological laxity (Ehlers Danlos etc) it is a different situation and the clinical cause needs to be addressed accordingly. Adult Acquired Flat Foot deformity is commonly due to tendon degeneration and this is an altogether different entity. My reading of the outcomes of arthroereisis in mobile flat foot in children would suggest that implant failure and pain should be expected. I strongly recommend that NICE does NOT recommend this procedure for mobile flatfoot in children which is a normal variant.	Thank you for your comment. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated.
8	Consultee 6 Specialist Advisor NHS Professional President British Society for Children's Orthopaedic Surgery	**1**	I agree [with] this section	Thank you for your comment.

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9	Consultee 7 consultant orthopaedic foot and ankle surgeon NHS Professional	**1**	Full agreement	Thank you for your comment.
10	Consultee 8 Specialist Advisor NHS Professional	**1**	The provisional recommendations are appropriate. Â In particular the fact that surgery for flatfeet in children is rarely indicated needs emphasis. Â The incidence of flatfoot in 1 year olds is 90%, in adults it is 20%. Â This shows that resolution is common and that flat feet amongst adults is so common as to be a normal finding. Â In addition flat feet are normally asymptomatic the inappropriateness of operating on asymptomatic individuals needs emphasis in the advice.	Thank you for your comment. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated.
11	Consultee 1 Specialist Advisor NHS Professional Consultant trauma and orthopaedic surgeon	**2.1**	I would not encourage, or even mention the use of steroid injections, as these can lead to tendon rupture	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
12	Consultee 2 Specialist Advisor NHS Professional	**2.1**	2.1.1 Â Should specifically refer to "Flexible flat foot. Rigid flat foot is Â different entity for which arthroereisis is contra-indicated.	Thank you for your comment. The title of this guidance states that this procedure is for mobile flat foot (the overview specifies that mobile is another term for flexible flatfoot).
13	Consultee 2 Specialist Advisor NHS Professional	**2.1**	2.1.2 Flexible flat foot is normal in children up until age 5 yrs. Â Severe flexible flat foot even in young children may be associated with disability. Although many children + adults may have no symptoms, some do. Â Symptoms may include, muscle fatigue, tendon / ligament pain, abnormal shoe wear.	Noted, thank, you.
14	Consultee 2 Specialist Advisor NHS Professional	**2.1**	2.1.4 Orthotics (foot supports) are usually used for first line treatment. Â Physiotherapy has not been shown to correct flat feet.	The list of current treatments and alternatives is not intended to be definitive.

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15	Consultee 2 Specialist Advisor NHS Professional	**2.1**	2.1.4 Corticosteroids are not used to treat flat feet Surgical decompression is not used to treat flat feet. Â Both of the above I imagine are mixed up for the management of tendinopathy which is sometimes seen in association with flat foot deformity. Â Surgical correction may involve: i) Â Arthroereisis ii) Lengthening of the calcaneus (needs bone graft) iii) Medial calcaneal displacement osteotomy iv) Isolated joint fusions v) Tendon repair / augmentation vi) Lengthening of the Achilles tendon or Gastrocnemius recession Adults frequently require combination of procedures because of 2ndry deformity.	The Committee considered this comment but decided not to change the guidance. The list of current treatments and alternatives is not intended to be definitive.
16	Consultee 3 Private Sector Professional Bupa Employee	**2.1**	2.1.2: is it the case that the self resolving phase is usually up to around six years old, and that children between 6 and puberty might have capacity to benefit eg be some of the highly selected patients of section 1.3?	Thank you for your comment. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated. There is no evidence available to stipulate these ages in the guidance.
17	Consultee 9 Specialist Advisor NHS Professional	**2.1**	Should only be considered in children who have failed conservative management.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
18	Consultee 5 NHS Professional	**2.1**	No evidence to support the use of orthotics in true mobile flat foot in children.	Thank you for your comment. Section 2.1 of the guidance lists some alternative treatments which have been used to treat this condition. The IP Programme does not compare the efficacy and safety of interventions against comparator procedures.
19	Consultee 6 Specialist Advisor NHS Professional President British Society for Childrens Orthopaedic Surgery	**2.1**	Flat foot can be looked upon as normal in the infant population, with the arch gradually developing. The majority of flat feet in children are asymptomatic and there is a danger of offering surgery in the asymptomatic population because of parental pressure. You correctly identify that flat feet can be associated with neuromuscular conditions such as cerebral palsy or gross ligamentous laxity. It is important that these conditions are correctly identified and therefore in children the assessment and management should be under the care of a childrens orthopaedic surgeon, who is trained in the assessment of the whole child, rather than one purely trained in the management of foot disorders.	Thank you for your comment. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated.

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20	Consultee 7 consultant orthopaedic foot and ankle surgeon NHS Professional	**2.1**	The indications for surgery should be valid and uneqivocal. Childrens flatfoot is frequently asymptomatic and fully functional. Cosmetic anxiety is no reason for a surgical assault.	Thank you for your comment. Section 2.1 of the guidance specifies the indications for treatment. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated.
21	Consultee 8 Specialist Advisor NHS Professional	**2.1**	Children with conditions and syndromes such as those listed in 2.1.2 should be under the care of a suitably trained paediatric orthopaedic surgeon who can take a holistic view. Treatment of the feet in isolation is inappropriate.	Thank you for your comment. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated.
22	Consultee 5 NHS Professional	**2.2**	Any implant that produces synovitis, breaks or causes a patient to be in pain such that it has to removed should be avoided. The only indication I am able to understand would be where the implant allows the cartilaginous anlage and subsequent ossification to change the bone morphology such that by maturity there is sustained correction once the implant is removed. Â This would clearly be for situations where the natural history is that the condition remains. Â There is however no evidence that mobile flat feet in childhood go on to develop degenerative disease and deformity. Â Indeed, there appears to be a natural resolution which implies that the body corrects spontaneously. Â In my opinion therefore there is no indication for this procedure in children with mobile flat feet.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated.
23	Consultee 6 Specialist Advisor NHS Professional President Bristish Society for Childrens Orthopaedic Surgery	**2.2**	I agree [with] this section	Thank you for your comment.
24	Consultee 2 Specialist Advisor NHS Professional	**2.3**	A number of cadaver studies have demonstrated significant reduction in stress to ligaments on the feet with this technique.	Thank you for your comment. This evidence is not relevant to the scope of the assessment of this procedure.
25	Consultee 4 Private Sector Professional	**2.3**	important not to mix data on different types of SinusTarsi implants that are different in material and design	Thank you for your comment. The IP Programme does not deal with assessment of specific devices. The guidance will be changed at section 2.1 to clarify that a number of devices can be used in the procedure.

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26	Consultee3 Private Sector Professional Bupa Employee	**2.3**	I cant follow section 2.3.1.	Thank you for your comment.
27	Consultee 5 NHS Professional	**2.3**	Outcomes for the case series 2.3.1 above as stated make no sense. The main outcome measure must be a quality of life indicator such as pain relief and improvement in function. Â In view of the fact that pain and functional limitation are not features of mobile flat foot in children this procedure is not indicated. Â Indeed, if it then gives rise to pain and functional limitation which, from my reading has been described, it is contraindicated.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
28	Consultee 6 Specialist Advisor NHS Professional President Bristish Society for Childrens Orthopaedic Surgery	**2.3**	I agree [with] this section	Thank you for your comment.
29	Consultee 8 Specialst Advisor NHS Professional	**2.3**	It does appear that much of the evidence considered and given prominence in the review was by authors I recognise as having a hand in the design of the prostheses and presumably a financial interest. Â I believe the advisors should reconsider this before definitive advice is given. Readers attention should be drawn to this with respect to several of the prostheses/techniques. Â In the only British study that seems to have been considered the procedure was found to be inneffective - should this not have been given more prominence ?	Thank you for your comment. The choice of studies for data extraction in table 2 of the overview was based on the study design and quality, number of patients included and the length of follow-up. The UK study will be added to table 2 in the overview.
30	Consultee 2 Specialist Advisor NHS Professional	**2.4**	It would be helpful to have the references used here to better understand the validity of these citations. Â Are all these complications associated with the newer free floating non silicone devices.	Thank you for your comment. The overview provides more details about individual studies.
31	Consultee 5 NHS Professional	**2.4**	As per Specialist Advisors. The evidence is not there for NICE to support this procedure in flexible flat foot in children. Â Nor is it there to support selected cases and I advise it be contraindicated in these children.	Thank you for your comment. Section 1.3 of the guidance will be changed to further describe patient groups for whom this procedure may be indicated.

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32	Consultee 6 Specialist Advisor NHS Professional President Bristish Society for Childrens Orthopaedic Surgery	**2.4**	I agree [with] this section	Thank you for your comment.
33	Consultee 8 Specialist Advisor NHS Professional	**2.4**	A 10% failure rate at 1 year would not be considered acceptable for other prostheses. Â Again the failure rate in the only British study was very high, reported despite the authors initial enthusiasm for the concept. Â One of the authors of that study has considerable experience advising government and should be specifically consulted.	Thank you for your comment. The consultee is referring to the Black et al (2000) study in appendix A. The failure rate in the study quoted is 36% (out of 22 implants). The studies presented to the Committee included one which reported a failure rate of 39% (11/28). The choice of studies for data extraction in table 2 was based on the study design and quality, number of patients included and the amount of follow-up. Specialist Advisers consulted in the course of the development of this guidance were nominated by their professional organisations.
34	Consultee 5 NHS Professional	**General**	I have been asked to comment on the procedure for the working party. Â I am on the executive committee of the British Society for Childrens Orthopaedic Surgery. Â This input source is not stated in your website article. Â Given that the procedure is proposed for children I would expect this source of advice to be stated and considered highly important.	Thank you for your comment. This society was approached for specialist advice, and this fact will be added to the overview.