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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Implants for mobile flatfoot

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how implants can be used in the NHS to treat people with mobile flatfoot. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because there is not a lot of information about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe mobile flatfoot or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 7.

What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. If a surgeon wants to insert an implant for mobile flatfoot, they should make sure that extra steps are taken to explain the uncertainty about how well it works and that success may depend on the cause of flatfoot, as well as the uncertainty surrounding potential risks of the procedure. They should also explain that additional procedures may be needed and that the implant may later need to be removed. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

The procedure should not be used for most children with mobile flatfoot. It may be used for selected children with mobile flatfoot caused by neuromuscular diseases (such as polio, spina bifida and cerebral palsy), skeletal dysplasia or ligamentous laxity (loose joints). It should only be performed by a team of specialist doctors and healthcare professionals. It may rarely be used for adults who have been very carefully selected as suitable.

NICE has encouraged further research into implants for mobile flatfoot. Studies should include details of which patients are selected, whether it is suitable for adults or children, whether any additional procedures were carried out and give results over a long period. Studies that compare the progress of patients who have the implant with those whose feet are left untreated would also be useful. NICE may review the procedure if more evidence becomes available.

Implants for mobile flatfoot

This procedure may not be the only possible treatment for mobile flatfoot. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is 'sinus tarsi implant insertion' or 'subtalar arthroereisis' for mobile flatfoot. The procedure is not described in detail here – please talk to your surgeon for a full description.

Flatfoot is a condition in which the arch of the foot has dropped and the foot lies flat to the ground. In rigid flatfoot the foot is permanently flat, whereas in mobile (also known as flexible) flatfoot the arch disappears on standing but reappears when sitting or standing on tiptoe. Mobile flatfoot is common and usually painless, particularly in children. However, some people do have foot pain. Most children and adults with mobile flatfoot do not need treatment, but supportive insoles and physiotherapy may help. Very rarely, surgery may be needed depending on the cause.

Implant insertion is carried out under a general or local anaesthetic. A cut is made on the outer side of the foot and the implant is placed into the space (called the sinus tarsi) between the heel bone and the bone in front of it. The implant devices vary in type, size and shape, but all aim to hold the arch of the foot up and correct the flatfoot. Depending on the cause, additional procedures may be carried out at the same time to the tendons and bones of the foot. After the procedure, a dressing or plaster cast and modified footwear and/or insoles may be used. In children, the implant may need to be removed at a later stage to allow for growth.

What does this mean for me?

If your surgeon has offered you an implant for mobile flatfoot, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your surgeon should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your surgeon before making your decision.

NICE has also decided that more information is needed about this procedure. Your surgeon may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?

Summary of possible benefits and risks

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 12 studies on this procedure.

How well does the procedure work?

In a study of 54 patients who were treated with an implant for mobile flatfoot, nearly a quarter of the patients said that their symptoms had completely gone and most had some reduction in their symptoms an average of 2 years later. Only 3% had no reduction in their symptoms at all.

Foot pain was reported before and after the procedure in a study of 37 patients. Before the operation, 22 patients had pain, whereas after the operation only 2 reported pain. In a study of 23 patients, it was found that patients who had the procedure had less pain after an average of 44 months.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the main success factors are quality of life, pain relief, improvement shown on X-rays, improved walking, normal foot shape and footwear, long-term improvement and using a scoring system to measure improvement.

Risks and possible problems

The percentage of patients who needed the implant removed varied from less than 1% to 39% in different studies. A patient had a fracture to the lower ankle bone 6 years after the procedure in one study, and a patient had loss of blood supply and collapse of a foot bone after 10 years in another. In other studies, problems included the development of fluid-filled holes (cysts) and bony lumps (spurs) on the ankle bone, severe hardening of the ankle bone, fragments found in the space in front of the heel bone and movement of the implant.

The study of 54 patients found that the implant moved out of place in 9% of feet after 1 year. In a study of 49 patients, fragments of either bone or implant were found in the space between the heel bone and the next bone in 1 foot.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that injury to nerves and loss of foot movement are possible problems.

More information about flatfoot

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. This guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'Sinus tarsi implant insertion for mobile flatfoot'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG196

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1903). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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