

Understanding NICE guidance

Information for people who use NHS services

Attaching a prosthetic limb or digit directly to bone

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

This leaflet is about when and how attaching a prosthetic limb or digit directly to bone can be used in the NHS to treat people who need a prosthetic limb or digit. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures 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 the procedure is quite new. This means that there is not a lot of information yet 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 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.

What has NICE said?

For some patients, this procedure may have advantages over traditional socket prosthetic limbs. However, there is not much good evidence about how well this procedure works or how safe it is, particularly in the long term. If a doctor wants to use this procedure, he or she should make sure that extra steps are taken to explain the uncertainty about how well it works, (especially in the long term) as well as the uncertainty surrounding potential risks of the procedure. 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.

A team of specialist doctors should decide which patients should be offered this procedure. The team should include a surgeon experienced in amputation and bone and tissue reconstruction, as well as rehabilitation specialists, including an expert in prosthetics and implant design.

Further information on the safety of this procedure and how well it works will be helpful. NICE is encouraging doctors to do more work in collecting and publishing information about this procedure. NICE may look at this procedure again if more information becomes available.

Attaching a prosthetic limb or digit directly to bone

This procedure may not be the only possible treatment. 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 'direct skeletal fixation of limb or digit prostheses using intrasosseous transcutaneous implants'. The procedure is not described in detail here – please talk to your specialist for a full description.

If a leg, arm, finger or thumb has been amputated or is missing at birth, an artificial substitute (known as a prosthetic limb if it relates to the arm or leg, or a prosthetic digit if it relates to a finger or thumb) may be fitted. Prosthetic limbs and digits usually have a socket and are held in place either by suction or by being strapped to the stump of the missing limb or digit. There may be rubbing between the stump and the socket, causing pain and the development of sores. Another way of attaching a prosthetic limb or digit involves a type of surgery in which the prosthesis is attached directly to the person's bone. This is known as direct skeletal fixation. The aim of this surgery is to produce a more comfortable and securely attached prosthetic limb or digit.

The surgery is done in two parts, which may be as two separate operations or as two stages in the same operation. The first part is to insert a metal implant into the bone of the stump. If two separate operations are being done, the wound is closed and left to heal, usually for 3 to 6 months. During this time it is expected that new bony tissue will

grow around the implant and anchor it in place. The second part of the procedure is then done to attach the prosthetic limb or digit by means of a connecting piece known as an abutment. One end of the abutment is inserted through the skin and connected to the implant. The other end is left exposed and the prosthetic limb or digit is attached to it. In the single operation both stages are done at the same time.

What does this mean for me?

If your doctor has offered you this procedure he or she should tell you that NICE has decided that the benefits and risks are uncertain, particularly about how well it works in the long term. This does not mean that the procedure should not be done, but that your doctor 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 doctor before making your decision.

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?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

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

How well does the procedure work?

One study looked at 43 patients who had an above the knee prosthetic leg held in place using a socket and 20 patients who had a prosthetic leg attached directly to the bone. Sixteen patients in the socket group reported restricted hip movement, compared with no patients in the bone group. Nineteen patients in the socket group reported 'moderate trouble' or 'a great deal of trouble' when sitting, compared to only 1 patient in the bone group. A second study of 32 arm or leg amputees showed that sensory appreciation of the prosthesis was better in patients who had the limb attached to the bone.

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

In a third study of 11 above the knee amputees who had this procedure, 9 were able to use their prosthesis all the time; however 5 of them had damaged the abutment section during a fall so had to have it replaced. A fourth study of 3 patients who had finger prostheses reported that the patients were able to use the prostheses normally when their progress was checked for up to 2 years after the procedure.

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 aim is for the procedure to work better than traditional surgery for patients who need a prosthesis fitting to a short amputation stump.

Risks and possible problems

In the study of 11 patients, 2 patients developed an infection more than a year after the procedure. The infection meant that the implant had to be removed.

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 possible problems include infection, problems with the implant itself and damaging the abutment section during a fall.

More information about prosthetic limbs

Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice 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. Interventional procedures 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 'direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IIPG270

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1633).

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

National Institute for Health and Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

ISBN 1-84629-756-7
N1633 1P Jul 08