NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant

If all or part of a leg or arm (limb), is missing at birth or amputated, an artificial limb (prosthesis) may be fitted. A prosthesis usually has a socket and is held in place by suction or by being strapped to the stump of the missing limb. A poor fit can lead to skin irritation and infection. In this procedure, a metal implant is inserted through the skin (transcutaneous) and into the centre of the bone (intraosseous) of the stump. A prosthesis is then attached to the metal implant (direct skeletal fixation). The aim is to produce a more comfortable and secure attachment for the prosthesis, and to prevent infection.

NICE is looking at direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant. This is a review of NICE's interventional procedures guidance on direct skeletal fixation of limb or digit prostheses using an intraosseous transcutaneous implant.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 24 July 2024

Target date for publication of guidance: November 2024

1 Draft recommendations

1.1 Direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant can be used in the NHS while more evidence is generated. It can only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wanting to do direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team with specific training and experience in the procedure and should include:

- an orthopaedic surgeon experienced in amputation and device implantation
- a plastic surgeon with experience in the necessary bone and soft tissue reconstruction
- an anaesthetist and
- rehabilitation specialists including:
  - experts in prosthetics
  - occupational therapists and
  - clinical psychologists.

1.5 The procedure should only be done in specialised centres by a multidisciplinary team with specific training and experience in the procedural techniques, and management and rehabilitation after the procedure.

Why the committee made these recommendations

The evidence for this procedure is limited in quality and mainly from observational studies. Short-term evidence suggests that people who have it after an amputation above the knee:

- have improvements in quality of life and
- are better able to carry out normal daily activities.

But there is evidence of serious complications such as fractures and infections. These can lead to additional treatments and surgery, which can have significant impact on a person's mental health.

It is unclear how well the procedure works in the long term or who would benefit most from having it. So, this procedure can only be used with special arrangements.

2 The condition, current treatments and procedure

The condition

2.1 Limb amputation is traumatic and affects quality of life. Lower-limb amputation (above or below the knee) is the most common reason for a person to use a prosthetic limb (customised prosthesis). The most common reason for lower-limb amputation is peripheral vascular disease. Other causes include trauma, infection, diabetes and cancer. Upper-limb amputations are less common and are mainly a result of trauma. A small proportion of people need prosthetic limbs because of congenital limb loss or deformities.

Current treatments

2.2 The customised prosthesis is fitted to replace the function of the missing limb and provide cosmesis for major amputations. The type of prosthesis depends on what part of the limb is missing. Conventionally, the prosthesis is attached to the residual stump by belts and cuffs, suction, or by a suspension system. The conventional prosthesis usually has a socket, which is custom made from a plaster cast of the stump. One of the main problems with this type of prosthesis is rubbing between the stump and the socket. This can cause pain, ulceration and improper distribution of body weight that can affect balance and lead to falls. This may mean the user has limited use of the prosthesis or may have to abandon it for a period because of poor fit.

The procedure

2.3 The procedure aims to surgically insert an OIP implant, producing a secure connection between the remaining bone and the implant for prosthetic attachment. The implant may be in 1 piece or modular with a separate small, metal extension (abutment).

2.4 The advantages of direct skeletal fixation of an OIP implant are:

- proper transfer of load from the prosthesis to the person's body
- better function and mobility (such as walking)
- improved comfort while sitting
- better balance
- fewer stump problems
- increased prosthesis use, and
- improved quality of life.

The potential problems are:

- soft tissue infection at the interface between the skin and the prosthesis
- deep infection
- fracture or loosening around the implant, and
- implant failure.

2.5 Direct skeletal fixation of limb prostheses using an OIP implant is done under general or regional anaesthesia (depending on the level of amputation). It is usually done in 2 operations separated by a period of time. In the first stage, a metallic implant (with either an outer surface threaded like a screw or a press-fit design) is inserted into the medullary cavity of the residual bone. Then healing components are attached to the implant to secure the bone graft during the healing period. The second stage of the procedure is done about 2 to 6 months later, after the implant has integrated into the bone (osseointegration) and the stump wound is completely closed and healed. It involves surgically removing the healing components and re-exposing the distal end of the implant. It is then attached to an abutment with an abutment screw or bridge component. The wound is closed with the abutment penetrating the skin. The external limb prosthesis can then be attached to the OIP

implant using various components, depending on the level of amputation.

2.6 The procedure may also be done in a single stage in which the 2 operations are done sequentially during a single session. But the 2-stage procedure is more common.

2.7 A period of extensive physiotherapy and rehabilitation follows, and the load on the prosthesis is gradually increased until full weight-bearing is allowed a few weeks later.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 1 HTA, 3 systematic reviews, 2 retrospective cohort studies, 2 retrospective reviews, and 1 cross-sectional observational study. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts, patient representatives and the committee considered the key efficacy outcomes to be: improvement in mobility, reduction in falls and quality of life.

3.3 The professional experts, patient representatives and the committee considered the key safety outcomes to be: pain, infection, fractures, implant failure, osteomyelitis, need for device removal and potential limb shortening.

3.4 Seventeen commentaries from people who have had this procedure were discussed by the committee. Submissions provided by 1 patient organisation representing people who have had this procedure were discussed by the committee.

Committee comments

3.5 Most of the evidence reviewed was in people who had above-knee amputations.

3.6 This procedure could provide significant benefit in some people who are unable to tolerate a conventional prosthesis and could provide a dramatic improvement in quality of life.

3.7 This procedure may be paired with a microprocessor prosthetic.

3.8 People being considered for the procedure should be informed of the significant risk of infections.

3.9 Appropriate post-operative care including management of soft tissues and long-term rehabilitation is important.

3.10 Patient commentary was mixed and included examples of both profoundly positive and negative experiences, but all people responding to the survey said they would recommend this procedure to another person in the same situation.

3.11 The patient experts explained how the procedure could be life-changing for some people but there is always a risk of complication. One patient expert said that infection can be extremely serious and lead to the further loss of bone. Both experts agreed that patient selection was a vital factor in deciding who has the procedure but that age should not predetermine whether someone is able to adhere to rehabilitation or recovery.

3.12 There is more than one device, and the technology and procedure are evolving.

3.13 The committee were informed that it is more difficult to secure an implant in a tibia than a femur, because of the shape of the bone.

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Chair, interventional procedures advisory committee
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