NICE guidance

Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants may have potential advantages for some patients compared with conventional prosthetic sockets. However, current evidence on the safety and efficacy of this procedure is inadequate in quantity and there is a lack of long-term follow-up. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, in particular with regard to the longer term, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants (see section 3.1).

1.3 Patient selection should be carried out by a multidisciplinary team which should include a surgeon experienced in amputation and in the necessary bone and soft tissue reconstruction, and rehabilitation specialists, including experts in prosthetics and implant design.

1.4 Further publication of safety and efficacy outcomes will be useful. Clinicians are encouraged to collaborate in the collection and publication of data, particularly in relation to adverse events such as infection and long-term performance of the implants. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 In the UK, lower limb amputation is the most common indication for a prosthesis. Amputation is most frequently a consequence of peripheral arterial disease; other causes include trauma or tumour. Upper limb or digit amputations are less common and usually result from trauma. A small proportion of patients require a prosthesis for a congenital deficiency.

2.1.2 Conventionally, the prosthesis is attached to the residual stump by belts and cuffs or by suction. The prosthesis usually has a socket, which is custom made from a plaster cast of the stump. However, friction between the stump and socket can cause pain and ulceration. Stump problems may significantly limit users of conventional prosthetic limbs.

2.2 Outline of the procedure

2.2.1 The procedure aims to establish an osseointegrated implant, produce a secure junction between the soft tissues and the implant to prevent infection, and provide an abutment for prosthetic attachment. The implant may be in one piece or modular (with a separate abutment) and its surface may be modified (for example, using a screw thread, a porous or roughened surface or adding a special coating) to enhance bone and soft tissue integration. During the procedure, the implant is introduced into the medullary cavity of the residual bone. The procedure may be done during a single operation (in which the wound is closed with the abutment protruding through the skin) or in two stages (first stage: insertion of the implant and second stage: attachment of the abutment). A

period of rehabilitation is usually required.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, see the overview.

2.3.1 A non-randomised comparative study of patients with transfemoral amputations reported restriction of hip flexion in 37% (16 out of 43) of patients treated with a socket prosthesis compared with 0% (0 out of 20) of patients treated with direct skeletal fixation of a limb prosthesis using an intraosseus transcutaneous implant (osseointegrated prosthesis) (p value not stated). 'Moderate trouble' to 'a great deal of trouble' when sitting was reported by 44% (19 out of 43) and 5% (1 out of 20), respectively. In a second non-randomised comparative study of 32 patients with upper or lower limb amputations, patients treated with bone-anchored prostheses demonstrated significantly lower thresholds for vibratory stimulation of the prosthetic limb than patients treated with socket prostheses (73.1 to 84.7 Hz and 84.9 to 95.4 Hz, respectively; $p<0.05$).

2.3.2 In a case series of 11 patients with transfemoral amputations, 9 patients (82%) used their osseointegrated prosthesis all day, every day (mean follow-up period not stated). This study reported that 45% (5 out of 11) of patients had implant abutments replaced because of damage caused by falls. A case series of 3 patients with finger amputations reported that all patients were able to perform normal daily activities using the prosthesis at follow-up periods of 16, 19 and 24 months.

2.3.3 One Specialist Adviser considered a key efficacy outcome to be improved function for patients with high amputations compared with conventional prostheses.

2.4 Safety

2.4.1 In the case series of 11 patients, infection requiring removal of the abutment and implant was reported in 18% (2 out of 11) of patients with transfemoral amputations (both after 1 year).

2.4.2 The Specialist Advisers listed anecdotal adverse events including infection and failure at the interface between the skin and the implant, peri-implant bone infections, loosening of the implant fixture, abutment deformity after falls and abutment fracture.

2.5 Other comments

2.5.1 The Committee noted that the technology for this procedure is continuing to develop and this may influence long-term outcomes.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.