National Institute for Health and Clinical Excellence

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

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NICE interventional procedure guidance 270

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Contents

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 the Institute's information for patients ('Understanding NICE guidance') 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. The Institute may review the procedure upon 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.

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, refer to the Sources of evidence.

2.3 Efficacy

2.3.1 A non-randomised comparative study of patients with transfemoral amputations reported restriction of hip flexion in 37% (16/43) of patients treated with a socket prosthesis compared with 0% (0/20) 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% (19/43) and 5% (1/20), 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 (73.1–84.7 Hz and 84.9–95.4 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% (5/11) 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% (2/11) 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. The Institute 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 describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

10 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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