NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of direct skeletal fixation of limb or digit prostheses using an intraosseous transcutaneous implant

If a leg, arm, finger or thumb has had to be amputated, or is missing at birth, an artificial substitute (known as a prosthetic limb or prosthesis) may be fitted. Prosthetic limbs usually have a socket and are held in place either by suction or by being strapped to the stump of the missing limb. In this procedure, a metal implant is inserted through the skin and into the centre of the bone of the stump. A prosthetic limb is then attached to the metal implant. The aim is to produce a more comfortable and securely attached prosthetic limb.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in January 2008.

Procedure name

- Direct skeletal fixation of limb or digit prostheses using an intraosseous transcutaneous implant

Specialty societies

- British Association of Plastic, Reconstructive and Aesthetic Surgeons
- British Limb Reconstruction Society
- British Orthopaedic Association
- British Orthopaedic Oncology Society
- British Society for Surgery of the Hands

Description

Indications

Lower limb amputation is the most common indication for use of a prosthetic limb in the UK. The most frequent reason for lower limb amputation is peripheral vascular disease, but other causes include trauma and tumours. Upper limb amputations are less common and are mainly a result of trauma. A small proportion of patients require prosthetic limbs because of congenital deficiency.

The Q-TFA (Questionnaire for Persons with a Transfemoral Amputation) is a self-report outcome measure designed to reflect current prosthetic use, mobility, problems and global health in non-elderly persons using a socket or osseointegrated prosthesis.

Current treatment and alternatives

The object of a prosthesis is to help replace as much of the function of the missing limb as possible, and to provide cosmesis. 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 or suction. The 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, which causes pain and ulceration. This may mean the user has to abandon the prosthesis for a period. Stump sores are one of the major causes of limitation for users of conventional prosthetic limbs.

What the procedure involves

Direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant may be carried out in two separate operations or sequentially as a single operation. In the first stage, a metallic implant is inserted into the medullary cavity of the residual bone. If two operations are being done, the stump wound is completely closed and allowed to heal. The implant may be in one piece or modular, with a separate abutment. The surface may be modified (for example by means of a screw thread, porous or roughened surface or addition of a special coating) to enhance bone and soft tissue integration. The second stage of the procedure is undertaken either at the same operation or approximately 3–6 months later, once osseointegration has taken place. It involves surgically re-exposing part of the implant and connecting it to a small metal extension, known as an abutment. The wound is closed with the abutment penetrating the skin, allowing attachment of the external prosthesis to the intraosseous implant. If the prosthesis is load-bearing, a period of rehabilitation follows during which a training prosthesis is used.

Theoretically, the potential advantages of direct skeletal fixation are the avoidance of stump problems and better transfer of load from the prosthesis to the human body which in turn allows better function. The potential problems

are infection at the interface between the skin and the prosthesis, fracture or loosening around the implant and deep infection.

Efficacy

A non-randomised comparative study of patients with transfemoral amputation reported that 37% (16/43) of patients with a socket prosthesis had restricted hip flexion compared with 0% (0/20) patients with an osseointegrated prosthesis (p value not stated)[1]. In the group with a socket prosthesis, 44% (19/43) had moderate to great difficulty when sitting, compared with 5% (1/20) of patients with an osseointegrated prosthesis. In a second non-randomised comparative study of 32 patients with upper or lower limb amputation, patients who had bone-anchored prostheses demonstrated significantly lower thresholds for detection of vibratory stimulation of the prosthetic limb compared with patients who had socket prostheses (73.1 Hz – 84.7 Hz compared with 84.9 Hz – 95.4 Hz, $p < 0.05$) [2]. Patients who had bone-anchored prostheses also demonstrated lower thresholds for detection of vibratory stimulation of the prosthetic limb compared with patients who had socket prostheses, but this difference was not statistically significant [2].

In a case series of 11 patients with transfemoral amputations, 9 (82%) used their osseointegrated prosthesis all day every day (mean follow-up period not stated). In this group, 45% (5/11) of patients had abutments replaced because of damage caused by falls[3]. In a case series of three patients with finger amputations, all were reportedly able to perform normal daily activities using the prosthesis[4].

Safety

In one case series, infection requiring removal of abutment and internal fixture was reported in 18% (2/11) of patients with transfemoral amputations (both after one year)[3]. The paper did not give any further details about these patients.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to direct skeletal fixation of limb or digit prostheses using an intraosseous transcutaneous implant. Searches were conducted via the following databases, covering the period from their commencement to 31/12/2007: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See appendix B for details of search strategy.)

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with amputated upper or lower limbs or digits.
Intervention/test	Direct skeletal fixation of limb or digit prostheses using an intraosseous transcutaneous implant.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on two non-randomised comparative studies and three case series[1–5].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Existing reviews on this procedure

There were no relevant published systematic reviews with meta-analysis or evidence-based guidelines identified at the time of the literature search.

Related NICE guidance

There is no NICE guidance related to this procedure.

Table 2 Summary of key efficacy and safety findings on direct skeletal fixation of limb or digit prostheses using an intraosseous transcutaneous implant

Abbreviations used: Q-TFA, Questionnaire for persons with a trans-femoral amputation

Study details	Key efficacy findings	Key safety findings	Comments
Hagberg (2005)[1] Non-randomised comparative study Sweden and UK Study period: not stated n = 63 Population: patients with unilateral transfemoral amputation for at least 2 years • Socket prosthesis = 68% (43/63) • Osseointegrated bone-anchored prosthesis = 32% (20/63) Mean age (years): • Socket prosthesis = 51 • Osseointegrated bone-anchored prosthesis = 46, p = 0.13 Mean number of years since amputation: • Socket prosthesis = 29 • Osseointegrated bone-anchored prosthesis = 19, p = 0.007 Mean stump length (cm): • Socket prosthesis = 22 • Osseointegrated bone-anchored prosthesis = 16, p < 0.001	Questions concerning normal prosthetic use and uncomfortable sitting were taken from the Questionnaire for persons with a trans-femoral amputation (Q-TFA). For sitting comfort, answers were given on a five-point Likert scale (0 = no trouble, 1 = slight trouble, 2 = moderate trouble, 3 = considerable trouble, 4 = a great deal of trouble). **Active range of hip motion** • Socket prosthesis – mean hip motion when wearing the prosthesis was decreased in all measured directions compared with mean hip motion when not wearing the prosthesis (p < 0.001 for all motions). • Osseointegrated prosthesis – range of motion in flexion extension was increased compared with range of motion in flexion extension when not wearing the prosthesis (4°, p = 0.017). Proportion of patients with restricted hip flexion (< 90°) when wearing the prosthesis: • Socket prosthesis = 37% (16/43) • Osseointegrated prosthesis = 0% (0/20) Analysis of between-group differences showed that the osseointegration group had statistically greater hip motion in all movements using the prosthesis compared with the socket group. **Sitting comfort** Proportion of patients reporting moderate to a great deal of trouble when sitting: • Socket prosthesis = 44% (19/43) • Osseointegrated prosthesis = 5% (1/20)	Not reported.	The paper describes Q-TFA as a targeted self-report questionnaire. The mean time since amputation was longer in the socket group than the osseointegrated group (29 versus 19 years, p = 0.007) and the mean stump length was longer (22 versus 16 cm, p < 0.001). No other demographic variable was significantly different between the groups. The authors state that a shorter stump length is expected to result in less motion, so the osseointegration group had a poorer baseline condition.

Abbreviations used: Q-TFA, Questionnaire for persons with a trans-femoral amputation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Inclusion criteria: unilateral transfemoral amputation for at least 2 years, for reasons other than vascular disease; between 20 and 70 years old; a prosthetic user, with the ability to walk continuously for at least 100 m. Median follow-up (for bone-anchored prosthesis): 5 years (range 3–10) Disclosure of interest: not stated			

Abbreviations used: Q-TFA, Questionnaire for persons with a trans-femoral amputation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Jacobs R (2000)[2] Non-randomised comparative study Study period: not stated Sweden n = 32 limbs Population: patients who had undergone upper or lower limb amputation. • Socket prosthesis = 47% (15/32) (7 upper limbs, 8 lower limbs • Osseointegrated bone-anchored prosthesis = 53% (17/32) (9 upper limbs, 8 lower limbs) Mean age (years): • Socket prosthesis = 35 • Osseointegrated bone-anchored prosthesis = 43 Mean time since amputation = 13 years Technique: Pushing forces or vibratory stimuli were applied to the prosthetic and normal limbs and also to the part of the bone-anchored implant that penetrated the skin or to the skin of the stump. Disclosure of interest: none stated	*Pressure stimulation* Following pressure stimulation (pushing) of the prostheses, intra-individual differences showed a significantly increased threshold level for both the socket (4.7–15.8 N) and bone-anchored prostheses (4.5–4.7 N) as compared with the contralateral control limb (2.0 – 6.3 N). The difference between groups was not significant. Detection threshold levels for pressure stimulation of prosthetic limbs (proportion of threshold level for control limb, scores greater than 1 indicate increased threshold levels): • Socket prostheses = approximately 3.5 (presented as a chart) • Bone-anchored prostheses = approximately 1.5 (presented as a chart) p = not significant An overall increase in pressure perception thresholds was noted for all prosthetic limbs, up to 60% for socket prostheses and 40% for bone-anchored prostheses. *Vibratory stimulation* Detection threshold levels for vibratory stimulation: • Socket prostheses = 84.9 Hz–95.4 Hz • Bone-anchored prostheses = 73.1 Hz–84.7 Hz $p < 0.05$ Thresholds were increased on an average 20% for socket prostheses but approached levels of the control limb for bone-anchored prostheses. For pushing and vibration of the implant and the stump, detection thresholds were not significantly different ($p > 0.1$).	None reported.	The aim of the study was to evaluate the psychophysical detection threshold level to vibrotactile and pressure stimulation of prosthetic limbs. The authors note that it has been reported that patients with bone-anchored prostheses seem to have a subjectively improved ability to feel their prosthesis and anchoring implant in the bone ('osseoperception'). The aim of the study was to gain more insight into osseoperception and obtain more information on the somatosensory feedback mechanisms with prosthetic limbs. The authors concluded that bone-anchored prostheses yielded better perception than socket prostheses.

Abbreviations used: Q-TFA, Questionnaire for persons with a trans-femoral amputation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Sullivan (2003)[3] Case series UK Study period: not stated n = 11 Population: patients with transfemoral osseointegrated prostheses Mean age (years): not stated Inclusion criteria: patients must have tried conventional socket techniques; patients must have reached full skeletal maturity and have normal skeletal anatomy; less than 70 years old; suitable for surgery based on medical history and physical examination. Exclusion criteria included: osteoporosis; body mass > 100 kg; hip limitations on the amputation side including hip flexion contractures, osteoarthritis and short femoral remnants; medical conditions that would add risk to the procedure; candidates who indicated a reluctance to comply with the protocol. Follow-up: up to 5.5 years Disclosure of interest: not stated	82% (9/11) of patients use the osseointegrated prosthesis all day every day. The first patient to enter the programme had been using a prosthesis for five and a half years at the time of report. Follow-up periods for other patients were not stated. 45% (5/11) of patients have had abutments replaced due to mechanical deformation following falls (in 2 cases, the abutment fractured). No implant damage has been observed. **Subjective feedback** *Negative aspects* - Patients commented that the programme took longer than they had initially thought and expressed frustration at the high number of visits to the centre and the slowness of the rehabilitation programme. *Positive aspects* – improved proprioception (accurate feedback in terms of the position of the leg and foot); osseoperception (improved sensory feedback from the surrounding environment); perceived energy consumption (patients felt that they were able to walk further and do more work wearing an osseointegrated prosthesis); patients commented that they no longer felt disabled and were able to participate with full daily living and activities such as cycling.	Infection (requiring removal of abutment and internal fixture) = 18% (2/11) (both after one year) No further information was given.	Results from the same study centre are also reported by Hadberg et al (2005)[1]. There may be some patient overlap between the studies. The authors note that currently osseointegrated prostheses are only considered for transfemoral amputees who have been unable to achieve a satisfactory level of rehabilitation using conventional socket techniques.

Abbreviations used: Q-TFA, Questionnaire for persons with a trans-femoral amputation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Manurangsee P (2000)[4] Case series Study period: not stated Thailand n = 3 Population: patients with traumatic amputation of the index and middle fingers at the base of the proximal phalanx. None of the patients could use standard prostheses because the stumps were too short. Ages (years): 16, 20, and 40 Technique: standard osseointegrating dental implants and abutments were used. Follow-up (months): 16, 19 and 24 Disclosure of interest: none stated	*Case 1 (20-year old right-handed man lost right index and middle fingers at the base of the proximal phalanx and right ring finger at the base of the middle phalanx)* The patient refused a toe-to-finger transfer to the ring finger. The skin and soft tissue healed around the titanium implants without complication. At 24 month follow-up, the patient was able to write and perform normal daily activities using the prostheses. He had deep pressure in the index, middle and ring fingers. Using the prostheses increased grip strength from 16% to 37%, using grip strength in the left hand as the control. *Case 2 (16-year old right-handed girl lost left index and middle fingers at the base of the proximal phalanx)* The patient was able to adequately perform daily activities. She had deep pressure sensation in both the index and middle fingers and grip strength was increased with the prostheses from 28% to 42%, compared with the left hand. She had some problems handwashing her clothes and the screw that fixed the abutment to the implant occasionally came loose. At 19-month follow-up, there were no other complications. *Case 3 (40-year old right-handed man lost right index and middle fingers at the base of the proximal phalanx and ring finger at proximal interphalangeal joint, in addition to multiple fractures of the hand)* Implants were used in the index and middle fingers. The movement of the metacarpophalangeal joint of all three fingers was limited owing to previous trauma. The patient was able to use his hand while performing daily activities without any problems during a 16-month follow-up period. He had deep pressure sensation in the index and middle fingers. Grip strength was increased from 14% to 28% compared with the left hand.	None reported.	A table in the paper states the follow-up periods as being 10, 13 and 18 months but the text describes them as 16, 19 and 24 months.

Abbreviations used: Q-TFA, Questionnaire for persons with a trans-femoral amputation			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Lundborg G (1996)[5] Case series Study period: 1990–1993 Sweden n = 3 Population: patients with traumatic amputation of the thumb undergoing fixation of osseointegrated prostheses In all cases, the amputation was at the metacarpophalangeal joint level. Ages (years): 18, 45 and 54 Follow-up: 18 months–3 years Disclosure of interest: none	*Case 1 (18-year old right-handed male)* The patient quickly learned to use his right-hand thumb prosthesis and achieved useful perception of tactile stimuli. At 3-year follow-up he scored 13 out of 24 in a shape/identification test and 79 out of 80 on the Sollerman test (measuring grip function). In the Moberg pick-up test, he reached excellent results bilaterally. He had no problems with writing or other activities related to his studies. *Case 2 (45-year old right-handed male)* The patient was very happy with the right-hand thumb prosthesis. His ability to use the thumb for fine manipulative tasks was very good. At 2.5-year follow-up, he scored 8 out of 24 on the shape/dimension test and 71 out of 80 on the Sollerman grip function test. On the Moberg pick-up test, he scored 82% of normal capacity with vision and 60% of normal capacity without vision, compared with the uninjured hand. The patient also had impaired sensibility of the index finger. *Case 3 (54-year old right-handed male)* At 18-month follow-up, the patient scored 'reasonably well' in tests of functional sensibility. Pulp pinch strength and lateral pinch strength were about half the value for the opposite hand. On the Sollerman grip function test, he scored 76 points, compared with 80 for the uninjured side.	Healing of the skin occurred without complications in all cases.	

Validity and generalisability of the studies

- Two studies included patients with transfemoral amputation, one included patients with upper or lower limb amputation and two studies included patients with finger or thumb amputations. It cannot be assumed that efficacy and safety of this procedures will be similar across those patient subgroups / indications.
- One study stated that patients must have tried conventional socket prostheses before undergoing implantation of an osseointegrated prosthesis[3]. Another study stated that patients were not suitable for a standard prosthesis because the stump was too short[4].

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr T Briggs, Professor K Robinson, Mr R Tillman (British Orthopaedic Association)

- All three Specialist Advisers described the procedure as definitely novel and of uncertain safety and efficacy.
- The main safety concern is infection at the interface between the skin and the implant. Peri-implant bone infections, failure of the skin prosthesis interface, loosening of the fixation, abutment deformity after falls and abutment fracture are also potential adverse events.
- Adverse outcomes for audit include chronic osteomyelitis and its possible long-term sequelae, infection and loosening of the implant.
- Outcome measures of benefit should be measured using a functional scoring system such as the Toronto Extremity Scoring System (TESS).
- The procedure should be restricted to specialist centres and appropriate patients.

Issues for consideration by IPAC

None other than those described above.

References

1. Hagberg K, Haggstrom E, Uden M et al. (2005) Socket versus bone-anchored trans-femoral prostheses: hip range of motion and sitting comfort. Prosthetics and Orthotics International 29(2): 153–63.
2. Jacobs R, Branemark R, Olmarker K et al. (2000) Evaluation of the psychophysical detection threshold level for vibrotactile and pressure stimulation of prosthetic limbs using bone anchorage or soft tissue support. Prosthetics and Orthotics International 24: 133–42.
3. Sullivan J, Uden M, Robinson KP et al. (2003) Rehabilitation of the trans-femoral amputee with an osseointegrated prosthesis: the United Kingdom experience. Prosthetics and Orthotics International 27: 114–20.
4. Manurangsee P, Isariyawut C, Chatuthong V et al. (2000) Osseointegrated finger prosthesis: an alternative method for finger reconstruction. The Journal of Hand Surgery 25A: 86–92.
5. Lundborg G, Branemark PI, Rosen B et al. (1996) Osseointegrated thumb prostheses: a concept for fixation of digit prosthetic devices. The Journal of Hand Surgery 21A: 216–21.

Appendix A: Additional papers on direct skeletal fixation of limb or digit prostheses using an intraosseous transcutaneous implant not included in summary table 2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Aydin C, Karakoca S, Yilmaz H (2007) Implant-retained digital prostheses with custom-designed attachments: a clinical report. The Journal of Prosthetic Dentistry 97: 191–5.	1 patient Follow-up = 3 months	At 3 months, the skin around the attachments appeared healthy and retention of prostheses was good. The prostheses restored some prehensile hand functions and aesthetic form of the hand.	Case report.
Bjorkman, Waites A, Rosen B et al (2007) Cortical reintegration of a replanted hand and an osseointegrated thumb prosthesis. Acta Neurochirurgica – Supplement 100: 109–12.	1 patient	Activation in primary sensory cortex was seen on functional magnetic resonance imaging, when stimulating the prosthesis. Cortical activation was more bilateral than in sensory stimulation of the contralateral healthy thumb.	Case report.
Holgers KM, Branemark PI (2001) Immunohistochemical study of clinical skin-penetrating titanium implants for orthopaedic prostheses compared with implants in the craniofacial area. Scandinavian Journal of Plastic Reconstructive Hand Surgery 35: 141–8.	4 patients	Duration of skin penetration ranged from 6 to 24 months. All patients had a clinical skin irritation around the implants at the time of biopsy. The number of inflammatory cells was higher in the area close to the interface than in the area distant to the skin-penetrating site and higher than in corresponding controls, but lower than in craniofacial specimens. The authors concluded that skin penetration of orthopaedic implants is as safe as craniofacial implants, which is a clinically well-established procedure.	The aim of the study was to evaluate the soft tissue around the implant using histochemical techniques.

Appendix B: Literature search for direct skeletal fixation of limb or digit prostheses using an intraosseous transcutaneous implant

Database	Date searched	Version searched
Cochrane Library	02/01/2008	Issue 4, 2007
CRD databases (DARE & HTA)	02/01/2008	Issue 4, 2007
Embase	31/12/2007	1980 to 2007 Week 52
Medline	31/12/2007	1950 to November Week 2 2007
Premedline	31/12/2007	December 28, 2007
CINAHL	31/12/2007	1982 to December Week 1 2007
British Library Inside Conferences	02/01/2008	-
UK Clinical Research Network Portfolio Database	02/01/2008	-
Controlled Trials Registry	02/01/2008	-

Search strategy used in Medline
The search strategy was adapted for use in the databases above

1	exp Amputation/
2	exp Amputation Stumps/
3	exp Amputation, Traumatic/
4	Amput$.tw.
5	disarticul$.tw.
6	hemipelvect$.tw.
7	or/1-6
8	Intraosse$ transcutan$ amputat$ prosthes$.tw.
9	ITAP.tw.
10	(intraosse$ or intra-osse$).tw.
11	(osseointegrat$ or osseo-integrat$).tw.
12	Osseointegration/
13	((Transcut$ or Transderm$) adj3 Implant$).tw.
14	((Transcut$ or Transderm$) adj3 prosthes$).tw.
15	((bionic$ or bone$) adj3 (implant$ or prosthes$)).tw.
16	(Skelet$ adj3 Fixat$).tw.
17	or/8-16
18	7 and 17