Osseocutaneous Integration of an Intraosseous Transcutaneous Amputation Prosthesis Implant Used for Reconstruction of a Transhumeral Amputee: Case Report

Norbert V. Kang, MD, Catherine Pendegrass, PhD, Linda Marks, MBBS, Gordon Blunn, PhD

Exoprosthetic replacement with an artificial limb is the main option for reconstruction after traumatic amputation of an upper limb. Direct skeletal attachment using an osseointegrated implant improves the ease of fixation of the exoprosthesis to the amputation stump. We now report the use of an intraosseous transcutaneous amputation prosthesis that is designed to achieve osseocutaneous integration. Osseocutaneous integration differs from osseointegration because the aim is to create a stable interface among the implant, the bone, and the soft tissues. This reduces the risk of soft tissue infection and troublesome discharge, which are problems encountered with current osseointegrated implants that focus largely on the bone–implant interface. We describe our experience with an intraosseous transcutaneous amputation prosthesis in a case of transhumeral amputation with 2 years of follow-up. *(J Hand Surg 2010;35A:1130–1134. Copyright © 2010 by the American Society for Surgery of the Hand. All rights reserved.)*

Key words Amputation, bone anchor, ITAP, osseocutaneous, osseointegration, transhumeral.

Direct skeletal fixation of an external prosthesis to an amputation stump has many advantages.[1] To achieve this fixation, a metal implant with a transcutaneous component is inserted into the residual skeleton to act as a bone anchor for the prosthesis. Osseointegration of the stem of the metal implant ensures that skeletal fixation is secure.[2] The external prosthesis is then fixed to the transcutaneous part of the implant so that it is effectively attached to the patient's skeleton. In the upper limb, this approach has been used for reconstruction after amputation of fingers and thumbs.[3–7] We are also aware that osseointegrated implants (Brånemark Integrum System; Integrum AB, Göteborg, Sweden) have been used for reconstruction of a small group of transhumeral and transradial amputees, although specific outcomes have never been published for this group of patients.[1]

Brånemark has defined osseointegration[8] as a state in which "there is no progressive relative movement between the implant and the bone with which it has direct contact." Osseointegration is the essential principle on which all bone-anchored implants rely for primary stability because this prevents loosening when the external prosthesis is attached. However, integration of a metal implant with the bone does not mean that the implant also becomes integrated with the soft tissues. Without specific measures, the skin around the transcutaneous part of the implant reacts in the same way as skin around an external fixator pin, and patients can experience multiple soft-tissue infections, chronic discharge, and even osteomyelitis.

The risk of problems at the skin–implant interface can be reduced. Different approaches have been de-

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Received for publication January 4, 2010; accepted in revised form March 22, 2010.

Some funding support was provided by Stanmore Implants Worldwide, the company that manufactured the ITAP implant (C.P. and G.B). G.B. is named as a co-inventor on the ITAP patent (U.S. 2007/0073412 A1) but receives no income or royalties related to this patent.

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0363-5023/10/35A07-0015$36.00/0
doi:10.1016/j.jhsa.2010.03.037

scribed to achieve this in previous reports of reconstruction after digital amputation.[3–7] In essence, the aim is to thin the skin and reduce its mobility relative to the transcutaneous part of the bone-anchored implant. Despite these maneuvers, there have been reports of continuing problems with the Brånemark Integrum System, including loosening of the implants, implant fractures, deep bone infections, superficial soft-tissue infections, and troublesome discharge.[9–10] We also have direct clinical experience of 18 patients in the United Kingdom who are users of the Brånemark system and have encountered similar problems. Close study of the patients in the United Kingdom has shown that the soft tissues at the interface with the implant remain excessively mobile, despite specific efforts to anchor the skin at this point. We have surmised that this degree of soft-tissue mobility indicates a failure to achieve cutaneous integration between the implant and the skin. Lack of cutaneous integration means that there is no seal between the internal and external environments, which might explain the continuing problems encountered with the soft tissues using conventional osseointegrated implants.

To address the issue of cutaneous integration, we examined the interface between the skin and the surface of a naturally occurring bone-anchored structure (deer antlers).[11–13] Our studies revealed that the stability of this interface is based on the same principles that others have discovered through trial and error.[3–7] Specifically, the skin at the interface with deer antlers is thin (no fat) and is held firmly onto the surface of the antlers by multiple collagen fibers, which have a similar morphology to Sharpey's fibers.[11–13] These fibers ensure that the skin remains immobile in relation to the antlers. To reproduce this biological interface, we designed a metal implant that reproduces the morphology of the surface of deer antlers as they pass through the skin—an example of biomimicry. This metal implant was then subjected to exhaustive animal testing in a goat model[11–13] before we performed surgery in our transhumeral amputee.

The result of these studies is the intraosseous transcutaneous amputation prosthesis (ITAP) implant. Unlike previous designs of bone-anchored implant, the ITAP implant is designed to integrate simultaneously with the bone and soft tissues to achieve osseocutaneous integration. Osseocutaneous integration is not synonymous with osseointegration, and it represents a step forward in the evolution of the concept of direct skeletal fixation for reconstruction. The critical part of the design of ITAP is a porous, subcutaneous flange that mimics the surface of the deer antler at the transcutaneous interface. The flange, and parts of the implant, are

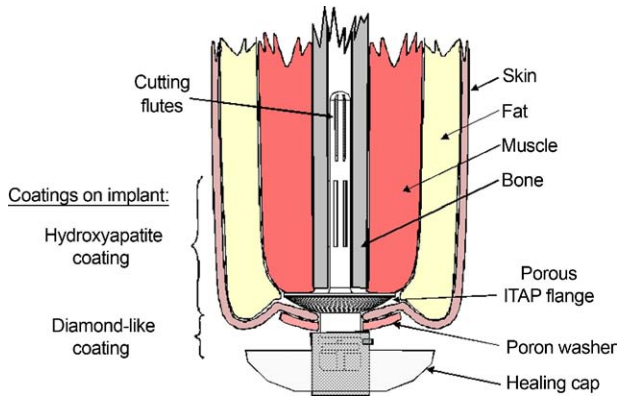

FIGURE 1: Titanium alloy ITAP implant in position. Cutting flutes prevent rotation. The flange is perforated with 0.7-mm holes, allowing soft tissue in-growth to anchor the overlying skin. This reduces relative movement of the skin and produces a seal between the internal and external environments. Healing cap (Stanmore Implants Worldwide) and Poron washer (Algeo Ltd., Liverpool, UK) are used to hold skin against the flange until adhesion is achieved.

coated with hydroxyapatite to further encourage soft tissue in-growth (Fig. 1). These design features encourage adhesion of the soft tissues onto the surface of the ITAP to reduce their mobility relative to the implant but, in common with all forms of bone-anchored implant, primary stability of the ITAP implant is achieved through osseointegration of the stem in the bone. Our goal of osseocutaneous integration using an ITAP implant is different from the aim of designs such as the Brånemark Integrum System, which achieves only osseointegration.

We describe the use of an ITAP implant to secure an external prosthesis in a transhumeral amputee.

CASE REPORT

A 48-year-old woman sustained a transhumeral amputation of her left, nondominant arm in the London Underground bombings (Fig. 2). She also sustained fractures of the left humeral neck and femoral shaft, a left-sided partial brachial plexus palsy, and burns to the left flank and thigh.

The patient considered, but then rejected, a standard prosthetic replacement because of difficulties with securing it to her amputation stump and restrictions in the range of motion of the shoulder joint when wearing the prosthesis. As an alternative, the patient was given the opportunity to use an ITAP implant. The implant was manufactured under the requirements of the Medical Devices Directive of the United Kingdom, which is regulated by the Medicines and Health Regulatory Authority. Permission was sought and obtained from the local hospital board to insert the implant in a human

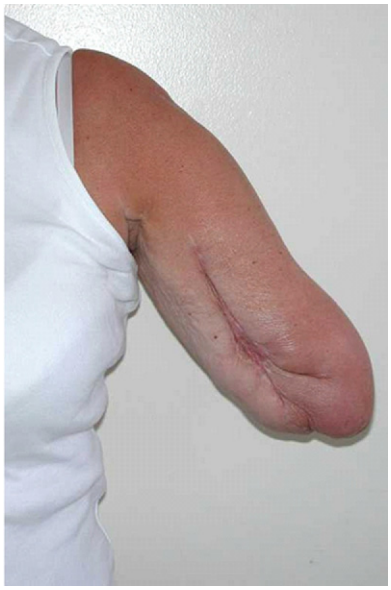

FIGURE 2: Preoperative state.

patient, and the National Institute of Clinical Excellence was informed in advance of surgery.

Plain x-rays and computed tomography scans were used to design a custom-built ITAP implant, together with a failsafe device. Psychological screening confirmed the suitability of the patient for surgery and defined her aims for having treatment. She had intensive physiotherapy to improve the strength and range of motion of the left shoulder and the density of the residual humerus.

At surgery (Fig. 3), the patient was placed in the right lateral position, and a tourniquet was applied to the stump. The residual muscles were reflected into anterior and posterior groups. The peripheral nerve stumps were buried in muscle. Heterotopic bone was excised, together with 16 mm of the normal bone. The medullary cavity was reamed by hand. The ITAP implant was inserted and pushed into position with a slap-hammer. Titanium mesh was secured around the end of the humerus to allow the muscles to be sutured to the bone, although it proved easier to suture the muscles to the underside of the porous flange of the ITAP with interrupted 2-0 PDS (polydioxanone suture; Ethicon, Edinburgh, UK).

Excess skin and fat were excised to create an asymmetric flap at the end of the stump. A circular area of fat overlying the ITAP flange was excised, leaving mainly dermis in contact with the porous metal. Thinning of the skin flap ensured that the skin integrated correctly with the flange structure of the ITAP implant. After thinning, the majority of the blood supply came from the subdermal plexus. A hole was punched through the thinned skin flap to allow the transcutaneous part of the ITAP implant to come through. The thinned flap was then sutured to the flange with interrupted 2-0 PDS.

The procedure was completed in less than 2 hours. The patient was discharged after 2 days. Marked swelling persisted for 2 to 3 weeks. We used a Poron washer to hold the skin against the flange while integration occurred (Figs. 1 and 3D). The washer was held in place with a healing cap, which was adjusted daily.

The patient was advised to remove the healing cap and shower her wounds daily. Exudate coming from the interface was wiped away with a clean gauze. Before replacing the Poron washer, healing cap, and any dressings, she applied a thin smear of Savlon ointment (Novartis Consumer Health UK Limited, West Sussex, UK) to the interface.

Rehabilitation was started immediately to maintain range of motion and strength at the shoulder while exposing the implant to increasing compressive and distractive forces. Bone pain was used to determine safe levels. The magnitude of the compressive force was measured with weighing scales—the patient pushed the ITAP directly onto the scales. Distraction forces were applied incrementally, adding increasing amounts of hardware to the ITAP until the full weight of a myoelectric prosthetic arm could be attached without discomfort by 40 weeks after surgery.

It is now 2 years after insertion of the ITAP implant. The ITAP has simplified the process of attaching and detaching the patient's myoelectric arm. She describes the process as being "clip and go." It has improved her function by giving her a near-normal range of motion at the shoulder with the prosthesis attached (Fig. 4). The skin–implant interface remains stable, with no serous discharge or pain (Fig. 5). The patient still uses a Poron washer between the ITAP and the prosthetic arm, although the soft tissue is clearly adherent to the ITAP flange. She has had no episodes of infection. She is able to swim in public pools, but she attaches a healing cap to protect other swimmers. Disabilities of the Arm, Shoulder, and Hand scores were obtained before and after surgery (with the prosthesis attached). Before surgery, her score was 34; one year after surgery, her score was 10.

X-rays at 2 years show that the implant and humerus have remained unchanged compared to immediately after insertion, suggesting that osseointegration has been achieved and is stable (Fig. 6).

DISCUSSION

There are relatively few published reports of direct skeletal fixation of a prosthesis for reconstruction in the upper limb. in the last 14 years, outcomes have been

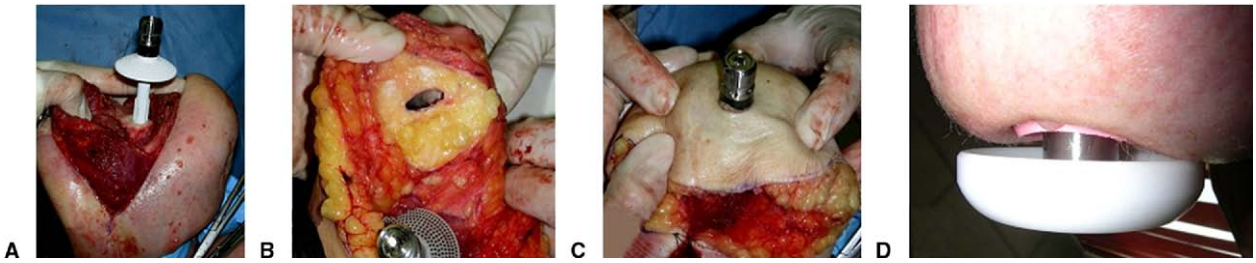

FIGURE 3: A The ITAP is inserted. **B** Skin over the flange is thinned. **C** The transcutaneous part of the ITAP is punched through the flap. **D** Healing cap with Poron washer (pink).

FIGURE 4: Near-normal range of motion at the shoulder with myoelectric arm attached at 2 years. **A** Arms at rest. **B** Shoulders abducted 90 degrees. **C** Shoulders in full abduction.

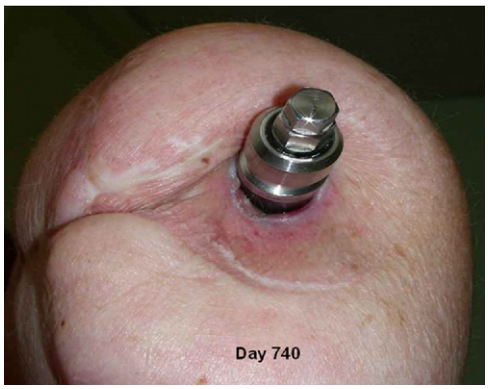

FIGURE 5: Skin–implant interface at 740 days, showing skin adherent to underlying flange.

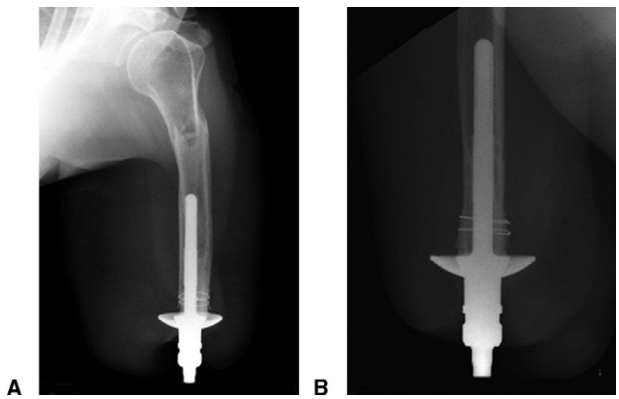

FIGURE 6: A, **B** Two years after insertion.

reported for 13 patients after digital amputation.[3–7] Hagberg has hinted at the outcomes of a small, but unspecified, number of upper limb amputees (transradial and transhumeral) using the Brånemark Integrum system,[1] but specific outcomes for this group of patients have not previously been reported in the literature.

All previous reports have described a 2-stage implant.[1,3–7,9] In contrast, the ITAP is inserted in one surgical step, resulting in a dramatic acceleration of rehabilitation and avoidance of further surgery—key motivations for many amputees. Use of a one-component implant also avoids any concerns over loosening, bending, or fracture of the secondstage component, which has been reported with the Brånemark Integrum System.[10] Bending and fracture of the ITAP implant is relatively unlikely because it is made of stiffer titanium alloy (modulus of elasticity for titanium 6/4 alloy is 127 GPa) rather than softer, commercially pure titanium, which has been used for all previous implants. However, we accept that if the transcutaneous component of ITAP were to fracture, revision would require removal of the entire implant, unlike a 2-stage implant. Therefore, a failsafe device—which is de-

signed to shear in half if the load applied to the prosthesis exceeds a specified limit (>10 kg)—is inserted between the ITAP and the external prosthesis. This also protects the humerus from fracturing in the event of a fall onto the reconstructed arm.

Previous reports of digital reconstruction suggest that relatively few problems are encountered at the skin–implant interface.[3–7] In these cases, the authors report making specific efforts to ensure that the skin at the interface with the implant is adherent to bone to reduce soft-tissue mobility. This also creates a seal between the internal and external environments and might explain the low risk of infection reported in these cases. However, this seal might be more difficult to achieve with higher-level amputees because of the larger amounts of redundant/dependent tissue in the arm/forearm or thigh. Sullivan et al[10] report problems with excessive soft-tissue mobility and discharge at the interface using the Brånemark Integrum System for transfemoral amputees. This suggests that an effective seal is not always achieved and might explain why the implant was removed in 20 of the patients using the Brånemark Integrum System for reasons including deep and superficial infection.[9] The ITAP is designed to overcome this problem through appropriate handling of the bone and soft tissues to achieve osseocutaneous integration. In our case, the skin–implant interface has remained free of infection and discharge since it was inserted 2 years ago, with the patient using her prosthetic arm daily, for most of the day, suggesting that the interface is robust and reliable. However, only long-term follow-up will confirm whether malignant degeneration will occur at this interface in the decades to come.

The ITAP provides amputees with another option for securing an external prosthesis. Surgery to insert the implant is relatively quick, and the bony surgery is simple, compared to other types of bone anchor such as the Brånemark Integrum device.[9] The critical step is the need to thin the skin over the porous flange and to secure it to the ITAP implant while cutaneous integration occurs. However, all the surgical steps can be easily mastered by all upper limb surgeons.

The ITAP has the potential to improve the comfort and function of prosthetic reconstruction for all upper limb amputees. In the longer term, it is possible that the ITAP might be inserted at the primary amputation, further reducing the interval between amputation and restoration of function. However, there are also potential disadvantages with direct skeletal fixation of an external prosthesis. These include additional surgery (to insert, revise, or remove an implant), cost and complexity, and the ever-present risk of infection (both deep and superficial). We hope that the risk of infection will be addressed through the use of the ITAP and similar devices. Nevertheless, it is worth noting that 13 of the 20 patients who had their Brånemark Integrum implant removed in the series reported by Hagberg and Brånemark[9] elected to have the implant re-inserted. Therefore, patients clearly feel that the benefits of direct skeletal fixation outweigh the disadvantages.

Future studies will determine the long-term outcome of the ITAP in larger groups of patients. Further, we anticipate that the ITAP and surgical maneuvers such as targeted re-innervation[14] will create a demand for improved upper limb prosthetics with increased function and control.

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