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Transcutaneous osseointegration for amputees

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Abstract Transcutaneous osseointegration for amputees (TOFA) is an evolving technology that has the potential to revolutionize the interface between the amputee and their prosthesis, showing potential at many levels of amputation. While no amputation is without its challenges, TOFA requires a highly specialized prosthesis and a multidisciplinary team that includes specialized surgeons, physical therapists, wound care teams, and social workers who guide the amputee through surgery, postoperative rehabilitation, and the chronic wound care that goes into maintaining the prosthesis. The infrastructure required to facilitate care pathways that lead to reliable, successful outcomes are unique in each health care setting, including those in advanced health care systems such as the United States and Australia. This article details the emerging evidence supporting the use of this prosthetic interface design and many of the challenges that providers face when establishing programs to offer this type of care in the United States.

Keywords: orthopaedic trauma, amputation, amputee, osseointegration, prosthesis, rehabilitation

Transcutaneous osseointegration for amputees (TOFA) is gathering momentum as a viable reconstruction and rehabilitation alternative for limb loss after high-energy trauma.[1–4] The technique was first successfully implemented in 1990 and over the past 30 years has undergone a gradual evolution with incremental changes in the implant design, surgical technique, and clinical indications.[3,5,6] As a dramatic departure from traditional socket-mounted prosthetic limbs (TSP), at this point it is natural to question when, if not now, this approach makes the successful transition from niche procedure/curiosity and assumes a greater role as an increasingly attractive reconstruction/rehabilitation option for amputees? To wit, is osseointegration finally ready for "prime time"? To answer these questions sensibly, we must first ask what are the contemporary complication rates, the current clinical outcomes, and the relative advantages of TOFA when compared with TSP?

Consider first the accepted limitations and known problems/complications associated with the use of a TSP because it is widely acknowledged that many amputees have difficulty and complaints related to the skin-socket interface.[3,5,7,8] Chafing, blisters, cellulitis, folliculitis, and ulceration are all common secondary conditions. This time-honored method of mounting a prosthetic limb is inherently unstable, and these issues are inevitably more frequent and more severe in amputated limbs with a short bony residuum and with soft tissues that are less than ideal.[7,8] Scars, flaps, and bony prominences all contribute to significant patient complaints that often limit prosthetic use and activity while both inadequate soft tissue and excess soft tissue can be equally problematic. Loss of proprioception and obstruction of adjacent joint range of motion are also considerations when using a TSP that leave many amputees prone to falls and often lacking the confidence to ambulate independently on uneven surfaces or in certain social situations.[7,8]

The main advantage of TOFA, irrespective of patient preferences, is that it effectively eliminates all problems associated with a socket.[2,3,9,10] Instead, concerns with the skin/socket interface are exchanged for the inconvenience of the transcutaneous stoma, the site where the implant exits the residual limb and allows connection to the endoprosthetic limb itself.[2,3,9,10] Infection is a concern, but clinical studies consistently demonstrate the risk of deep infection is smaller than most assume; implant loosening and the need for implant removal is in fact very uncommon.[2,10] Although the risk of superficial infection is greater, this generally responds rapidly to oral/parenteral antibiotics, although stump revision and stoma modification is sometimes necessary. In a multicenter international study of 91 transfemoral TOFA patients conducted in Australia and the Netherlands, the risk of infection was greatest in women, smokers, and those with BMI $>$ 25, whereas the general complication rate or need for further surgery was increased again in women and in those with a larger BMI.[10]

The transition to a single-stage procedure has been an important aspect in the surgical approach, one that has resulted in demonstrably better outcomes, particularly for transfemoral

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TOFAs.[11] This has occurred in parallel with a generally more enthusiastic approach to soft-tissue resection resulting in amputation residua with less redundancy, thereby limiting the potential for persistent pendulous tissue that can be symptomatic.[3,9,12] Less motion and inherent stability in the soft tissues surrounding the stoma creates a wound that is stable and more likely to eventually adhere to the distal end of the skeletal residuum, resulting in turn in less drainage and a decreased risk of infection.[9,12] Equally important has been the introduction of a more structured approach to the assessment and management of the inevitable neuromas and frequent neuropathic components to an amputee's pain. The emergence of targeted muscle reinnervation as another aspect of the surgical reconstruction of an amputated limb, complimenting the contributions of TOFA, is an additional consideration that falls far beyond the scope of the discussion here.[9,13]

As with all surgical procedures, patient selection is perhaps the most critical component of the algorithm leading to the highest rate of successful outcomes.[11,14,15] The importance of the multidisciplinary team in preoperative evaluation and perioperative management is another mandatory component of the protocol, and the value of shared decision-making with an informed, motivated patient with realistic patient-specific goals cannot be over emphasised.[11,14,15] The indications are strongest for those amputees who are completely unable to use a prosthetic limb for various combinations of reasons or those who struggle to obtain a satisfactory fit with a TSP and require multiple fittings annually. Other amputees choose TOFA as an alternative to TSP because of perspiration and odors in warm climates or because the TOFA makes donning/doffing the artificial limb far more convenient and less time-consuming. While peripheral vascular disease and diabetes were long considered contraindications, early clinical experience in carefully selected patients has been consistently positive, and this is no longer true.[16]

Two completely different designs of implants currently dominate the market, both titanium.[3] The Swedish Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA^{TM}) implant is a cannulated screw-type implant that remains essentially unchanged since it was first introduced in 1990 and is the only TOFA implant that has been granted FDA approval. However, the implant design has more generally evolved dramatically over time, and several manufacturers have adopted a titanium press-fit philosophy, in many ways analogous with a Wagner-style hip arthroplasty stem. The Australian Osseointegrated Prosthetic Leg (OPL) implant is characteristic of this design and is the device that has been used most often around the globe.[3] It includes antirotation splines proximally and is porous-coated only on the distal 8 cm to encourage rapid bone ingrowth and adherence while limiting the probability of extensive stress shielding that was typical of the earlier fully coated IPL cobalt-chrome device.[3,17]

Postoperative rehabilitation is the final critical consideration and is fundamental to achieving an optimal outcome.[11,14,15] Established protocols are essential to maximize the benefit and restore confident gait in a controlled, graduated fashion that allows the patient to progress to independent ambulation over 12 weeks.[11,14,15] An initial stage of static loading begins immediately postoperative, advancing by 5 kg every few days until reaching 50% of body weight or 50 kg by 10–14 days. The second phase involves use of a light leg with a manually locked knee for early gait training with protected weight-bearing between parallel bars. In the third and final phase, the patient is fit with their definitive prosthetic limb, using 2 crutches until the 6-week mark. For the next 6 weeks they ambulate with a single crutch in the contralateral hand until the 12-week mark.[11,14,15]

A study of the clinical outcomes of 37 transfemoral TOFA patients at a minimum 2 years postoperatively confirmed significant and consistent improvements in objective functional tests, including the 6-Minute Walk Test and the Timed Up and Go.[2] Validated subjective patient-reported outcomes including the Questionnaire for Persons with Transfemoral Amputation and SF-36 also exhibited predictable and clinically meaningful improvements. Complication rates were very acceptable; although there was a 43% rate of infection, all but 6% responded to a course of oral antibiotics.[2] A separate study evaluated the risk of periprosthetic fractures associated with TOFA and reported a 6% cumulative risk.[18] These were all managed successfully by treating the fractures on their own merits, and none of the TOFA implants required removal after an adjacent fracture.

Evaluation of a database of almost 600 TOFA patients is currently underway at the Limb Reconstruction Centre at Macquarie University Hospital (Sydney, Australia), comparing the clinical outcomes after single-stage surgery with those after 2-stage surgery. All investigations involving human subjects and/or the use of patient data for research purposes was approved the Committee on Research Ethics at the institution at which the research was performed in accordance with the Declaration of the World Medical Association, and all informed consent was obtained as required. This includes 86 2-stage patients at a mean of 6.3 years postoperative and 506 single-stage patients at a mean of 3.4 years postoperative. For all amputees, the revision rate after 2-stage surgery was 10.4%, and for single-stage surgery the revision rate was 3.5% (P-value = 0.00453; significant at $P < 0.05$). Similar reductions in the need for additional surgery after either 2-stage or single-stage surgery were also observed for fractures (6.8% vs. 3.0%), debridement (19.3% vs. 5.8%), neurectomy (14.8% vs. 4.0%), and stump refashioning procedures (37.5% vs. 3.5%).

How to Establish an Osseointegration Program in the United States

It has been nearly 33 years since Dr. Rikard Branemark performed the first successful TOFA.[19] Until more recently, there has been slow growth of the field among a small number of practitioners and scientists worldwide. However, after many lessons learned in these early days, the past decade has seen a major acceleration in the successful performance and acceptance of TOFA as a power tool for amputees.[20–23] The greatest bulk of this experience has been outside of the United States and most notably in Australia.[4] Over the past few years, several surgeons in the United States have begun offering TOFA to patients. In addition, there is a great interest among many other surgeons to do the same.[24,25]

Despite a high level of interest, it remains very challenging to establish a successful osseointegration program in the United States. For a number of reasons, establishing the necessary building blocks to create a successful Osseointegration (OI) program is more involved than offering almost any other operation. We will discuss each of these below, but they generally include surgeon experience/training, understanding and access to implants, coordination with prosthetist, specially trained rehabilitation staff, special challenges working with payers, and the need for a true multidisciplinary team. Below, we outline the nature of these challenges and some of our experiences in how they can be overcome.

The first key ingredient to starting an OI program is a surgeon dedicated to providing comprehensive care for limb optimization of the amputee. For a surgeon to decide if they are a good fit for this role, they must start with a good understanding of the challenges and demands that they will face. TOFA is a key part to limb optimization for many amputees, but placing the implant is only a part of what is required for a successful patient outcome. The first concern is that at the time of implantation surgery the details of soft-tissue management are critical to a successful outcome. Some of these concepts are contrary to what is required for a traditional amputation, and understanding the detail requires additional training and experience to master and even more relevant is to understand what is required for postoperative care. Although many OI implants appear similar to total hip implants placed in reverse, the details of postoperative care are completely different. The rehabilitation protocols require a graduated weight-bearing and transition to prosthetic wear that takes time and is very intensive, frequently requiring surgeon input. In addition, most patients will experience some sort of issue with the stoma site where the implant exits the skin. These issues most commonly include superficial cellulitis, hypergranulation tissue, or a patch of dry necrosis requiring dressing care. All of these issues are typically transient and do not prevent a successful long-term outcome. However, they require a great deal of time to manage in terms of clinic visits, calls, and care coordination. In my experience, this is most akin to managing treatment with circular external fixation and the attendant percutaneously exiting external fixation pins. A key difference with OI that is somewhat similar to hydroxyapatite-coated Schanz screws in the tibial shaft is that with OI time these issues abate as the stoma matures. The burden of management related to these issues is highest in the early going and is typically greatly reduced after the first 6 months. There will still be occasional issues that arise with the stoma, but the frequency and severity greatly decline for the great majority of patients. It is critical for the prospective surgeon to evaluate the ability of their practice and themselves to manage these challenges before deciding to embark on performing OI surgery.

Once a surgeon has decided they want to take on this challenge, they need to gain experience and training. This is best done by partnering with a surgeon performing OI to observe cases and clinical care. These opportunities used to be quite limited and mostly abroad, but as OI programs become more established in the United States, it is increasingly available at home. There are also some opportunities provided by implant companies to assist in training and education. They are also often able to provide support at the time of the operation. However, it cannot be overstated that placing the implant is only a part of this operation, and training on the soft-tissue management aspects is critically important and should not be overlooked.

Apart from the above surgeon factors, there are other key obstacles to overcome. The first is to understand the available implant systems and obtain access. There are several systems currently being implanted of which 2 are by far the world leaders. One of these is the OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) system design by Rikard Branemark, and the most current design is offered by Integrum, and this is currently the only fully FDA-approved system. The OPRA is a 2-stage system that requires placement of the deep implant within the bone to first allow osseointegration to occur and then a second stage to refashion the residuum and place the components that exit the stoma. In this system, bone anchor is based on a screw type mechanics on the outer surface of the implant and relies on ingrowth to the titanium surface.[19,23] The second system is the Osseointegrated Prosthetic Limb (OPL) which was designed by Munjed Al Muderis and is offered by Osseointegration International. The OPL is a press-fit style implant that also relies on ingrowth onto the titanium surface. A key difference is that the OPL and other press-fit devices are designed to allow for a 1-stage reconstruction in which both implantation and residuum refashioning are both performed at the same surgical session.

In terms of gaining access to implants, it is best to contact the company for information on the system and to help plan for training before planning a surgical case. The other aspect is gaining payer approval. At present, OPRA is the only fully FDA-approved implant system. For this reason, most commercial insurers will often only approve surgery with this device. In the United States, the OPL is available when a custom device is required to meet special patient's needs. We have found that gaining approval from commercial payers can be difficult largely because the field is new and not well understood, codes for osseointegration surgery do not exist, and alternative approval pathways are not well defined. With effort, it is often possible to gain the payer approval, but it is not straightforward in most cases. This is likely to change as the procedure becomes more familiar, codes are developed, and other systems gain FDA approval, but for now these remain challenges.

The final challenge is creating a multidisciplinary team. This starts with a prosthetist and rehabilitation team who are educated in using OI implants to optimize prosthetic care. Close collaboration with a prosthetist and rehabilitation team are essential to optimize the gains achieved with OI surgery. In addition, amputees often have other challenges that need to be addressed as part of their comprehensive care. Pain management and psychiatric care familiar with the challenges faced by this population can be a critical successful outcome in many patients.

Despite these issues, it is important for fully informed willing surgeons to overcome these challenges. TOFA can be a life-changing intervention for many amputees with the potential to allow new levels of function and return to activities previously not possible. The process of providing this care will likely become easier with time but now is the time for capable and dedicated surgeons to provide this care to the amputee community.

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