From Bench to Bedside

From Bench to Bedside: A Perfect Fit? Osseointegration Can Improve Function for Patients with Amputations

Benjamin K. Potter MD

The first patent for a suction socket for patients with lower limb amputations in the United States was filed during the Civil

War [5]. Subsequently, numerous advances in prostheses and surgical techniques have dramatically improved the functional potential of

many patients with limb loss. Unfortunately, while the materials used have evolved, many basic fitting techniques and socket-design principles have not changed for decades. Therefore, the primary patient-prosthesis interface—the socket—has not kept pace with the new surgical techniques or the microprocessors, sensors, and motors that have enabled these recent advances. As such, amputation socket-related problems ranging from ulceration, folliculitis, malodor, sweating, and loss of suspension, discomfort and pain—all of which can dramatically decrease patient function and satisfaction—persist largely unmitigated.

Enter osseointegration, the direct skeletal attachment of a prosthesis to a residual limb. The concept of osseointegration began in the mouths of patients and mind of Per Invar Brånemark using dental implants during the middle of the last century. Starting with successful translational studies in rabbits, Dr. Brånemark successfully demonstrated that bone could rigidly adhere and “heal” to implanted titanium fixtures. He rapidly moved to human use for reconstructive oral surgery, and the results of his early efforts were impressive—despite working in

A Note from the Editor-In-Chief:
I am pleased to present the next installment of “From Bench to Bedside,” a quarterly column written by Benjamin K. Potter MD. Dr. Potter is a clinician-scientist in the Department of Orthopaedics at Walter Reed National Military Medical Center and in the Department of Surgery at the Uniformed Services University of Health Sciences. His column investigates important developments that are making—or are about to make—the transition from the laboratory to clinical practice, as well as technologies and approaches that have recently made that jump. The institution of one or more of the authors (BKP) has received, during the study period, funding from Congressionally Directed Medical Research Programs.

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B. K. Potter MD
Orthopaedic Surgery Service,
Department of Surgery, Uniformed
Services University of Health Sciences,
Bethesda, MD, USA

B. K. Potter MD (✉)
Walter Reed National Military Medical
Center, 8901 Wisconsin Ave,
America Building (19),
2nd Floor – Ortho, Bethesda,
MD 20889, USA
e-mail: Benjamin.k.potter.mil@mail.mil

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the theoretically (and, microbiologically speaking) heavily colonized and contaminated environment of the human mouth. During a 15-year period, 2768 fixtures were implanted into the jaws of 371 patients. At nearly 6 years of followup, 81% of the maxillary and 91% of the mandibular fixtures demonstrated continuously stable bridges [1]. These concepts were further extrapolated to bone-anchored hearing aids and related implants [7], and the use of osseointegration has persisted in this arena to the present day.

Despite Per Invar Brånemark's endodontic successes and achievements with press-fit hip and knee arthroplasties that rely on internal osseointegration, transcutaneous applications remained elusive and hypothetical until Per Invar's son, Rickard Brånemark, established just such a program. Rickard developed a textured long-bone fixture modified from his father's dental screw design and began an osseointegration program for those with limb loss in Sweden in the 1990s [3]. Subsequently, Horst Aschoff in Germany developed a press-fit implant for transcutaneous osseointegration [2]. Initial progress was slow, and setbacks and treatment failures common, until Brånemark's team adopted a standardized treatment protocol [6]; likewise, Aschoff's design has been modified twice to

transition the transcutaneous portion of the implant from a porous interface to a polished design, resulting in a dramatic reduction in skin complications and infection rates. The technologies have since spread to several programs throughout Europe and in Australia based on variations of these two implant designs.

The potential advantages of osseointegration for patients with amputations, long theoretical, now have been convincingly demonstrated. These include improved patient function as assessed by validated outcome measures, patient satisfaction, osseoproprioception, as well as gait and energy expenditure. Most importantly, patient comfort can be dramatically improved by obviating socket related problems and residual limb pain. Aseptic loosening (2%–6%) and periprosthetic fracture (0%–4%) have occurred at relatively low and ostensibly acceptable rates [2, 3, 6, 9]. However, concerns regarding infection by way of the skin-implant interface persist. Superficial infection rates have been, not unexpectedly, as high as 55% [7], but are typically successfully managed with increased stoma and transcutaneous adapter care and short duration oral antibiotics. Deep infections requiring implant removal have occurred at a rate of 2% to 3% [3, 7].

While it is becoming clear that osseointegration is relatively safe, it is

important to note that these procedures are not, at this point, indicated for all persons with limb loss. Osseointegration may be indicated for those with amputation who cannot tolerate regular use of a conventional prosthesis due to socket-related problems such as pain, poor soft-tissue coverage or recurrent breakdown, major volume fluctuations, or suspension problems due to extremely short residual limbs. Successful osseointegration may profoundly improve function, but the procedure should not be offered to high-functioning patients with limb loss who can tolerate a conventional socket. Additionally, the osseointegration procedure itself, whether performed as a single or two-stage procedure, is only one piece of a larger program. Associated rehabilitation protocols generally include early postoperative care, lifelong stoma care and monitoring, progressive graduated weight-bearing protocols, and gait training that can last longer than 6 months before unrestricted ambulation is permitted. Careful candidate patient screening and counseling thus remains critical.

In the United States, a handful of osseointegration procedures for patients with limb loss have been performed using custom devices. The Food and Drug Administration (FDA) has recently granted a humanitarian device exemption to the Osseoanchored

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Prostheses for the Rehabilitation of Amputees device developed by Brånemark for use at the transfemoral amputation level [8]. Most recently, a group led by Roy Bloebaum at the University of Utah, building off of their work in a successful ovine model [4], and the associated Veterans Administration hospital recently performed the first osseointegration surgeries in the United States that were part of an FDA trial. Subsequently, osseointegration for patients with amputation has arrived in the United States, and these developments are exciting for many of those with amputations and the surgeons and rehabilitation teams who care for them.

Research regarding complementary technologies to improve bone fixation, infection mitigation, and/or skin-implant interface stabilization must continue concurrently to improve device longevity and safety, and continued vigilance is necessary to report device-related complications and monitor implant longevity in order to

introduce these promising technologies in a responsible and conscientious manner.

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