

Osseointegration: A Novel Technology for Amputees

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Abstract

Osseointegration is a promising but unproven technology for amputees that has a potentially large clinical and policy impact. This technology requires direct testing in randomized trials of sufficient size and duration to distinguish reliably between the null hypothesis of no effect and the alternative hypothesis of a small to moderate effect.

At present, 2.1 million Americans have experienced limb loss and it is estimated that the prevalence will double in the next several decades. Each year, in the US alone 185,000 amputations are performed. Further, 1558 military personnel have lost limbs during the wars in Afghanistan and Iraq. In addition, however, the epidemic of type 2 diabetes, which is due primarily to the increasing prevalence of obesity, continues to increase at alarming rates in the US and worldwide. Over 50% of patients with diabetes who undergo limb amputation will require an amputation of the other leg within the next few years. Of persons with diabetes who have a lower extremity amputation, over 50% will require amputation of the second leg within 2-3 years.

Thus, the clinical and policy implications of gathering a sufficient totality of evidence on this promising but unproven technology for amputees are large.

Keywords: Osseointegration; Amputees; Randomized trials

Commentary

Osseointegration is derived from the Greek "osteon" meaning bone and the Latin "integrare" which means to make whole. The term is defined as a direct contact between living bone and the surface of the load-bearing titanium implant. Since 1995, osseointegration for amputees has been in clinical use. Osseointegration can be performed on any extremity amputation, including femur, tibia, humerus and radius/ulna. This novel technique utilizes a skeletal integrated titanium implant which is connected through an opening in the stump to an external prosthetic limb. This allows direct contact to the ground, which provides greater stability, more control, and minimizes energy consumption [1].

Today, when a patient undergoes an amputation, the component parts (socket, knees, feet, hands) are much more sophisticated than they were years ago. The distal stump shrinks and expands, and the socket becomes too tight or becomes too loose and in many instances are the source and the cause for skin breakdown and infection. Prosthetic devices are heavy because the device requires a socket for attachment. Because the artificial limb is attached with a socket, proprioception for the extremity is completely lost.

This titanium implant is modeled on the anatomy of the human body and takes the load back directly to the bone, the joint above, and associated muscles. This titanium implant allows the prosthetic device to be taken on and off with a simple quick and safe connection between the stump and the lower prosthesis. No longer is the prosthetic device attached to you, but it becomes a part of you,

resulting in much greater comfort and walking control as proprioception is gained in the extremity.

Taking on and off the prosthesis is very easy and takes less than ten seconds. Due to the solid fixture to the bone it accurately connects in the exact spot each and every time you attach the prosthesis. This device can be used with all types of prosthetic componentry. With this new technology the days of fiddling around with time consuming and cumbersome suction, socks and liners is over. Using this titanium bone implant allows for natural loading of the hip joint and the femur, which encourages bone growth and creates a more natural gait and requires less physical exertion. Any weight gain or fluid variations of the distal stump have no effect on the use of the prosthetic limb. It eliminates the bulky socket providing a much more natural streamlined look in clothes. This device allows for full freedom of movement from walking to cycling and recreational activities. Muscular strength is developed freely, which minimizes muscle wasting of the distal stump. Movement of the affected extremity is not restricted by the protruding edges of a socket, allowing for greater ease and comfort sitting, standing and walking. The direct connection between the femoral bone implant and knee enables free natural pivoting movements. The knee prosthesis can be easily attached and removed within just a few seconds. Because the titanium implant goes directly into the bone, the patient regains the ability to feel the ground and can differentiate between different surfaces such as carpet, grass, tile and uneven ground, which also allows for movement in unfamiliar areas in dim light.

A poorly fitting socket can increase an amputee's energy consumption by 100%. Surgery is usually a single procedure followed by early mobilization a few days after the surgery, allowing rapid recovery and minimizing the time spent away from normal day to day

activities. In some cases, a two-stage procedure is required with a short interval of six to eight weeks between the first and second stage surgeries followed by an early mobilization rehabilitation program. This type of implant for amputees makes a conventional socket in a prosthetic device unnecessary.

With respect to durability, for orthopedic amputation procedures, the longest clinical follow-up as of today is approximately 20 years [1]. In this regard it is interesting to note that endosseous dental fixtures, or titanium dental implants, may last for 50 years. As regards amputation secondary to devascularization conditions such as diabetes and other metabolic diseases, these may result in significant reductions to blood supply of the bone and soft tissue which, in turn, could impede the healing process and lead to infection and necrosis [1]. Based on these considerations, until a sufficient totality of evidence emerges, osseointegration for amputation secondary to devascularization conditions such as diabetes and other metabolic diseases, should be performed only in carefully selected patients.

As there are no large scale randomized trials directly testing the efficacy of this promising, but unproven, technology has not yet been approved by the United States (US) Food and Drug Administration. The necessary randomized evidence should accumulate from three centers of excellence in the US which will conduct the discovery research necessary to complete the totality of evidence [2,3]. These include the Paley Institute in West Palm Beach, Florida, the University of California San Francisco, and the Uniformed Services University. These centers of excellence create the unique and crucial opportunity to conduct a large scale randomized trials of sufficient size and duration to detect reliably the most plausible small to moderate but clinically worthwhile benefits. Thus, a sufficient totality of evidence that includes reliable data from a large scale randomized trial could emerge after the next few years.

The clinical and policy implications of gathering a sufficient totality of evidence are large. Specifically, 2.1 million Americans have experienced limb loss and it is estimated that the prevalence will double in the next several decades [4,5]. Each year, in the US alone 185,000 amputations are performed. Further, 1558 military personnel have lost limbs during the wars in Afghanistan and Iraq [5]. In addition, however, the epidemic of type 2 diabetes [6] which is due primarily to the increasing prevalence of obesity [7], continues to

increase at alarming rates in the US and worldwide. Over 50% of patients with diabetes who undergo limb amputation will require an amputation of the other leg within the next few years [5]. Of persons with diabetes who have a lower extremity amputation, over 50% will require amputation of the second leg within 2-3 years.

With respect to costs, hospital charges alone totaled over \$8 billion and the lifetime health costs of amputees is over \$500,000 or 2/3 higher than those without limb loss. Finally, insurance costs in the US alone are \$12 billion annually [8].

It is plausible that osseointegration will turn out to be a “beautiful hypothesis slain by ugly facts” [9] but, it is equally plausible that this novel technology will provide enormous benefits to the amputees who pose large as well as increasing clinical and policy challenges in the US and worldwide.

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