WORKSHOP
Osseointegrated Prosthetic Limbs: Recent Developments and Future Directions

Organizers:
Mark Ehrensberger, PhD
Sujee Jeyapalina, PhD

Speakers:
Rickard Brånemark, MD, MS, PhD
James P. Beck, MD
Jeremy Gililland, MD
Jonathan Forsberg, MD, PhD
Experience with the OPRA system

Rickard Brånemark, MD, MS, PhD
University of California San Francisco

Introduction: Transfemoral amputations due to trauma or tumor surgery often cause problems with conventional socket prostheses. In 1999 we initiated the prospective OPRA study (Osseointegrated Prosthesis for Rehabilitation of Amputees) using standardized surgery, equipment and rehabilitation program. This implant was recently approved by FDA.

Methods: The surgery consists of a two-stage procedure. First a titanium implant (fixture) is inserted into the remaining skeleton. Six months later a second implant (abutment) is inserted into the first penetrating the skin. Gradual increase of loading and activity are initiated over a 6-month period.

Results: The OPRA study includes 51 patients with 55 implants (1999 – 2010). The follow-up is 2 years. Four implants have been removed due to loosening (3) or infection (1). One patient was lost to follow-up. Two patients were excluded. The cumulative fixture survival rate was 92%. Forty-one superficial skin infections were observed in 28 patients and 6 deep infections in 4 patients. Nine mechanical complications were reported in 4 patients (bent or fractured implant parts) and 3 skeletal fractures occurred. Prosthetic use, prosthetic functions and global quality of life were improved, and prosthetic problems were reduced (all p<0.001)

Discussion: Development of a new treatment concept is a tedious and time-consuming process which have to be carefully monitored and controlled. Despite infections and mechanical complications, this treatment is improving quality of life for amputees and the success rate is presently better than 90 % at 2-year follow-up.

Transfemoral Osseointegrated Prosthesis-Utah Implant Design Principles, Translational Research and Clinical Outcomes.

J Peter Beck, MD¹,²; Jeremy Gililland, MD¹,²

¹University of Utah, Salt Lake City, Utah
²Department of Veterans Affairs Salt Lake City Health Care System

Background: The benefits of percutaneous osseointegrated (OI) skeletally docked artificial limbs are well recognized in multiple clinical studies [1-8]. Currently used osseointegrated limb docking systems differ in design, device materials, surface methods of osseointegration, means of skin attachment, surgical techniques and rehabilitation times to full ambulation. These previous studies have also identified the risks of mechanical failure, aseptic loosening, stress shielded bone resorption and infection associated with their OI devices [1-6]. Using lessons learned from translational large animal models, and observed human device implementation in Europe, the Utah Osseointegration Research Program developed a new osseointegrated skeletal docking system for use in transfemoral amputees [9-11]. The Percutaneous Osseointegrated Prosthesis (POP) device was approved for a Federal Drug Administration (FDA) early feasibility study (EFS) that began in December of 2015 and is scheduled to end in April of 2019. DJO Surgical is the device manufacturer of record [12].

Materials and Methods: The femoral stem of the POP device is made of grit-blasted medical grade Titanium (Ti) alloy, with the distal 3 cm coated with a porous Ti surface composed of two distinct populations of pore sizes. The POP device caps the end of the transected femur and is connected via Morse tapers to a “low energy” Titanium Niobium Nitride coated cylinder that terminates into a Ferrier-coupler to which the prosthetic limb is attached. Patients for the study were selected using carefully structured inclusion/exclusion criteria, as well as a psychological evaluation. Ten patients with unilateral transfemoral amputations were selected from the United States Veterans Administration population. They underwent amputation revision and implantation of the Utah POP device as a first stage procedure. Six to eight weeks later, a second surgery established a shallow stoma and docking of the patient’s own artificial limb. Patients began supervised weight-bearing ambulation in Physical Therapy, 24 hours after the second stage surgery. They were monitored at 5 weeks, 3, 6 and 12 months with serial X-Rays, DEXA scanning and multiple functional tests.

Results: All EFS patients were successfully fitted with their prosthetic limb within 24 hours of Stage 2 surgery. All patients were able to immediately load the limb as tolerated. All ten patients progressed to ambulation with an assistive device within 14 days of the Stage 2 procedure and were discharged to home with no post-operative fractures. Eight of ten patients progressed to independent ambulation with no assistive devices by the 5-week follow-up. One older patient, aged 69 years, requires a cane for balance. A reduction in the average prosthesis don and doff times of 91.4% and 70.8%, respectively, was observed at 5 weeks.

Two patients experienced device removals: one patient due to early loosening of the device at 5 weeks and the other due to a proximal periprosthetic fracture following significant trauma at 7 months. One perioperative and two late superficial infections (9 and 10 months) were resolved with antibiotic treatment. Clinical results to-date have demonstrated low preliminary infection rates, no distal cortical bone resorption, improved objectively tested functional outcomes, as well as improved patient reported outcomes. Periprosthetic bone density increased in all seven
patients that have completed 1-year follow-up. Eight of the 10 patients will have completed the 1 year study in April 2018.

**Conclusions:** To date, the new POP device, implanted in 2 surgical stages, has led to immediate weight-bearing, and observed increase in function and prosthetic satisfaction in 9 patients, some now up to 23 months since initiation of ambulation; with low rates of post-operative complications and all with measurably increased bone density at the bone/implant interface.

**References**

Over the past thirty years, the concept of attaching an external prosthesis directly to the skeleton has become a reality. At least six unique designs have been developed and tested in patients with major extremity amputations in Sweden (Integrum AB, Mönidal Sweden), the United Kingdom (Stanmore Implants, Elstree UK), Germany (EKSA Implants Lübeck Germany), Australia (OrthoDynamics, Sydney Australia) and the United States (Biomet Inc. Warsaw Indiana and DJO Global, Vista CA). Each is designed to form a durable attachment to a long bone, exit the skin, and attach to a functional prosthesis. The approach is useful in the subset of patients who cannot tolerate regular wear of traditional, socket-based prostheses and complements existing DoD efforts such as the DARPA Revolutionizing Prosthetics and HAPTIX programs, targeted muscle reinnervation, regenerative peripheral nerve interfaces, and implantable myoelectric sensors for terminal device control. Furthermore, this technology permits the evaluation and validation of advanced prosthetic components (e.g., microprocessor or powered components) while avoiding confounding socket-related issues. Though osseointegration is uniquely suited for patients with combat-related upper and lower amputation levels, the technique is complex, and requires a coordinated pathway in order to be safely and successfully implemented. To this end, the DoD Osseointegration Program is establishing osseointegration as a capability within the Military Health System by evaluating currently available implants, providing subject-matter expertise to academia and other government agencies, while coordinating the development of complementary and next-generation technology.