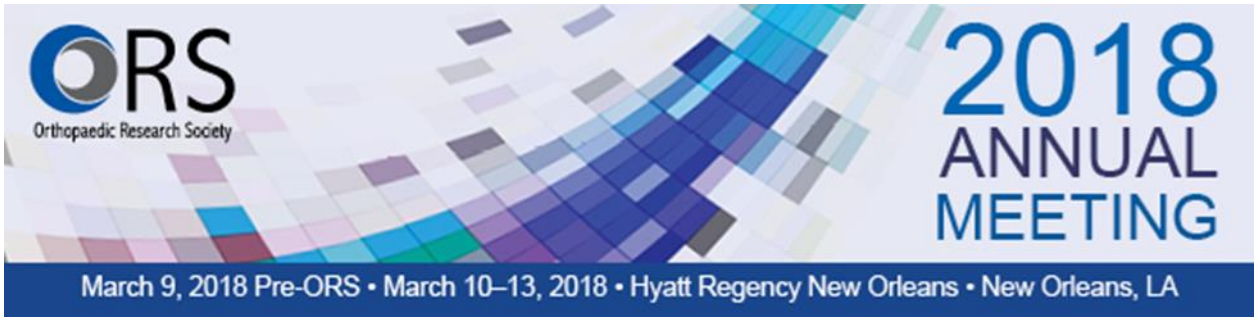

WORKSHOP
Osseointegrated Prosthetic Limbs: Recent Developments and Future Directions

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Experience with the OPRA system

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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.

Citation: Brånemark R, Berlin Ö, Hagberg K, Bergh P, Gunterberg B, Rydevik B. A novel osseointegrated percutaneous prosthetic system for the treatment of patients with transfemoral amputation: A prospective study of 51 patients. Bone Joint J. 2014 Jan;96-B(1):106-13.

The Department of Defense Osseointegration Program

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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, Möndal 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.