Translation Model for Developing a Single Stage Percutaneous Osseointegrated Implant for Amputees

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Statement of Purpose: With remarkable advances in battlefield medicine, the U.S. Military is now saving 98% of wounded warriors who would have previously died, including warriors who have multiple amputations and others with limited residual limb length. Another major factor is increasing limb loss rates with motorcycle use. Many patients do not have enough limb length to utilize socket technology or experience soft tissue irritation which leads to disuse osteopenia and muscle atrophy.

Percutaneous osseointegrated implants have been introduced in Europe for select amputees as an alternative to socket technology. Despite early patient satisfaction and the new phenomenon of osseoperception, there remain serious concerns about this technology.

The main concern remains periprosthetic infection. Abutment breakage and two-stage implantation that can require 12-18 months of rehabilitation before full weight bearing and ambulation are likewise deterrents to use. The clinical objective is to develop a single stage model, similar to the total joint replacement paradigm, so patients can follow a similar recovery program. Before introducing this concept clinically, we propose that a translational research model is needed to optimize implant design and performance and assure that periprosthetic infection can be limited or prevented.

Sheep were chosen because of reasonable weight range, docile temperament, relatively uniform bone structure, and bone remodeling characteristics similar to human bone (Willie et al.). The goal of this report is to demonstrate that the model has been established, report the results of the first 14 animal operations and report on the testing of the first hypothesis.

The first hypothesis tested in the model states: Subdermal porous coating will allow viable skin attachment sealing to the implant-skin interface, preventing periprosthetic infection.

Methods: Ninety survival Columbus female sheep will be used in this study (10 Time=0, non-survival; and 20 ea. for 3 month, 6 month, 9 month, and 12 month survival groups). At each time period (survival groups), 17 of the implants will have a subdermal porous titanium coating (52.1±16.5% pore size) donated by Thortex Corporation (Portland, OR, USA) and 3 implants without porous coating. This experimental design will test the hypothesis based on power analysis. Ten animals in each group will be used for histology, 7 for biomechanical testing and 3 for determining the natural infection process over the course of the 3, 6, 9, and 12 month time periods.

CT images were previously taken of the metacarpal III bones in sheep, demonstrating that 3 implant sizes would be needed. The implants were made from titanium.

After establishing an anterior skin flap, the right forelimb was transected at the distal metaphyseal flare of the third metacarpal. The metacarpal was fitted with a primary percutaneous, intramedullary osseointegrated prosthesis and the animal was allowed to recover and immediately bear weight. A titanium Morse taper protrudes from the distal surface extending through the skin flap. It is met with a titanium adapter which connects to the exoprosthesis (Figure 1). The exoprosthesis is made of a Delrin core surrounded by a 70A durometer polyurethane. The operative site was examined daily for periprosthetic and systemic signs of infection, and cultures were taken, as required, with dressing changes. Limb weight bearing gait forces were measured before and after implant surgery.

The one year sheep were gait tested monthly with weight bearing forces measured using a force plate. Radiographs were taken preoperatively, immediately post-operatively and at 3, 6, 9, and 12 months intervals.

Figure 1: Postoperative x-ray of implanted sheep bone.

Results: Of the current 14 survival sheep to date, the average post-operative time is 3 months with the longest at 6 months. To date, there have been no signs of infection of the skin-implant interface. Skin marsupialization at the skin-implant interface has also been avoided. In addition to tightly-adhered skin over the subdermal portion of the implant, a thick and dry cuticle-like ring has formed in all sheep at the implant-skin interface. Utilizing a multimodal pre-emptive analgesia program, animals are immediately weight bearing within the first post-operative hour, and have remained relatively free of pain indicators. The porous coating was observed to immediately interlock with both the bone and the skin. The porous coating provided immediate immobilization of the skin flap.

Conclusions: A previous sheep model using a transcortical pin distal to the knee joint line, without a subdermal barrier, showed that the onset of infection occurred within 3-6 weeks. None of the animals in the current investigation have demonstrated clinical signs of infection. Force plate analysis at 3 months post-operative, has demonstrated approximately 15% unloading of the prosthetic limb compared to the pre-operative force plate measurements.

The establishment of this model should make a significant contribution to establishing the principles for the safe clinical introduction of the osseointegration implant technology in the United States in the near future.

Reference: Willie BW. JBMR-A 2004:69A(3):567-576.

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