

24-Month In Vivo Evaluation of a Percutaneous Osseointegrated Prosthetic System in a Translational Sheep Amputation Model

Sujee Jeyapalina^{1,2}, James Peter Beck^{1,2}, Kent N Bachus^{1,2,3}, Roy D Bloebaum^{1,2}

¹Bone and Joint Research Laboratory, DVA SLC HCS, 500 Foothill Blvd (151F), Salt Lake City, UT

²Department of Orthopaedics, University of Utah Health Care, Orthopaedic Center, 590 Wakara Way, Salt Lake City, UT

³Orthopaedic Research Laboratory, University of Utah Orthopaedic Center, Salt Lake City, UT

Statement of Purpose: Since the European groups have bypassed the importance of translational animal studies during the development of percutaneous osseointegrated prosthetic (POP) implants for amputees, there have been several setbacks, including aseptic and septic loosening, infections, and abutment breakage [1-3]. It is believed that some of these complications could have been avoided if appropriate animal models were used to examine the progress of tissue-implant integration of the current POP implants prior to their clinical introduction. This study was undertaken to collect translational data for an upcoming FDA approved feasibility study of a novel POP design for transfemoral amputees. This work is an extension of a previous translational sheep amputation model, which prevented infections for up to 12 months [4]. However, the epidermis at the skin margin continued to migrate (marsupialize) proximally along the implant surface, exposing the interconnecting porous surface coating to the external environment [4]. It was suggested that this exposed coating could provide an ideal nidus for bacterial colonization and may be detrimental for the longevity of the implants. It was therefore hypothesized that the epithelial migration and subsequent exposure of the porous coating to the external environment could limit the longevity of a porous coated POP implant system intended for attaching exoprostheses for patients with limb loss.

Methods: Using an institutionally approved protocol, “amputation and implantation” surgeries were performed on 7 skeletally mature sheep [5]. Following the surgery, animals were allowed to ambulate freely for 24 months. Until their euthanasia in December of 2013, all sheep are being systematically observed and evaluated for their general health and signs of infection at the implant-skin interface. The implant exit sites are mainly being assessed for presence of fresh/dried-out discharge, infection, skin erosion, gait abnormalities and the condition of the implant exit site.

Results: One animal was lost due to improper fit and of the implant into the intramedullary canal. This had resulted in implant toggling within the modularly canal and infection at 6 weeks post-implantation; this animal was excluded from the study. Periodical clinical observations (Figure 1) on the remaining animals indicated that the porous coating of the implant was gradually exposed with longer implant in situ times. Moreover, fifteen month post-implantation, one animal exhibited clinical signs of infections at the implant exit site. This animal was treated with antibiotics for a week, but without any success and was then sacrificed. 23-month post-implantation, 5 animals remain without any infections.

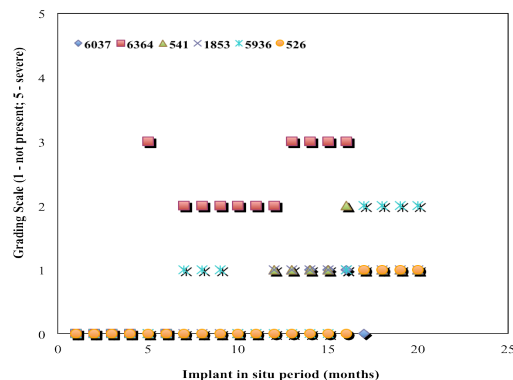


Figure 1: A representative graph showing the observed skin erosion around the implant. Grades 0 - 5 represent “not present”, “mild”, “progressive”, “severe” and “very severe”, respectively. “Mild” referred to exposed porous coating of the post.

Conclusions: Clinical data indicated that most of the animals, which had a good skin-seal and limited marsupialization at the skin-porous coating interface, maintained an infection-free interface. So far, the data showed that when the marsupialization exposed the subdermal barrier region, then the periprosthetic tissue was vulnerable to infection. It was therefore believed that techniques to prevent skin marsupialization are essential to maintain long-term infection free POP skin-implant interfaces.

Acknowledgement: This research is supported by the Department of Defense (W81XWH-11-1-0435) grant, and financial supports from Office of Rehabilitation R&D Service, DVA SLC HCS, The Albert & Margaret Hofmann Chair, and the Department of Orthopaedics, University of Utah School of Medicine, Salt Lake City.

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