

## **10725 - Osseointegrated Transcutaneous Device for Amputees: A Large Animal Model**

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### **ABSTRACT**

#### **Background**

Traditional above-the-knee amputation prosthetics utilize a stump-socket interface for attachment that are well-known for skin problems, sitting difficulty, disuse osteopenia, and increased work of ambulation.

#### **Questions/Purposes**

The aim of our study was to evaluate a newly-designed, osseointegrated transcutaneous implant in a large animal model. Our hypothesis was that the implant would limit infection risk from the outside environment, despite the transcutaneous nature, while demonstrating osseointegration at the bone-implant interface.

#### **Methods**

Four Dorset sheep underwent a two-staged surgical procedure for forelimb placement of an osseointegrated transcutaneous implant utilizing Compress® technology (Biomet Inc, Warsaw, IN) that provides approximately 600 pounds of force (lbf) at the bone-implant interface. Two sheep received a long internal prosthesis (90 mm) and two sheep received a short internal prosthesis (46 mm). The first-stage consisted of retrograde intramedullary implantation of the device with stump closure. The second-stage, six-weeks later, consisted of externalization of the original device with attachment of an exoprosthesis. The animals were assessed daily for signs of infection, fracture, or implant failure. Sixteen weeks after the initial surgery, the animals were euthanized and the operative limbs, along with the attached implant, underwent radiographic and histological analysis for osseointegration.

#### **Results**

No implant failures occurred. Periprosthetic fractures occurred in both animals that received the longer internal prosthesis. One healed with splinting and the other underwent a second surgical procedure to advance the amputation site more proximal. No fractures occurred in the shorter internal prosthesis group. One infection occurred in the longer internal implant group that was likely related to surgical contamination. It healed well with antibiotic treatment. There was no evidence of histological infection at the study conclusion in any of the animals. Bone-implant osseointegration was demonstrated in two of the three limbs that underwent histological analysis.

#### **Conclusions**

This unique implant demonstrated osseointegration at the bone-implant interface while limiting infection risk from the outside environment. This is the first time that an osseointegrated transcutaneous implant utilizing Compress® technology has been tested in a large-animal model and demonstrated positive outcomes. Translational research involving human studies should be considered.

