INTRODUCTION
A percutaneous osseointegrated implant, as a docking system for prosthetic limbs, has been considered around the world as an alternative to conventional socket technology. The European experiences in Sweden, Germany, and England have shown significant increases in mobility, activity levels, and gait performance amongst amputees, although hindered by a high infection rate and long recovery period [1-4]. In order to shorten the recovery period, a single stage operative procedure was proposed, based on the paradigm of total joint replacement. In contrast to the two-stage procedure, which has been performed in Europe, this procedure allows immediate loading on the implanted bone within 24 hours of the operation. To achieve this goal, we have hypothesized that a porous coated implant, with proper “fit and fill”, would allow immediate weight bearing without aseptic loosening. A translational large animal amputation study was undertaken to test this concept.

METHODOLOGY
Ninety five survivor (Columbus) female sheep were selected for this study. The right forelimb was transected at the distal metaphyseal flare of the third metacarpal and was fitted with a primary percutaneous exo-prosthetic implant (Figure 1(a)). The prosthetic hoof was then secured to the fixation mechanism and Morse taper of the implant (Figure 1(b)). Following the surgery, the operative site was examined daily for the first two weeks and then, once a week thereafter for skin-implant, periprosthetic, and systemic signs of infection. Sheep were sacrificed at predetermined time periods of 0, 3, 6, 9, and 12 months. Following necropsy, right (implanted) and left (non-implanted) forelimbs were harvested, processed and then embedded in polymethyl methacrylate.

As indicated in Figure 2, host bones were cut and separated into three regions (porous coated (a), fluted groove (b), and smooth (c) regions) with respect to the surface characteristics of intramembranous implants. Two millimeter thick sections were generated after sectioning, grinding and polishing; at least 3 cross- sections were generated per region. These sections were then carbon coated, imaged using scanning electron microscope, and evaluated for percentage bone ingrowth, porosity, appositional bone index, and mineral apposition rate [5].

RESULTS AND DISCUSSION
Backscatter electron (BSE) imaging has revealed that the bone had ingrown into the porous coated region (Figure 3). The percentage of bone (0-, 3- and 6-month groups) measured within the porous coating shows increasing ingrowth of bone into the porous spaces as a function of post-operative survival time. The data also indicates that the contact area of the implant with bone increases with post-operative survival time, and complete contact (100%; Figure 4(a)) of the implant with the porous coated region was achieved by 6 months. In order to quantify the remodeling rates, MAR of all three regions were calculated and graphically presented in Figure 4(b). This graph illustrates that the rate of remodeling of the porous coated region decreased from 3 to 6 months, whereas the rate of remodeling of other regions increased with post operative survival time. Such observations may be related to increased bone resorption due to stress shielding around the porous coated region, as this was prevalent and increased with time in follow-up radiographs. The radiographic data (Figure 5) shows that proximal binding of the implant occurred at region (a) and this led to stress shielding and subsequent distal cortical bone resorption at region (b).

In summary, our results indicated that a prosthesis that allows load bearing, a single stage surgical procedure and immediate porous coating interlock by good “fit and fill”, can achieve excellent bone/prosthesis osseointegration and immediate post operative weight bearing. This was an encouraging result and future 9- and 12-month animal data (which is currently being analyzed) will give us further indication of modeling, remodeling and adaptation behaviors of host bone tissue to support endo-prosthetic attachment.

Acknowlegdement
This research is supported by Department of Defense (PRMRP Grant No. PR054520), Office of Rehabilitation R&D Service, DVAHCS, Salt Lake City, UT, The Albert & Margaret Hofmann Chair, and the Department of Orthopaedic, University of Utah School of Medicine, Salt Lake City, UT.

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