INTRODUCTION:
Exoprosthetics are currently attached to a residual limb by means of a socket; however, these devices are problematic for patients with short residual limbs. A hopeful alternative to attach exoprosthetics to short residual limbs is to use percutaneous, osseointegrated implants.

Recently, an ovine model was established to assess these endoprostheses in a 12 month study. The purpose of this study was to determine the stability of these implants over time by studying bone ingrowth and periprosthetic remodeling, and performing implant tensile pullout tests on Time “0” and 3, 6, 9, and 12 month survival animals.

METHODS:
Subjects
A total of 100 skeletally mature sheep were divided into Time “0,” 3 Month, 6 Month, 9 Month, 12 Month, and 12 Month groups. Under anesthesia, the right forelimb was removed at the distal portion of the Metacarpal III bone at the metaphyseal flare and fit with an osseointegrated implant. At the distal end of the implant, a Morse taper post extended through the skin and, by means of a titanium adapter, connected to a Delrin/polyurethane exoprosthesis. The Metacarpal III bone and implant were harvested post-mortem and half were assessed for bone ingrowth/ periprosthetic remodeling and half for mechanical tensile testing. This experiment has been approved by the local institutional animal care and use committees.

Bone Ingrowth and Periprosthetic Remodeling
The Metacarpal III bones were fixed with buffered 10% formalin for 72 hours and dehydrated in a graded series of alcohol incubations and embedded in polymethyl methacrylate. At least three, 2 mm thick cross sections were generated from the porous coated section of each implant. These sections were carbon coated for 25 seconds and evaluated for percentage bone ingrowth.

Each specimen was examined in a scanning electron microscope (JSM 6100; JEOL Incorporated, Peabody, MA) using the backscattered electron (BSE) detector (Tetra; Oxford Instruments, Cambridge, UK) and a solid state BSE detector; Novan system 6, Thermo Fischer) at 100 times magnification. BSE imaging analysis was conducted to determine the amount of bone present in the porous coated and periprosthetic regions of each implant. Presence of bone in the porous coated region was measured as the area occupied by bone divided by the area of the image field, including the area occupied by bone.

Tensile Test
To attach the implant to the equipment for tensile testing, a 0.5-inch diameter hole was drilled through the titanium implant proximal to the Morse taper post, and all soft tissue was removed for potting. The fixation was improved by placing drywall screws perpendicular to the shaft in the proximal end of the metacarpal beyond the tip of the implant. The proximal end of the metacarpal was then submerged in melted Cerrobend low melt potting material in a custom made, 5-inch diameter, 4-inch tall cylindrical aluminum pot. The Cerrobend potting compound was then cooled with running water until it became solid.

Each specimen was clamped in place and a stainless steel rod was placed through the 0.5-inch diameter hole drilled through the endoprostheses and connected to the actuator of a hydraulic material testing system (Model 8500, Instron Corp, Canton, MA). The implant was pulled uniaxially at a constant rate of displacement until failure of the bone-implant interface occurred. Failure was taken to be the maximum force recorded during testing.

RESULTS:
Bone Ingrowth and Periprosthetic Remodeling
Presently, eight Time “0,” six 3 Month, and two 6 month animals have had bone ingrowth and periprosthetic remodeling measured. At Time “0”, the percentage of bone ingrowth was found to be 3.1%. Three months later, the ingrowth increased to 30 ± 15% and progressed to 40 ± 13% by 6 months (Figure 1).

The percentage of bone at the periprosthetic host bone region (bone just outside the porous coating) significantly increased from Time “0” to 3 months. On average, periprosthetic regions of 3 and 6 months groups have 20-30% more bone fraction than that of Time “0” group, thus indicating new periprosthetic bone formation (Figure 1).

DISCUSSION:
The small percentage of bone measured for the Time “0” group (3.1%) represents the amount of bone chips impacted into the porous coated spaces during implantation. At 6 months, the bone ingrowth had increased to nearly 40%. This is consistent with literature, where bone ingrowth continues into porous spaces up to 9 months in human [1].

Meanwhile, the periprosthetic bone formation increased 20-30% over 6 months. This could be due to loading of the implants causing higher than normal physiological stress concentration on host periprosthetic trabecular bone, leading to bone adaptation to dissipate forces.

The bone ingrowth and periprosthetic remodeling is consistent with the findings from the tensile test. The initial stability of the implant was excellent at 2500 N for the tensile test. However, due to the bone ingrowth and periprosthetic remodeling, the stability doubled to nearly 5000 N by 3 months. The results from this study are very promising regarding the bone-implant interface. Over the next 6 months, bone ingrowth, periprosthetic remodeling, and bone implant strength will be assessed for the remainder of the subjects from each time group. This will lead to a better understanding of bone-implant stability and help in creating safe percutaneous, osseointegrated implants for humans.

REFERENCE:

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