INTRODUCTION:
Limb amputation is a devastating event resulting in associated loss of everyday function and a massive change in the quality of life. To date, socket technology is the standard of care to attach, or dock, the exoprosthetic device to the residual amputated limb in an attempt to impart partial restoration of use and function. However, sockets are not without shortcomings: they can overload and irritate adjacent soft tissues, can cause disuse osteoporosis of the residual limb, can be difficult to properly fit due to weight fluctuations and muscle atrophy, and difficult if not impossible to use with short residual limbs. More reliable and secure limb attachment would facilitate implementation of new technologies that expand prosthetic function and user capabilities. It is for these patients that a new approach to limb attachment and functional integration is needed.

Percutaneous osseointegrated implants, as a docking technology for exoprosthetic limbs, are being considered around the world as alternatives to sockets. The European experience with skeletonally fixed percutaneous exoprosthetic attachment has shown significant increases in mobility, activity levels, and gait performance among amputees enjoying this technology when compared to their previous conventional socket technologies. While these achievements are encouraging, the European technique requires two-staged surgical procedures, sometimes up to 18-months apart, to place the osseointegrated anchoring implant. The second stage places the percutaneous attachment to the implant. Infections of the soft tissues neighboring the percutaneous pylon are reported and occasional deep infection of the implant requires removal. These limitations remain sources of critical concern.

The overall goal of our research team is to develop an infection-free percutaneous osseointegrated implant system, using a one-stage operative protocol, which can be introduced into the amputee population based on translational research. In order to achieve this goal, the first phase of the program was to develop a weight bearing animal model that would confirm the potential for the single stage procedure. The criteria required for our model were that it should have similar bone healing and remodeling rates as human bone, have a weight range similar to humans and have a bone structure that would limit the number of implant sizes required.

METHODS:
CT images of 12 metacarpal III bones, retrieved from sheep carcasses, were taken with a GE High Speed CTI single slice helical scanner. One millimeter thick slices were taken every millimeter along the entire length of each bone at a pitch of 1 (1x1x1), MAS=100, and kV=100, and a FOV (field of view) =16. Using MIMICS (Materialize, USA), 3D reconstructions of the metacarpals were obtained and the entire metacarpal reconstructed. Specifically, the intramedullary canal was reconstructed and 3D renderings of 3 sizes of stylized implants were created. Carcass soft tissue dissection and skin flap blood supply studies were done before beginning pilot survival study surgeries on sheep intended for the single-stage operation.

The titanium implants were designed in house and manufactured by Medicine Lodge, Inc. (Logan, UT). The porous coated titanium, on the grit-blasted surface of the implant, was applied and donated by Thortext Corporation (Portland, OR) (Figure 1). The porous coating was characterized by SEM/BSE analysis (Figure 1) and demonstrated a 52.1±16.5% pore size with a highly irregular and roughened surface. This allowed the coating to immediately interlock with the bone and undersurface of the skin at the time of implantation.

RESULTS:
Of the ten pilot sheep, one sheep was sacrificed due to an undersized implant that lacked proper fit and fill. Of the remaining nine animals, all remained infection-free, and load bearing for up to 3 months (with an average of 6 weeks) as of the time of this submission. Of nine animals, none showed gait abnormalities or soft tissue signs of infection based upon culture studies and clinical observations. Marsupialization of the skin, at the porous coating–Morse Taper-skin interface, a common problem with percutaneous devices, was absent. These data were supporting evidence that the implant design and porous coating met our objectives of assuring initial skin attachment and immobilization and thus prevented early infection.

DISCUSSION:
Our sheep weight-bearing model should become a platform to provide important translational information prior to the introduction of osseointegrated implant technology into the US health care system. Without such a model (one that allows biomechanical, material evaluation, skin integration, osseointegration and microbiological animal studies), it appears premature to introduce this technology into patient care based only on the current world literature and the European clinical experience.

There are several anecdotal reports in the popular press concerning the introduction of this technology in canines, but methodical, long-term data collection has not been done. The level of amputation and the limb involved is also variable. Long term post-operative x-rays, microbiological and infection documentation, and data on skin and bone changes are needed. Our model will allow carefully controlled clinical follow-up studies, based on power analysis, and the further development of hypotheses testing.

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