Skin Tissue Response to a Percutaneous Osseointegrated Implant: A Sheep Amputation Model

INTRODUCTION
A direct attachment of the artificial limb to a percutaneous implant, which is anchored to the residual bone, has been proven to provide an ideal and robust docking system in clinical trials [1]. While these patients have vastly improved functions and osseo-perception [2], the clinical problem of superficial and deep infection remains unsolved. Skin-implant site hygiene and conventional antibiotic therapy have failed to prevent infections consistently [3, 4]. Infection rates in European patients are reported to be between 17% and 30% for significant infections [4, 5]. This high infection rate still remains the source of clinical concern especially due to the inadequate physiological skin seal at the implant-interface.

To create a permanent skin seal at the implant-skin interface, it was hypothesized that a porous coated subdermal attachment incorporated onto an endo-prosthetic implant (Figure 1) would prevent infection by immediately gripping the skin tissue at the implant exit site, and subsequently providing scaffolding for skin ingrowth and attachment. This could establish a physiological barrier to bacteria. To achieve our goal, a large animal amputation study was undertaken.

METHODS
The right forelimbs of survivor (Columbus) female sheep were transected at the distal metaphyseal flare of the third metacarpal and six were implanted with porous coated (Fig 1(a)) and nine of them with smooth (control group; Figure 1(b)) osseointegrated implants. The prosthetic hoof was then secured to the fixation mechanism of the Morse taper of the implant. Following the surgery, the operative site was examined daily for the first two weeks and then, once a week thereafter for peri-prosthetic and systemic signs of infection. Sheep were sacrificed at predetermined time periods of 0, 3, 6, 9 and 12 months. Following necropsy, the right (implanted) forelimbs were harvested, processed and embedded in poly(methyl methacrylate). Histological analysis was conducted to determine the host tissue response to the porous coating then embedded in poly(methyl methacrylate). Histological analysis was conducted to determine the host tissue response to the porous coating. Sheep were sacrificed at predetermined time periods of 0, 3, 6, 9 and 12 months. Following necropsy, the right (implanted) forelimbs were harvested, processed and then embedded in poly(methyl methacrylate). Histological analysis was conducted to determine the host tissue response to the porous coating and peri-prosthetic skin attachment to the implant. Two mm thick sections that were taken at the skin-implant interface were ground and polished to approximately 25µm thickness, stained with a preheated solution of Hematoxylin and Eosin and examined at X4, X40 to X50 magnification using a light microscopy.

RESULTS AND DISCUSSION
The gross photomicrographs of the implant-skin interface at different post operative time periods are given in Figure 2. The major observation was the skin migration/downgrowth as a function of the post-surgical survival period. Measurements made from the photomacroscopic images showed that the terminal skin progressively migrated at a rate of 1.6 ± 0.5 mm/month between 3 to 6 months. Even though several 9- and 12-month group animals were sacrificed on time, due to long dehydration and tissue processing, it was not possible to present the data at this time. However, in a recent 12-month animal group (Figure 2), it appears that the migration may have been arrested and the physiological skin seal maintained, but more data is required.

Although a physiological skin seal is seen at the implant-skin interface, a closer microscopic examination of the interface demonstrates a lack of papillary dermal blood supply and a devitalized epithelium with flattened rete ridges (Figure 3(i)). Both vitalized and devitalized epithelial layers are seen near the interface in (b) and (c). Blood vessels (B) are clearly visible inside the porous coatings.

Figure 2: Photomicrographs of the H&E stained cross-sections of the implant-skin interface clearly showing skin migration. There has been approximately 1.6 mm/month migration between the 3- and 6-month group animals (calculated from random samples of 3- and 6-month group animals).

Figure 3: Photomicrographs, (a), (b) and (c), show skin-implant interface of 6-month animals (magnifications X20, X20 and X50 respectively). A physiological epithelial (skin) seal with the porous coating is shown at the implant exit site (a). Both vitalized and devitalized epithelial layers are seen near the interface in (b) and (c). Blood vessels (B) are clearly visible inside the porous coatings.

Summary
Despite of some early migrations, the skin seal remained durable for up to 12 months and prevented the peri-prosthetic infection (n=17). It appears that all the sheep with the porous coated subdermal barrier will make it to their assigned follow-up periods (3, 6, 9 and 12 months) without any clinical, microbiological, or bone tissue indications of infections.

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References