A Pig Model to Evaluate the Ability of Porous P^2 Titanium Coated Subdermal Disks to Prevent Infection in Transcutaneous Implants

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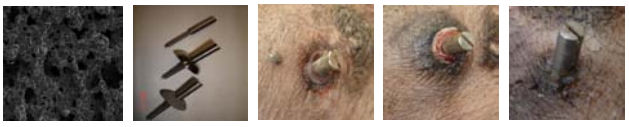
STATEMENT OF PURPOSE: The European clinical trials have shown that a direct skeletal attachment of prostheses via osseointegrated implants significantly increases the mobility, activity levels, and gait performance amongst patients with limb loss. However, widespread implementation of this technology is hindered by high infection rates originating at the skin-implant interface [1-2]. Improved integration of the skin with implant surface is expected to resolve this problem by reducing infection rates and subsequent implant failures. Thus, it is hypothesized that an implant with a subdermal barrier coated with P^2 titanium porous coating (Figure 1(a)) will (1) integrate with soft tissue to maintain the anatomical skin seal at the skin-implant interface and (2) prevent infection. An animal study was undertaken to test this hypothesis. As controls, implants with a smooth subdermal barrier and implants without a subdermal barrier (post only) were used to test the ability of a porous coated subdermal barrier to stabilize the skin at the time of surgery and prevent infection.

METHODOLOGY: 24 female Yucatan Miniature pigs were divided into 3 groups of 8 by a random number generator. The implants were surgically inserted into the medial aspect of the right tibia in accordance with the approved IACUC protocol, in which each pig received one bi-cortical screw (Figure 1(b)) fitted with a porous coated subdermal barrier or a smooth subdermal barrier or post-only attachment. Following implantation, the transcutaneous sites were monitored daily for clinical signs of infection and inflammation using a Checketts grading system [3]. At the completion of a 16-week post surgical period, or if a persistent infection was observed, the animal was sacrificed and the implant with its surrounding tissue harvested and processed for histology. Macroscopic images were taken to assess the skin-implant interface.



(a) (b) (c) (d) (e)

***Figure 1**: (b) SEM images of P2 coating. (a) The bi-cortical screw system used for this study. Representative photographs of implant exit site taken at necropsy (16 weeks after implantation); showing implants with a smooth subdermal barrier (c), a post-only (d), and a porous coated subdermal barrier (e).*

RESULTS AND DISCUSSION: The survival data shows 7 pigs from the smooth subdermal barrier implant group, 3 pigs from the diskless implant group, and 2 pigs from the porous coated implant group were sacrificed prior to the completion of the 16-week period. A Kaplan-Meier survival curve is used to represent outcome (Figure 2).

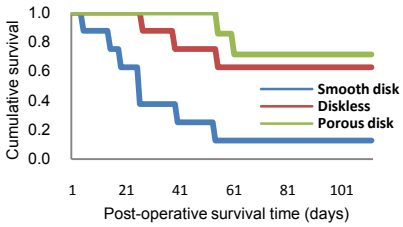


***Figure 2:** Kaplan-Meier survival curve*

This data shows there are statistical significance between smooth and porous coated implant groups (p=0.006), smooth and post-only implant groups (p=0.026); but, no statistical significance between the porous coated and post only implant groups (p=0.591). However, histological analysis showed differences between these groups.

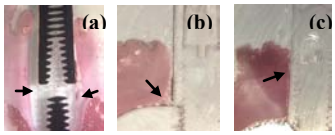


***Figure 3:** Representative photomacrographs (X2) of skin-implant interfaces stained with H&E; showing post-only (a), a smooth subdermal barrier (b), and porous subdermal barrier (c) groups. Controls (a) and (b) show a higher degree of skin marsupialization compared to the porous coated implant design (c) with P^2 type coating. Arrows indicate down-growth.*

Figures 1 and 3 demonstrate that both control groups (smooth and post-only) have created large sinus tracts around their respective implants; whereas, the implant with a porous coated subdermal barrier stabilized the skin at the interface had limited the formation of a sinus tract, but, failed to eliminate initial skin marsupialization. The gap around the percutaneous post indicates a lack of skin integration and presents a possible pathway for pathogen invasion, leading to the increased rate of superficial tissue infections.

CONCLUSIONS: In summary, the results partially support our hypothesis. Even though, a porous coated subdermal disk has integrated with the skin to limit the marsupialization, it failed to prevent infection completely. This model has verified the effectiveness of P^2 coating to limit the skin marsupialization as well as presenting a positive infection signal. It is recommended that surface modification of P^2 coating with bio-interactive proteins be considered to seal the skin and may result in prevention of marsupialization and subsequent infection in future studies.

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