Transcutaneous Porous Tantalum Implants Promote Bone but Not Sufficient Soft Tissue Ingrowth to Reduce Periprosthetic Infection

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Statement of Purpose: Infection prevention is a challenge that remains with transcutaneous osseointegrated implants intended for prosthetic attachment in amputees [4]. Previous studies have shown various porous materials allow tissue ingrowth [1,3,5]. However, no study appears to have examined tissue attachment for the purpose of preventing transcutaneous infections. The purpose of this investigation is to determine if transcutaneous porous tantalum implants can reduce pin track infection rates by allowing enough tissue attachment to maintain the periprosthetic skin barrier. The porous tantalum implant was compared to a smooth titanium implant.

Methods: A 2.7-mm diameter pin with a hexagonal cross-section and length of 36-mm was placed through both cortices of the tibia of New Zealand White rabbits so that the pin protruded through the skin on the lateral side. Nine rabbits received a smooth titanium pin. Eleven rabbits received a tantalum pin (porosity 75% to 80%) because of pilot work indicating that the tantalum pins had a higher probability of bending or breaking. The rabbits were inoculated weekly with $1x10^8$ *S. aureas* for an increased infection challenge[2]. The rabbits were euthanized when they showed clinical signs of pin track infection or at the end of the 24-week trial.

Using aseptic technique, cultures were obtained of muscle, blood, and bone at euthanasia. The rabbit was considered infected if at least one culture was positive, and there were clinical signs of infection. The tibia was embedded and sectioned to measure bone ingrowth by using backscatter electron imaging [1,5]. The sections were stained with Sanderson's™ Rapid Bone Stain with Acid fuchsin counterstain for analysis of soft tissue attachment under the light microscope (2x). Gaps between the soft tissue and the pin were measured since any gaps could be a pathway for bacteria (Figure 1).

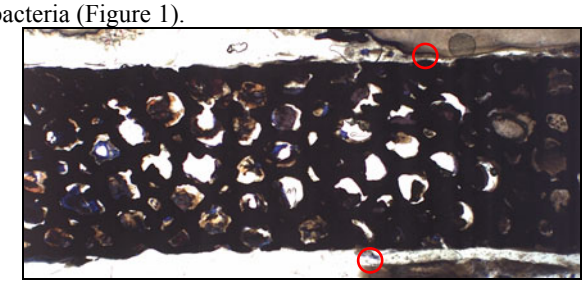

Figure 1 - Tantalum pin showing two gaps between the soft tissue and pin that could have provided a pathway for bacteria to infect the muscle tissue.

Statistical Analysis, for comparing infection rates, included a log-rank test for equality of survivor functions and, for comparing tissue attachment, an unpaired t-test.

Results/Discussion: The data demonstrated that the tantalum pins did not prevent pin track infection better than smooth titanium pins (p=0.248, Figure 2). All rabbits were euthanized due to clinical signs of infection during the first 10 weeks.

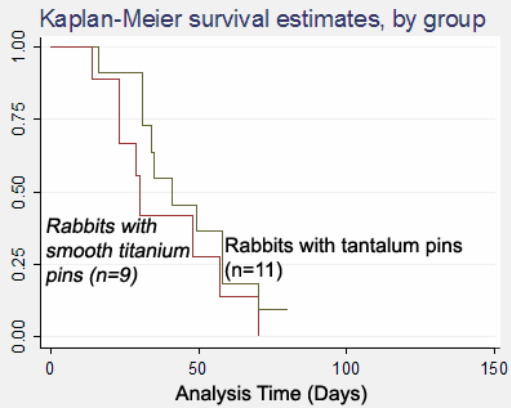

Figure 2 - Kaplan-Meier curve showing that the porous tantalum pins did not prevent infection any better than the smooth titanium pins (p=0.248).

Although the tantalum pins had soft tissue in the majority of the pores, gaps of at least 0.056-mm were between the pin and the soft tissue (Figure 1). The gap size around the tantalum pins (0.377 ± 0.333-mm, n=7) was not different from the titanium pins (0.246 ± 0.157-mm, n=5) (p=0.192). The bone ingrowth into the tantalum pins was 20% ± 14% at an average *in situ* time of six weeks.

Conclusions: Porous tantalum was successful in promoting bone ingrowth but did not achieve soft tissue attachment. Because of the gaps between the pin and soft tissue, it is proposed that the failure of porous tantalum pins in reducing the infection rate is the result of excessive skin mobility at the skin/pin interface. Skin mobility could have caused the soft tissue to break away from the pin leaving pieces of soft tissue in the tantalum pores and the gaps between the soft tissue and pins. Thus, a porous tantalum implant may not have promoted sufficient bonds between the skin and implant resulting in a breakdown of the skin barrier and, consequently, periprosthetic infection. Regional skin immobility strategies in conjunction with implants that promote soft tissue ingrowth should be considered for future studies investigating methods of transcutaneous infection prevention.

Acknowledgements: We wish to thank TATRC for providing funding (W81XWH-05-1-0628), the Zimmer Corporation for donating the pins, and Tyler Epperson for his extra efforts in the laboratory.

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