Sphere Templated Angiogenic Regeneration (*STAR*™) Biomaterial for Reducing Infection Associated with Percutaneous Devices

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Percutaneous catheters are essential in patient care; they are used for many functions including dialysis, chemotherapy and nutritional supplementation. The skin barrier breach for the device typically has poor sealing that predisposes the patient to infection, especially with extended use.

Previous rodent studies have shown that the *STAR*™ biomaterials with specific pore sizes promote cell anchorage and cutaneous integration. Here we present results for *STAR*™ biomaterial catheter cuffs evaluated in a pig model. The study objective was to determine if an exit site seal could be formed sufficient to protect against bacterial infection.

Methods: Porous silicone *STAR*cuffs™ were fabricated from Dow Corning Silastic MDX4-4210 according to US Published Patent Application 2008/0075752 providing 36-µm spherical pores interconnected by 15-µm throats. Figure 1 shows corresponding SEM images.

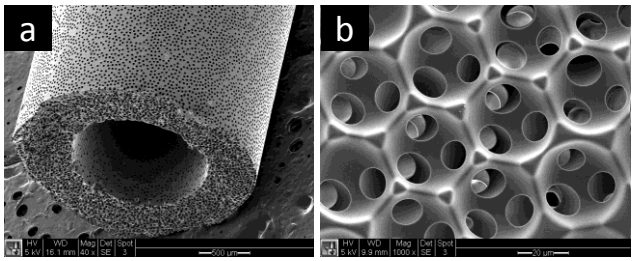

Figure 1. (a) *STAR*cuff™. (b) *STAR*™ pore structure.

In each of two 35-kg domestic pigs (Genetiporc, Inc.), twelve 4-cm segments of size 5F silicone catheter tubing were implanted percutaneously in the dorsum, with the exterior end sealed with a plug of silicone. Half of the implants (6 in each animal) were fitted with *STAR*cuffs™ positioned at the skinline.

The test sites on both animals were sprayed with chlorhexidine antiseptic on days 0, 3, 7, and 14 and protected inside a breathable sealed compartment. On day 23, the wound sites on one animal were inoculated by placing a porous polycarbonate ring loaded with 10^4 CFU of *S. aureus* onto the skin around the implant; the other animal received polycarbonate rings loaded with PBS only. The rings were removed on Day 24. Digital photos and infrared thermography images (FLIR P640) were taken at days 0, 3, 7, 14, 23, 24, 25, and 28. The animals were euthanized on Day 28. Samples were harvested and submitted for either histological analysis or quantitative bacterial culture.

Results: During the first week of the experiment, some implants migrated inward enough that they were fully subcutaneous. However the majority lost were plain catheter tube controls, an indication that the cuffs had already achieved a degree of tissue adhesion.

We used infrared thermography to measure the temperature of the implants relative to the surrounding skin. Figure 2 shows the temperature of the implants on the challenged animal. The temperature of uncuffed control implants increased significantly over the 5-day period, while the temperature of the implants fitted with *STAR*cuff™ remained constant. On the control animal that did not receive the challenge, the temperature of the plain control implant remained constant.

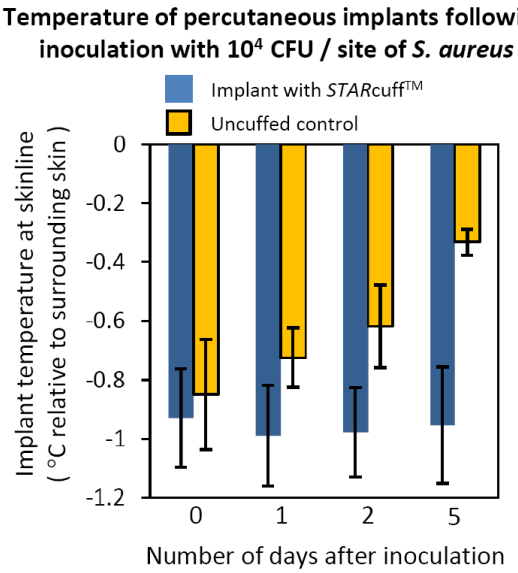

Figure 2. Infrared thermography results.

Conclusions: We believe that the increase in temperature of the uncuffed control implants is a result of inflammation due to the presence of bacteria near the tissue-implant interface. The lack of a temperature rise for the implants with *STAR*cuff™ suggests that they are less prone to infection than uncuffed implants. We will discuss this thermography result and its relationship to histopathology and quantitative bacterial culture data.

References:

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