Preparation and Mechanical Testing of an Antimicrobial Coated External Fixation Pin

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Statement of Purpose: Patients with traumatic injuries that include soft tissue and orthopaedic wounds are at high risk for infection, catastrophic loss of tissue and impaired wound healing. In a clinical series, Mahan concluded that all external fixation pin sites are contaminated and 75% of pin tips cultured positive for infection [1]. More recently, in a consecutive series of 285 patients, Parameswaran showed that infection rates can range from 4% to 20% [2].

A potential solution to this problem presents itself in the form of an antimicrobial coating for external fixation pins. However, such a coating is susceptible to partial or complete removal during placement due to mechanical forces. An antimicrobial coating comprising calcium phosphate and gentamicin was applied to a pin and the coating durability was tested by drilling through a human fibula. The pins and bone were then examined under magnification and challenged with *S. aureus* to determine the condition of the coating.

Methods: External fixation pins (OrthoPro, LLC., Salt Lake City, UT) were plasma treated with 3-glycidoxy-propyltrimethoxysilane followed by mineralization of $CaPO_4$ according to [3,4]. Upon drying, gentamicin was incorporated by dipping the pins into a 5% gentamicin sulfate solution in 50% ethanol.

A section of human fibula was processed according to Good Tissue Practices (GTP). This generous gift of tissue was processed from a donor for whom research consent was given. The antimicrobial coated external fixation pins were driven through the mid diaphysis of the fibula. On the first attempt the fibula cracked upon the pin hitting the second wall of cortical bone. The single cortical wall containing the pin was split along the length of the bone segment to release the pin prior to plating. For the second pin, the tissue was reconstituted in 0.9% NaCl before drilling, to more closely match clinical conditions. After driving the pin, it was visually examined under magnification. The pins and/or bone segments were then placed in Mueller-Hinton agar plates inoculated with *S. aureus* to detect the presence of gentamicin.

Results/Discussion: Formation of a self assembling monolayer of silane molecules on a stainless steel, titanium, or polymeric medical device (external fixation pin, prosthetic implant, etc.) followed by deposition of a calcium phosphate thin film onto the monolayer is an attractive platform for delivery of bioactive agents. A drug can be incorporated into the calcium phosphate film via coprecipitation with the $CaPO_4$ or by dipping the coated device into a suitable solvent containing the bioactive agent. After placement of the device, the drug is released by both diffusion and by ablation of the calcium phosphate film. In many clinical applications, however, the coating is subjected to pronounced mechanical forces. Such is the case for the coating of a self-tapping external fixation pin. Although the first attempt at drilling the fibula resulted in splitting of the fibular shaft upon hitting the second cortical wall, it was found that reconstituting the fibula in 0.9% NaCl prior to drilling allowed the pin to be driven through both cortical walls. An examination of the pin under magnification shows evidence of the coating on the threads after they had passed through the cortical wall (Figure 1b). After visual examination, the pin and the bone segment housing the pin were plated on cultures of *S. aureus* to test for antimicrobial efficacy. The result clearly shows the antimicrobial efficacy of the coating in the immediate vicinity of the pin after driving it through the fibula (Figure 1a).

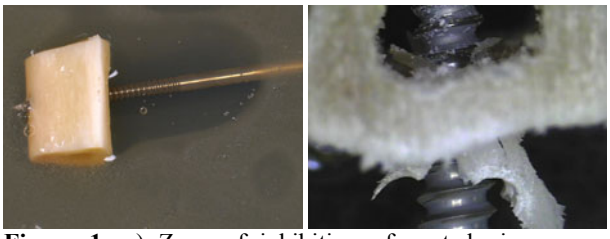

Figure 1: a) Zone of inhibition of coated pine screwed through bone. b) Magnified (15x) image of coated pin after penetration through bone.

Conclusions: The use of a thin film calcium phosphate coating as a platform for delivery of local antibiotics remains an attractive option for attenuating wound site infections in orthopaedic settings. The thickness of the coating (10-20 μm) reduces the likelihood of interference with the function of the coated device. Additionally, the calcium phosphate film is compatible with autoclave sterilization, allowing the device to be sterilized under conditions available in third world countries or field hospital conditions. Herein, we have demonstrated the feasibility of using a thin film calcium phosphate coating on an external fixation pin for local delivery of the antibiotic gentamicin. Studies are needed to confirm the efficacy of this coating in a clinical setting. This coating should prove adaptable to other orthopaedic hardware such as pedicle screws or fixation plates.

References:

[1] Mahan J Orthopedics 1991;14: 305-308.
[2] Parameswaran AD J Orthop Trauma 2003;17:503-507.
[3] Campbell AA J Biomed Mater Res 1996;32(1):111-118.
[4] Bunker BC Science 1994;265:1839-1841