Toward an Antimicrobial Coated External Fixation Pin

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Statement of Purpose: Patients with traumatic orthopedic injuries are at high risk for organism colonization of exposed tissue and infection, which can cause 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 contamination [1]. More recently, in a consecutive series of 285 patients, Parameswaran showed that infection rates can range from 4% to 20% [2].

Conventional strategies for pin-site care provide less than optimal results; once normal skin flora enter the pin track they have unfettered access to bone, exposing the patient to a potentially serious infection. One solution to this problem is prevention of organism migration along the pin track, providing protection against entry into the wound site. Such protection can be efficiently obtained through an antimicrobial coating applied to the fixation pin during manufacturing. Such a coating may be susceptible to partial or complete removal due to pronounced mechanical forces encountered during placement. Chemical etching may provide a way of partially shielding the coating from said forces, thereby preserving antimicrobial content post-drilling. Additionally the coating will be preserved at the entry-point into bone.

Another benefit of such a coating is the provision of antimicrobial agent at the wound site, which can potentially lessen the need for systemic administration of antibiotics.

Methods: Bar stock stainless steel and external fixation pins were subjected to various etching conditions followed by drilling through simulated bone material as follows. Medical grade stainless steel orthopedic screws and bar stock were chemically etched by treating with a solution of 30% HNO_3 - 6% HF for 30 min at 50 ˚C. Additional etching conditions included concentrated HCl at 50 ˚C and oxalic acid. The screws were then thoroughly neutralized, rinsed, cleaned, and then coated with a poly(vinyl) alcohol (PVA) solution containing a fluorescent dye as an antimicrobial surrogate. After acid-catalyzed aldehyde crosslinking the screws were drilled through simulated bone material (Sawbones biomechanical test blocks) and remaining adhered polymer was observed. Additionally a crosslinked silver sulfadiazine/PVA coating was employed to measure initial silver elution prior to drilling to gauge silver release from the screw above the bone entry point, and to assess zones of inhibition (*S. aureus* on Mueller-Hinton agar, incubated overnight at 37 ˚C) generated by the coating after drilling. Silver elution from pins containing the PVA / silver sulfadiazine coating was examined by immersion in a simulated electrolyte solution, incubation at 37 °C, and the full solution replacement at 1, 4, 24, and every 24 hours thereafter. Silver content was then quantified using graphite furnace atomic absorption spectroscopy.

Results/Discussion: Both the 30% HNO_3 - 6% HF for 30 min at 50 ˚C and the concentrated HCl at 50 ˚C gave good etching results, as shown in Figure 1 for the former experiment. Use of the fluorescent dye as an antimicrobial surrogate proved more difficult in practice than simply using the antimicrobial agent of interest, silver sulfadiaze. Silver elution was measured in quantities exceeding 1.5 $\mu g/cm^2$ per day through 14 days. The assay was stopped at 14 days due to meeting the previously established end-point, but the data acquired suggested elution might continue for an extended period beyond 14 days. Plating the screws on *S. aureus* after drilling revealed zones of inhibition greater than 13 mm for the drilled portion of the screw.

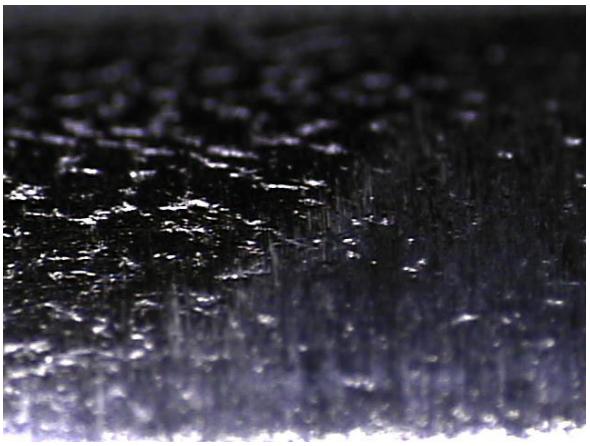

Figure 1: a) Magnified (31x) image of 30% HNO_3 - 6% HF etched bar stock adjacent to the native stainless steel surface.

Conclusions: The use of a PVA/silver sulfadiazine coating on a fixation screw for suppression of organism migration down a pin track is an attractive option for attenuating wound site infection rates in orthopaedic settings. We have demonstrated the potential efficacy of such a coated device through chemical etching, silver elution, and microbial inhibition studies.

References:

[1] Mahan J. Orthopedics 1991;14: 305-308.
[2] Parameswaran AD. J Orthop Trauma 2003;17:503-507.