Efficacy of Three Antibiotic Loaded Polymer Coatings for Bone Screws

Zane Hartsell[1], Alex Hoban[1], Joel Bumgardner[1], Harry Courtney[2], Mark Gosney[3], Warren Haggard[1]
1 University of Memphis, 2 Veterans Affairs Medical Center and University of Tennessee Health Science Center, 3 Smith & Nephew Orthpaedics, Inc

Statement of Purpose: Contamination of bone extremity fracture sites with bacteria can be complex to treat [1]. An opportunity to provide controlled release of antibiotics by a degradable polymeric coating on orthopaedic bone fixation implants is a promising treatment approach [2,3]. The focus of this research was to select three potential biodegradable biomaterials (Chitosan, Poly L-Lactic Acid, and Degradable Polyurethane), load them with antibiotics, coat medical implants and test their antibiotic elution, and their mechanical and biological efficacy in a comparative study.

Methods: Orthopaedic fixation screws were utilized for this study because they have the opportunity to be inserted directly into the contaminated or compromised region of a patient with a bone fracture. Sterilized screws were coated with Chitosan, Poly L-Lactic Acid (PLLA), or Degradable Polyurethane solutions that had been impregnated with tobramycin. Each screw was dip coated by hand for approximately 1 second and placed on a custom rotating drying wheel (30 RPM) to facilitate even coating thickness. Screws (n=5 for each coating type) were tested for zones of inhibition of growth of *Staphylococcus aureus* (*S. aureus)*, elution (7 day period in PBS), insertion (abrasion testing in predrilled 20 pcf polyurethane foam) (Pacific Research, Vashon, WA), and eluates tested for inhibition of growth of *S. aureus* in broth. All samples were weighed before coating, after coating, and post testing to allow for normalization of the results based on weight of coating and quantity of Tobramycin. Controls (coatings without tobramycin) were run for the zone of inhibition and elution studies to ensure results were not influenced by solvents leaching out or degradation products of the coatings.

Results: Each of the coating types produced a zone of inhibition approximately 26 mm in diameter (range 25-29 mm), and there was no statistically significant difference between the coatings (Figure 1). There was a small zone of clearing on the control samples coated with chitosan without tobramycin (10mm) suggesting there is an innate antimicrobial effect of the chitosan material. The controls for both the polyurethane and PLLA showed no to minimal effect on growth of the bacteria. The elution study showed that the chitosan coating had the largest burst release while the PLLA showed a release over 48 hours and the polyurethane produced a consistent elution over the 168 hour study (Figure 2). The polyurethane coating was the most durable coating in the abrasion testing with a weight loss of 1.78±0.89%, as compared to 21.18±18.03%, and 3.3±2.53% with the chitosan and PLLA, respectively. Testing for antibacterial activity of a 1:10 dilution of eluates indicated that only the first time point of the chitosan coated screw group inhibited staphylococcal growth.

Figure 1: Zone of inhibition results: uncoated (left) and PLLA coated (right)

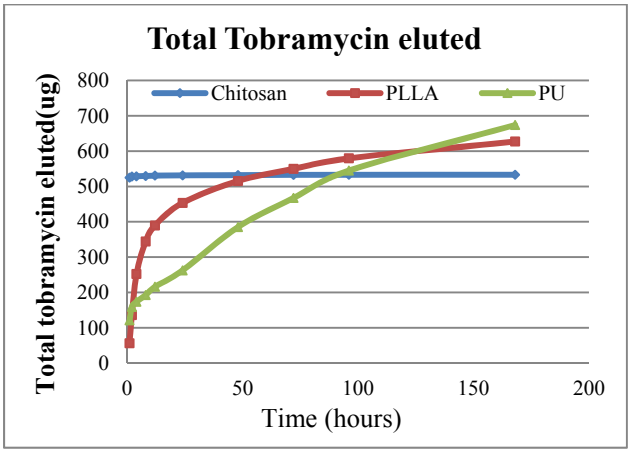

Figure 2. Elution results of total tobramycin released.

Conclusions: This preliminary study demonstrates that there are benefits and limitations of the three coatings selected for analysis. While all three of the coatings provide zones of inhibition on agar plates the chitosan coating was the only one that was able to reduce the S. aureus growth in broth and only its early elution time point was effective. The polyurethane coating was able to provide the most resistance to delamination of the coating during implantation. Future studies with higher antibiotic concentrations will be needed to see if the coatings can be further modified to prevent infection in these contaminated bone fractures.

References:

1. Keating, J. F. JOT 1996: V10 (5), 298-303.
2. Porter, J. R. Biotechnology Progress 2009: V 25(6), 1539-1560.
3. Sungwon Kim. EUR J PHARM BIOPHARM 2009: V 71(3), 420-430.