AN IN VIVO ANALYSIS OF A BIOMIMETIC APATITE COATING GROWN ON TITANIUM SURFACES

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Introduction: Osteoconductive mineral coatings represent an established technology for enhancing the integration of orthopedic implants with living bone. However, current coatings have limitations related to fabrication methods, attachment strength to metal substrates, and in vivo performance. Most coatings in the market today are fabricated using a plasma-spraying technique, which is mainly a line-of-sight methodology and therefore does not cover all surfaces of a complex implant (deep grooves or surface porosities). These coatings do not fare as well as cementing techniques in short-term implant fixation. However, bone cement has been associated with implant loosening after 7-10 years post-operation due to production of debris particles and poor micromechanical integration with bone; it is still currently the gold standard for implant stabilization. Low temperature solution deposition is a new coating technique wherein the device to be coated is immersed in a saturated solution of the coating constituents and precipitation is then allowed to proceed. This method allows for a three-dimensional uniform coverage of all areas of the implant. This improves the surface area of the coating exposed to the bone, and may increase the fixation to newly formed bone. It varies from other coating techniques due to the relatively low temperature conditions that exist during the fabrication of the coating. This allows for the formulation of a low density, biodegradable, thin coating on a surface. This study will focus on the in vivo evaluation of a biodegradable HA coating fabricated under these conditions. The ability of this coating to promote bone ingrowth and apposition to the implant surface was assessed in vivo in an established canine bone chamber model.

Materials and Methods: Implantable bone chambers were assembled with five Ti6Al4V HA coated coupons lying adjacent to four uncoated coupons within a polyethylene shell casing. The sterile chambers, with dimensions of 8mm wide x 25mm long x 10mm deep, contained 4 coated channels and 3 uncoated channels each. Each coupon had 5mm x 8mm of its surface exposed to the channel, making a volume of 40mm³ that was available for tissue ingrowth per channel. The chambers were implanted into the lateral metaphysis of the distal femur of 8 skeletally mature large coonhound dogs. The chambers were harvested and processed for histological and Backscattered Electron Imaging (BEI) analysis. Samples were cut slightly off center and in a plane parallel to the tissue-coupon interface. Bone linear ingrowth, area ingrowth and continuous apposition percentages were calculated using sections stained with Stevenel’s Blue and Van Gieson’s picro fuschin. Gross histological analysis and SEM/BEI analysis of the chamber sections was also conducted to analyze the in vivo response to the coated and uncoated coupons. All statistical analysis was done using a repeated measures general linear model.

Results: The linear ingrowth percentages did not differ significantly between the two treatments in all study groups. However, area ingrowth and apposition percentages exhibited significant differences between treatments in all study groups (p<0.05). These results are shown in Table 1.

<table>
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<tr>
<th></th>
<th>6wk C*</th>
<th>6wk U*</th>
<th>8wk C*</th>
<th>8wk U*</th>
<th>12wk C*</th>
<th>12wk U*</th>
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<td>Area (%)</td>
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<td>Apposition (%)</td>
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<td>20.47</td>
<td>2.39</td>
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Table 1: Area Ingrowth and Apposition % of coated and uncoated channels at 3 time points- all time points displayed significance (p < 0.05) between treatments; *C = coated; U = uncoated

In general, coated samples filled the channels width-wise with far less fibrous tissue encapsulation than uncoated samples. The 8 and 12 week uncoated samples contained well oriented fibrous tissue rich with fibroblasts while 6 week samples contained more immature fibrous tissue. Coated samples also contained a direct bone/implant interaction throughout a greater portion of the channel length, with areas of osteoelastic activity interspersed between the attached bone to metal. The fibrous tissue layer seen in the uncoated channels was continuous with an occasional projection of trabeculae through the fibrous interface layer (Figure 1a & b).

Discussion: In vivo experiments demonstrated that under controlled conditions, the HA coating did stimulate osseointegration with the metal surface with a reduction in fibrous tissue encapsulation. By examination of all time periods with histology and BEI, it was observed that the HA coating dissolved quickly after implantation. BEI showed that 6 week and 8 week samples exhibited the stable coating only in areas where bone had become apposed to the metal surface (Figure 1c). All other areas contained no traces of the coating. The 12 week samples contained no coating, even in areas with direct bone apposition. This observation suggests that the coating is degrading rapidly once implanted in vivo, and may be stabilized by the attachment to bone initially. It may then become incorporated in the new bone and then remodeled as the bone matures. No distinction in the coating/bone interface was therefore observed. Analysis of treatment versus time exhibited a general peak in bone ingrowth between 6 and 8 weeks post-surgery, with a decline in ingrowth at the 12 week time period. This indicates that osteoblast activity dominates for the first 8 weeks during new bone formation, with greater osteoclast activity occurring after that time period. Linear ingrowth percentage was the only analysis that showed no difference between coated and uncoated specimens. Although bone did grow into the uncoated channels, gross observation of the specimens showed that the uncoated channels in all study groups contained bone that was surrounded by a fibrous tissue sheath. This suggests that area ingrowth and continuous bone apposition measurements may be a better indication of the fixation ability of the HA coating. Since both area ingrowth and continuous bone apposition percentages were significantly higher in coated channels than in uncoated channels, this new HA coating may in fact improve the fixation of an implant to bone. Previous studies have shown that there may be a correlation between direct bone apposition to a metal surface and mechanical strength of the interface. Mechanical strength tests will be done in the future to test this theory and determine if bone/metal fixation was in fact improved.

References:
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Figure 1a*                           Figure 1b*                     Figure 1c*

a. Coated 8wk channel showing greater apposition and area ingrowth
b. Uncoated 8wk channel showing greater fibrous tissue encapsulation
c. Coated 8wk channel showing stabilization of coating at bone/metal contact points

* light grey: metal coupon; grey: bone; dark grey: fibrous tissue (only shown in figure 1b)

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