In-Vivo Performance of a Novel Bioabsorbable Suture Anchor in a Rabbit Femoral Model

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Statement of Purpose: The purpose of this work was to test the *in-vivo* performance of a novel polyester-based composite material in a rabbit femoral model. Although aliphatic polyester-based biomaterials have a history of being biocompatible and non-toxic, there still exists a need to optimize the formulation and in turn degradation properties of composite materials. A number of commercially available PLA-based products have been reported as having not fully resorbed after > 5 years in patients. In certain cases, a significant inflammatory response due to remnants and fibrous encapsulation required the implant material to be surgically removed [1]. In addition, the acidic by-products of aliphatic polyester formulations, when used as the sole implant material, may cause inflammatory reactions due to autocatalysis and burst release effects [2]. As a result, the particular combination reported in this study, a PLA-based polymer combined with micron-size porous β-tricalcium phosphate (β-TCP), is an attractive composite material for the following reasons: 1) meets the criteria for mechanical performance; 2) β-TCP buffers the polymer acidic by-products; 3) the polymer formulation has an adequate degradation profile. It was hypothesized that the polymer composite would have significant degradation after one year *in-vivo* in a rabbit femoral model.

Methods: Sample fabrication- Poly(lactide-co-glycolide) (PLGA) 90:10 was compounded with β-TCP (10-30μm ave. diameter). Two treatment groups were fabricated: 1) PLGA + β-TCP (25wt%); 2) PLGA + β-TCP (50wt%). Samples were sterilized via gamma, and implanted into the femoral condyle of female rabbits. At 24 and 48 week time points, explants were harvested. MicroCT (Skyscan, Belgium) was used for obtaining slices and 3-D renderings. Calcified sections were prepared and stained with hematoxylin and eosin, Weigert Van Gieson and Masson's Goldner's Thrichrome (MTG).

Results/ Discussion: MicroCT images showed that there was bone growth in the area surrounding the implant for both formulations at 24 and 48 week time points. The 48 week samples also had new bone formation within the implant region. Although the Skyscan software can quantify "new bone growth", these values cannot be regarded as meaningful due to the similarity of the calcium phosphate density and bone density when performing this analysis. Therefore, microCT was used for qualitative purposes only. In order to assess new bone formation, histology and histomorphometry were used.

Histology images showed that the material was non-toxic and biocompatible. Osteoid formation was visible at the implant interface. Mineralized trabeculae generally closely entwined the implants for both formulations and both time points. Histology images also showed changes in the shape of the implant, which can be attributed to the degradation process.

The 48 week time point showed a relatively higher amount of new bone formation within the area of the implant when compared to the 24 week images (Fig. 2). These results are indicative of improved degradation and bone in-growth relative to the slow degrading PLA implants [1].

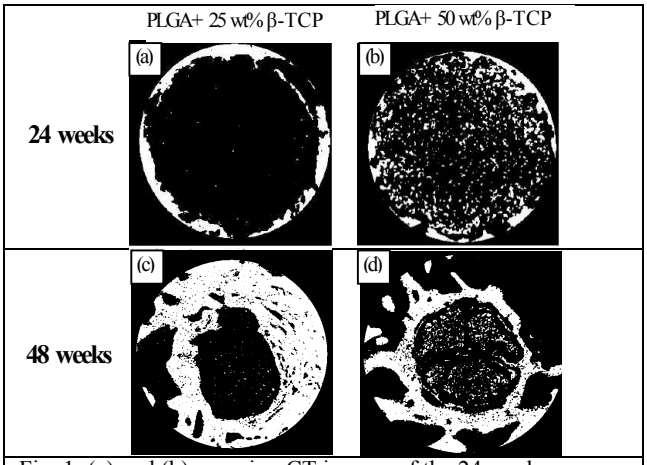

Fig. 1: (a) and (b) are microCT images of the 24 week samples; (c) and (d) are images of the 48 week samples. 48 week samples showed bone ingrowth within the implant.

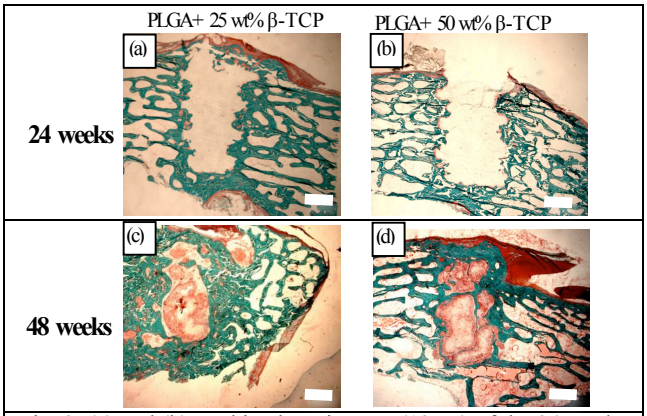

Fig. 2: (a) and (b) are histology images (12.5x) of the 24 week samples; (c) and (d) are images of the 48 week samples (scale bar= 1mm). MTG 24 week staining showed new bone formation at the implant/ native bone interface. There was substantial degradation and new bone formation at 48 weeks.

Conclusions: MicroCT and histology showed material degradation, especially after 48 weeks, for both formulations. The results are promising, as this may be a viable material for producing devices that resorb within a 2 to 3 year time frame, while allowing *de novo* bone formation to proceed in parallel with material degradation. A follow up study will be planned with a 90 week time point to further confirm that most or all of the material has fully resorbed. In addition, biocompatibility (via histology analysis) will be performed.

References:

[1] Bergsma EJ. J Oral Maxillo. 1993;5:666-670.
[2] Maquet V. Biomat. 2004;25:4185-4194.