Histologic and Histomorphometric Analysis of Two Graft Materials in a Non-instrumented Canine Interspinous Spinal Fusion Model

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Statement of Purpose: Iliac crest bone graft (ICBG) has long been considered the gold standard for spine fusion procedures. The significant complication rate due to harvesting and limitations in the quantity available has encouraged researchers to develop alternative materials. Biomimetic calcium phosphate (CaP) ceramics have been widely used as bone graft substitutes due to their excellent biocompatibility, good bone conduction and unlimited availability. Recently calcium phosphate ceramics having specific surface structures have been shown to enhance and accelerate bone regeneration [1]. In the current study, we compared a novel tricalcium phosphate (TCP) bone graft material and a commercially available Bioactive β-TCP/Bioglass (Vitoss BA) material for bone formation, in a non-instrumented canine interspinous spinal fusion model.

Methods: This study evaluated the efficacy of the novel composite of TCP ceramic combined with a dissolvable carrier (AttraX® Putty, NuVasive Inc., San Diego, CA) versus the commercially available Bioactive β-TCP/Bioglass/Collagen composite (Vitoss BA, Orthovita/Stryker, Malvern, PA) in a non-instrumented canine interspinous spinal fusion model. The physicochemical properties of both ceramics within the composites were evaluated by XRD, SEM and Hg-intrusion porosimetry (Table-1 and Figure-1). TCP within AttraX Putty is a β-TCP ceramic with a specific surface area of 1.85 m^2/g and total porosity of 72% (among them 22% volume of pores smaller than 1 µm). The TCP within Vitoss BA is β-TCP as well, while it has a specific surface area of 0.36 m^2/g and a porosity of 78% (among them 1% volume of pores smaller than 1 µm). A single level non-instrumented interspinous lumbar fusion was performed at L3-L4 in 8 adult male mongrel dogs. During the surgery the spinous processes and the vertebral body between L3 and L4 were exposed on the left and right side by blunt separation, and decorticated to elicit bleeding. 5cc of each graft material was placed on either right or left side of the spinous processes, bridging the adjacent levels. The intact interspinous ligament maintained separation of the two graft materials. This study design provided intra-animal comparison of the two graft materials. During the surgeries no bone marrow aspirate or growth factors were added to either graft materials. At twelve weeks, animals were euthanized and implants were embedded in PMMA for routine histology and histomorphometry evaluation for bone formation.

Results: No inflammation or signs of graft rejection were evident for either group after a 12-week implantation. Abundant new bone (20.7±6.7%) was formed in AttraX implants between the spinous processes (Figure-2), while no bone formation (0%) was observed in any of the Vitoss BA implants.

Table – 1: Physicochemical comparison of both graft materials. Novel TCP has increased surface area and nanopores compared to Bioactive β-TCP.

Properties	TCP	Bioactive β-TCP
Crystalline Structure	β-TCP	β-TCP
Specific surface area (m^2/g)	1.85	0.36
Total Porosity (%)	72	78
Porosity <1µm (%)	22	1

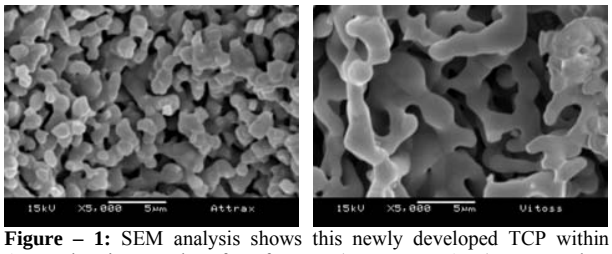

Figure – 1: SEM analysis shows this newly developed TCP within AttraX has increased surface features (e.g. pores <1µm) compared to TCP within Vitoss BA.

Although abundant bone formation was observed histologically with the TCP graft material, complete bridging from one spinous process to another was neither expected nor observed histologically. This is typical of this model [1] and it is assumed to be due to excessive motion across the non-instrumented defect.

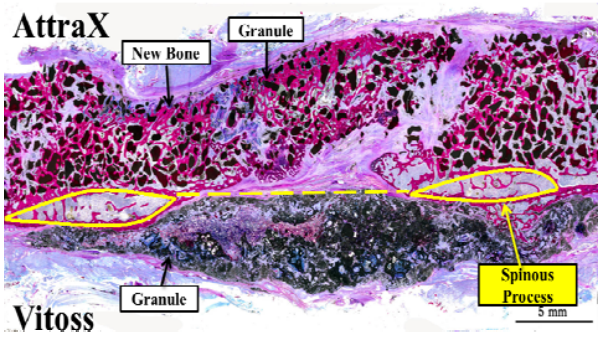

Figure – 2: Example of a histological section. Abundant bone formation (red) is evident around the TCP granules (black) in AttraX implants but no bone formation was observed with the Vitoss BA implants.

Conclusions: The results clearly show that, this novel TCP graft material (AttraX) resulted in significantly higher amount of new bone when compared to the commercially available Vitoss BA. This increased bone formation may be attributed to the unique surface structures including an increased percentage of pores smaller than 1µm.

References:

1. Yuan H, PNAS 2010; 107(31): 13614-13619