A Novel Resorbable, Osteoconductive Tetracalcium Phosphate - Phosphoserine Bone Adhesive for Spinal Fusion: Initial in vivo Studies in a Rabbit Posterolateral Fusion Model

Howard Eisenbrock DO; Brian J. Hess BS, MBA; George W. Kay DMD, MMSc; Michael C Brown BS; David J. Kosh; Andrey Marchenko BS; Jonathan R. Slotkin MD; Eric J. Woodard MD

[Institution]

Click To Add Logo

Introduction

We describe initial in vivo investigations of a novel calcium and phosphoserine-based bone adhesive. This material shows a unique constellation of properties including rapid self-setting, immediate tensile and load-bearing strength, and notable capacity to adhere to both bone and metal. This material is gradually biodegraded and replaced by bone through bone growth and remodeling. The aim of this study was to examine the tensile strength of this material and its prospective radiographic findings in a rabbit posterolateral fusion model.

Methods

Twelve adult New Zealand White rabbits underwent testing at the L5-6 level. The transverse process (TP) were exposed and decorticated at L5 and L6 bilaterally using a high speed drill. Rabbits received either freeform syringe-injectable or preformed solid-state material. One rabbit was used as a negative control. All rabbits were analyzed using Cone Beam Computed Tomography (CBCT) every three weeks. Selected animals were chosen for biomechanical testing at 3, 6, and 10 weeks. Tensile strength testing was done at both L5/6 (experimental level) and L4/5 (control).

Results

In this study our T=0 data shows a 1.66x increase in tensile strength with freeform syringe-injectable material compared to control (131.4 N vs. 79.1 N). Later data points show an even greater increase in strength as compared to control: 283.7 N at 10 weeks with freeform and 257 N,283.7 N, and 288.5 N at 3,6,and 10 weeks respectively for preformed material.

Conclusions

This material has shown initial promise to be a valuable adjunct for posterior spinal fusion as evidenced by initial strength testing and imaging data. Ongoing in vivo and in vitro testing will determine what role it may have in future spine surgery.

Learning Objectives

By the conclusion of this session participants should be able to 1) Understand the potential role of the material 2)Conceptualize spinal fusion without the use of instrumentation, 3) Advance knowledge of nanomaterials

References

1. An experimental lumbar intertransverse process spinal fusion model. Radiographic, histologic, and biomechanical healing characteristics. Boden SD et al. Spine (Phila Pa 1976). (1995)

2. Fischer CR, Cassilly R, Cantor W, Edusei E, Hammouri Q, Errico T. A systematic review of comparative studies on bone graft alternatives for common spine fusion procedures. European Spine Journal. 2013;22(6):1423-1435. doi:10.1007/s00586-013-2718-4.

3. Rajaee, S. S., Bae, H. W., Kanim, L. E., & Delamarter, R. B. (2012). Spinal fusion in the united states: Analysis of trends from 1998 to 2008. Spine, 37(1), 67-76

4. Renub Research, "Global Spinal Fusion Market, Procedure Volume and Forecast (November, 2015) 5. National Center for Biotechnology Information. U.S. National Library of Medicine, n.d. Web.

05 Apr. 2016. <http://www.ncbi.nlm.nih.gov/pubmed/2131139

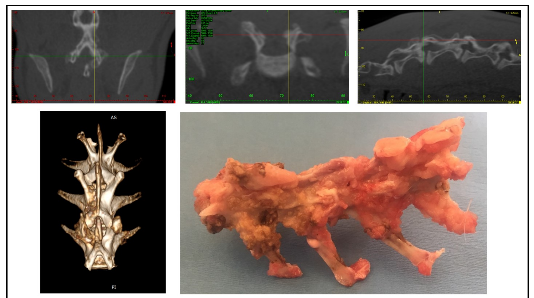

Figure 1 (A-E): Coronal (1-A), Axial (1-B), Sagittal (1-C), and 3-D reformatted (1-D) CBCT images of control rabbit sacrificed at ten weeks. Explanted spine with L4/5,5/6 segments (1-E).

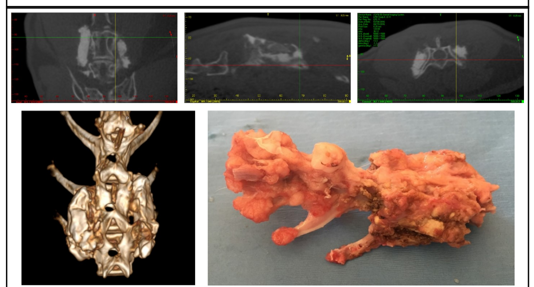

Figure 2 (A-E): Coronal (2-A), Axial (2-B), Sagittal (2-C), and 3-D reformatted (2-D) CBCT images of test rabbit implanted with solid-state material. Explanted spine with L4/5,5/6 segments (2-E).

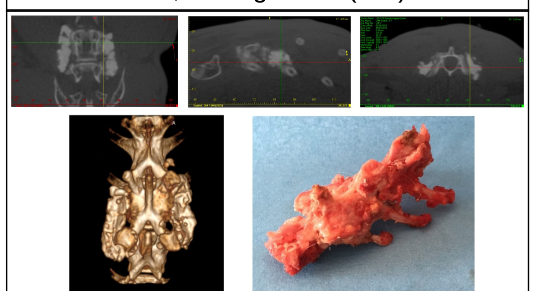

Figure 3 (A-E): Coronal (3-A), Axial (3-B), Sagittal (3-C), and 3-D reformatted (3-D) CBCT images of test rabbit implanted with freeform injectable material. Explanted spine with L4/5,5/6 segments (3-E).

Bar graph. Tensile strength