# Comparison of Silicated–Apatite and β-TCP Granules in a Critical Size Bone Defect Model

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**Statement of Purpose:** Using a 1.5 mm radial defect model in rabbits, the objective of this study is to compare the quality and rate of bone healing in animals treated with silicated calcium phosphate granules to β-TCP Granules in a critical size long bone defect model.

**Methods:** A total of 12 skeletally mature (<6 months) New Zealand White Rabbits underwent surgery for a 1.5 cm critical size defect of the left radius. One animal was excluded from the β-TCP Granules group due to an ulna fracture which occurred prior to the study's endpoint. Each defect site was randomly assigned one of two treatments;

- **Treatment 1:** 0.8% Si-apatite (n=6)
- **Treatment 2:** β-TCP Granules (n=5)

Prior to implantation, each test article was mixed with a 1:1 ratio of bone marrow aspirate (BMA) harvested from the greater trochanter of the femur. A total of 0.3 cc graft material + BMA was delivered into the defect site using a modified 1 cc syringe. All animals had an *in-life* duration of eight weeks.

After the animal was sacrificed, the entire forearm was harvested, trimmed of soft tissue and placed in 10% neutral buffered formalin for fixation. Each sample was scanned using a Scanco Micro CT80 for 2D and 3D imaging and qualitatively scored for fusion.

Post scanning the samples were trimmed, dehydrated, and embedded in methyl methacrylate for undecalcified histology. Two slides, 50 – 70 µm thickness, were prepared by the cutting/grinding method of Donath[1] on an Exakt cutting/grinding system. The slides were stained with Sanderson's Rapid Bone Stain and Van Gieson's stain. Slides were semi-quantitatively scored for degree of bridging, bone formation and histomorphometry.

For all data, significance was determined at the 95% confidence level, $p < 0.05$.

**Results:** Analysis was performed on 0.7X magnification images of each of the stained slides (2 per sample). Blinded observers scored for both degree of bridging and bone formation[2]. Both scores resulted in no significant difference for all treatments as seen in Table. 1.

| Treatment Group | Degree of Bridging | Bone Formation |
|---|---|---|
| 0.8% Si-apatite | 2.9 ± 1.8 | 3.5 ± 0.8 |
| β-TCP Granules | 2.9 ± 1.6 | 3.4 ± 0.5 |

**Table 1.** Mean histological scores for bone bridging and formation.

Histomorphometric evaluation of percentage of bone area and residual test article was quantified for each group. A T-test was run on bone area scores and residual test article showing no significant difference between the two groups in either measurement. Percentages were calculated for both groups as a function of average area divided by region of interest (ROI) as shown in Figure 1.

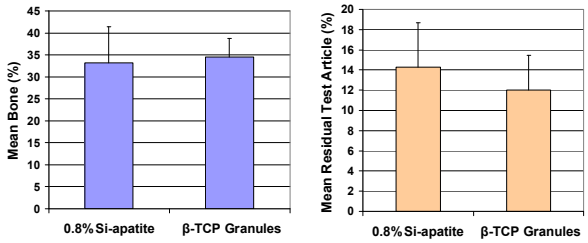


**Figure 1.** Mean percentages of area for new bone growth and residual test article.

Qualitative µCT analysis was performed on 2D renderings of each animal. Each 2D rendering was graded as either fused or not fused based off of two images. No statistical differences were observed with fusion occurring in 5/6 0.8% Si-apatite animals and 4/5 β-TCP Granule animals.

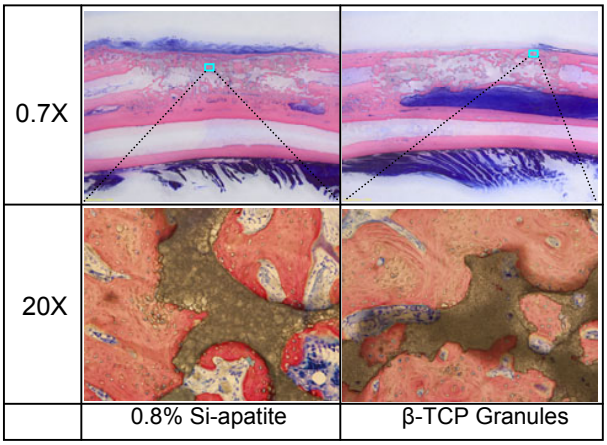


**Figure 2.** 0.7X and 20X magnifications of Sanderson's Rapid Bone stain and Van Gieson's stain for each treatment.

**Conclusions:** The results of this study indicate that both treatment groups are suitable materials for treating defects of long bones and extremities. When comparing the test articles, both groups showed equivalency for bone bridging and bone formation (histological analysis) as well as fusion rate (µCT analysis). There was no significant difference in average bone area or residual test article (histomorphometry) when comparing the two groups. In summary, both the Si-apatite and β-TCP materials resulted in equivalent levels of new bone formation and defect healing in this animal model.

**References:**

1) Donath K and Breuner GA. J Oral Pathol. 1982;11:318-326.
2) Bodde E, et al. Biomed Mater Res A. 2008;85:206-17