**QUANTITATIVE EVALUATION OF BONE APPOSITION TO CORTOSS AT 1 YEAR**

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Relevance to Musculoskeletal Condition: Implant loosening is associated with inadequate load-sharing interface between implant and bone. Bioactive glasses are understood to have osteoconductive properties\(^1,2\). This study evaluates the bone apposition of a composite with bioactive glass.

**Introduction:** Cortoss™ is a novel injectable composite that contains bioactive fillers in a Bis-GMA based resin system. These bioactive fillers strengthen the composite while providing an osteoconductive stimulus. Cortoss with and without bioactive fillers was evaluated in this study. Our hypothesis was that the bone apposition would be higher in the bioactive composite versus the non-bioactive control.

**Materials and Methods:** Cortoss was aseptically manufactured and packaged by Orthovita®, Inc. (Malvern, PA) in two formulations: with bioactive filler and without (control). The surgical procedures were performed in accordance with the Animal Care and Use Committee at Toxicon. Eleven New Zealand White rabbits had bilateral femoral defects (3.5 mm dia.) in the proximal, distal and mid-diaphysis of the femur. The sixty-six defects were randomized and Cortoss was injected to repair the cortical defect. The animals were sacrificed at 4, 24 and 52 weeks. Forty-four samples were retrieved and embedded for non-decalcified histology; the remaining were decalcified. Non-decalcified slides (10 µm) were stained with H&E or Paragon and were assessed using transmitted light. Unstained samples were evaluated with a scanning electron microscope (JEOL 840A) equipped with an energy-dispersive X-ray microanalyzer (EDAX) in a back-scattered mode. The Affinity Index, defined as the bone in direct contact to the entire composite perimeter\(^3\), was quantified from the SEM images (20X) using Image Pro-Plus software. Values were expressed as the mean ± standard deviation and compared using a one-way ANOVA with a Tukey’s post hoc test (Minitab). A Student’s t-test was used to compare groups and the confidence level was set at 95%.

**Results:** Histological analysis indicated the neighboring tissue was normal adipose or hematopoietic tissue in the medullary canal. In addition some fibrous tissue was seen at the perimeter of both composites, although its presence abated as the bony apposition increased with time. The Affinity Index of the bioactive Cortoss at 4 weeks was 28.3 ± 18.6, at 24 weeks was 22.1 ± 18.6 and at 52 weeks was 40.7 ± 16.7 (Figure 1). The Affinity Index of the non-bioactive control at 4 weeks was 20.9 ± 24.3, at 24 weeks was 17.2 ± 11.4 and at 52 weeks was 18.8 ± 12.0. The quantitative evaluation of each SEM image (Figure 2) indicates that at 1 year the bioactive Cortoss had twice the bone apposition of the non-bioactive control. The amount of bony apposition increased with time for bioactive Cortoss, but these differences were not statistically different. Comparison between the two formulations indicate that significantly more bone apposition occurred at 52 weeks for the bioactive Cortoss.

Elemental analysis revealed a chemical interdigitated fit between bone and composite. As Figure 3 suggests, the Calcium and Phosphorus (yellow, red) ions have substituted for the Sodium ions of the bioactive filler as well as infiltrated the composite perimeter. These results further demonstrate the affinity of bone to the bioactive Cortoss.

**Discussion:** In comparison to the nonbioactive control, the bioactive Cortoss demonstrates improved osteoconductive properties based on Affinity Index. The Affinity Index is a valuable tool for assessing bony apposition in this model, since the majority of the perimeter is in a location normally absent of bone. These results suggest the composite may be useful for load-sharing applications where the bonding strength may prevent implant loosening.

**References:**