CT-based Evaluation of Ultra-Porous Beta-Tricalcium Phosphate in Extremity Bone Defects at One Year

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Introduction: Reports utilizing CT-based analysis are rare in human trials of bone void fillers for extremity lesions despite CT yielding more precise details than traditional radiographic evaluation. The purpose of this study was to evaluate CT-based bone incorporation on one year CT scans as part of a larger randomized prospective study comparing ultraporous beta-tricalcium phosphate (Vitoss) alone vs. combined with bone marrow. The hypotheses were that bone incorporation is greatest in (1) smaller defects and (2) younger patients and that (3) cortical reconstitution is less advanced than that of medullary bone.

Methods: Under an IRB-approved prospective study, 21 patients (age 4-65) underwent surgery to remove benign bone lesions and were placed into two treatment groups. One group had the defect filled with Vitoss (n=10) and in the other group the defect was filled with Vitoss and bone marrow aspirate (n=11). The patients received one year follow up CT scans to look at bone regrowth. Five patients also received a 2-year follow up scan and one patient had a 3-year CT. The lesions occurred in several anatomical locations: fibula (n=3), tibia (n=2), clavicle (n=2), humerus (n=2), metacarpal (n=2), and femur (n=10). Of the 21 patients, 7 of the femoral lesion patients had intramedullary rods in place and were excluded from this study due to the artifact created by the metal on the CT scans. Mimics® software was used to analyze the scans in the axial, coronal and sagittal planes. Masks were created to differentiate the Vitoss remaining, the new bone growth and the original bone (Figure 1). The Mimics® software constructed a 3D image of the bone providing the volumes of Vitoss remaining and new bone growth. To determine the size of the cortical defect remaining, an ellipse was assumed to approximate the dimensions with major and minor axis diameters measured on the 3D image (Figure 2). In order to normalize the size of each defect to the various bones, the major and minor axes were averaged and then compared to the diameter of the entire bone creating a defect ratio.

Figure 1. Example frame from axial CT scan. The Vitoss has a red mask and can be viewed as extremely radiodense material. The new bone has a yellow mask and can be seen surrounding the Vitoss and has a greater radiodensity than normal bone.

Figure 2. Example of elliptical estimation for defect size and the directional measurements.

Variables collected from CT data included: (A) volume of Vitoss remaining, (B) volume of new bone growth (combined trabecular and cortical bone), (C) original volume of Vitoss (assumed to be the sum of A and B), (D) major and minor axis diameters of defect, (E) bone diameter, (F) defect ratio (average of D major and minor/E), and (G) bone regrowth ratio (B/C). For the patient subset that had a two-year follow up, regression analysis was performed to see what effect age had on the fractional change of bone regrowth ratio, average diameter of the defect, and total bone regrowth.

Figure 3. Vitoss remaining after one year as a function of the original amount of Vitoss used.

Results: There was no difference between the two groups in regards to defect ratio (p = 0.497), or the amount of bone regrowth (p = 0.395). The volume of Vitoss remaining after one year was dependent on the Vitoss volume used originally to fill the defect (Figure 3), following a quadratic relationship (r² = .994) such that Vitoss volume remaining increased dramatically beyond an original Vitoss volume of 40,000 mm³. The defect ratio at one year was relatively small (mean (sd): 0.187 (0.148)) and bone regrowth ratio was high (mean (sd): 0.76 (0.133)). Using a regression model, there was a strong inverse relationship between age at grafting and both fractional defect ratio change (r² = .871), and fractional average diameter change of the defect (r² = .879), but there was no relationship between age and fractional bone regrowth (r² = .0357). For the patient that had three years of follow up, CT scans of the cortical defect continued to decrease in size (Figure 4).

Figure 4. 3D reconstruction showing the progressive cortical growth to close the defect in the patient that had a 2-year and 3-year follow up scans.

Discussion: Hypotheses 1 and 2 were supported by the data, with evidence of greater incorporation of Vitoss in the smallest defects and in younger patients. While hypothesis 3 remains unproven due to difficulty in being able to accurately distinguish medullar from cortical bone regrowth, anecdotal evidence suggests that closure of the cortical defect proceeds slowly over a several year period.