Introduction: Synthetic bone graft materials are of clinical interest due to the morbidity, disease transmission potential, and procurement issues incurred with autograft or allograft. Calcium sulfate, a ceramic material, holds promise as a clinically reliable graft material. In this study, calcium sulfate was compared to spontaneous healing with no graft material and autogenous bone graft.

Methods and Materials: A cylindrical cavity, 13 X 50 mm, was drilled axially into the proximal canine humerus bilaterally. Calcium sulfate dihydrate (CaSO₄) was supplied sterile by the manufacturer as 4.7 x 3.0 mm circular tablets. This test material was placed in one humerus while the contralateral humerus received either no graft or a comparable volume of cancellous autogenous bone. The study consisted of nineteen large male mongrel dogs divided into three groups. One group of seven dogs received 50 tablets of CaSO₄ in one humerus and 6cc of autogenous bone in the contralateral humerus. The second group consisting of five dogs received 50 tablets of CaSO₄ in one humerus and no graft material in the contralateral humerus. Both groups were studied for six weeks. A third group consisting of seven dogs received 50 tablets of CaSO₄ in one humerus and 6cc of autogenous cancellous bone in the contralateral humerus and was studied for 24 weeks. Radiographs were obtained immediately postoperative and at 3, 6,12, and 24 weeks. Following euthanasia with a supersaturated solution of pentobarbital, the paired humeri were retrieved and sequentially sectioned at 1 mm intervals for undecalcified histology. Stained sections were studied by light microscopy. Image analysis of backscattered-electron SEM images was used to quantify the amount of bone within the defects, excluding identifiable areas of residual CaSO₄ or autograft fragments. The data were analyzed using MANOVA and paired t-tests.

Results: All dogs were weight bearing within two days following the procedure, and all wounds healed in a routine manner. Radiographically, the tablet density had diminished to approximately 50% of that in the immediate postoperative period at three weeks and by six weeks was only minimally detectable in the medullary defect. Non-grafted defects were evident radiographically while all humeri grafted with autograft appeared filled with new bone. At 24 weeks, none of the tablets were visible.

Quantitation of the amount of bone in the defects indicated that at 6 weeks more bone was present in the CaSO₄-treated defects (mean 16.6%, range 8.5-22.8%) than in either the autologous graft- treated defect (9.4%, range 4.5-13.6%) (p=0.018) or the untreated defect (3.7%, range 2.3-4.6%) (p=0.005). At 24 weeks, there was no significant difference in the amount of bone whether a defect had been treated with CaSO₄ (9.6%, range 5.6-12.3%) or with autogolous bone (10.7%, range 9.9-12.2%) (p=0.351).

Histologically, the non-grafted humeral defects contained slender trabeculae at the periphery one-third of the defect margin which was contiguous with the native bone. However, no bone was present in the central aspect which was filled with fibrous tissue. The humeri grafted with autogenous bone in both time periods demonstrated trabecular formation throughout the defect. In the 24 week group, the trabecular formation in the grafted defects was more organized and dimensionally the trabeculae were thicker. In all groups, medullary defects grafted with CaSO₄ tablets contained new bone with trabecular spicules and slender trabeculae formed between the tablets. Of greater interest was the bone that formed replacing the resorbed tablets. This formed in a unique pattern consisting of concentric circular lamellae which were thicker at the peripheral aspect of the tablet site than in the central aspect. At six weeks, small amounts of residual material were evident predominantly in the more central region of the tablet site, while at 24 weeks only rare sites of minute residual material were seen in only a few histological sections. When evident these small fragments of calcium sulfate where encompassed within the formed trabeculae.

Bone that formed at the site of previous tablets had become contiguous with the surrounding adjacent and native bone in many areas indistinguishable from autogenous grafted sites.

Discussion: Calcium sulfate used as a synthetic bone graft material in this study demonstrated excellent biocompatibility. Bone developed between the tablets and replaced the resorbed tablets without an adverse inflammatory response. Interestingly, tablet resorption occurred beyond six weeks until completely replaced by bone within 24 weeks. This comparative study revealed that the amount of bone formed with calcium sulfate was approximately 4 times that of spontaneous healing in the empty defect and equivalent to that found with autogenous bone graft. This bone formation was qualitatively similar to that developing with autogenous bone graft. The pattern of bone formation is unique with the tablets and implies guided bone formation. These findings provide secure clinical basis for use of calcium sulfate to treat medullary defects.

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