

## Human bone response to CS/PLLA composite

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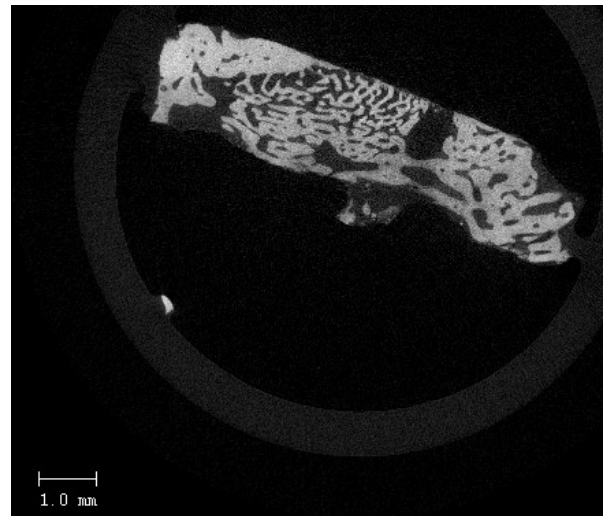
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**Statement of Purpose:** Calcium sulfate (CS) is completely biodegradable, biocompatible, osteoconductive and nontoxic bone graft material. It is a unique bone graft because it is angiogenic, hemostatic and possesses guided tissue regeneration properties. It ~~is~~ has been used as a bone graft in dentistry and medicine for more than 1030 years. However, it undergoes fast degradation and in some cases (larger dental bone defects like molar extraction and sinus augmentation sites), is completely degraded even before bone is fully grown in the defect area. Recently, a composite of calcium sulfate and PLLA (CS-CR), with a controlled degradation profile, was developed to address this problem. In vitro and in vivo studies have shown that CS-CR composite undergoes slower degradation than pure CS and stimulates vigorous bone growth in rabbit tibial intramedullary canal. Clinical studies were carried out to study bone response to CS-CR in humans.

**Methods:** CS-CR pellets were mixed with pure CS in a ratio of 80:20. Normal saline was added to this mixture as a setting solution. The mixture was implanted in the extraction sites of 8 patients. A dense PTFE barrier was placed on top of the graft and the site was closed. Patients were allowed to heal for 4-6 months. During this period, they were followed every two months and x-rays were taken. After 6 months, a core of bone from the center of the extraction site was removed. Dental implant was placed in the site. Core was examined by micro CT scan. Histology and histomorphometry of the cores is also being conducted to obtain additional data about the quantity and quality of bone growth in the extraction sites.

**Results:** CS-CR pellets underwent controlled degradation in molar extraction sites. All of the sites are healing well radiographically. No untoward reaction has been observed in any of

the patients. MicroCT scans showed vigorous bone growth in sites filled with CS-CR pellets. (Fig 1). Currently histomorphometry and histology studies are being carried out for additional data.



**Fig 1:** Micro CT scan of a core obtained from a molar extraction site 5 months after implantation with CS-CR pellets.

**Conclusions:** CS-CR is an excellent bone graft material, particularly for relatively large dental bone defects like molar extraction and sinus augmentation sites.

### References:

1. Mamidwar S., Weiner M., Alexander H., Ricci J. In Vivo Bone Response to Calcium Sulfate/ PLLA Composite. *Implant Dentistry*. Accepted for publication.
2. [Scarano A. Degidi M. Iezzi G. Pecora G. Piattelli M. Orsini G. Caputi S. Perrotti V. Mangano C. Piattelli A. Maxillary Sinus Augmentation with Different Biomaterials: A Comparative Histologic and Histomorphometric Study in Man. \*Implant Dentistry\*. 15\(2\):197-207, 2006 Jun.](#)