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Bone Replacement and Grafting with a Biologically Active Ceramic Composite

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A composite of $Ca_3(PO_4)_2$ and $MgAl_2O_4$ spinel is biologically active and has enduring strength. Its strength depends on the spinel phase. The flaws in the spinel depend on the grain size of the calcium phosphate phase and are not altered by dissolution. The calcium phosphate, α tri-calcium phosphate, controls the tissue response. Bone bonds to the implant. A design for a bone graft as a replacement for a section of the diaphysis of a canine femur provides for tensile, compressive, torsional and bending load; and for the physiological processes of bonding and remodeling. A bone plate, used to stabilize the implant at time of surgery was removed after about one year. Over seven years of service have been achieved without internal or external fixation.

Key words : Bioceramic, Bone graft, Bone replacement

I. Introduction

A biologically active ceramic composite that has enduring strength can be made from a mixture of about 50 volume percent calcium phosphate $Ca_3(PO_4)_2$ and spinel $MgAl_2O_4$. The spinel is insoluble and contributes enduring strength. Spinel was chosen because it does not react with calcium phosphates when fired at high temperatures, and because it is bioinert. The calcium phosphate is soluble and contributes tissue compatibility. It can have various Ca:P ratios and include fluorine.[1,2] The properties of the 50% mixture are given in Table 1.

II. Properties or Biocompatibility

The spinel and calcium phosphate phases remain separate after firing. (Fig. 1) When polished the hard spinel phase projects above the calcium phosphate. (Fig. 2) When etched to remove the calcium phosphate the spinel phase is composed of sintered euhedral crystals. (Fig. 3)[3,4] The holes left after removal of the calcium phosphate phase had been filled with calcium phosphate. They were larger

Table 1. Properties of the Composite

Composition	$\alpha Ca_3(PO_4)_2$ and $MgAl_2O_4$
Compressive strength	199 MPa
Tensile strength	70 MPa
Youngs Modulus	114 GPa
Reversible Thermal Expansion	10.7×10^{-6}/°C
Bulk Density	3.09 gm/cc
True Density	3.37 gm/cc
Ca: P ratio	1.62

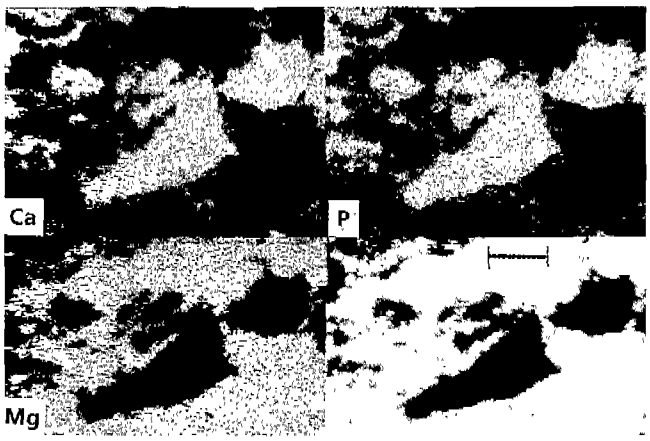

Fig. 1. X-ray fluorescent images of the cation distribution in a section of the composite. 2000X, 5 μm bar.

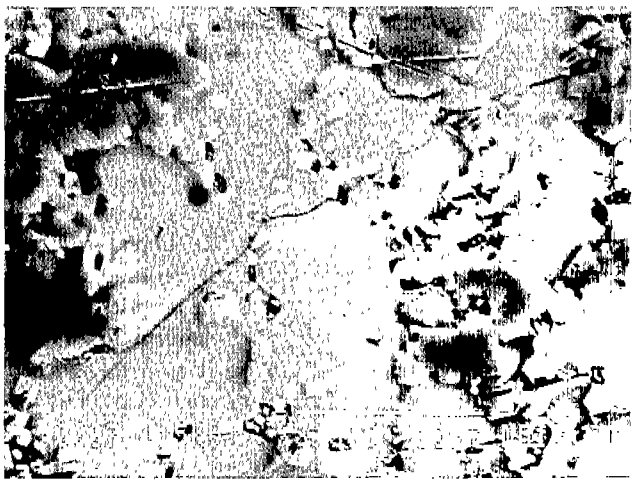

Fig. 2. Polished Section showing euhedral spinel crystals embedded in calcium phosphate matrix. 3500X.

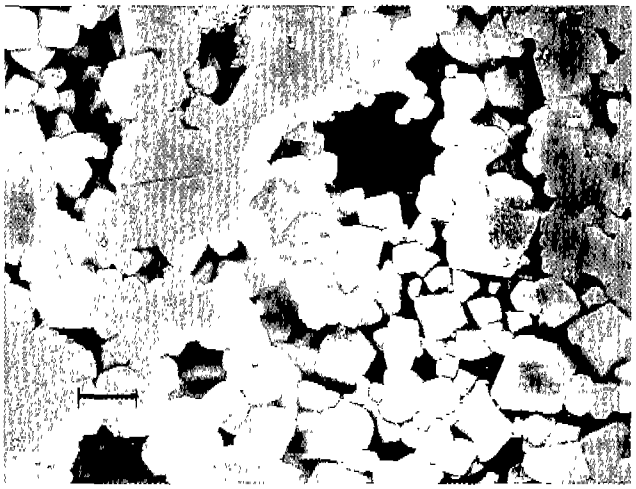

Fig. 3. Micrograph of the composite after removing the phosphate phases with 8% EDTA 20 minutes. 5000X, 2 μm bar.

than the spinel grains and are the high temperature form, α tricalcium phosphate. This is a metastable form that has higher solubility than the β form normally present at room temperature. This increases the bioactivity of the phosphate phase. Calcium phosphates are often non stoichiometric. A calcium phosphate was chosen with a Ca:P ratio of 1.62 because it is similar to the ratio for hydroxyapatite in bone. After firing the mineral was α tricalcium phosphate. The strength is controlled by the spinel skeleton. The flaws in the skeleton are produced by the calcium phosphate phase. When the calcium phosphate on the surface dissolves the flaws are not changed so the composite has enduring strength. This is an improvement over block HA and TCP implants, where the strength is reduced by the tissue/implant interactions.

1. Biocompatibility

The calcium phosphate, at about 50 volume percent, is an immediate source of calcium and phosphorous in solution to stimulate bone regeneration. Experiments to evaluate its compatibility show that bone bonds well to the implant. (Fig. 4)[5] When compared to commercial sapphire and titanium alloy tooth roots the composite is superior in the amount of early bone contact. (Fig. 5)[6] The inert sapphire and metal alloy have a slow increase in bone contact area over a few months; then the bone contact area decreases. The decrease is the result of a thickening fib-rous tissue layer that separates the bone from the implant. This is characteristic of all currently-used metal, ceramic and plastic implants; and is a principal cause of aseptic loosening. Aseptic loosening is the principle mechanism for implant failure. The composite is not recognized as a foreign body because the calcium phosphate component dominates the chemical activity at the implant surface. As shown in Fig. 5 the composite does not decre-ase in bone contact area with time. This makes it possible to design implants where the bone bonds to the im-plant and remodels as necessary to sustain the implant viability.

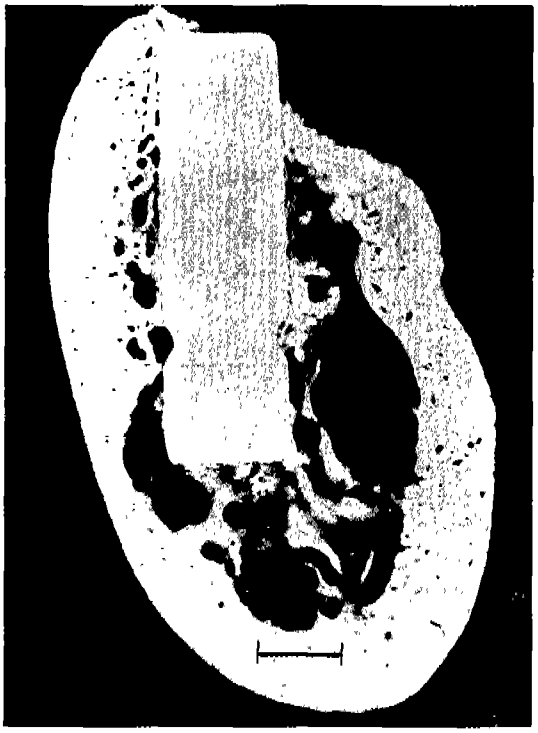

Fig. 4. Microradiograph of a Tooth Root in a Canine Mandible after 12 months. 4X, 2 μm bar.

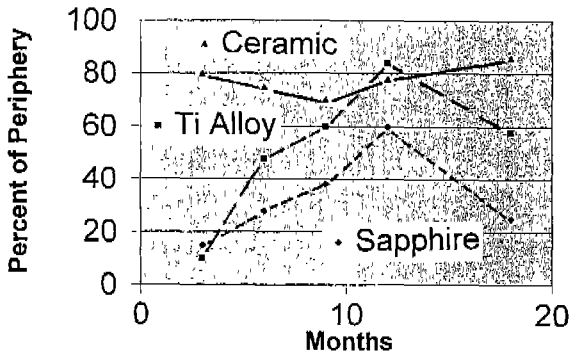

Fig. 5. Areas of Bony Contact obtained by image analysis for the Composite, single Crystal sapphire (Kyocera) and titanium alloy (Corvent) as a function of time.

III. Bone Grafting

1. Porous Bone Grafts

Early experiments with the composite were conducted using tubular implants containing large pores for tissue in-growth. (Fig. 6)[8] The pores were larger than 200 μm diameter to permit Haversian systems to penetrate and bond the implant to the bone. The junction of the large pores were smaller, so the bone ingrowth was confined to a few millimeters and did not penetrate the entire implant. The presence of the pores weakened the implant mechanically, so it was necessary to have a large area of bone contact. The cortex enlarged to accommodate the

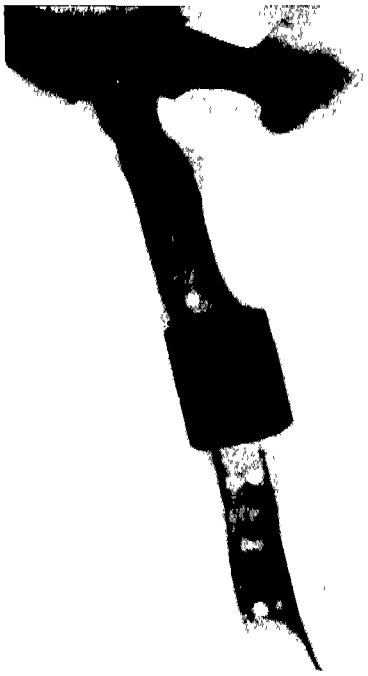

Fig. 6. Radiograph of a porous fluorapatite/spinel composite immediately after removing the stainless steel bone plate at 36 weeks.

large outer diameter of the implant. The intermedullary structure of the distal and proximal bone regenerated through the inner hole of the implant. However, large pores weaken the implant and the bone did not develop a structure of sufficient strength to compensate. Therefore, the design was modified to improve tissue attachment.

2. Bone grafting with a Dense Composite

A good experimental test of a bone graft is to determine if tissue will bond to it as a functional replacement for a section of bone. Replacing a section of the diaphysis of a long bone in a dog is such an experiment. The long bones have a dense cortex with both endossius and periosseous vascular support for bone maintenance. They are subject to tensile, compressive, torsional and bending loads. Tissue attachment requires accommodation of all these loads. This was provided for in the geometry of the implant design. (Fig. 7)[8,9] The slots at the ends are dove-tailed to prevent withdrawal and accommodate tensile loading. The cross-sectional area of the dense implant was the same as that of the bone, so that the adjacent bone would experience the same level of compressive stress that it would if the implant were not there. The dove-tails provide for torsional strength. Bending was accommodated by the provision for tension and compression. However, to aid in tension and bending longitudinal grooves were provided on the exterior of the implant to allow cortical bone to bridge across the implant. Holes connecting the intermedullary cavity to the grooves were made large enough for blood from the interior to support the bone in the grooves.

For each experiment a section of bone was removed from the diaphysis of the femur of a dog, and an implant was supported with a compression bone plate. (Fig. 8) The wall thickness, groove size and dovetail size was varied for several implants. Results were followed radiographically and histologically. Tissue response was best when the wall thickness was similar to that of the cortex and

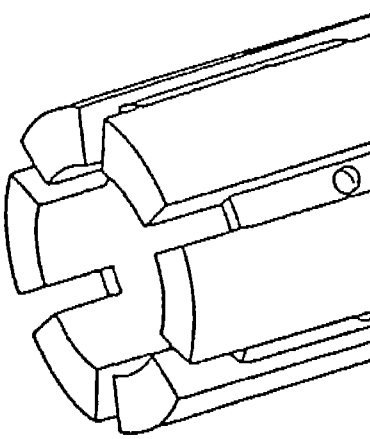

Fig. 7. Geometry of the "bone-bridge" implant for replacement of a section of the diaphysis of a canine femur.

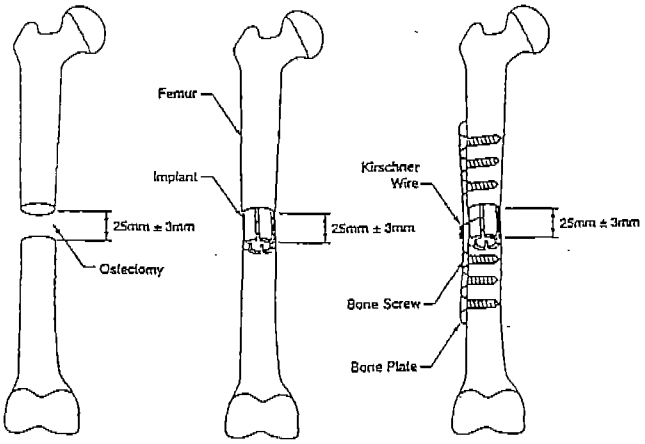

Fig. 8. Surgical procedure for implanting the composite shown in Fig.7. Left, an ostectomy to remove a section of femur. Middle, the desired location of the implant. Right, the method of stabilization with a stainless steel compression plate and screws.

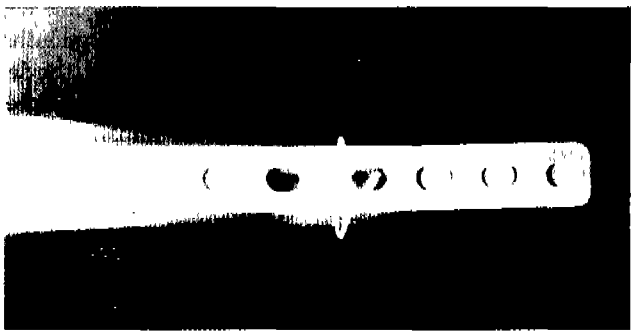

Fig. 9. Radiograph taken immediately after surgery. 6/28/90.

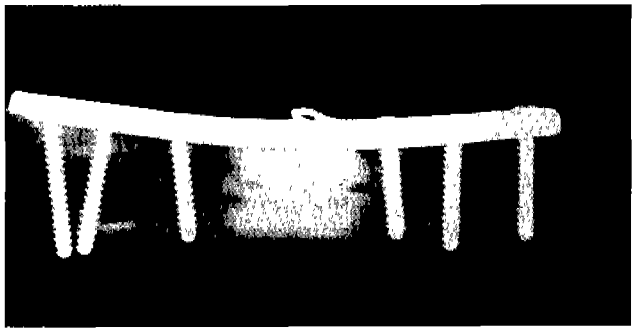

Fig. 10. Radiograph after 55 weeks. 7/25/91.

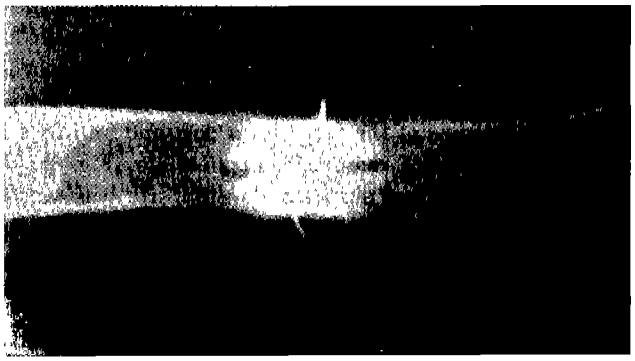

Fig. 11. Radiograph after removing the bone plate. 8/14/91.

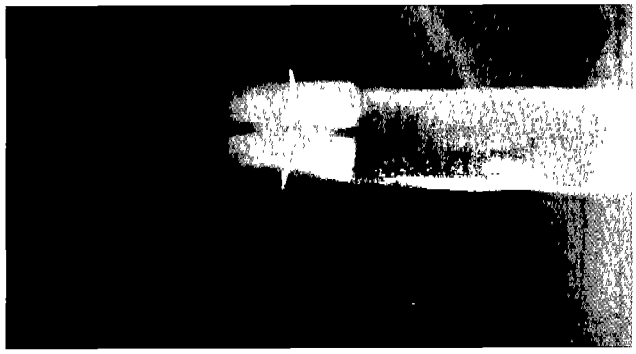

Fig. 12. Radiograph two and one half years after removing the bone plate. 3/29/94.

when the dove-tail and grooves were about equal to the spaces between. The most successful, radiographically, was not removed. (Fig. 9, 10) After fourteen months the bone plate was removed. (Fig. 11) The implant remained viable. Remodeling occurred over the next 24 months. (Fig. 12) This dog is still alive and active, using the leg with normal action in walking, running and jumping after seven years. The tissue is supporting the implant. There are no other supports. This is a successful bone-graft replacement of bone with an inorganic implant.

IV. Conclusion

The requirements for a successful bone graft include:

1. An implant containing calcium phosphates to prevent formation of a fibrous capsule by the foreign-body response.
2. An implant with enduring strength.
3. A geometry of design to accommodate the loads imposed.
4. A geometry of design to allow the normal physiological processes of the surrounding bone to develop supporting bone and to maintain that support.
5. Suitable aseptic surgical procedures to support the implant until the bone can support itself; and to remove that support if and when it is desirable to do so.

V. Patent Status

Foreign and domestic patents are pending.

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