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AN ENHANCED ALLOGRAFT MATERIAL FOR REPAIR OF BONE DEFECTS

Background

The increasing numbers of joint implant revision surgeries have created a growing demand for an effective material to repair osseous defects. Autograft bone has been the standard treatment for repair of defects, non-unions, and arthrodeses, but it has the disadvantages of an additional operation, surgical site morbidity, and limitation of quantity and shape.

Structural allografts are used for repair of segmental defects and particulate allografts are used for cavitary defects. These allografts appear to function primarily as an osteoconductive scaffold. Disadvantages of allogeneic materials include cost, preoperative and operative preparation time required, problems with shaping and placement, difficulty with fixation in-situ, fatigue fracture, and non-union. Other tissue-derived components for bone repair in addition to allograft are: demineralized bone matrix (DBM), bone morphogenetic protein (BMP), growth factors (TGFβ1), and autogenous bone marrow.

Several non tissue-derived constituents of bone repair materials are incorporated in commercial products which are intended to accomplish the bone grafting task. Some of these non tissue-derived components include: coralline-based HA (ProOsteon), calcium sulfate pellets (OsteoSet), Ca and PO_4 rich amorphous glass (Bioglass), and a combination of HA, TCP, and bovine fibrillar collagen (Collagraft).*

The Need

The ideal bone repair material to serve the needs of both patients and surgeons have the following characteristics: (1) osteoconductive, (2) osteoinductive, (3) biocompatible, (4) formable to any shape, (5) structural integrity, (6) remains where placed, and (7) easy to prepare and implant. Some currently available materials fulfill some of these criteria, but none fulfills all of them.

Scientists performing research in the discipline of tissue material science have developed a new method of tissue processing that provides tissues with near ideal characteristics for skeletal repair. The tissue processed by this method, Opteform®, answers the need for an allograft material that has both osteoinductive and osteoconductive qualities while avoiding the delivery/application difficulties of autografts, other allografts, and constituent materials of bone such as bone chips and demineralized bone matrix.

Material Properties of Opteform®

Opteform® consists of human-derived allograft material components: demineralized bone matrix and cortical-cancellous bone chips in an inert carrier. This agglomerate material possesses the unique property of being fully formable at a temperature of approximately 45°C and becomes a resilient solid when its temperature falls to 38°C or lower. Based on the historical performance of its constituents, the material will provide an environment for the reconstruction of bony defects that is both osteoinductive and osteoconductive.[2,3]

Osteoinductivity

Osteoinductivity is the capacity of a material to "induce" cells in the area to generate bone of their own accord.[1] Demineralized Bone Matrix (DBM) has been demonstrated by many investigators to be osteoinductive.[1,2,3] Its effectiveness to induce the formation of new bone is dependent upon its concentration and the carrier in which it is introduced into tissue. Figure 1 shows the effect on osteoinductivity of various concentrations of DBM. The Opteform® carrier contains 24 to 33 percent DBM. Figure 2 demonstrates the superiority of the Opteform® carrier over standard DBM.

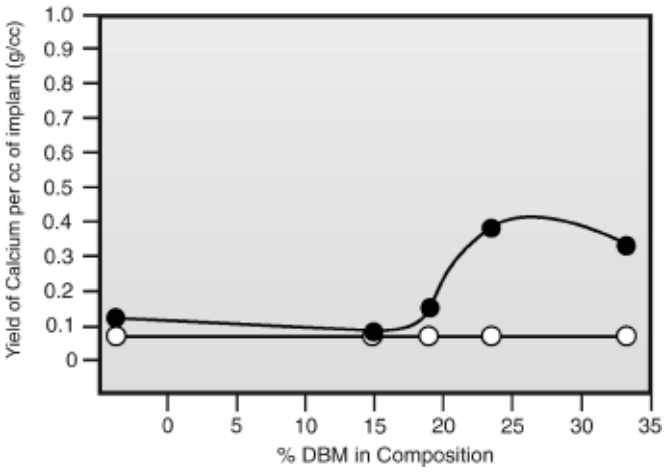


Figure 1: Yield of Calcium from Opteform Carrier/DBM Compositions. A function of weight percentage of DBM.[4]

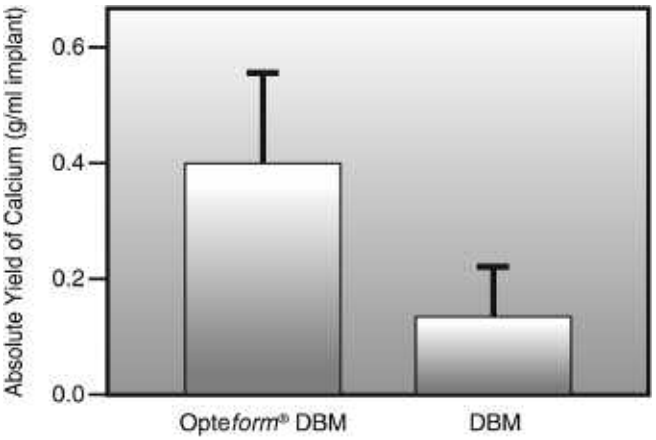
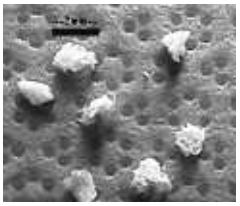


Figure 2: New bone formation as determined by yield of calcium normalized to implant volume.[4]

*The following products are trademarks of their respective vendors:
ProOsteon - Interpore, Inc.
OsteoSet - Wright Bio-orthopaedics
Bioglass - US Biomaterials, Inc.
Collagraft - Zimmer, Inc.

Osteoconductivity



Osteoconductive materials "conduct" bone growth across defects when implanted into osseus tissue.[1] The osteoconductive element of Opteform® consists of uniform one to three millimeter particles of cortical-cancellous bone allograft (left). The carefully controlled shape of the particles improves the handling properties and enhances formability for a more precise fit in various irregularly shaped defects.

Formability

Opteform® is a moldable material. When heated above 43°C, it has a consistency similar to the dough stage of bone cement. When the material cools to slightly above body temperature (38°C), it sets to a resilient solid material. Five preformed shapes facilitate rapid molding of Opteform® to the shape of common bone defects, though the material can be molded into any shape.

The photos below show a 90mm partial disk being prepared for implantation in an acetabular reconstruction. The aseptically processed disk is heated in its packaging using either a self contained warmer unit or warm saline placed in a basin. It can also be rewarmed and reformed if this should be necessary in a particular operative situation.

Summary

The characteristics of Opteform® are:

- Formable
- Fits any defect well
- Remains where placed
- A familiar grafting material (allograft)
- Becomes solid at body temperature
- Load sharing
- Osteoinductive
- Osteoconductive

Early results indicate that the method of tissue processing used to prepare Opteform® yields allograft material that provides major benefits in the reconstruction of bone defects.

References

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