Injection Behavior of Bone Substitute Materials, in Contained Subchondral Bone Defects: Summary of a Study Conducted at the Hospital for Special Surgery, New York

Dinely A. Colon, Byung Jo Victor Yoon, Thomas Anthony Russell, Frank P. Cammisa, Celeste Abjornson

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Introduction

Bone Substitute Materials (BSM, aka bone void fillers) are used in orthopaedics for a range of procedures including filling bony defects. BSM exist in a variety of material types, including allograft-based products such as demineralized bone matrix (DBM), and ceramic-type materials such as calcium phosphate (CaP) or calcium sulfate (CaS) products.

BSM commercial products are available in a number of forms, including preformed shapes, moldable putties and "injectable" pastes, with different handling properties and performance characteristics. For most open indications, such as voids associated with fractures or posterior spine procedures, putties and preformed shapes are easy to place and meet performance needs. For minimally-invasive closed applications, however, including the Subchondroplasty® (SCP®) Procedure, which requires delivery of BSM into closed bone defects, also called bone marrow lesions (BML), the extent to which a material is truly injectable takes on greater clinical significance.

To evaluate the true handling behavior of commercially-available BSM into such a closed environment, a study was undertaken by Celeste Abjornson, PhD at the Hospital for Special Surgery, New York.

Study Summary

Eight commercially-available materials (Chart 1) were injected into artificial trabecular bone material (PVF 12.5 closed-cell polyurethane foam, Pacific Research Laboratories, Washington1,2), under controlled conditions simulating the clinical conditions of an SCP procedure. A PMMA was included in this study in the form of Simplex P from Stryker. Although Simplex P is not indicated for use as a bone void filler, it is included for comparison for surgeons familiar with the handling properties of PMMA. [To verify the model, a subset of materials was also injected into cadaveric samples.] Each material was prepared according to manufacturer's instructions; materials were then injected at a fixed rate using a standardized injection technique for all materials, to minimize evaluation variables. Technique included:

- Insertion of a standard 11-gauge injection cannula into the foam, to a pre-drilled depth of 37mm;
- BSM injection through cannula using standard 1cc syringes, at a rate of 2mm/sec, with pressure per syringe measured as extrusion force/second;
- Samples were allowed to set per manufacturer's instructions, then evaluated.

PRODUCT NAME	MANUFACTURER	COMPOSITION
AccuFill®	Zimmer Biomet	Nanocrystalline CaP
Beta-bsm™	Zimmer Biomet	Nanocrystalline CaP
CERAMENT™[3]	Zimmer Biomet	HA and CaS
HydroSet™[4]	Stryker	Hydroxyapatite
Norian® SRS5	DePuy Synthes	Carbonated Apatite
PRO-DENSE®[6]	Wright Medical	CaS and CaP
STRUCSURE™ CP[7]	Smith & Nephew	Ca-deficient Apatite
Simplex™ P[8]*	Stryker	PMMA

Chart 1: Materials tested and manufacturer's described composition

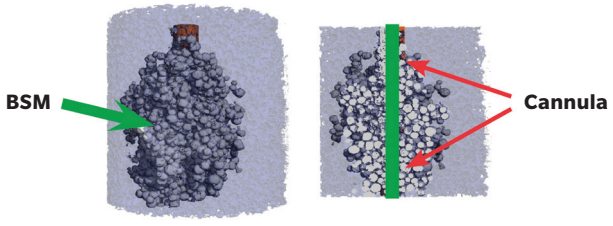

Figure 1: µCT reconstruction of an AccuFill BSM/artificial bone sample in full and cut views

Mass of material was measured before and after injection, and each sample radiographed and imaged with micro CT to evaluate injection pattern and BSM volume. For the micro CT analysis, samples were segmented to allow differentiation of BSM, cannula and artificial bone. Samples were 3D-reconstructed to show full volume view (F, Figure 1) and slice at zero plane (C: mid-diameter of the injection cannula). From CT images investigators determined BSM volume, foam volume and volume fraction. These data were used to evaluate performance

of each BSM relative to technique behaviors important for a successful Subchondroplasty Procedure: truly injectable into closed cancellous defects without material physical change (e.g., phase separation); and consistent, reproducible flow pattern through and interdigitation with the trabecular bone and defect.

Results

Most Calcium-compound BSM failed to inject into the simulated cancellous bone: Beta-bsm, PRO-DENSE, CERAMENT, HydroSet, and Norian SRS all phase separated. Only AccuFill and STRUCSURE CP succeeded. AccuFill injection resulted in statistically greater weight and volume of material injected than STRUCSURE CP, and the lowest maximum insertion force of all eight products tested (Figures 2, 3, below). AccuFill also flowed in a consistent, even distribution pattern, whereas STRUCSURE CP's pattern was uneven and inconsistent. Simplex P (PMMA cement)* could be injected, developing a volume and pattern similar to AccuFill, but only at a statistically higher force and with the destruction of the local trabecular material. The remaining materials showed no or almost no flow into the trabecular model. Figure 4 shows micro CT patterns of flow for all tested materials.

Conclusion:

AccuFill was the only material found to be "truly-injectable" into a closed cancellous bone model as well as demonstrate adequate interdigitation of BSM into the simulated trabecular bone.

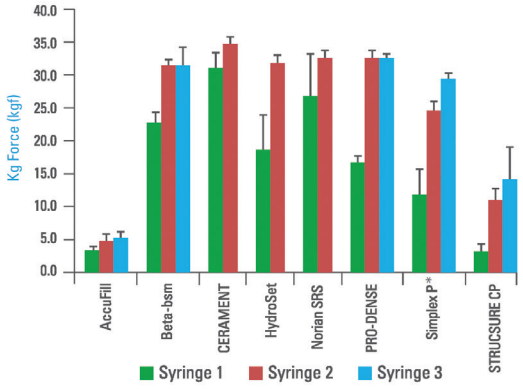

Figure 2: Avg. maximum injection force for each syringe run, all materials

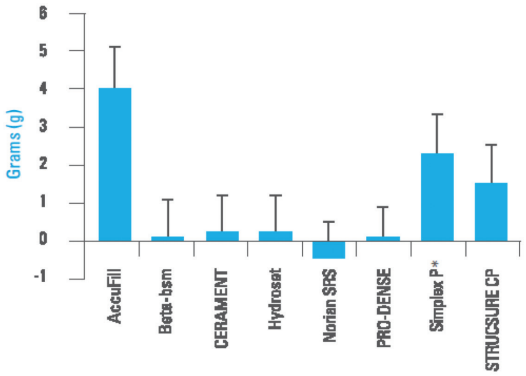

Figure 3: Net weight of injected materials

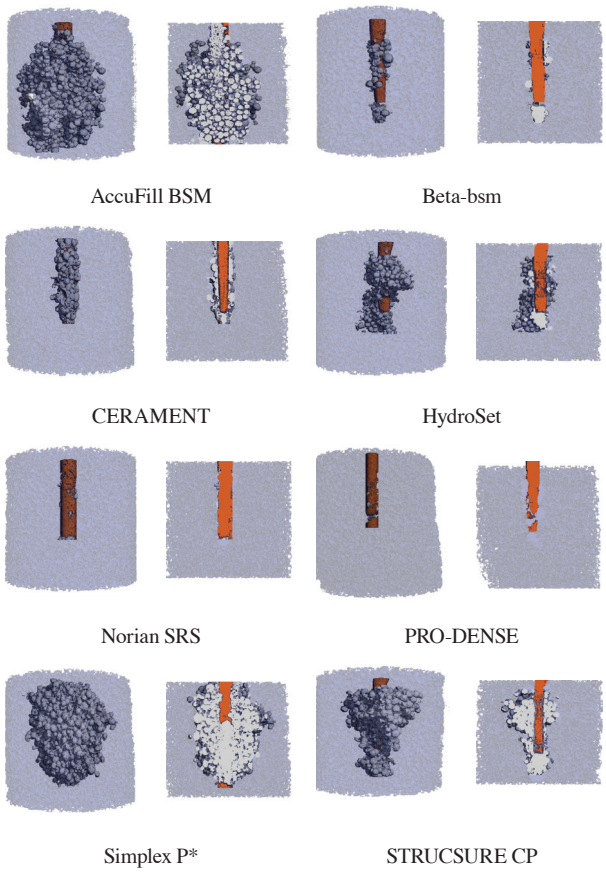

Figure 4: Representative μCT reconstructions of BSM in foam samples; in whole and cut views

Notes

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AccuPort® Delivery Cannula and AccuMix® Mixing System are Manufactured by: Zimmer Knee Creations 56 East Bell Drive, P.O. Box 587, Warsaw, IN 46581, USA. AccuFill® BSM is Manufactured by: ETEX Corporation, 55 Messina Drive, Braintree, MA 02184, USA.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

Legal Manufacturer
Zimmer Knee Creations
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581
USA

Legal Manufacturer
AccuFill BSM Manufactured By:
Etex Corporation
55 Messina Drive,
Braintree, MA 02184
USA

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