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Bone&JointScience
Our Innovation in Focus

Vol 03, No 10 - December 2012

Evaluation of Hardware Use with STRUCSURE◊ CP Macroporous Calcium Phosphate Bone Graft Substitute

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Summary

The purpose of this study was to address hardware insertion through STRUCSURE CP Bone Graft Substitute (BGS; Smith & Nephew, Inc., Memphis, TN, USA), an injectable, self-setting calcium phosphate material. STRUCSURE CP was injected into voids in synthetic bone foam blocks. At specific times post-injection (0, 4, 8, 30, 60, and 120 minutes), some samples were pre-drilled with pilot holes while other samples were left undrilled, and then bone screws were inserted into all of the samples. The BGS was allowed to harden for 24 hours, followed by axial pullout testing. Results revealed that the screw pullout strengths were the same among the groups, regardless of the time post-injection and the method by which the hardware was inserted, indicating that the insertion of the hardware through the material at the times tested does not affect the hardening or final mechanical integrity of the BGS. This study supports the use of hardware alongside STRUCSURE CP and demonstrates that hardware can be placed through the material over a wide range of time, starting immediately after injection.

Background

Synthetic bone graft substitutes (BGSs) are a popular choice for filling bone voids and cavitary defects. These materials act as osteoconductive scaffolds that inhibit fibrous tissue infiltration and support cell migration and attachment [1]. Several types of material are available for use in the clinic, including calcium phosphate and calcium sulfate. These materials are often used in conjunction with standard methods of fracture fixation, such as bone plates and screws [2].

STRUCSURE CP (Smith & Nephew, Inc., Memphis, TN, USA) is an injectable, self-setting calcium phosphate synthetic BGS. It is intended for bony voids or defects that are not intrinsic to the stability of the bony structure, and is replaced with bone during the healing process. Once mixed, the material develops a paste-like consistency that is cohesive enough to resist wash out by biological fluids, such as blood, and has a gradual setting profile that results in hardening to a compressive strength of 24 MPa (roughly twice the strength of cancellous bone) after 24 hours at body temperature (98°F) and in vivo conditions [3-5]. Furthermore, the material can be used in conjunction with hardware and may be injected into the bone void before or after hardware placement. However, there are questions regarding when and how the hardware can be inserted through the BGS.

The purpose of the current study was to evaluate the effect of hardware insertion through STRUCSURE CP at various time points. This was achieved by measuring the pullout strength of bone screws inserted into the material at specific chosen intervals post-injection. This study also examined whether there is a difference between manual insertion of a screw into BGS that has not been pre-drilled versus pre-drilling and subsequent screw insertion. It was hypothesized that the gradual setting profile of the material would provide clinicians flexibility as to the timing and method of hardware placement.

Materials and Methods

Synthetic bone foam with a density of 15 pounds/cubic foot was sectioned into blocks. A void, 12.7 mm diameter by 25.4 mm deep, was created in each of the foam blocks. The foam blocks were conditioned by placing them in phosphate buffered saline (PBS) at 37°C for 24 hours.

Prior to injection, the blocks were removed from the PBS and blotted dry. STRUCSURE◊ CP was mixed and injected into the voids per kit instructions (2 minutes of mixing and 2 minutes for injection). The samples were then placed in a container maintained at constant relative humidity (96%) and temperature (32°C). At select time points (0, 4, 8, 30, 60, and 120 minutes post-injection), the BGS samples underwent insertion of the fully threaded 5.0 mm diameter x 60 mm length PERI-LOC◊ VLP osteopenia bone screw (Smith & Nephew, Inc., Memphis, TN, USA). Table 1 describes the specific groups that were tested. All screws were inserted by hand.

For Group 1, a screw was inserted to a depth of 19 mm into the BGS samples that did not have a pre-drilled pilot hole (Figure 1). For Group 2, the samples were pre-drilled with a 2.7 mm drill (recommended pilot hole for the screw) at 700 rpm, followed by insertion of the screw to a depth of 19 mm. The drill setup was the same as that used in a previous study evaluating the BGS [6]. All samples from Groups 1 and 2 were then placed back into the humidified container at 37°C for 24 hours of hardening.

After 24 hours, axial pullout was conducted on an MTS 150/RF machine (MTS Systems, Eden Prairie, MN, USA) with a 5 kN load cell. The test setup is shown in Figure 2. It should be noted that a metal washer was used such that the fixture restrained the cement during the pullout test to prevent failure of the cement/sawbone interface. A pre-load of 1.1 N and a tensile load along the longitudinal axis at a rate of 1 mm/min were applied. The failure load of each sample was recorded. A one-way ANOVA with TUKEY post-hoc analysis was conducted to compare the effect of screw insertion on the failure load. Statistical significance was set at $p < 0.05$.

Results and Discussion

Gross observations of the STRUCSURE CP samples indicated that the material was soft immediately after injection, became firmer over the testing period, and was fully hardened at the end of the 24-hour period.

Screws were successfully inserted into all samples. At 0, 4, and 8 min, the screws could be easily inserted into the undrilled material (Group 1). At 30, 60, and 120 min, the samples were firmer and could be drilled with the 2.7 mm drill bit followed by subsequent screw insertion (Group 2) without difficulty. Screws could also be inserted into the undrilled samples without difficulty after 30 min (Group 1). However, slight resistance was encountered during

Table 1: BGS sample allocation.

Time (minutes post-injection)	No Pre-Drilled Pilot Hole (Group 1)	Pre-Drilled Pilot Hole (Group 2)
0	N = 5	–
4	N = 5	–
8	N = 5	–
30	N = 5	N = 5
60	N = 5	N = 5
120	–	N = 5

Figure 1: Screw inserted into STRUCSURE CP.

insertion into undrilled samples after 60 min (Group 1). These results are in line with findings from our previous STRUCSURE° CP study, which found that the material was soft at the 8-minute time point and firmer by 30 minutes [6]. Moreover, qualitative results revealed that pre-drilled BGS (drilled 8-30 min after injection) is stable and undamaged with no observed cracking [6].

The average failure load of each group measured using pullout testing after 24 hours of hardening is shown in Figure 3. For reference, 800 Newtons is equivalent to 180 pounds-force. There were no statistically significant differences among the groups. All of the screws maintained the same degree of purchase in the material. In this study, the strength of the interface between the BGS and the hardware after 24 hours was found to be the same regardless of the time post-injection and the method by which the hardware was inserted (no pre-drilling versus pre-drilled holes). This indicates that the insertion of the hardware through STRUCSURE CP at the times tested does not affect the hardening, screw pullout strength, or final mechanical integrity of the BGS among the different groups.

Conclusions

STRUCSURE CP is intended for bony voids or defects that are not intrinsic to the stability of the bony structure. Rigid fixation techniques are often recommended for use in conjunction with the material. When using this BGS, this study suggests that surgeons have a significant window of time after injection (2 hours, as tested in this study) during which to insert hardware through the material without affecting BGS hardening. The decision of whether to pre-drill is left to surgeon discretion. This study supports the use of hardware alongside STRUCSURE CP BGS.

References

1. Allison DC, Lindberg AW, Samimi B, Mirzayan R, Menendez LR. A comparison of mineral bone graft substitutes for bone defects. US Concology & Hematology 7(1): 38, 2011
2. Hak DJ. The use of osteoconductive bone graft substitutes in orthopaedic trauma. J Am Acad Orthop Surg 15(9): 525, 2007
3. McCalden RW, McGeough JA, Court-Brown CM. Age-related changes in the compressive strength of cancellous bone. The relative importance of changes in density and trabecular architecture. J Bone Joint Surg Am 79(3): 421, 1997
4. Giesen EB, Ding M, Dalstra M, van Eijden TM. Mechanical properties of cancellous bone in the human mandibular condyle are anisotropic. J Biomech 34(6): 799, 2001
5. Yeni YN, Fyhrie DP. Finite element calculated uniaxial apparent stiffness is a consistent predictor of uniaxial apparent strength in human vertebral cancellous bone tested with different boundary conditions. J Biomech 34(12): 1649, 2001
6. Granberry L, Ewing M, Rose J, Moore CM. Evaluation of drilling and screw insertion effects on STRUCSURE° CP macroporous calcium phosphate bone graft substitute. Bone&Joint Science (KLEOSmd) 2(11), 2011

Figure 2: Pullout strength test setup.

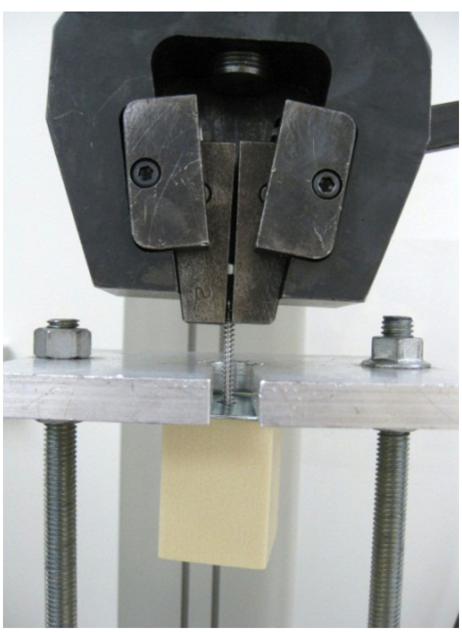
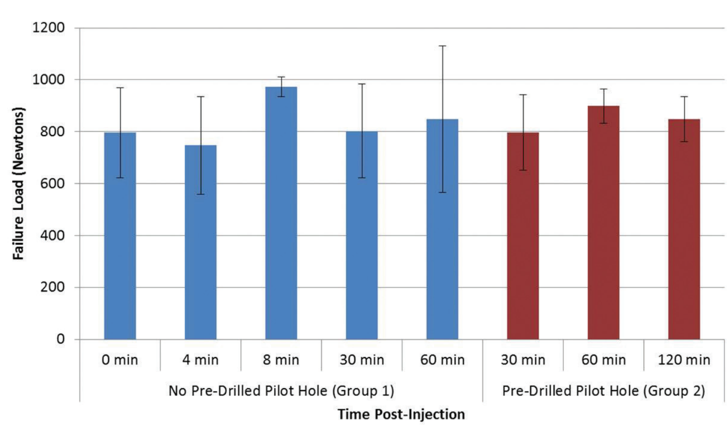


Figure 3: Pullout strength testing results. Screws were inserted into STRUCSURE° CP at the times indicated post-injection, and the samples were allowed to harden for 24 hours prior to measuring the failure load. Data are presented as mean ± standard deviation. No statistically significant differences were found among the groups.



US: Lit.No: 10601085A

Produced by Scientific & Medical Affairs,
Smith & Nephew Inc.
Published by KLEOS, the medical education service
from Smith & Nephew

Published December 2012

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