BoneSync™ Cement: A Biomechanical Analysis of Rotator Cuff Repair Augmentation in Open-Cell Foam Block

Arthrex Orthopedic Research

Background

Poor bone quality induces several challenges for arthroscopic rotator cuff repairs. Poor-quality bone of the proximal humerus can increase the chances of anchor pullout and require revisional surgery.[1] Calcium phosphate bone cement, such as BoneSync cement, can be useful for augmenting poor-quality bone.[2]

Materials and Methods

BoneSync cement has a set time of 6-10 minutes, and hardening occurs 24 hours postimplantation.[2] Several timepoints (0 minutes, 5 minutes, 10 minutes, and 24 hours) were selected to evaluate the fixation strength of Biocomposite 4.75 mm SwiveLock® anchors augmented with BoneSync cement throughout the hardening process. Timepoints were defined as the amount of time from the start of mixing until tensile testing was conducted.

Sample Preparations

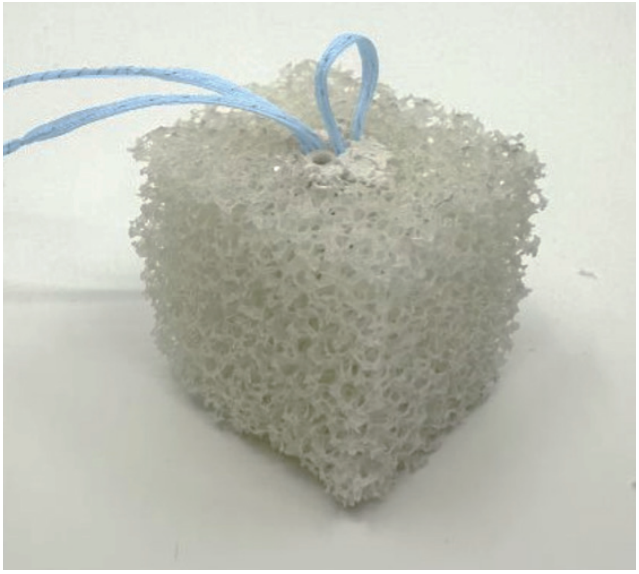
Open-cell foam block was selected to mimic poor bone quality. A hole was punched into the 7.5 pcf open-cell foam block using a SwiveLock punch.

FiberTape® suture was threaded through the eyelet of a SwiveLock anchor to form a loop. For control group samples (no BoneSync cement), SwiveLock anchors were immediately inserted into the punched hole with the loop held around a 0.5-inch dowel rod.

For all other samples, BoneSync cement was mixed with 0.8 cc phosphate-buffered saline (PBS) according to the packaging instructions. The mixture was injected into the punched hole using a delivery cannula, and then the SwiveLock anchor was inserted directly following injection (Figure 1).

Each sample was closed in a jar of PBS and placed in a 37 °C (body temperature) environmental chamber for a set amount of time (5 minutes, 10 minutes, or 24 hours). Zero-minute timepoint samples were not immersed in PBS.

Figure 1. Prepared BoneSync cement sample



Tensile Testing Method

Once removed from the PBS, the suture loop was attached to a hook and the foam block was secured under a box fixture. A preload of ~0.1 N was applied. Following the preload, tensile testing was performed at a rate of 5 mm/s until failure. The maximum load (up to 3 mm of displacement), displacement at maximum load, and failure mode were recorded.

Results

The maximum load was defined as the maximum load achieved at or before 3 mm displacement. Displacement at 3 mm was used to represent clinical failure for this application.

Figure 2 shows the mean maximum load at each time point. Significant differences were found between the control group and 10-minute ($P = .009$) and 24-hour ($P < .001$) timepoints. The failure mode for all samples was anchor pullout (Figure 3).

Figure 2. Maximum load at or before 3 mm of displacement for each timepoint[3]

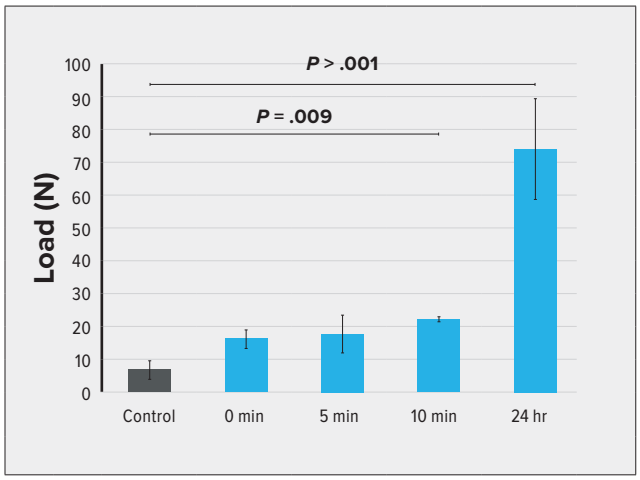
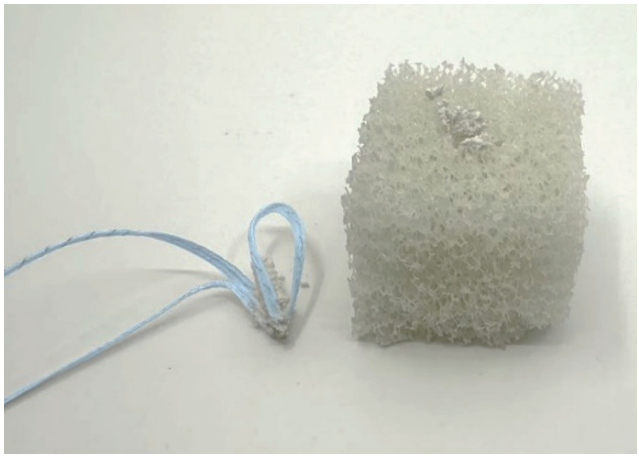


Table 1. Maximum Load Data (Mean ± SD)[3]

Timepoint	Maximum Load (N)
Control	6.67 ± 2.27
0 min	15.4 ± 2.02
5 min	17.1 ± 5.61
10 min	22.2 ± 1.38
24 hr	74.2 ± 14

Figure 3. Failure mode for all samples was anchor pullout



Conclusions

The presented porous sawbones model with BoneSync™ augmentation demonstrates significantly higher ultimate loads at the 10-minute and 24-hour timepoints compared to the models without BoneSync augmentation. The time-zero analysis provides evidence that BoneSync augmentation in poor-quality bone may be more resistant to pullout forces after the specified setting time.

References

1. Kirchhoff C, Braunstein V, Milz S, et al. Assessment of bone quality within the tuberosities of the osteoporotic humeral head: relevance for anchor positioning in rotator cuff repair. *Am J Sports Med*. 2010;38(3):564-569. doi:10.1177/0363546509354989
2. Miyamoto Y, Ishikawa K, Takechi M, et al. Tissue response to fast-setting calcium phosphate cement in bone. *J Biomed Mater Res*. 1997;37(4):457-64. doi:10.1002/(sici)1097-4636(19971215)37:4<457::aid-jbm3>3.0.co;2-k
3. Arthrex, Inc. Data on file (APT-06573). Naples, FL; 2024.

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