Mechanical Efficacy of Calcium Triglyceride Bone Cement for Pedicle Screw Augmentation


Introduction PMMA bone cement is the gold standard for reinforcement of osteoporotic bone in surgical procedures of the spine such as augmentation of stripped pedicle screws and vertebral decompression, including vertebro/kyphoplasty procedures. Calcium triglyceride bone cement is a potential alternative to PMMA, exhibiting mechanical properties similar to bone, good adhesion and porosity, and a low exothermic curing temperature. The cement comprises three individual components of two fatty acid liquids and one calcium carbonate powder, mixed in a similar fashion as PMMA. Recently shown to maintain function as an osteoconductive scaffold within osteoporotic bone, it is pending FDA clearance for human use.

The purpose of this study was to test the mechanical efficacy of calcium triglyceride bone cement specifically for pedicle screw augmentation, with particular elucidation of mechanical screw purchase as a function of post-mix curing time.

Materials and Methods Pedicle screw augmentation was tested directly, employing ASTM standard 1 ½" thick cellular polyurethane bone-analog foam (12.5 lbs/ft³, Pacific Research Laboratories) as a uniform test bed model of cancellous bone. This cancellous analog was chosen to provide modest screw purchase without augmentation, and for its ability to limit penetration of cement to a characteristic radial distance from the screw, thus producing a uniform structural construct for all test cases. Stainless steel screws were chosen to match the thread pitch, diameter, and length commonly used in pediculor fixation. Standard pilot holes were pre-drilled in the cancellous analog for all test cases, placing screws to full 1 ½" length of screw threads, corresponding to bone block thickness. A bottom plate support fixture with a 1" diameter aperture was centered at the test site.

On-axis screw pull-out tests were performed at a uniform rate of 1 mm/second via self-aligning universal joint. Baseline control tests, without cement augmentation, were performed by inserting screws into pilot holes at full depth, without any stripping. All other test conditions included physical stripping of the threads by clamping the bone block between steel plates, turning the fully-inserted screw tip against the bottom plate 10 revolutions, and pulling it out on-axis to further strip the pilot hole. Screws augmented with calcium triglyceride cement (Kryptonite Bone Cement™, Doctors Research Group, Inc.) were tested after mixing the three cement components for one minute, loading a syringe with liquid cement, injecting the stripped pilot hole (open bottom taped over) with 1.5 ml of cement, and manually inserting the screw. Curing time was referenced to the start of mixing, testing screw augmentation at discrete intervals ranging from 30 minutes to 24 hours. 44 tests were conducted across various curing time points, ensuring 4 individual tests for prescribed test cases at defined time points. Linear regression of strength versus curing time was performed to assess the immediate temporal performance of cement augmentation. Statistical comparisons for control versus 1 hour and 24 time points were performed using unpaired t-tests corrected for the multiple comparisons.

Results Non-stripped, non-augmented control screws required a tensile pull-out force of 1018 ± 76 N (229 lbs) to remove them from the bone analog used in this construct (Fig. 1). This force was reduced to 148 ± 18 N (33 lbs) for stripped pilot holes with same-size screws reinserted. At the 1 hour curing time point, augmented strength of stripped screws (1441 ± 110 N) exceeded the strength of non-stripped control tests by 42% (p = 0.0024) and stripped controls more than 8-fold (p = 0.0003). Maximum strength was demonstrated after two hours, reaching 2789 ± 213 N for the 24 hour time point. Interestingly, this increase in strength for cement augmentation followed a strong linear correlation to curing time between 30 and 90 minutes, increasing 37 N per minute (Fig. 2).

Failure modes of the test constructs reflected the mechanical phenomena, and were evident by visual inspection of the tested constructs. Small particles of bone analog on control screws coincided with stripping threads, whereas taffy-like cement coated the screws at early curing time points. At later time points, cured cement transferred stress from screw threads to the peripheral boundary of cement penetration, fracturing the relatively weaker bone analog to produce cylindrical fragments (Fig. 3).

Discussion Pedicle screws are common in spinal surgery, and can become problematic when used in osteoporotic bone. When pedicle screws strip through relatively weak lower-density bone, a larger diameter screw is often used if possible. Thereafter, surgical options turn to augmentation with cement or additional hardware, with the goal of achieving adequate initial mechanical strength and stiffness for surgical constructs. Although alternatives to PMMA have demonstrated efficacy for pedicle screw augmentation, most require substantially longer curing times relative to PMMA.

The calcium triglyceride cement tested in this study demonstrated potential for mechanical efficacy in augmentation of pedicle screws, regaining baseline control strength within 45 min of initial mixing, and just 15 min beyond the recommended post-mix application time of 30 min. When placed in trabecular compartments in the mouse distal femur, appositional bone remodeling persisted within the open porosity of the cement throughout the 15-month period examined, whereas contralateral sham limbs of female mice demonstrated a complete absence of trabecular bone. Collectively, these studies suggest that calcium triglyceride cement may provide mechanical and biological properties beneficial for augmentation procedures in osteoporotic bone.

References

Poster No. 1759 • 55th Annual Meeting of the Orthopaedic Research Society