Calcium Triglyceride versus Polymethylmethacrylate Augmentation: A Biomechanical Analysis in Intact and Revision Models

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Introduction: Secure fixation of screws in bone for fracture repair or attaching instrumentation is crucial for successful clinical outcomes. Circumstances often necessitate augmenting screw fixation particularly in osteoporotic bone. PMMA is the standard of care for pedicle screw augmentation in the osteoporotic spine and improves pullout strength, but is nonabsorbable and undergoes an exothermic reaction which may cause local thermal necrosis and protein denaturation (1,2). Calcium Triglyceride (CTG) (Kryptonite Bone Cement\textsuperscript{1,2}, Doctors Research Group Inc., Southbury CT) is a novel osteoconductive bone adhesive that undergoes a nonthermogenic reaction and porosity expansion upon mixing its biologically derived components.

Objective: To compare the pullout strength of CTG augmentation versus the gold standard, PMMA, in primary and revision models.

Materials & Methods: For a uniform test bed, blocks of solid rigid polyurethane foam (ASTM grade 20PCF, 0.32g/cc, Pacific Research Laboratories, Vashon Island WA) were prepared according to ASTM standards. This bone would be considered an osteoconductive analog for the pedicle (3). After the components of PMMA (N=11) and CTG (N=11) were individually mixed in a standardized fashion, 0.2 ml was injected from deep to superficial along a predrilled pilot hole followed by immediate insertion of a monoaxial pedicle screw (6.5mm x 35mm; US Spine Inc., Salt Lake City UT). An unaugmented group (N=10) was also repaired. Blocks cured for 24 hrs (mimicking a patient getting out of bed postoperative day), and screws were pulled out at a rate of 5mm/min by materials testing equipment. For the revision model, the unaugmented group, after screw pullout, was augmented with 0.8 ml PMMA (N=5) or CTG (N=5) as detailed above and screw pullout performed similarly.

Results: Loading curves differed among the models (Fig 1). Construct stiffness of the augmentation groups were significantly higher than the unaugmented group (p<0.0001) but not from each other (p>0.7) (Table 1). Stiffness was not different between revision models (p>0.08).

PMMA and CTG augmentation caused more bone to adhere to the screw and pullout at failure, with CTG having qualitatively more adhered bone (Figs 2,3). A one-way ANOVA for the pullout strengths indicated a significant difference among all primary models (p<0.0001). For the revision models, the pullout strength for CTG was statistically different from PMMA (p<0.0003).

Conclusion/Discussion: CTG augmentation of pedicle screws resulted in significantly higher axial pullout strength in intact and revision models compared to PMMA, a potentially clinically advantageous property when challenged with osteoporotic host bone.

In a prior study, CTG required 2 hours cure time to achieve maximum pullout strength and increased axial pullout strength over the unaugmented screw (4). Similar to our data, the pullout strength of the CTG repair surpassed the unaugmented constructs.

CTG’s unique properties of adhesion and porosity expansion perhaps enhanced initial interdigitation of the augmentation through the pores of the bone blocks, effectively increasing the surface area of bone-augmentation interface and affording stronger fixation and failure at the bone – augmentation interface in comparison to PMMA’s mode of failure at the bone – screw interface.

Given that the components of CTG are biologically derived, bioabsorbable in vivo, and expand upon polymerization to possess pores allowing for in-growth of host bone, secondary implant fixation with CTG potentially allows for dynamic integration of host bone into the augmentation interface though a process of repair and remodeling similar to fracture healing (5-7). In contrast, PMMA functions similar to mechanical grout as it is relatively biologically inert which raises concerns for particulate debris and third body wear.

Acknowledgements: This experiment was made possible by the donations of Calcium Triglyceride from Doctors Research Group Inc. and the pedicle screws from US Spine Inc.

Significance: The improved biomechanical performance of CTG vs PMMA augmentation in this pedicle screw model may provide a clinical advantage when challenged with porous bone, fragility fractures, or increased risk of loss of fixation.

Results:

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intact</th>
<th>PMMA</th>
<th>CTG</th>
</tr>
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<tbody>
<tr>
<td>Pullout Strength (N)</td>
<td>2089 (110)</td>
<td>2470 (212)</td>
<td>2426 (70)</td>
</tr>
<tr>
<td>Revision</td>
<td>2757 (56)</td>
<td>2678 (69)</td>
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Table 1: Stiffness (between 100 and 500N) and pullout strength (std dev) for intact and revision models.

References: