EVALUATION OF CALCIUM PHOSPHATE BONE CEMENT USED AS AUGMENTATION FOR CANCELLOUS INTERFERENCE SCREW FIXATION IN A PORCINE KNEE

Introduction:
Recent research regarding knee ligament reconstruction has centered on the fixation of various graft materials in bone tunnels. Much of this work revolves around one general notion: strong initial fixation with rapid bone-to-bone or bone-to-tendon healing is necessary if patients are to withstand aggressive rehabilitation without compromising their grafts. Recently, an in vivo curing, non-exothermic, high strength calcium phosphate cement has been developed and used successfully for fortification of cancellous bone in various fracture models. This cement has been shown to improve the initial stability and pullout strength of both large and small screws used for internal fixation in fracture management[1]. In addition, it is bioabsorbable through osteoclastic activity and serves as a remodeling bone mineral substitute[2]. The purpose of our study was to evaluate the initial effects of this cement in soft tissue tunnel fixation.

Methods:
Nine pairs (n=18) of porcine stifle joints were obtained from one-year-old animals at a regional slaughterhouse. From each joint, we harvested a 10-mm-wide strip of patellar tendon. The tendon’s insertion on the patella was maintained, and a 10-mm-diameter x 25-mm-long bone plug was harvested from the tibial tunnel. From this construct, we established a patella-patellar tendon-bone plug complex (p-PTG) to be used for testing. Limbs were stripped of all soft tissue, and using a flat saw cut at equal levels of both limbs, we removed the tibial plateau subchondral bone plate with its articular surface. Closed tibial tunnels 25mm in length were then drilled in the cancellous bone of the medial side of the cut tibial plateau. Subjective bone quality was noted by the surgeon during tunnel reaming. In the study group, the tibial bone plug of the p-PTG was inserted into an 11.5-mm-diameter tunnel to allow interference screw fixation and cement augmentation. In the control group, the p-PTG was inserted into a 10.5-mm-diameter tunnel and fixed only with an interference screw. Cementing technique involved approximately 3ccs of BoneSourceTM (Orthofix, Inc., Winston-Salem, NC) cement being applied to the tunnel wall on the cancellous (screw side) gap area before bone plug insertion and subsequent interference screw fixation. We then performed a standard interference screw technique (7 or 9mm) with notching and guide pin assistance. Specimens were allowed to cure for 12 to 24 hours, ensuring complete cement hardening. Then, specimens were mounted on a custom jig, cyclically loaded to subfailure loads of 50 N and then tested to failure on an Instron model 1125 materials testing machine (Instron, Canton, MA) at a strain rate of 10mm per second. Failure strength, construct stiffness, and mode of failure were recorded for each specimen. Comparisons between the study and control groups were made using a paired t-test (SPSS, v. 8.0, SPSS, Inc., Chicago, IL). A p value less than 0.05 was considered to be statistically significant.

Results:
We found failure strength to be greater in the cement group than in the control group (p = 0.04, Table 1). When compared within each pair, the cement side was, on average, 25% stronger than the control side. Construct stiffness was also somewhat greater in the cement group, although this was not a statistically significant difference (p = 0.31). Comparisons within each pair showed a mean increase in stiffness of 18% in the cement group when compared with the control group. We found failure strength to be lower in bones judged subjectively poor by the surgeon for both the cemented and the control group. No differences were observed in the percentage strength increase with cement augmentation when comparing good versus poor bone. Most (79%) of the control group failures occurred from bone plug and interference screw pullout. Further examination indicated that these had released through the screw-bone tunnel interface while leaving the screw-bone plug interface unstripped and intact. In three of these seven specimens the screw remained physically attached to the bone plug after failure. In contrast, the cemented group most often failed at the screw-bone plug interface (59%) with cancellous stripping of the bone plug. The authors have not received anything of value from a commercial or other party related directly or indirectly to the subject of my presentation.

Table 1. Means (standard errors) for materials testing data.

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<tr>
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<th>Cement Group</th>
<th>Control Group</th>
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<tr>
<td>Failure Strength</td>
<td>478.1 (53.8)</td>
<td>406.2 (54.9)</td>
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<tr>
<td>(N)</td>
<td>201 (3.1)</td>
<td>176 (2.2)</td>
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<tr>
<td>Stiffness (N/mm)</td>
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Discussion:
Multiple theoretical advantages exist regarding the application of a biologically compatible and integrative bone cement for use in soft tissue tunnel fixation. In our initial investigation, failure strength was found to be statistically increased when cement was used, assuring that at time zero no detriment to pullout integrity occurs. In addition, failure mode was somewhat different in the cement group, appearing to protect the screw-tunnel wall interface. This may suggest that cement augmentation may increase screw stability and screw pullout strength, similar to the results of previously published fracture work. Hypotheses to explain this effect include the following: 1) mass effect (heavy grout) during interference screw application, 2) stabilization of the screw in the cancellous bone protecting the screw-tunnel interface, 3) fortification of the cancellous bone in general, and 4) elimination of any gaps in the tunnel. A slight increase in failure strength, as demonstrated in this study, may not warrant clinical consideration by itself; however, we believe that the positive results of this study potentially lend themselves to the following clinical situations: 1) graft width to tunnel mismatch (large grafts), 2) revision surgery (bone loss), 3) poor tibial metaphyseal bone, 4) tibial joint interference screw fixation, and 5) bioabsorbable fixation. Further research is warranted to determine cyclic loading behavior, compatibility of the graft-cement interfaces, healing of the tendon in the bone cement environment, interaction with the intra-articular environment, and interaction with bioabsorbable fixation prior to any consideration of clinical application.

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References:

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