INTRODUCTION
Symptomatic injury to the tendons of the rotator cuff typically requires surgical intervention to restore full functionality to the shoulder. Rotator cuff tears are common in older patients, affecting up to 54% of the population over the age of 60.1,2 Patients in this age group commonly exhibit decreased bone density, and a reduction in cancellous bone in the greater tuberosity has been shown to be associated with full-thickness tears.3 In these patients, there is a risk that suture anchors used to repair the tendons could be pulled out of bone either intraoperatively or during the post-operative healing period. Surgeons have reported a feeling of anchor loosening in poor quality bone,4 which may necessitate the use of a larger anchor or could potentially compromise the repair.

One potential method to reduce the risk of anchor loosening or pullout is to augment anchor fixation in bone using a bone cement or bone substitute. It has been previously demonstrated that polymethylmethacrylate (PMMA) bone cement is effective in augmenting the fixation strength of suture anchors;5 however, cementitious compounds (CaP) cements have become increasingly popular and exhibit potentially advantageous properties. HydroSet™ bone substitute is a fast-setting, injectable, osteoconductive, and osteointegrative CaP cement that undergoes an isothermic conversion to hydroxyapatite. It is hypothesized in this study that HydroSet™ will augment the fixation of polyetheretherketone (PEEK) anchors in a low density foam model.

METHODS
Materials: Stryker Joint Preservation 5.5 mm PEEK IntraLine™ fully-threaded suture anchors were utilized in this study. Low density 0.16 g/cc cellular rigid foam (Sawbones, Pacific Research Laboratories) was chosen since this model has been suggested to be an appropriate osteoporotic bone model.1 HydroSet™ (Stryker) bone substitute was utilized as the augmentation medium.6 Pilot holes were formed in the foam using the appropriate punch-tap for the IntraLine™ anchors.

Anchor Augmentation and Testing: HydroSet™ was mixed for 45 seconds and subsequently inserted manually into the pilot holes. Suture anchors were immediately inserted and the foam was mounted to the testing system (MTS 858 Mini Bionix, MTS) with the sutures clamped using pneumatic grips (Fig 1). After the designated setting time (4.5 min or 24 hr after initial mixing), the anchors were loaded in uniaxial tension at a rate of 30 mm/min until failure (n = 6-7). Peak load was determined from the resulting load-displacement graphs. Control groups consisted of anchors tested in the same foam model without HydroSet™ (n = 8), and anchors tested in 0.24 g/cc solid rigid foam to represent higher density bone (n = 8). Testing was conducted at room temperature (21°C). Augmented anchors designated for the 24 hr time point were stored under humidified conditions at 37°C.

Statistical Analysis: Means and standard deviations were calculated for each group. A one-way ANOVA was performed to determine the effect of testing condition on anchor pullout strength. A series of hypothesis tests with linear contrasts were subsequently performed with differences considered significant at p<0.05 (SYSTAT 12).

RESULTS
Cross-sections of the augmented anchors in the foam revealed that the interface between the anchor body and the foam was filled with HydroSet™, with the bone substitute interdigitating into the pores in the foam (Fig 2A). Augmented anchors that were pulled out of the foam exhibited bone substitute engaged between the anchor threads (Fig 2B). Maximum loads obtained for the anchors in 0.16 g/cc cellular and 0.24 g/cc solid foam were 29±5 lb and 64±4 lb respectively (p=0.0001) and were considered the baseline values for comparison (Fig 3). The failure mode exhibited in the low density foam was anchor pullout, whereas soft eyelet pull-through was the failure mode for all anchors in the solid foam. HydroSet™ augmentation had a significant effect on anchor fixation strength compared to the non-augmented anchors in 0.16 g/cc foam (p<0.0001). Augmentation increased the maximum load by 100% and 136% for the 4.5 min and 24 hr time groups, respectively, compared to the non-augmented group in 0.16 g/cc foam (p=0.0001 for both contrasts). In addition, the 24 hr set time increased the maximum load by 13% when compared to the 4.5 min set time (p=0.0008). The failure mode changed from 66.6% anchor pullout (33.3% eyelet pull-through) after 4.5 min to 100% eyelet pull-through at 24 hours. The 4.5 min set time resulted in fixation strength less than that exhibited in 0.24 g/cc foam (p=0.02); however with the two time points considered together, augmentation resulted in fixation strength that was not statistically different from pullout in 0.24 g/cc foam (p=0.62).

DISCUSSION
The objective of this study was to evaluate the augmentation of suture anchors with an injectable and osteoconductive bone substitute in a low density foam bone model. Reflective of the clinical condition in poor quality bone, anchors failed under lower loads in the low density cellular foam compared to the solid foam. HydroSet™ was shown to be effective in augmenting anchor fixation in this osteoporotic bone model, returning the maximum loads to values achieved in the higher density foam. The findings indicate enhanced anchor fixation after only 4.5 minutes from the initiation of HydroSet™ mixing, suggesting the potential for this bone substitute to prevent intraoperative anchor pullout. Maximum loads were further increased after 24 hours of setting, reaching values statistically similar to the maximum loads in 0.24 g/cc foam, suggesting stronger augmentation post-operatively.

This study was performed in a closed-cell osteoporotic foam model as a proof of concept. The extent of augmentation may have been influenced in an open-cell model, in which the bone substitute could potentially have engaged a larger volume of foam. Furthermore, while these data demonstrate the potential for HydroSet™ to augment fixation in a foam model, further studies can be performed in clinically-relevant cadaveric models to evaluate augmentation in bone and under aqueous conditions that would be encountered during an arthroscopic cuff repair.

REFERENCES
7The United States FDA has not approved HydroSet™ bone substitute for the use described in this study.

Augmentation of Suture Anchor Fixation with a Calcium Phosphate-Based Bone Substitute

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