Introduction
Constrained condylar knee (CCK) replacements provide varus-valgus stability in revision and primary TKA when the patient presents with poor collateral ligaments. Due to the increased implant loads, the tibial component is designed to be implanted with an augment stem to improve fixation. We conducted an in vitro experiment [1] that, similar to conflicting studies [2-4], indicated the inconclusive effect of a stem and the highly variable behavior of the implant motion under load. Utilizing finite element (FE) analysis, we determined that the measurements of the implant motion were very sensitive to shear loading conditions [5]. In addition, the mechanical stability of the tibial component is limited by failure of the cancellous bone directly beneath the tibial tray [6]. Consequently, determining the relative motion of the implant with respect to the bone is, at best, an indirect assessment of the potential risk to the cancellous bone.

The goals of this study, therefore, were to develop specimen-specific FE models consistent with the experimental findings, and use them to determine directly the structural effect of an augment stem in protecting the underlying cancellous bone.

Methods
Ten pairs of fresh-frozen tibiae were obtained (mean age 66.1 yrs, SD 8.2 yrs, range 52-76 yrs) and scanned with density phantoms using a GE9800 CT scanner. Three-dimensional models of the outer bone surfaces were generated from the processed CT data with Studio (Geomagic, NC). Based on the previous experimental design, each specimen was modeled with an appropriately-sized Insall-Burstein II CCK (Zimmer, IN - sizes 59, 64, 69). One side of each pair was randomly chosen as a control without an augment stem; the contralateral tibia had a 75 mm augment stem. The implant position with respect to the bone was computed from AP and ML radiographs of the implanted tibia, and the creation of the bone-implant mesh was programmed in TrueGrid (XYZ Scientific, CA) to efficiently develop consistent specimen-specific meshes (~20,000 linear elements; ~22,000 nodes).

Elemental elastic moduli for the bone were based on the CT data and a statistical model of the density-modulus relationship. Four empirical relations [7-10], specific to the human proximal tibia were transformed into a mean material model +/− a standard deviation to model the uncertainty in determining material properties.

In the in vitro experiment, the tibial components were loaded with a femoral condyle (medial load of 3000 N; 10 N-m varus moment), and a six degree-of-freedom load cell was mounted beneath the tibial potting to measure axial and shear loads. The FE models were loaded with a rigid surface representing the femoral component (in extension) in two ways: (1) axially loaded and constrained against transverse displacements (constrained force); (2) axially loaded along with AP and ML forces from the experiment (measured forces). The distal bone was fixed at the same position as the tibial potting in the experiment.

The models without an augment stem were displacement-compatible to represent a fully-cemented implant; a frictional interface (µ=0.5) modeled the uncemented augment stem. Initially, the underside of the tray remained bonded to the cement. As a worst case, a debonded cement interface (µ=1.0) was also modeled in case the severe eccentric load initiated interface failure.

The 120 FE models (ten specimen-specific meshes, three material relations, two load cases, and two interfaces) were analyzed with ABAQUS (v5.8, HKS, RI). The global motion of the tray and the relative motion of the tray with respect to the bone were compared between the experiment and the specimen-specific models utilizing paired t-tests. The minimum principal stresses and strains were obtained from a region of proximal cancellous bone underneath the tray for the models and compared with repeated-measures ANOVA.

Results
The experimental results were highly variable, and no significant reduction of implant motion was found for the augment stem compared with the unstemmed implant. The magnitudes of the displacements and rotations observed in the FE models were consistent with the experimental results, particularly for the mean (E) and less stiff (E-SDa) material model. The motions were also highly variable in the FE analyses when the measured forces were applied (Table 1) and the effect of a stem was insignificant. In every case, however, the stem reduced the stress and strain levels in the proximal cancellous bone (Fig 2) regardless of the force or interface conditions. Furthermore, the stresses and strains were less variable; there was no statistical difference between the constrained and measured forces (RM-ANOVA, p>0.1).

Discussion
The variability in both the experimental and numerical results highlighted the sensitivity of the implant motion to the applied shear loads acting on the articular surface. The bone, however, remained consistently loaded beneath the tibial tray as indicated by the smaller variation for the strain magnitudes and the similarity of the strains, regardless of the loading conditions. The augment stem reduced the strain magnitudes below possible yield values, particularly for bone with a reduced modulus. This study indicated that the conflicting results in the literature, which are based on measures of implant motion, do not directly assess the structural advantages of the augment stem. The FE models, validated with the experiment, provided additional insight and will be extended to evaluate the mechanics and design of augment stems.

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