Biomechanical properties of an artificial ligament produced from demineralized bone for anterior cruciate ligament reconstruction

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INTRODUCTION: Surgical reconstruction of the anterior cruciate ligament (ACL) traditionally involves replacing the torn ligament with a substitute graft derived from tendon or from other sources such as the iliotibial band. Autografts provide adequate tissue ingrowth and biocompatibility, but may be complicated by harvest site morbidity. Allografts eliminate concerns with donor site morbidity, but are associated with an immunogenic response and delayed graft incorporation into the host. The use of demineralized bone as an ACL replacement has been proposed to overcome the limitations associated with both autograft and allograft tissue, while providing adequate flexibility and tensile strength. In addition, creep has been shown to be much greater for tendon-based grafts than for normal ACL's. The amount of creep elongation is directly related to the free length of the soft tissue portion of the grafts which is always longer than the normal ACL. Thus, the use of demineralized bone as a graft material that minimizes the length of the soft tissue portion should reduce the potential for development of laxity post-op. The purpose of this study is to evaluate the biomechanical properties of demineralized cortical bone for use as a ligament replacement.

METHODS:, Nine strips of human cortical bone, approximately 1 cm wide and 0.5 cm thick, were produced from human tibia and processed at the University of Miami Tissue Bank. The ends of each specimen were coated with paraffin wax blocks and submerged in 1 M hydrochloric acid for approximately 96 hours. The active testing length ranged from 3.5 to 4.0 cm and was completely demineralized with the ends remaining bony to facilitate anchoring in the bone tunnel and to minimize creep. The specimens were gripped at the bony ends in wedge grips and mounted on a material testing machine (MTS model 858 MiniBionix II) to evaluate the viscoelastic properties and the tensile strength to failure. For creep testing, a constant 200 N load was applied to each specimen and held at that load for 5 minutes. For stress relaxation, the specimen was subjected to 10 minutes of cyclic loading, at a rate of 1 Hz, in displacement control from 0.4% to 4.4% strain of the active test length. Then, for tensile testing, the specimens were loaded to failure at 100% strain rate per second. The ultimate tensile strengths were recorded in Newtons (N) and then normalized by use of their cross-sectional areas (expressed in megapascals [MPa]).
The calculated biomechanical properties were compared with those of native ACLs and commonly used allografts, including anterior tibialis tendons (ATs) and fan-folded iliotibial bands (FITBs), under the same testing parameters. All data are presented as mean ± standard deviation. Significant differences were determined by use of the Mann-Whitney U test and statistical significance was ascribed to a threshold P value of 0.05

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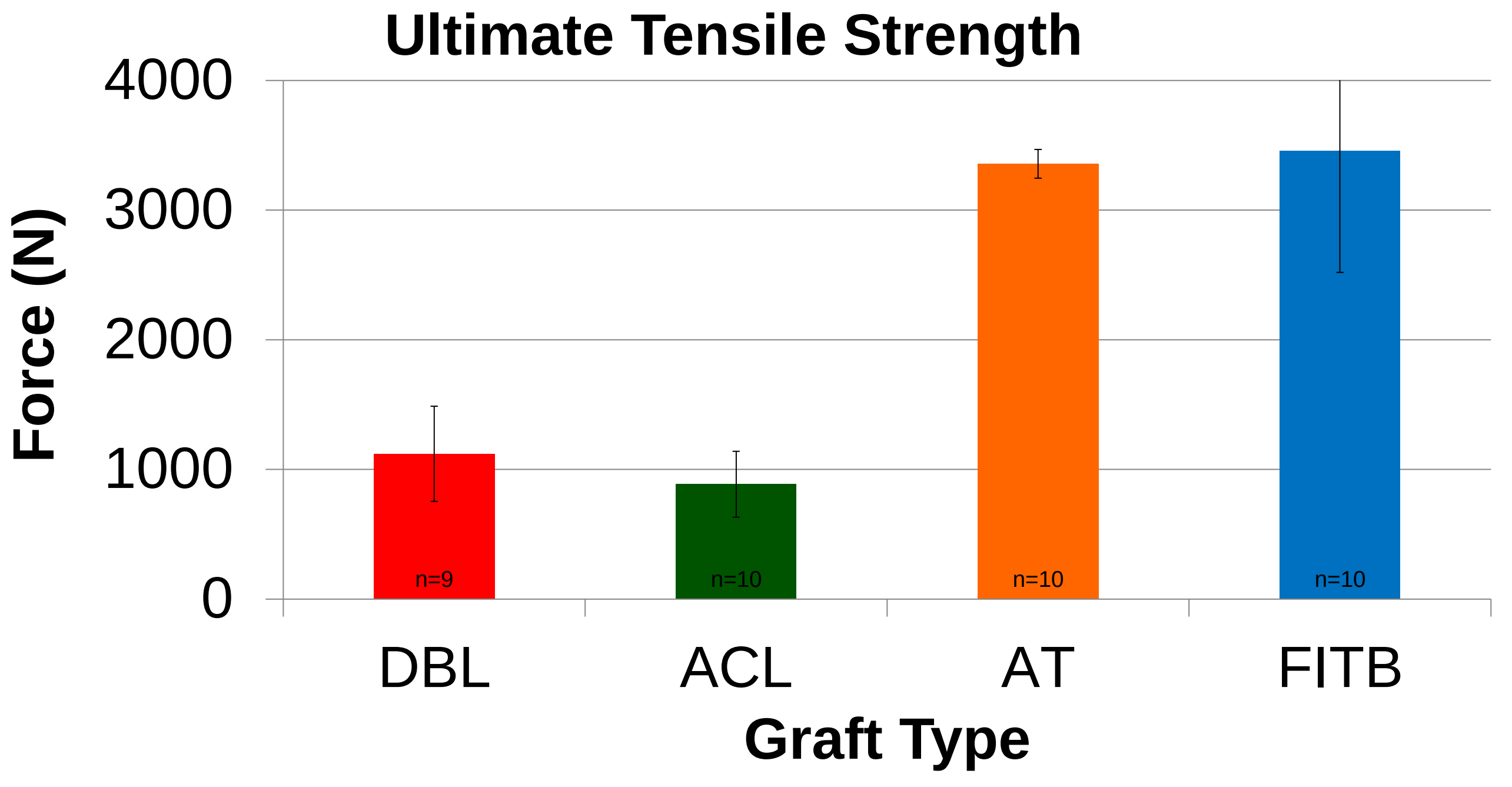
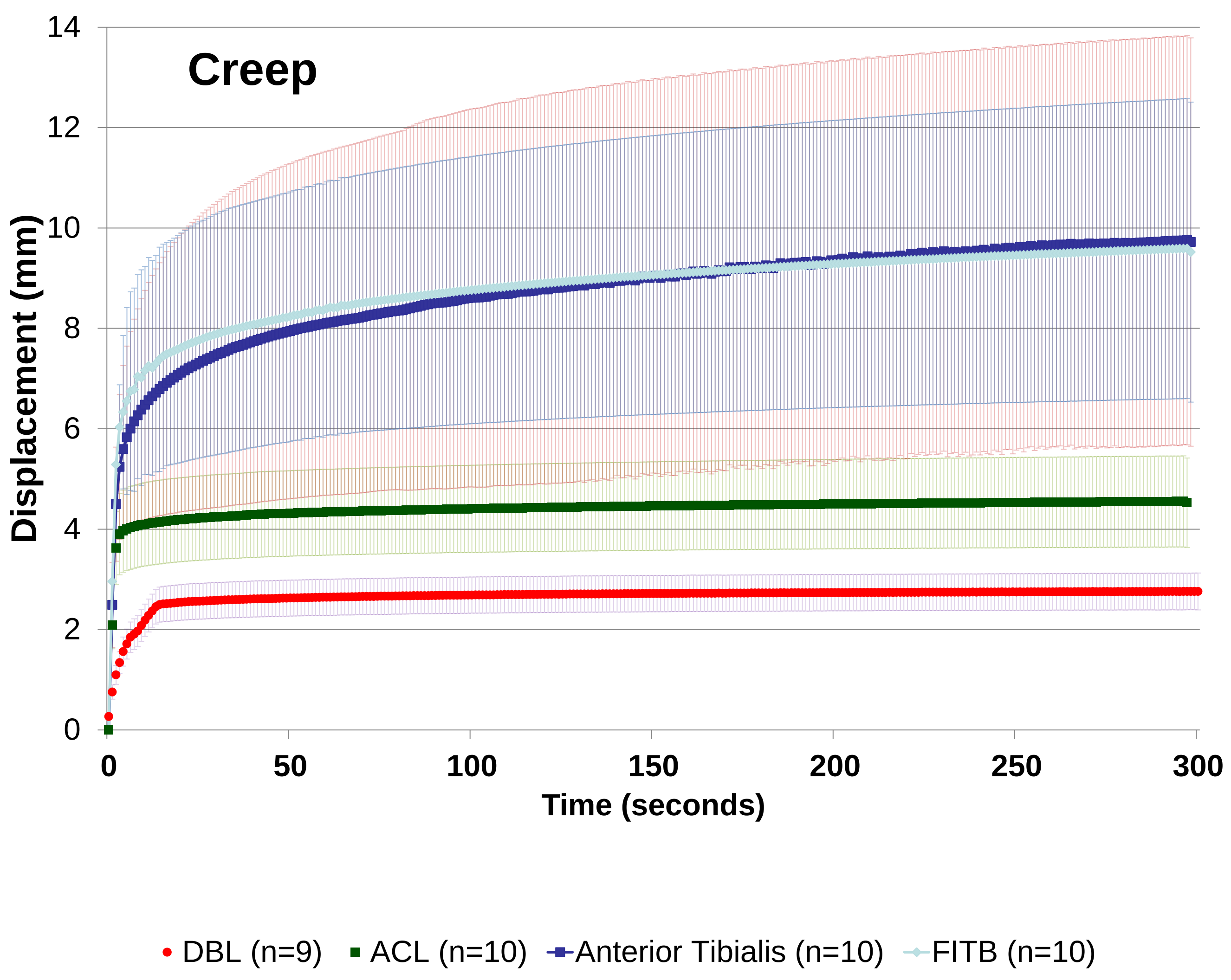
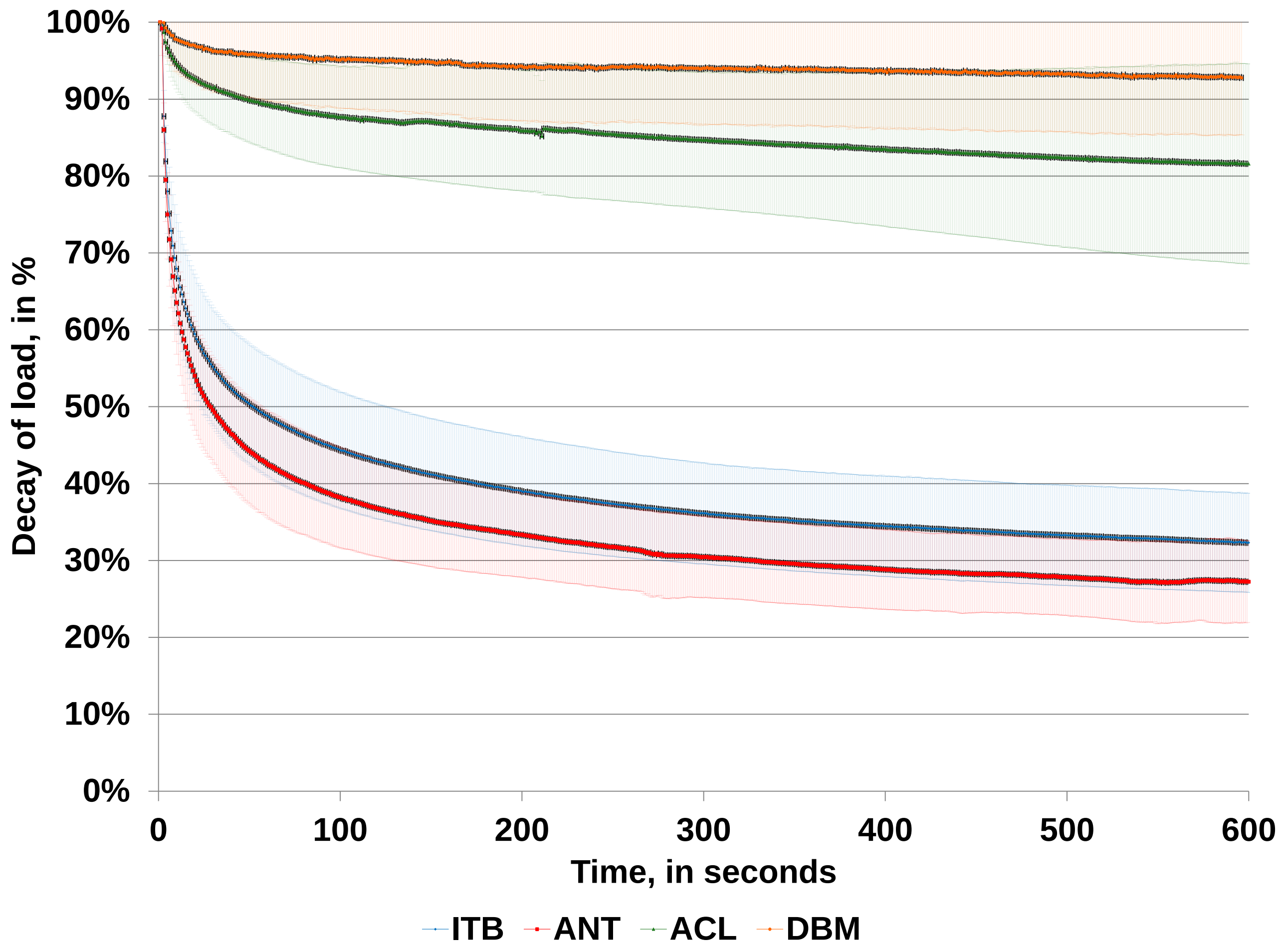
Results: The mean ultimate tensile strength to failure for the artificial ligaments made from demineralized bone (DBL) was 1095 ± 352 N, which corresponded to a stress to failure of 14.4 ± 6.0 MPa. Although the DBLs showed greater strength than ACLs (886 ± 254 N), the difference was not statistically significant (P=0.35). However, the ultimate tensile strength and stress to failure of the ATs (3357 ± 111 N and 50 ± 12 MPa) and FITBs (3459 ± 939 N and 48 ± 11) was significantly higher (P=0.003) than that of DBLs (Figure 1).

The DBLs displayed significantly (P< 0.001) less viscoelastic creep properties in comparison to the ACLs, ATs, and FITB allografts. The DBLs only reached a mean final plateau of 2.8 ± 0.4 mm during creep testing, whereas the ACLs (4.5 ± 0.9 mm; P=0.001), ATs (9.7 ± 4.0 mm; P=0.0003), and FITBs (9.5 ± 3.0 mm; P=0.0003) exhibited a significantly greater creep response (Figure 2). The mean decrease in initial stress during our cyclic stress-relaxation test of DBLs was only 9% after 5 minutes, compared to 19%, 73%, and 68% for ACLs, ATs, and FITBs, respectively. Based on the reduced stress-relaxation function, the stress-relaxation behavior of DBLs (0.91 ± 0.07) was similar to that of ACLs (0.81 ± 0.13; P=0.0536) (Figure 3). However, there was significantly less stress-relaxation observed during testing of the DBLs in comparison to that of ATs (0.27 ± 0.05; P=0.0001), and FITBs (0.32 ± 0.06; P=0.0001). At the beginning of the stress-relaxation test, DBLs had much lower forces with the initial strain compared to the others, but after 10 minutes of stress-relaxation testing, the DBLs stabilized at a minimal force of 156 ± 38 N which was similar to the final plateau values for ATs (166 ± 40 N; P=0.4274) and FITBs (181 ± 46 N; P=0.4057) but significantly lower than that of ACLs (222 ± 29 N; P=0.0015).

Discussion: Our data suggest that there are only minimal differences for the ultimate tensile strength between DBL and ACL, further supporting the claim that demineralized bone has sufficient strength to withstand loading as a ligament replacement. We utilized only human tibias in our study so further work is warranted to assess these differences in human bone. The viscoelastic behaviors of creep and stress relaxation are important in describing the response of ligaments and tendons to loads during daily activities, increases in knee laxity over time. Additionally, the initial force applied to tension the graft during ACL reconstruction will exhibit less relaxation over time, and thus reduce the need for preconditioning.
At one year following ACL reconstruction with a demineralized bone graft on a goat model, Jackson et al.[3] found dense regular connective tissue and numerous fibrocytes and blood vessels within the intra-articular graft substance resulting in a 550% increase in the mean strength of the grafts. Future studies should investigate the time required to achieve optimal changes to the DBL's mechanical and structural properties for it to function as an acceptable ligament replacement.







SIGNIFICANCE: An artificial ligament derived from demineralized bone has the potential to fulfill the need for achieving a ligament replacement that provides long-term strength, flexibility, and recovery to mimic that of the original, undamaged ligament.

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