Biomechanical Testing of GraftLink® TS for ACL and PCL Reconstruction

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ORIGINAL RESEARCH ARTICLE

Introduction:

Human tendon allografts are widely used for sports medicine applications. Compared to autograft, allografts offer distinct advantages including no donor site morbidity, predictable graft shapes and sizes, decreased post-operative pain and stiffness, and decreased operative times.[1, 2] Furthermore, the use of low-dose, ultralow-temperature gamma irradiation substantially reduces the risk of disease transmission while also maintaining the biomechanical properties of the graft.[3-5] Allograft tendons are commonly used for anterior cruciate ligament (ACL) reconstruction but may also be used for posterior cruciate ligament (PCL) reconstruction. To prepare these grafts, tissues such as recovered patellar tendon, anterior and posterior tibialis tendon, peroneus longus, semitendinosus, or gracilis tendon can be utilized for cruciate ligament reconstruction. Whichever graft type is employed, it must be able to reproduce the complex anatomy of the native ligament or tendon, match its normal strength, and allow for strong and secure fixation. Many surgeons prefer to use pre-sutured graft constructs, such as GraftLink® Construct (LifeNet Health or Arthrex), to repair the ACL or PCL because they are consistent and can reduce operating room time. Several articles discuss successful, arthroscopic techniques for ACL and PCL reconstruction using tendon allografts, including the GraftLink® All-Inside® Technique.[6-8] The new GraftLink TS design requires only three strands allowing for a 33% longer construct. This longer construct allows the graft to be used for both ACL and PCL reconstruction (Figure 1). The purpose of this study was to compare biomechanical properties and design of this three-strand, pre-sutured loop tendon allograft design, GraftLink TS (GL TS), to the strength and displacement of the four-strand, pre-sutured tendon allograft, GraftLink (GL).

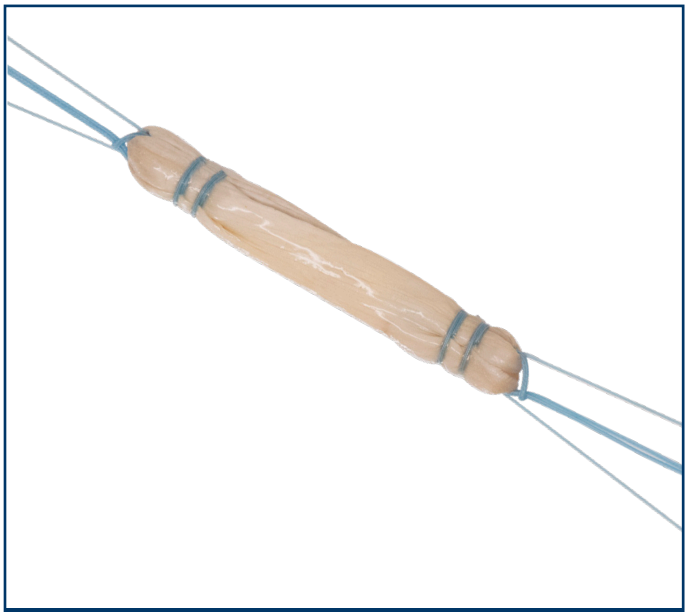

Figure 1. GraftLink TS

Materials and Methods:

Fourteen matched donor pairs consisting of peroneus longus and anterior and posterior tibialis tendons, each from contralateral limbs, were used to construct the grafts, and prepared according to the established processing protocol. The fourteen GraftLink TS constructs were prepared with contralateral tendons; folding the tendons into themselves to create the three-strand construct. The starting and final dimensions of each graft were recorded. All grafts were processed with Allowash XG®, which includes cleaning, disinfection, and terminal sterilization following packaging according to LifeNet Health specifications. The grafts were then stored at -80°C until testing. The grafts were thawed at room temperature and kept moist with normal saline until testing.

Mechanical testing was performed using an INSTRON Model 3367 (INSTRON, Canton, MA) with a 30kN load cell attached to the crosshead. The grafts were first tensioned to 20 lbf on the prep station with the AR-7210 loops for three minutes. The constructs were then mounted with 1/8" quick links on both ends of the grafts and the tails on the tibial side of the graft were tied around the dowel of the Tendon Mechanical Fixture. Each construct was tensioned to a 10 N pre-load and pre-cycled 10 times from 10 to 50 N at 1 Hz. The constructs were then cycled 500 times from 50 to 250 N at .9 Hz (approximately 1 Hz) and then pulled to failure at 20 mm/min. Yield load data were determined by BlueHill 2.0 software. Video files of the test were analyzed for average cyclic displacement using MaxTRAQ. The mean yield load and cyclic displacement were reported, and statistical analysis was completed using a two-sample t-test. In addition, GL TS constructs were compared to the primary acceptance criteria, yield load ≥450 N and average cyclic displacement ≤3 mm, as previously reported.[10]

Results

All GL TS constructs passed the primary acceptance criteria: yield load ≥ 450N and average cyclic displacement ≤ 3mm (Figures 2 and 3). The average yield load of the GL and GL TS constructs were 938.878 N and 920.775 N, respectively. The yield loads of the two constructs were not significantly different (p-value = 0.809). The average cyclic displacement of the GL and GL TS constructs were 1.300 mm and 1.243 mm, respectively. The average cyclic displacement of the GL TS constructs were not significantly different than the GL constructs (p-value = 0.812).The GL TS constructs with tails on the tubular side of the construct did not significantly differ in yield load or average cyclic displacement from the constructs with tails on the fanned end with a p-value of 0.944 and 0.883 respectively. The modes of failure for 11 of the 14 GL TS constructs were isolated to the femoral side of the graft, whereas all 14 GL grafts failed due to separation of the terminal ends, as was expected.

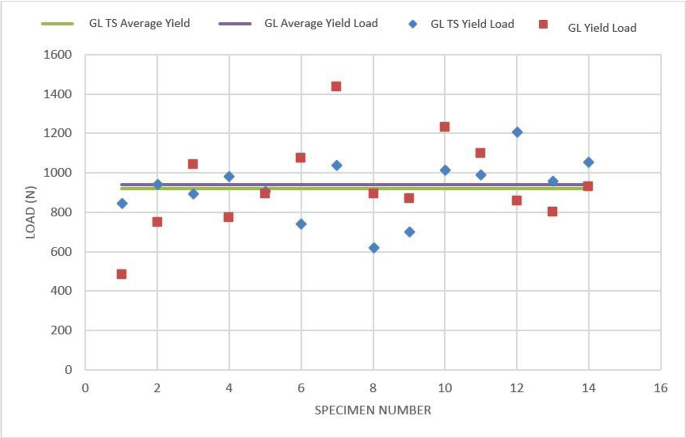

Figure 2. Yield load for each GL and GL TS Specimen with group averages.

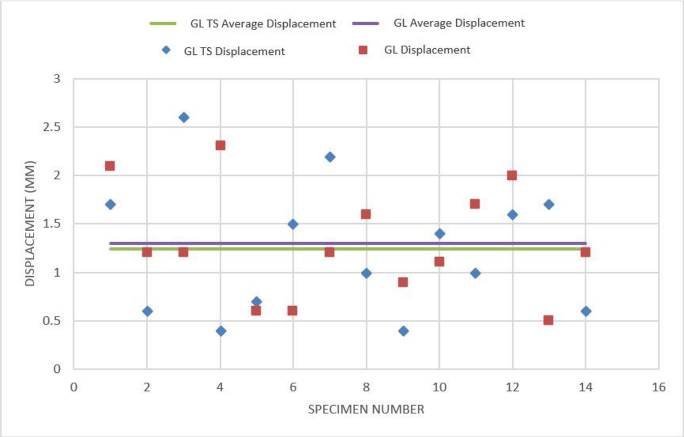

Figure 3. Average displacement for each GL and GL TS Specimen with group averages.

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Discussion:

The strength and complex structures of the anterior and posterior cruciate ligaments assist in ensuring knee stability. Thus, the primary objective of cruciate ligament reconstruction is to restore normal knee mechanics and stability.[2] The purpose of this biomechanical study was to characterize the GL TS three-strand design by testing it in comparison to the original GL four-strand design.

The literature has suggested that tissues are subjected to forces up to one-fifth of their ultimate loads under normal conditions. Based on this conclusion the ACL and PCL are reported to have a maximum load of 432 N and 320 N, respectively.[10-12] Accordingly, a minimum 450 N ultimate load specification serves as a suitable criteria for both ACL and PCL grafts. All GL TS constructs passed this acceptance criteria with an average yield load of 920.77 ± 154.15 N and average cyclic displacement of 1.24 ± .68 mm, which far exceeded the acceptance criteria of ≥450 N and ≤ 3mm displacement, respectively. These measurements are in agreement with those found in the literature. Kennedy et al. found similar results when measuring the tensile strength and yield point of native cadaveric anterior and posterior cruciate ligaments, reporting an average yield point of 40.2 ± 2.8 kg (~394.2 ± 27.5 N) and 81.3 ± 5.1 kg (~797 ± 50 N), respectively. Another important aspect of graft design is consistency. The standard deviation for both constructs was within a narrow range (±6.9% and ±6.2% respectively), suggesting that both the 3 strand and 4 strand designs provide consistency of graft strength.

Understanding how grafts fail under excessive stress can expose potential design flaws, which was the purpose of the modes of failure tests. The modes of failure for 11 of the 14 GL TS constructs were isolated to the femoral side of the graft, which was expected because it was not supported with secondary fixation. Similarly, Forsythe et al. reported the most common mechanism of PCL graft failure was slippage and displacement from the femoral end. However, due to the yield loads of the GL TS construct being well above the acceptance criteria of ≥450 N, it is believed that this mode of failure would not be seen in vivo due to the weaker TightRope® fixation used in the actual reconstruction. Furthermore, the three constructs with yield loads less than 800 N were the smallest diameter allowed for this design, and these samples showed that even the smallest diameter grafts still passed the acceptance criteria for yield and displacement. All GL constructs shared the same failure mode of terminal end separation, which was expected due to the continuous loop design. The result from the two-sample t-test showed no significant difference in yield load or cyclic displacement between the GL TS and GL construct indicating a strong and biomechanically sound graft design for ACL and PCL reconstruction.

Summary

Both GraftLink and GraftLink TS are strong and consistent constructs appropriate for both ACL and PCL reconstruction, with average yield loads exceeding those of native ligaments. Furthermore, the three-strand GraftLink TS and four-strand GraftLink designs are equivalent in strength and displacement, while also maintaining graft to graft consistency.

References

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