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ORIGINAL ARTICLE

BIOMECHANICAL ANALYSIS OF ROTATOR CUFF REPAIR UTILIZING THE TENDON-TO-BONE SEAM TECHNIQUE

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ABSTRACT

Aim: To report the biomechanical performance of a novel "Tendon-to-Bone Seam" (TBS) rotator cuff repair technique and compare the results to those previously obtained with knotted and knotless transosseous-equivalent (TOE) constructs using similar protocols to assess relative performance.

Materials and methods: Eleven fresh-frozen human cadaveric shoulders underwent creation of full-thickness supraspinatus tears (approximately 2.0–3.0 cm). All specimens were repaired using the TBS technique by one of four fellowship-trained shoulder surgeons, utilizing a mattress-stitch pattern medially and a zig-zag pattern laterally. Repairs were tested using a mechanical test system under cyclic loading from 10–180 N for 30 cycles and 4–302 N for 500 cycles, followed by load-to-failure testing. Gap formation, yield strength, and ultimate strength were measured and compared with prior TOE repair data.

Results: Gap formation for the TBS repair technique was 0.30 ± 0.47 mm after 1 cycle and 0.33 ± 0.55 mm after 30 cycles at 180 N. After 500 cycles at 302 N, gap formation was 0.90 ± 1.03 mm. Yield strength was 600.70 ± 93.60 N with corresponding gap formation of 1.21 ± 1.26 mm. Ultimate strength was 747.80 ± 153.80 N with corresponding gap formation of 1.68 ± 1.45 mm.

Conclusions: Rotator cuff repair utilizing the TBS repair technique demonstrated reduced gap formation and increased fatigue, yield, and ultimate strength as compared to prior biomechanical cadaveric studies evaluating the TOE repair. Moreover, the strength of the TBS repair technique exceeds the maximal force the supraspinatus and infraspinatus rotator cuff muscles can generate.

KEYWORDS

Rotator cuff, biomechanical, trans-osseous, double row, single row, tendon seam

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INTRODUCTION

Rotator cuff tears are very common orthopedic injuries, and the incidence of these tears have continued to increase as the population continues to age[1,2]. Due to the prevalence of rotator cuff tendon tears, rotator cuff repair (RCR) surgery remains one of the most commonly performed orthopedic soft tissue procedures[3,4]. Randomized control trials have demonstrated better functional outcome scores and overall pain reduction after RCR compared with non-operative management[5,6]. Despite advances in both surgical technique and instrumentation, the average failure rate as defined by lack of tendon healing after RCR is approximately 20-40%; with some studies demonstrating failure rates as high as 94%[6-9]. These RCR failures occur most commonly within the first year following surgery and are associated with inferior functional outcomes, increased healthcare costs, and need for further surgery[7]. Previous studies have demonstrated that the direct and indirect annual healthcare costs of failed primary RCR in the United States are estimated to be approximately $440 million; every 5% improvement in primary RCR healing may result in more than $84 million in short-term downstream annual healthcare saving[7].

While systematic reviews have demonstrated that a healed RCR results in statistically improved patient-reported outcomes, motion, and strength compared to non-healed rotator cuffs, the ideal repair construct to achieve a well-healed RCR remains unknown[10]. Single row (SR), double row (DR), and transosseous-equivalent (TOE, aka "suture-bridge") techniques have been described. The TOE repairs offer several biomechanical advantages compared to traditional SR or DR repairs, including increased footprint contact, higher tendon-bone interface pressures, decreased gap formation at the healing enthesis, and increased ultimate strength[11]. As a result, TOE has been widely utilized for rotator cuff repair for close to 20 years, with only slight variations attempting to improve the strength of the repair. However, studies have failed to demonstrate adequate fatigue strength, yield strength, and gap stability with TOE repairs. Moreover, TOE repairs can result in the more challenging type 2 medial rotator cuff failures, which pose increased challenges in the revision setting and often lead to irreparable rotator cuff tears[12,13].

The ideal rotator cuff repair construct would both enable early mobility and reduce the risk of retear by mechanically providing strong multi-point fixation broadly distributed over the rotator cuff footprint, offering greater fatigue and yield strengths than the forces generated by the rotator cuff muscles, and maintain stability until healing is complete[14]. It is hypothesized that biomechanical cadaveric testing of the TBS technique will result in similar or increased fatigue, yield and ultimate strengths, as well as similar or reduced gap formation compared to prior biomechanical cadaveric studies utilizing the TOE repair[15-17].

Value	Result
Age (years)	57.6 ± 17.5, range 29-84
Weight (kg)	62.2 ± 14.8, range 38.1-81.6
Gender	5 females; 6 males
Shoulder	5 left shoulders; 6 right shoulders

Table 1. *Cadaver demographics (11 specimen).*

MATERIALS AND METHODS

Simulated full-thickness rotator cuff tears were created in 11 fresh-frozen human cadaveric specimens and subsequently underwent RCR using the Integrity Orthopaedics Tendon Seam™ Repair System (Maple Plain, MN USA) by one of four experienced orthopedic shoulder surgeons. Shoulder cadaveric demographics are outlined in *Table 1*. The mean age of cadaveric specimens in this study is similar to that of the previous TOE biomechanical study that had a reported mean age of 57 ± 6 years; range, 50-68 years[15].

Biomechanical analysis was performed at TRIA Surgical Skills Lab in Bloomington, MN and the Integrity Orthopaedics' wet lab in Maple Plain, MN. Each biomechanical assessment was performed in close alignment with previous cadaveric biomechanical studies evaluating the TOE repair[15,16].

Rotator cuff repair technique

Full-thickness rotator cuff tears were created by sharply dissecting the entire supraspinatus tendon from the greater tuberosity and surrounding tissue to isolate it for testing. This approach was performed on 11 samples resulting in full-thickness supraspinatus tears measuring approximately 2.0-3.0 cm. The simulated repairs were performed via both open (n = 4) and arthroscopic (n = 7) approaches. All rotator cuff tears were repaired utilizing the TBS technique. The TBS technique is comprised of a medial seam of anchors stitched in a mattress pattern with approximately 5-7 mm spacing between anchors and sutures tensioned independently followed by a lateral seam of anchors stitched in a zig-zag pattern with similar spacing and suture tensioning; repairs averaged 6 medial seam anchors in a mattress stitch pattern with the same average number of anchors in a lateral seam zig-zag pattern *(Fig. 1)*.

Rotator cuff repair device

The Tendon Seam™ Repair System consists of a single-use deployment device and disposable magazines with an array of 4 or 8 cartridges each containing 2 mm diameter, 10 mm long PEEK toggling anchors and locking sutures strung together along a single UHMWPE suture *(Fig. 2 and 3)*. This design enables multiple interconnected yet independent fixation points, allowing tendon to bone attachment without suture passers, knot tying or managing multiple sutures. The 2 mm diameter anchors

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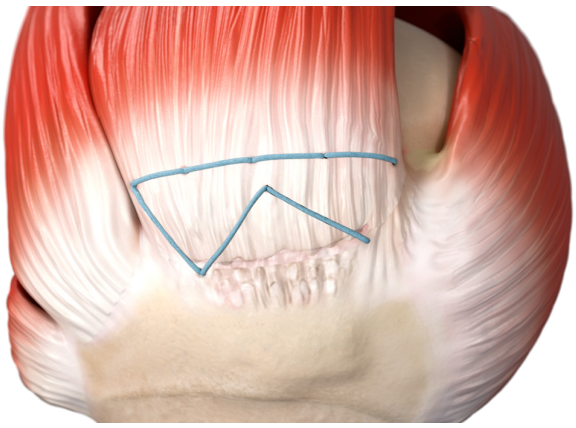


Figure 1. *Tendon-to-Bone Seam (TBS) repair technique.*

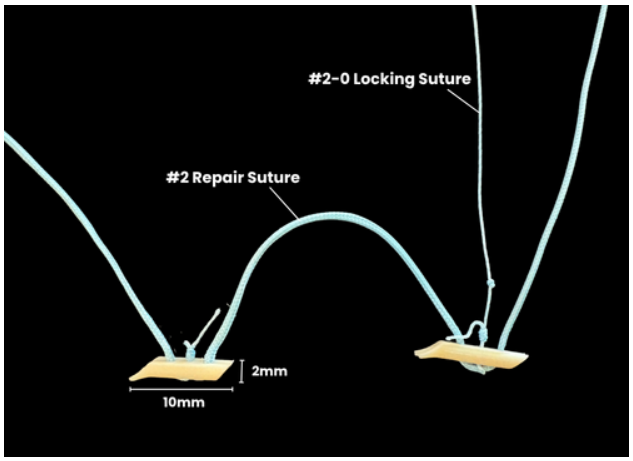


Figure 2. *Representative segment of the Tendon Seam™ implant construct comprised of PEEK toggling anchors strung together along a single #2 Repair Suture. Each stitch (between anchors) is individually tensioned by pulling the Repair Suture. Each anchor is individually locked by pulling the #2-0 Locking Suture, which breaks away after cinching the Repair Suture.*



Figure 3. *Tendon Seam™ deployment device.*

and associated 2.5 mm diameter holes permit tightly spaced, flexible fixation points across the repair footprint. The unoccluded anchor holes provide venting of the intramedullary space allowing bone marrow to access the repair, potentially supporting tendon-to-bone healing.

Biomechanical testing

After the repair was completed, the specimen was dissected to isolate the repair for testing, and the tendon was secured to the tester using a nylon strap, sutures, and vice grips as needed at the muscle tendon junction. The proximal humerus was cut approximately at the mid-shaft. The ends of a nylon strap, approximately 10-12 inches in length, were stitched to the inferior and superior aspects of the tendon using No. 5 suture *(Fig. 4)*. The strap was positioned as distal as possible, parallel to the tendon, to create a loop in the nylon strap which could be used to attach the strap to the mechanical test system (MTS; TestResources, Shakopee, MN, USA). After the strap was attached to the tendon, the humeral shaft was then mounted to a custom fabricated fixture to constrain the humerus and position the repair relative to the MTS. The fixture had two primary sections, an open and V-block style section in which the humeral head and humeral shaft were positioned, respectively. Both sections had adjustable cross-members positioned over them with a bolt location at the center of each cross-member. A combination of pointed and flat tipped bolts were utilized at these bolt locations to prevent both rotation and translation of the humerus during testing after the bolts were torqued down. The fixture was positioned so that the strap connected to the tendon was parallel to the pull vector of the MTS and the fixture was set at 30 degrees of glenohumeral abduction for testing. The proximal humerus was mounted in a custom fabricated fixture which was oriented in 30 degrees of glenohumeral abduction. For all repairs, a MTS equipped with a 113.4 kgf load cell, was used to load each repair cyclically from 10 N to 180 N for 30 cycles to be consistent with prior biomechanical cadaveric studies evaluating the TOE repair[15,16] and again from 4 N to 302 N for 500 cycles. The second cyclic loading condition was added to simulate the maximal force the supraspinatus and infraspinatus rotator cuff muscles can generate, approximately 302 N, and to represent the estimated number of cycles a repair may experience during its healing period[18]. Following the two cyclic loading conditions, each repair underwent tensile testing to measure the yield and ultimate strengths. Gap formation at the repaired tendon edge was measured by comparing the repaired tendon edge position relative to the greater tuberosity prior to testing to its position after completing 1 and 30 cycles at 180 N, 500 cycles at 302 N, at yield load, and at ultimate load. Measurements were made optically utilizing magnified still-frames of the test video and calibrated using reference objects of known dimensions (primarily suture) and scaling accordingly. Measurements were performed by a single reviewer, and test articles were not blinded as only the TBS construct was tested in this study.

Statistics

A two-sample t test was used to compare the biomechanical properties of the TBS system repairs to the TOE repairs. The data from each cycle of interest were compared statistically between repairs. The two sample t-test was chosen due to matched-pair specimens not being used and there is complete independence between

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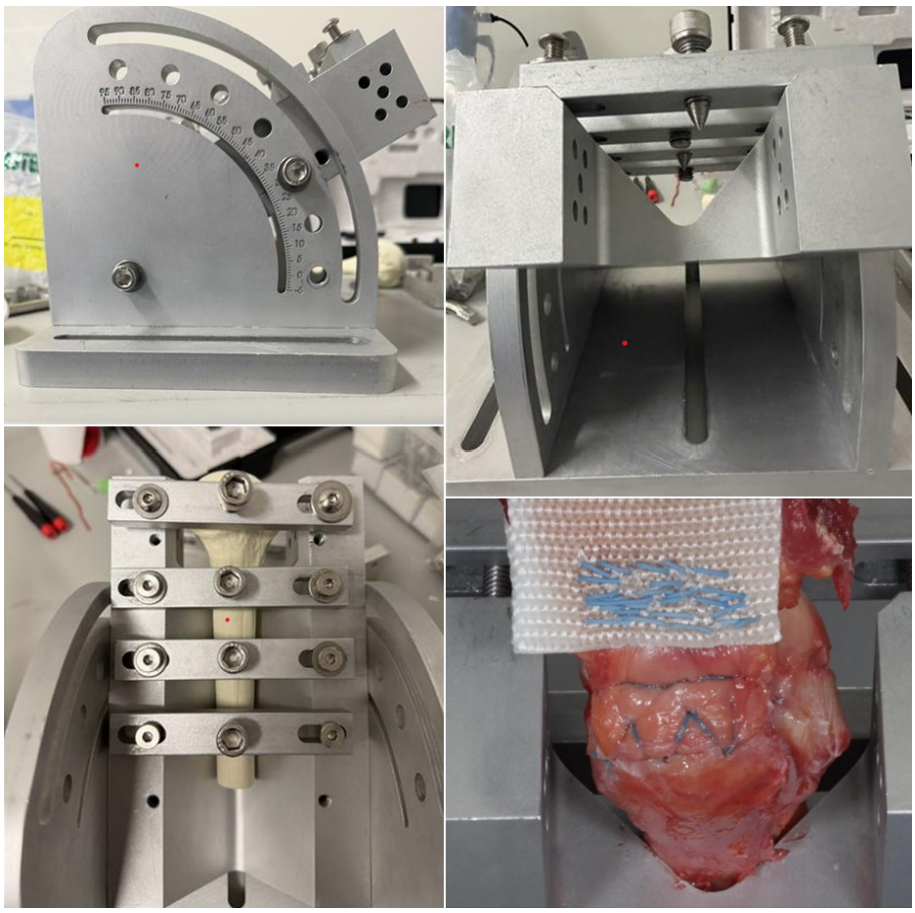


Figure 4. *Custom fabricated humeral fixture.*

	Gap at 180 N, 1st cycle (mm)	Gap at 180 N, 30th cycle (mm)	Gap at 302 N, 500 cycles (mm)	Gap at yield (mm)	Gap at ultimate (mm)	Yield strength (N)	Ultimate strength (N)
Knotted TOE[15]	2.38 ± 0.84	3.74 ± 1.51	DNS	6.11 ± 1.97	9.62 ± 3.74	260.3 ± 69.5	443.0 ± 87.8
Knotless TOE[16]	5.05 ± 1.93	8.10 ± 3.76	DNS	9.91 ± 3.34	13.94 ± 6.89	183.0 ± 41.0	254.0 ± 61.0
Tendon-to-Bone Seam	0.30 ± 0.47	0.33 ± 0.55	0.90 ± 1.03	1.21 ± 1.26	1.68 ± 1.45	600.7 ± 93.6	747.8 ± 153.8

Table 2. *Biomechanical cadaveric study test results of various rotator cuff repair constructs. Abbreviations: DNS, did not study.*

the TBS specimens and the ones studied by Park et al.[15,16]. The level of statistical significance was set at $p < 0.05$. Thus, data for gap formation, yield strength, and ultimate strength are reported as averages and standard deviations, consistent with prior biomechanical cadaveric studies evaluating the TOE repair[15,16].

RESULTS

All 11 specimens were used for all measurements. Total gap formation for the TBS repair technique after 1 cyclic load at 180 N had a mean value of 0.30 ± 0.47 mm. Total gap formation after 30 cyclic loads at 180 N was significantly less with TBS repairs vs those previously reported with Knotted TOE and Knotless TOE repairs[15,16], with mean values of 0.33 ± 0.55 mm, 3.74 ± 1.51 mm, and 8.10 ± 3.76 mm, respectively ($p = 0.003$, $p = 0.004$). Each TBS repair remained intact after an additional 500 cyclic loads at 302 N. Additionally, the total gap formation after the additional 500 cyclic loads at 302 N of the TBS repair remained significantly less with mean values of 0.90 ± 1.03 mm *(Table 2)*. The yield load was significantly greater for the TBS repairs vs Knotted TOE and Knotless TOE repairs, with mean values of 600.70 ± 93.60 N, 260.30 ± 69.50 N, and 183.00 ± 41.00 N, respectively ($p = 0.00$, $p = 0.00$). The total gap formation at yield continued to remain significantly less for TBS repairs vs Knotted TOE and Knotless TOE repairs despite yielding at significantly higher loads, with mean values of 1.21 ± 1.26 mm, 6.11 ± 1.97 mm, and 9.91 ± 3.34 mm, respectively ($p = 0.001$, $p = 0.002$). The ULTF was significantly greater for the TBS repairs vs Knotted TOE and Knotless TOE repairs, with mean values of 747.80 ± 153.80 N,443.00 ± 87.80 N, and 254.00 ± 61.00 N, respectively ($p = 0.00$, $p = 0.00$). The total gap formation at ULTF continued to remain

significantly less for TBS repairs vs Knotted TOE and Knotless TOE repairs despite failing at significantly higher loads, with mean values of 1.68 ± 1.45 mm, 9.62 ± 3.74 mm, and 13.94 ± 6.89 mm respectively ($p = 0.004$, $p = 0.008$).

The failure location of each TBS repair tested was recorded. In seven samples, failure occurred at the repair-bone interface. In three samples, failure occurred at the tendon with suture pull-through. In one repair, failure occurred both at the tendon with suture pull-through as well as medial to the medial row. In this repair, prior to loading the specimen it was noted there was a notch defect present in the area that failed; the notch defect was created during dissection of the tendon for testing, and it started to fail concurrently with the tendon failure at the footprint. Therefore, type 1 failures occurred in 11/11 (100%) and type 2 failures occurred in 1/11 (9%) of specimens[13,19]. In all cases, the anchor and suture components of the construct remained intact without any disconnection of the anchor from the suture or fractures of the anchor.

DISCUSSION

The results of this biomechanical cadaveric study demonstrate less total gap formation as well as superior fatigue, yield and ultimate strength utilizing the TBS repair compared to prior biomechanical cadaveric studies evaluating the TOE repair[15,16]. A comparison of the results of this study to these prior TOE studies is shown in *Table 2*.

The improved time-zero biomechanics of the Tendon-to-Bone Seam construct may afford earlier postoperative mobilization than current repair techniques for two key reasons. First, the fatigue and yield strength of the TBS construct significantly exceed the maximal force the supraspinatus and infraspinatus rotator cuff muscles can generate. Second, gap formation under load for the TBS construct is decreased relative to current repair techniques which may contribute to improved tendon-to-bone healing.

Rotator cuff repair techniques have continued to evolve over the years. First, numerous biomechanical studies have demonstrated improved contact area and tensile strength, decreased gap formation, increased ultimate strength, and superior time-zero structural properties with DR repairs compared with SR repairs[15,20-22]. However, meta-analyses have failed to demonstrate significant improvement in clinical outcomes with DR repair[23-26]. Next, TOE repairs gained popularity. Potential advantages of the TOE repair include decreased tendon strangulation with preserved vascularity, increased contact area pressure, load sharing and more uniformed stiffness, tension reduction on each individual anchor, and avoidance of synovial fluid under the repair[11,27,28]. Despite less gap formation, higher ultimate strength, and reduced synovial fluid leakage with knotted TOE repairs[16], knotless TOE repairs then gained in popularity after some studies have demonstrated an increased myotendinous junction failure (type 2) with knotted TOE repairs[19,29,30]; some cadaveric studies have demonstrated increased gap formation as well as reduced yield and ultimate strength with knotless TOE repairs[16,31]. Despite the biomechanical advantages of the TOE repair over DR repair, several studies have failed to demonstrate clinical significance[32-34]. The TBS technique does not utilize any knot tying and thus is likely to reduce the risk of tendon strangulation, microcirculatory compromise and surgeon variability in knot security. Additionally, the construct was designed to flex with the native tendon to allow for micromotion beneath the compression which may have a favorable circulatory profile. The TBS repair technique offers the advantages of the TOE repair along with improved repair stability, decreased gap formation and greater fatigue, yield, and ultimate strength.

Failure of an RCR has economic, psychological, and physical burdens to the patient and the healthcare system. The type of rotator cuff failure plays an important role in the salvageability of the rotator cuff tendon and may preclude revision repair. Cho et al.[19] previously reported on retear patterns following RCR; type 1 failures occur at the tendon-bone interface while type 2 tears occur medial to the repair. Type 2 failures, especially those that occur at the myotendinous junction, are often more challenging and may prevent revision repair due to an inadequate amount of remaining tendon attached to the rotator cuff musculature to adequately fixate to the footprint or allow for intra-tendonous repair. A systematic review demonstrated type 2 failures in as many as 62% of failed TOE repairs[12], and the authors of this review concluded that DR and TOE RCRs significantly increase the risk of medial rotator cuff failure. While knotless TOE repairs are easier to perform and may reduce the risk of type 2 failures, they have been shown to have inferior biomechanical strength and excessive gap formation in cyclic loading[16,17]. Conversely, when loading the TBS RCR to failure in this biomechanical study, the failure mode was almost exclusively type 1, while simultaneously providing superior biomechanical performance.

Lastly, the TBS anchors offer the bone-preserving advantage of the increasingly popularized all-suture anchors, while additionally leaving behind unoccluded holes that allow free access to bone marrow elements encouraging maximum tendon-to-bone healing[35].

This study has several limitations. First, all rotator cuff tears in this study were artificially created which may not adequately replicate naturally occurring tendon tears. Secondly, this study has similar inherent limitations as those presented in the biomechanical cadaveric studies evaluating TOE repairs[15,16], as this study was similarly designed. Moreover, a small-sample size was used for this study and a power-analysis was not performed for this cadaveric study. Additionally, this manuscript is not a direct comparison of TOE and TBS repair techniques. Comparison of the TBS data in this study was compared against the reported outcomes in prior biomechanical cadaveric studies and lends itself to discrepancy between

the inherent differences in approach and testing. The authors also acknowledge that cyclic loading and load-to-failure protocols nominally identical across laboratories may yield systematically different results due to differences in fixture geometry, gripping technique and tendon hydration. Lastly, the TBS and TOE RCRs were performed independently by different teams at different times with unmatched specimen pairs. Bone and tendon quality as well as tendon characteristics likely varied among the studies; however, these variables are inherent to cadaveric studies in general and may more accurately reflect a generalized population.

CONCLUSION

Rotator cuff repair utilizing the TBS repair technique demonstrates less total gap formation as well as greater fatigue, yield and ultimate strength compared to prior biomechanical cadaveric studies utilizing the TOE repair. Moreover, the TBS repair technique has fatigue and yield strengths which exceed the maximal force the supraspinatus and infraspinatus rotator cuff muscles can generate.

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