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Synthetic coracoclavicular ligament vs. coracoclavicular suspensory construct for treatment of acromioclavicular dislocation: a biomechanical study

Mario H. Lobao, MD, R. Bruce Canham, MD, Roshan T. Melvani, MD, Brent G. Parks, MSc, Anand M. Murthi, MD*

Department of Orthopaedic Surgery, MedStar Union Memorial Hospital, Baltimore, MD, USA

Background: A synthetic ligament (LockDown, Worcestershire, England) has become available to treat complete acromioclavicular dislocation with promising clinical results and potential benefit to avoid postoperative loss of reduction. We investigated the biomechanics of this synthetic ligament in a simulated immediate postoperative rehabilitation setting, hypothesizing that the synthetic ligament would demonstrate less superior coracoclavicular displacement to cyclic loading and higher ultimate load-to-failure values than a coracoclavicular suspensory construct.

Methods: Seven matched-pair cadaveric shoulders (mean age at time of death, 79 years) were loaded cyclically and to failure. One specimen in each pair was randomly assigned to the synthetic ligament or coracoclavicular suspensory construct. Superiorly directed 70-N cyclic loading for 3000 cycles at 1.0 Hz was applied through the clavicle in a fixed scapula simulating physiologic states during immediate postoperative rehabilitation, followed by a load-to-failure test at 120 mm/min.

Results: After 3000 cycles, the superior displacement of the clavicle in the synthetic ligament (9.2 ± 1.1 mm) was 225% greater than in the coracoclavicular suspensory construct (2.8 ± 0.4 mm, 95% confidence interval [CI] 3.4, 8.3; $P < .001$). Average stiffness of the synthetic ligament (32.8 N/mm) was 60% lower than that of the coracoclavicular suspensory construct (81.9 N/mm, 95% CI 43.3, 54.9; $P < .001$). Ultimate load-to-failure of the synthetic ligament was 23% (95% CI 37.9, 301.5; $P = .016$) lower than the coracoclavicular suspensory construct (580.5 ± 85.1 N and 750.2 ± 135.5 N, respectively).

Conclusion: In a simulated immediate postoperative cadaveric model, the synthetic ligament demonstrated poorer biomechanics than the coracoclavicular suspensory construct. These findings suggest that a coracoclavicular suspensory construct may be preferable to a synthetic ligament if early rehabilitation is intended.

Level of evidence: Basic Science Study; Biomechanics

Keywords: Acromioclavicular joint; instability; dislocation; synthetic ligament; LockDown; coracoclavicular ligaments; acromioclavicular reconstruction

Institutional Review Board approval was not required for this basic science study.

*Reprint requests: Anand M. Murthi, MD, c/o Lyn Jones, MA, ELS, Editor, Department of Orthopaedic Surgery, MedStar Union Memorial Hospital, 3333 North Calvert Street, Suite 400, Baltimore, MD 21218, USA.

E-mail address: lyn.m.jones@medstar.net (A.M. Murthi).

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Acromioclavicular (AC) injuries are frequent among young contact-sports athletes.[17] Most lesions are sprains treated conservatively, although symptomatic high-grade disruptions may require operative management if nonoperative measures fail.[1,17] A multitude of surgical techniques have been described to reduce and stabilize symptomatic AC joint separations.[1,17] Loss of reduction reported after most AC joint surgeries[5,9,30,32,34] challenges surgeons to pursue stronger materials, new grafts, and synthetic substitutes.

Loss of reduction is still the most common complication of AC joint stabilization surgery[3] regardless of the recent focus on augmentation of the coracoclavicular (CC) ligaments with tendon grafts,[13,23] suspensory constructs,[7,40,41] and synthetic ligaments.[13,29,34] Reoperation due to failure of reduction of both biologic (7%) and nonbiologic (8.2%) CC reconstructions is above the 5.3% rate reported for the modified Weaver-Dunn technique.[3] Long-term radiographic studies have shown even higher rates of partial loss of reduction (displacement) ranging from 30% to 53%,[8,9,11,16,19,21] and they recommend mild over-reduction at the time of surgery to achieve anatomic reduction afterward.[18,31,39] The best evidence available slightly favors biologic CC reconstruction over synthetic devices based on functional outcome scores[13] and a hook plate to maintain postoperative CC distance.[47] However, anatomic reconstructions with tendon grafts have been shown to have the highest incidence of clavicle fracture among AC surgeries,[17] and hook plates commonly present osteolysis requiring removal of hardware.[34]

A new synthetic ligament (LockDown, Worcestershire, England)[42] has become available to treat high-grade (Rockwood grade III and V) AC dislocations with good biological response[24] and promising early clinical results in Europe.[2,4,20,26,45,46] The device is a 3-dimensional double-braided polyethylene-terephthalate mesh uniquely designed to wrap around the coracoid and clavicle, minimizing the use of bone tunnels. Potential benefits are high tensile strength to allow early rehabilitation, pretensioned fibers to avoid postoperative loosening and loss of reduction, no donor-site morbidity, construction designed to minimize bone tunnel–related fractures, and ability to act as scaffold for a fibrous pseudo-ligament connecting the coracoid to the distal clavicle,[44] providing long-term stability. However, no comparative biomechanical data have yet been reported.

We investigated the immediate postoperative biomechanics of this synthetic ligament comparing it to a coracoclavicular suspensory construct (CCSC) with similar features: CC construct only (not both AC and CC), minimum bone tunnels, no donor-site morbidity, and strength and stiffness similar to those of native CC ligaments. We hypothesized that the synthetic ligament would demonstrate less superior CC displacement to cyclic loading and higher ultimate load to failure than a CCSC at a simulated postoperative time-zero early rehabilitation.

Materials and methods

Specimen preparation

Eight fresh-frozen matched-pair cadaveric shoulders were thawed and screened for signs of previous surgeries and musculoskeletal deformities. One pair was excluded because of presence of an unstable os acromiale on one side. Specimens in the remaining 7 matched pairs (4 male and 3 female with age 55-95 years at the time of death; mean ± standard deviation 79 ± 5.2 years) were randomized to receive either the synthetic ligament (3 right and 4 left shoulders) or a CCSC (4 right and 3 left shoulders).

Each shoulder was disarticulated at the glenohumeral joint and dissected of all soft tissue, with the AC and CC ligaments being left intact. The proximal two-thirds of the clavicle was fixed to a PVC pipe with 2 orthogonally placed 1.6-mm Kirschner wires and then embedded with polyester resin (Bondo; 3M, Maplewood, MN, USA). The scapula was also potted with resin in a custom block from the inferior angle to the edge of the glenoid.

A single fellowship-trained surgeon performed all surgical procedures. Each construction reproduced the exact CC distance measured at the intact shoulder. Visual anatomic reduction of the AC joint was ensured on all specimens before biomechanical testing. We did not resect the distal clavicle.

Surgical constructions

Synthetic ligament technique

The surgical technique followed the steps previously described.[20,45] Before the synthetic ligament was installed, the CC ligament remnants were meticulously removed from the coracoid and clavicle to avoid interposition. The synthetic ligament was looped underneath the coracoid from medial to lateral and threaded through its soft loop to secure attachment at the base of coracoid process.[20,45] The free end was then passed from inferior to superior, wrapped around the clavicle from posterior to anterior, and tensioned. We meticulously placed the LockDown at the exact level of the native conoid ligament based on a previous study demonstrating that anatomic reduction and stability of the AC joint depend on positioning the synthetic ligament at the level of the conoid tubercle.[5] The hard loop was then fixed to the anterior surface of the clavicle with a 3.5-mm bicortical screw and accompanying washer through a 2.5-mm drill role (Fig. 1). The drill hole was carefully positioned in a slightly medial oblique trajectory to ensure that the tip of the screw did not contact the ligament posteriorly (Fig. 2).

Coracoclavicular suspensory construct

We chose a CCSC with features similar to those of the synthetic ligament analyzed: CC construct only (not both AC and CC), minimum bone tunnels, no donor-site morbidity, and strength and stiffness similar to those of native CC ligaments.[35] Coracoacromial ligament transfers, combined AC-CC reconstruction techniques, CC screw fixation, and hook plates did not meet these criteria. A CCSC technique using two 2-mm ultrahigh-strength long-chain polyethylene tapes (FiberTape; Arthrex, Naples, FL, USA) cerclage sutured to the distal clavicle matched these characteristics. This technique has shown equivalent strength and

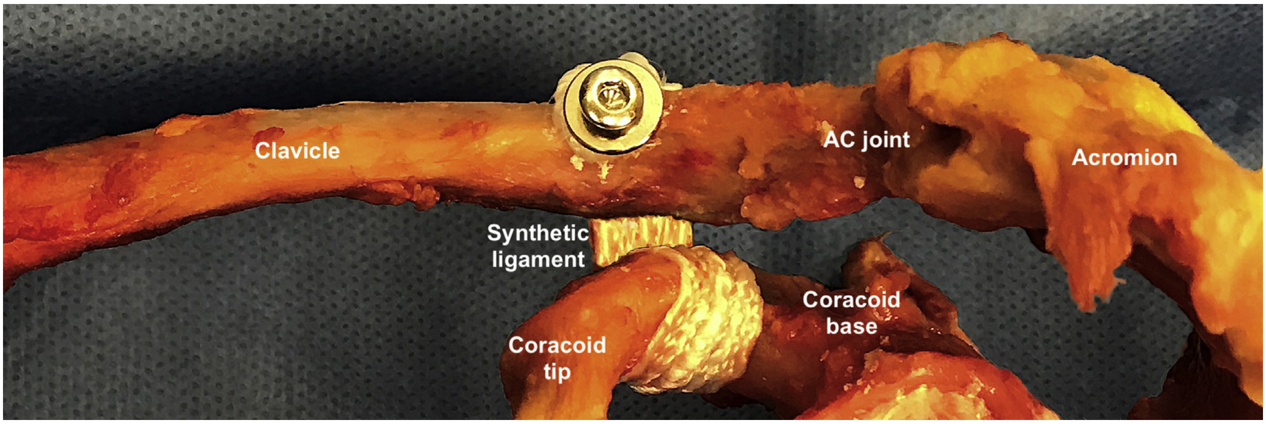

Figure 1 Anterior view of the synthetic ligament device looping underneath the coracoid and fixed to the anterior aspect of the clavicle with a 3.5-mm screw. *AC*, acromioclavicular.

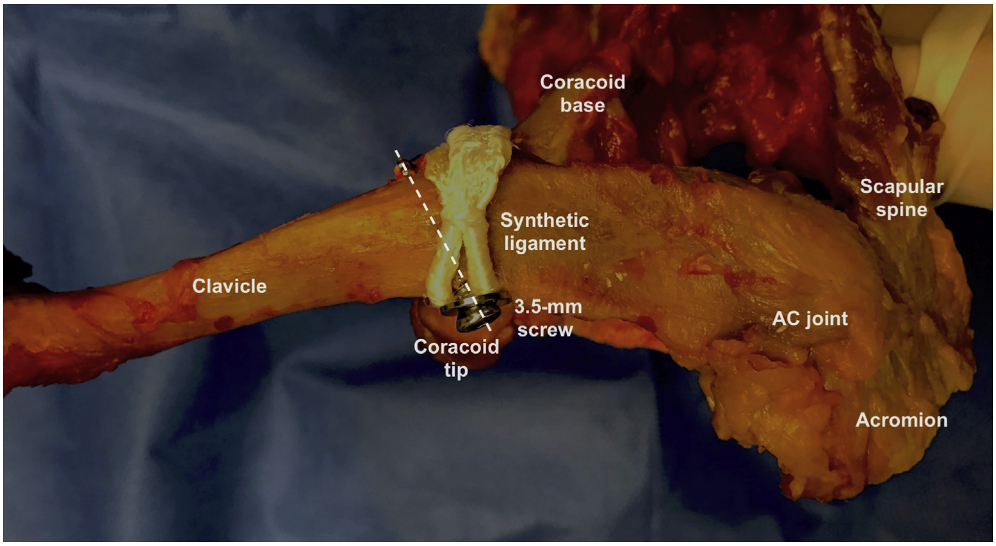

Figure 2 Superior view of the synthetic ligament wrapping around the posterior-superior aspect of the clavicle. The dashed line indicates the obliquity of the screw positioned to avoid impingement of the mesh. *AC*, acromioclavicular.

rigidity to native CC ligaments,[27] low rate of clavicle fracture,[17] and equivalent AC stabilization compared with other techniques.[27,48] Moreover, recent meta-analyses of clinical studies have disclosed synthetic ligaments and CCSC to have the lowest rates of complications among AC surgeries.[17,34]

The surgical technique was as previously described.[12] Both tapes were initially looped underneath the coracoid. Two 2.4-mm tunnels were drilled in the anatomic insertion area of the trapezoid and conoid ligaments (25 and 45 mm medial to the lateral edge of the clavicle, respectively, on the center of the anterior-posterior clavicle width) (Fig. 3).[1,5,36] One tape was passed through the clavicular tunnels and tied with standard knots, and the second tape was wrapped around the distal clavicle and stabilized with a racking hitch knot, creating a double CC cerclage. No metallic buttons were used to avoid altering the stiffness of the construct. Finally, tapes were tied to restore the same CC distance measured in the intact specimen and to achieve visual anatomic reduction of the AC joint (Fig. 4).

Mechanical testing protocol

Before testing, each shoulder was thawed overnight and kept at room temperature (24°C). Specimens were tested using a servo-hydraulic system that included an MTS load cell of 5000 N capacity with a resolution of 0.1% of full-scale reading (MTS 858 Bionix II; MTS Systems Corporation, Eden Prairie, MN, USA) in a 2-step process for each construction: cyclic sawtooth wave-form superiorly directed load to a maximum force of 70 N for 3000 cycles at 1 Hz applied through the distal clavicle in a fixed scapula,[15] followed by a load-to-failure superior tensile test at 120 mm/min.[30,33]

The potted clavicle was attached to the load cell so that the scapular body was vertically in line with the actuator. Initially the scapula was allowed to float on the MTS base frame to ensure rotation-free vertical alignment of the load direction. Both clavicle and scapula were then rigidly fixed to the actuator and the base of the MTS frame, respectively. A 10-N load was applied to all

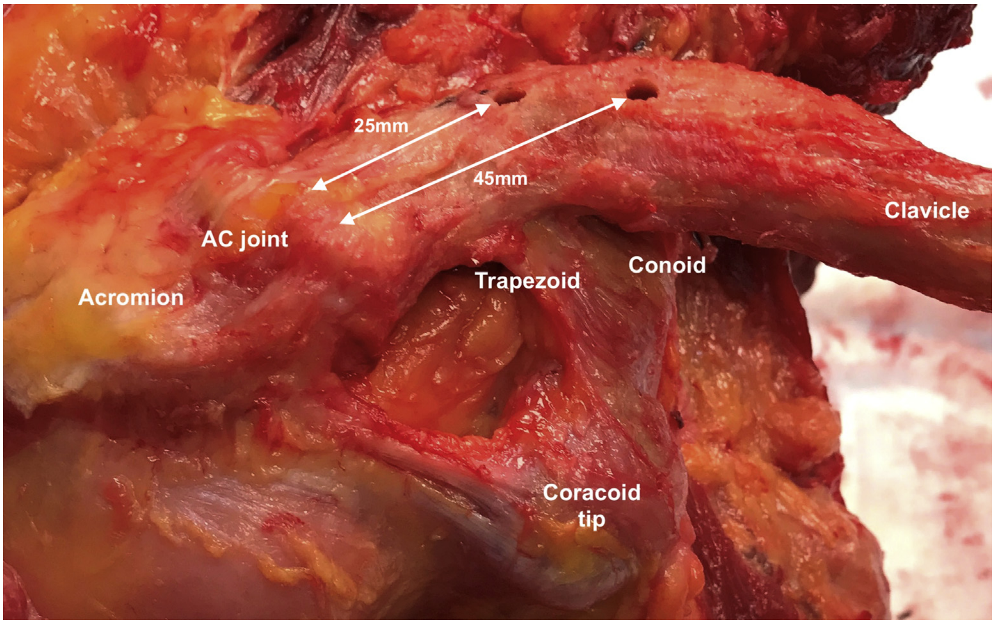

Figure 3 Anterior oblique view of the distal clavicle showing the bone tunnels positioned in the anatomic insertion of the coracoclavicular ligaments (conoid and trapezoid). *AC*, acromioclavicular.

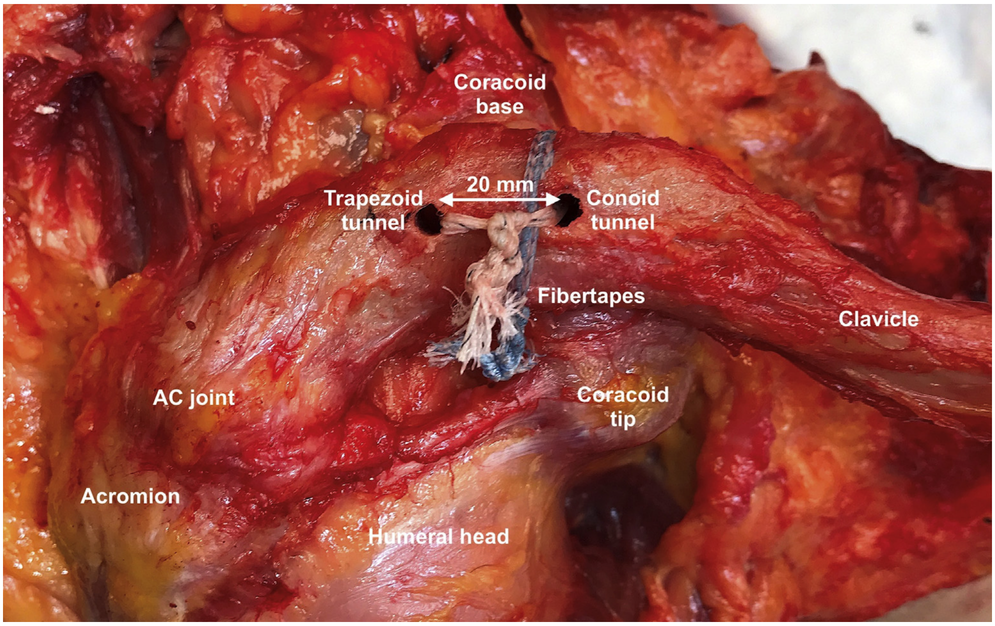

Figure 4 Superior view of the anatomic AC joint reconstruction with FiberTape showing the 2 anatomic tunnels drilled in the clavicle and the 20-mm bone bridge between the holes. *AC*, acromioclavicular.

specimens before the start of the cyclic loading to remove any slack in the system so that the maximum cyclic load of 70 N would not result in any additional slippage or backlash as bones were rigidly attached to the frame.[33] The load cell was then zeroed in the position that corresponded to the intact CC distance of each specimen. Specimens were kept moist with 0.9% saline throughout testing.

Our cyclic loading protocol followed the methodology described by Mazzocca et al.[33] The average load exerted on the CC ligaments attributed to the weight of the arm ranged from 46.7-71.9 N.[25] Loading of 3000 cycles to 70 N in the superior direction corresponded to estimated work going through the distal clavicle in an early passive- to active-motion rehabilitation protocol for 6 weeks postoperatively, a period in which CC stability relies solely on synthetic components of the constructs.[33,37,48]

Although settling has been reported in similar biomechanical studies,[27,28,33] we opted not to precondition specimens before testing because it was our intention to evaluate both constructs in a

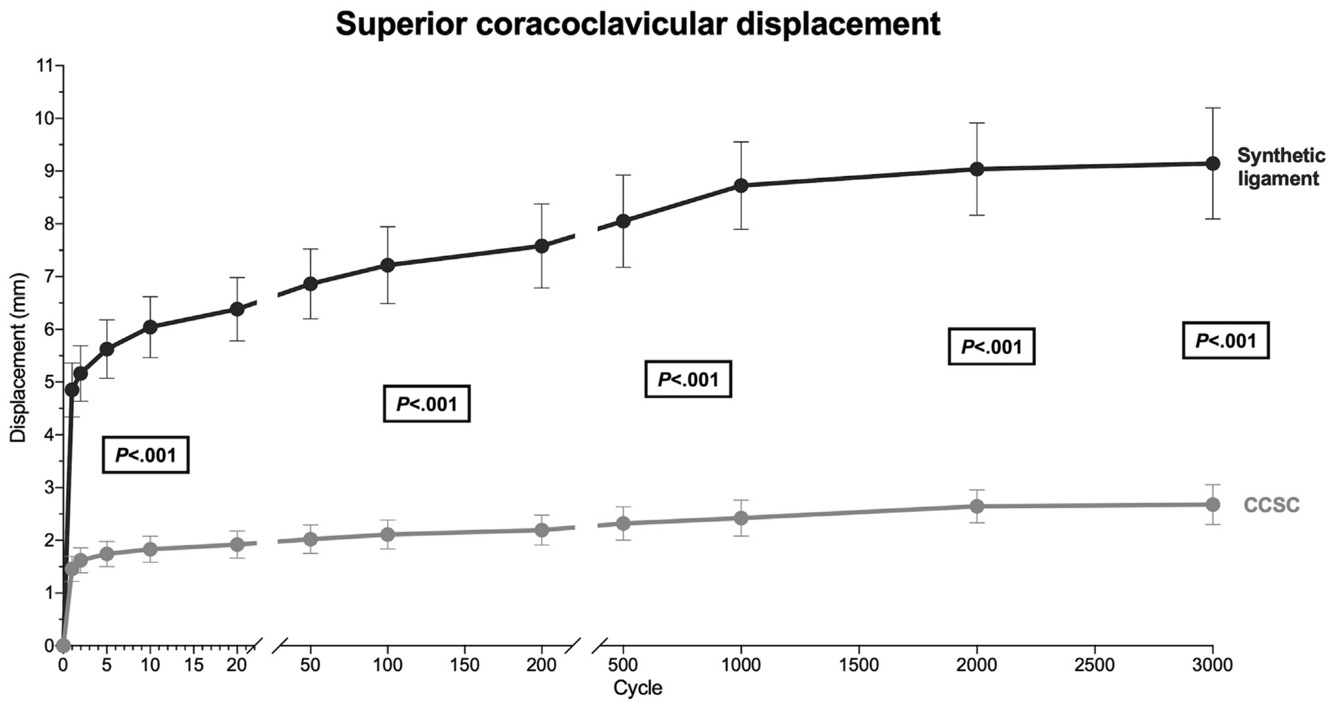

Figure 5 Superior coracoclavicular displacement in cyclic loading. Curves for both synthetic ligament and CCSC are parabolic, indicating that most of the displacement happened on the preconditioning phase (first 20 cycles). *CCSC*, coracoclavicular suspensory construct.

simulated immediate postoperative setting, and preconditioning is not done in vivo. Moreover, the LockDown synthetic ligament claimed to have pretensioned fibers in its mesh, which would have the potential benefit of minimal creeping phenomenon, and we intended to test this feature.

Measurements

Net superior CC displacement values of both constructs were measured at every cycle with precision of 0.1 mm.[33] Stiffness was calculated on each cycle from the slope of the linear portion of the load-displacement curve between 25 and 60 N ($R^2 >$ 0.99).[30] All load-displacement curves presented a toe region below 20 N and achieved linearity between 25 and 60 N, followed by a shoulder above 65 N. The overall stiffness of each construct was calculated by averaging all 3000 cycles. Cycles 1, 2, 5, 10, 20, 50, 100, 200, 500, 1000, 2000, and 3000 were represented on the graph.

To assess load to failure, the servohydraulic system was set to monotonically load each specimen and stop when a drop in force of 50% from the maximum applied force was reached.[30] The peak force measured for each specimen was reported as the ultimate load to failure. The mode of failure of each construct was visually analyzed and reported.

Statistical analysis

All data were tested for normality using the Shapiro-Wilk test and for equal variance using the Brown-Forsyth test (SigmaStat 4.0; Systat, San Jose, CA, USA). If data were normally distributed and equal in variance, superior CC displacement in each cycle and the ultimate load-to-failure values were compared between the 2 construct groups using *t* tests. Displacement values within each group were compared using 1-way repeated measures analysis of variance, followed by a Tukey post hoc test. Welch *t* test was used to compare stiffness in the 2 construct groups if variance was unequal. Data are shown as mean ± standard error of the mean with 95% confidence interval (CI). *P* values <.05 were considered significant.

Power analysis was based on our pilot study comparing superior displacement of the synthetic ligament vs. the CCSC in the second loading cycle. The power analysis determined that 7 specimens would provide 80% power to detect a statistically significant difference at a *P* level of .05. The effect size for this comparison was 3.4.

Results

The first cycle revealed a mean superior CC displacement in the synthetic ligament group (4.8 ± 1.3 mm) 233% higher than in the CCSC (1.4 ± 0.6 mm, 95% CI 2.2, 4.6; $P < .001$). Both groups reached 53% of the overall cyclic displacement test in the first cycle. On the second cycle, the synthetic ligament (5.2 ± 0.5 mm) also presented 218% higher superior displacement than the CCSC (1.6 ± 0.2 mm, 95% CI 2.3, 4.8; $P < .001$). Displacement was consistently greater in the synthetic ligament at every subsequent cycle analyzed (*P* <.001 for all comparisons; Fig. 5). After 20 cycles, the synthetic ligament (6.4 ± 0.6 mm) showed 232% higher displacement than in the CCSC (1.9 ± 0.3 mm, 95% CI 3.0, 5.9; $P < .001$). By the 20th cycle, 70% of the overall

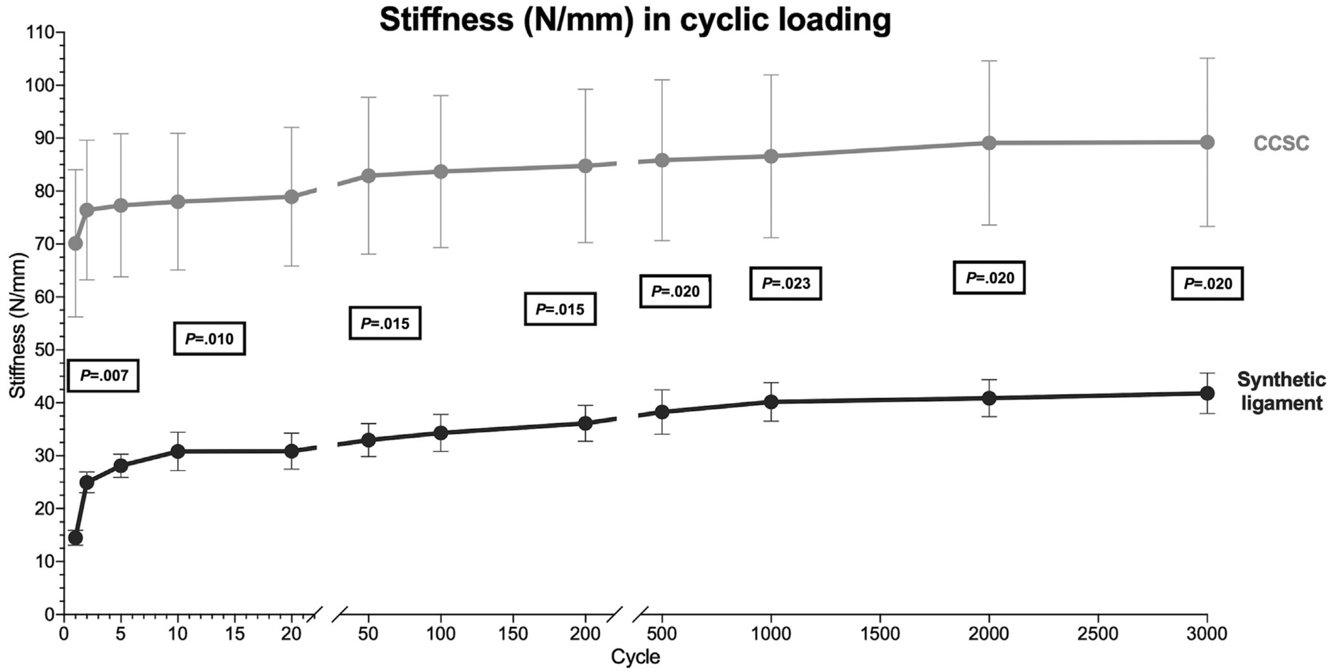

Figure 6 Stiffness in cyclic loading. Both synthetic ligament and CCSC curves reach a plateau after 10 cycles. *CCSC*, coracoclavicular suspensory construct.

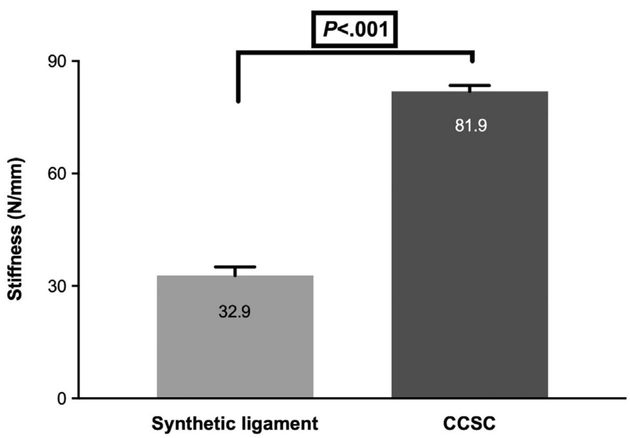

Figure 7 Average stiffness of both constructs throughout the cyclic loading test. Values represent the mean stiffness measured throughout the cyclic loading test. *CCSC*, coracoclavicular suspensory construct

displacement of the test was obtained in both groups. At the end of 3000 cycles, the superior displacement of the synthetic ligament (9.2 ± 1.1 mm) was still 225% greater than in the CCSC group (2.8 ± 0.4 mm, 95% CI 3.4, 8.3; $P < .001$).

Stiffness of the synthetic ligament was significantly lower than that of the CCSC group on every cycle analyzed (Fig. 6). The overall stiffness averaged throughout the test for the synthetic ligament (32.8 ± 2.3 N/mm) was 59% lower than that of the CCSC (81.9 ± 1.6 N/mm, 95% CI 42.0, 53.6; $P < .001$) (Fig. 7).

The maximum load-to-failure of the synthetic ligament (580.5 ± 32.2 N) was 23% lower than that of the CC suspensory construct (750.2 ± 51.2 N, 95% CI 37.9, 301.5; $P = .016$) (Fig. 8).

Six specimens in the CCSC group failed by coracoid base fractures and 1 failed by clavicle fracture in the level of the tunnels. In the synthetic ligament group, there were 2 coracoid base fractures, 3 spiral clavicle fractures extending from screw to the pot, 1 screw pullout, and 1 transverse scapular body fracture (Fig. 8). The scapula fracture demonstrated the highest load-to-failure value (730.9 N) in the synthetic ligament group.

Discussion

The most important finding of this study was that the CCSC outperformed the synthetic ligament in all parameters analyzed, refuting our hypothesis. The synthetic ligament demonstrated more than 3 times higher vertical CC displacement than CCSC on every cycle analyzed. Overall stiffness and ultimate load to failure of the synthetic ligament were, respectively, 59% and 23% lower than those of the CCSC. The current time zero data suggest that the synthetic ligament may not prevent loosening and loss of AC and CC joint reduction in an early rehabilitation protocol.

These findings support the mixed findings in the limited literature on clinical use of synthetic ligaments. Failure due to graft rupture, loosening, and exacerbated immunologic reaction to debris formation was observed in early synthetic

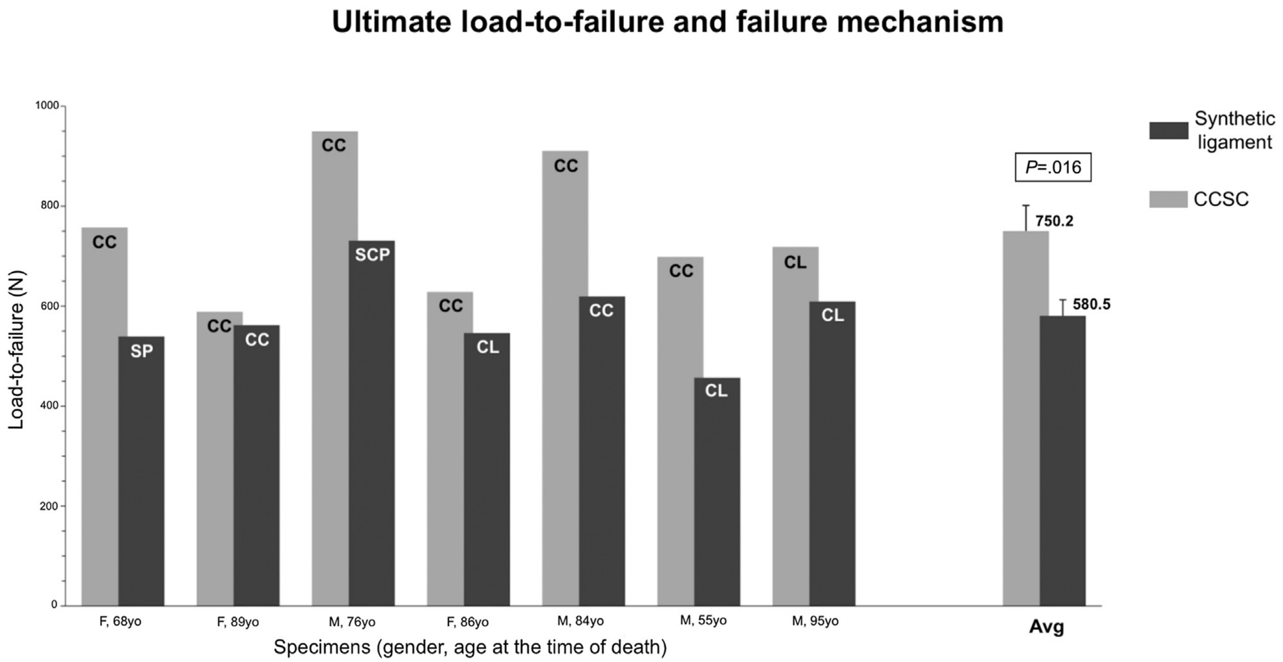

Figure 8 Ultimate load-to-failure and failure mechanism. The bars represent each individual specimen load-to-failure values for both groups (synthetic ligament and CCSC) and the letters indicate the failure mechanism. The 2 bars on the right show the average load-to-failure values of each construct. *CC*, coracoid fracture; *SP*, screw pullout; *F*, female; *yo*, year-old; *SCP*, scapula fracture; *M*, male; *CL*, clavicle fracture; *Avg*, average; *CCSC*, coracoclavicular suspensory construct.

ligaments made of silk and other materials (Dupont, Gore-Tex, Dacron, and 3M Kennedy).[6] Modern manufacturers have used polyethylene-terephthalate fibers in 3-dimensional weaving constructions (LockDown/Surgilig,[4,20,26,45,46] LARS LAC,[13,29] SEM LAC,[22] Ligastic,[47] Neoligaments[43]) to resist traction, torsion, and abrasion and to achieve porosity for fibroblast ingrowth.[24] The pretensioned fibers should allow early postoperative rehabilitation without loosening and loss of reduction. Most clinical studies have not objectively assessed residual AC and CC subluxation of synthetic ligaments, and postoperative immobilization and rehabilitation protocols have varied.[13,14,22,26,45,46] One clinical study reported one-third of patients with superior migration of the distal clavicle, with a 6.3-mm average increase in CC distance.[4] Another study showed mild to moderate AC subluxation in all patients despite an average superior migration of 7 mm and good clinical outcomes.[20] Uncontrolled clinical studies[4,20,22,29,43,45,46] and 2 comparative studies[14,26] have shown early and midterm improvement in functional scores using synthetic ligaments for treating AC dislocations in Europe. However, one randomized clinical trial demonstrated superior clinical and radiographic outcomes in semitendinous allograft CC reconstruction compared with a synthetic ligament for chronic AC dislocation,[13] and another showed superiority of a hook plate in maintaining postoperative CC distance.[47] Complications of synthetic ligaments include distal clavicle osteolysis,[38] residual pain,[4] coracoid fracture,[20] calcification of CC ligament remnants,[20] skin irritation due to the clavicular screw,[4] and scapulothoracic bursitis.[46]

A biomechanical analysis of positioning the synthetic ligament concluded that correct placement of the ligament at the level of the conoid tubercle is crucial to anatomic AC joint reduction and stability.[42] No clinical studies have detailed ligament positioning, but device misplacement may have been a cause of postoperative AC joint subluxation in those studies. In line with clinical data,[20] our study found significant distal clavicle superior migration after cyclic testing despite meticulous positioning of the synthetic ligament. The increase in CC distance after 3000 cycles and the large percentage of overall displacement in the first 20 cycles (preconditioning phase) suggest that the synthetic ligament would not hold AC joint reduction in an immediate postoperative rehabilitation protocol. Possible causes of subluxation in our study were elongation of the mesh or the unwrapping effect a loaded synthetic ligament applies to the distal clavicle. Based on the current data, longer immobilization or postponing rehabilitation until the connective tissue ingrowth into the synthetic ligament matures may prevent residual subluxation of the AC joint.

The reported strength of the LockDown (1730 N)[2] is more than double that of the native CC ligament (519-815 N),[1] but the ultimate load-to-failure obtained for the synthetic ligament group in our study was 731 N. We speculated that this difference could be attributed to weakness of cadaveric bone as a result of advanced age at the time of death. However, the CCSC consistently presented higher load-to-failure values than did the synthetic ligament although both techniques were done in matched shoulders.

Concern about clavicle fractures drove our choice of a CCSC instead of a tendon graft reconstruction to compare with the synthetic ligament. Minimizing bone tunnel–related fractures is a potential benefit of both the synthetic ligament and CCSC. Despite good biomechanical[28,33] and clinical results,[1,23,34] anatomic reconstructions with tendon grafts have been shown to have the highest incidences of clavicle fractures among AC surgeries,[17] and the risk of fracture is directly related to the size and number of tunnels drilled.[10,15,17,30,34] However, our study showed that 3 of 7 shoulders in the synthetic ligament group failed by spiral clavicle fractures. The LockDown construct wraps around the posterior aspect of the clavicle, fixing to a bicortical anterior screw acting to deflect the applied vertical distraction force to a posteriorly directed rotational torque to the distal clavicle, potentially resulting in spiral fractures.

The high occurrence of coracoid fractures in the CCSC group suggested that the tapes cut through the bone when first submitted to cyclic loading, which might have led to fracture in the load-to-failure test. This finding may suggest that postponing rehabilitation of patients undergoing CCSC could help to prevent cerclage-cutting complications. The greater width of the synthetic ligament compared with the tapes might have helped to avoid coracoid fractures in the synthetic ligament group because of better distribution of loads. For the same reason, incorporating metallic buttons or biologic grafts into the CCSC clinically could reduce the risk of the cerclage sawing through the coracoid.[41] Moreover, biologic grafts and synthetic ligaments are expected to integrate with nearby bone structures through fibrosis or tissue ingrowth (neoligament),[44] which would reduce the long-term risk of cerclage-cutting complications.

Both synthetic ligament and CCSC displacement-cycle curves are parabolic (Fig. 5), meaning that early cycles had higher displacement with the same force than later ones. Knowing the elongation characteristics of each construction is important for decision making on the amount of over-reduction a surgeon should apply at the time of surgery. Our data suggest that a 3-mm CC over-reduction would be enough to achieve anatomic reduction after early rehabilitation of CCSC, whereas the synthetic ligament would require 3 times more over-reduction to achieve optimum length.

Our study has several limitations. Cadavers imperfectly mimic living tissue and cannot account for healing potential. Excising all soft tissues from the scapula and clavicle removed important secondary stabilizers of the AC joint, such as the trapezium-deltoid-pectoralis fascia, which might have influenced the results. Previous cyclic loading may have interacted with the load-to-failure values, which in this study represent a residual capacity of the constructs to fail after 3000 cycles. Although absolute load-to-failure values may differ, the same difference found between the 2 constructs would still exist for load-to-failure without initial cyclic loading. We did not test the AC joints for anterior-posterior translation, which might have been favorable to the synthetic ligament because the construct wrapped around the posterior aspect of the clavicle and stabilized the AC joint by pushing the distal clavicle anteriorly. Also, our study only evaluated CC reconstruction without addressing the AC joint. Additional reconstruction of the AC joint capsule has been shown to increase stability after a CC ligament reconstruction.[8]

Conclusion

In a simulated immediate postoperative cadaveric model, the synthetic ligament demonstrated poorer biomechanics than the CCSC. These findings suggest that a CCSC may be preferable to a synthetic ligament if early rehabilitation is intended.

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Disclaimer

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