Axial-Plane Biomechanical Evaluation of 2 Suspensory Cortical Button Fixation Constructs for Acromioclavicular Joint Reconstruction

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Background: Although numerous suture-button fixation techniques for acromioclavicular (AC) joint reconstruction have been validated with biomechanical testing in the superior direction, clinical reports continue to demonstrate high rates of construct slippage and breakage.

Purpose: To compare the stability of a novel closed-loop double Endobutton construct with a commercially available cortical button system in both the axial and superior directions.

Study Design: Controlled laboratory study.

Methods: Six matched pairs of fresh-frozen cadaveric upper extremities were anatomically dissected and prepared to simulate a complete AC joint dislocation. One side of each pair was reconstructed with the double Endobutton (DE) construct and other side with the dog bone button (DB) construct. The specimens were then tested using a materials testing machine, determining initial superior and axial displacements with a preload, and then cyclically loaded in the axial direction with 70 N for 5000 cycles. Displacement was again measured with the same preloads at fixed cycle intervals. The specimens were then loaded superiorly to failure.

Results: At 5000 cycles, the mean axial displacement was 1.7 mm for the DB group and 1.2 mm for the DE group ($P = .19$), and the mean superior displacement was 1.1 mm for the DB group and 0.7 mm for the DE group ($P = .32$). Load at failure was similar (558 N for DE, 552 N for DB; $P = .96$). There was no statistically significant difference in the modes of failure.

Conclusion: Biomechanical testing of both constructs showed similar fixation stability after cyclical axial loading and similar loads to failure.

Clinical Relevance: The strength of both constructs after cyclical loading in the axial plane and load-to-failure testing in the superior plane validate their continued clinical use for achieving stability in AC joint reconstruction procedures.

Keywords: acromioclavicular joint; biomechanics; coracoclavicular ligament; Endobutton; anatomic reconstruction

Dislocation of the acromioclavicular (AC) joint is a common orthopaedic injury, yet there is no consensus regarding what constitutes optimal treatment. Pioneering biomechanical studies have led to the development of surgical techniques that stabilize the AC joint using constructs that replicate the native anatomy, thereby allowing for rotational movements while tightly constraining translational ones.[5,7] Both tendon grafts as well as suture button configurations have been validated in biomechanical testing and yielded improved clinical results.[16,26] However, despite improvements in clinical scores, high rates of fixation slippage resulting in joint subluxation have been reported.[14,21,22] In addition, the size and number of drill holes required have resulted in fractures of both the coracoid and clavicle.[4,15,23] Furthermore, although cyclical and load-to-failure testing have

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demonstrated good stability, testing protocols have primarily been limited to testing in 1 plane (superior-inferior [SI]), possibly limiting the predictive value of the in vitro results.

A novel technique was first introduced by the senior author (S.S.)[24] in 2007 to minimize joint subluxation and fracture risk while maintaining high clinical satisfaction. A suture button construct utilizing a continuous loop requiring only one 4.5-mm hole in each bone was described. An additional stitch along the course of the trapezoid component of the coracoclavicular (CC) ligament was designed to limit posterior translation. Clinical results of the construct have been consistently favorable, and biomechanical testing by Grantham et al[8] validated its stability in both the anterior-posterior (AP) and SI planes.[25] However, biomechanical testing of neither the double Endobutton construct nor other common constructs has included testing in the axial plane. Recent studies have demonstrated that significant axial forces in the range of 20 to 34 N are generated across the AC joint during shoulder abduction and rotation motions that are expected with routine daily activities.[10,19] These forces actually exceed the superior and posterior loads on the AC joint during physiologic range of motion and are a potential source of not only direct stress but also abrasive wear on suture material that may contribute to construct loosening or failure. Testing in the SI plane alone ignores these potential problems.

The purpose of the current biomechanical study was to compare the stability of a novel closed-loop double Endobutton construct with a commercially available cortical button system in both the axial and vertical planes. We hypothesized that the closed-loop double Endobutton construct would demonstrate excellent biplanar joint stability after both cyclical and failure loading in the axial plane. In addition, we anticipated that the closed-loop design would perform better than a contemporary commercially available suture button construct that requires knot fixation.

METHODS

Specimen Preparation

Twelve fresh-frozen cadaveric specimens (mean age, 68 ± 15 years) consisting of 6 matched pairs of shoulders, were obtained from a commercial donor bank for research purposes (Science Care). All specimens were screened to exclude those with history of musculoskeletal disease or surgery. Cadaver demographics are displayed in Table 1. Specimens were stored at –20°C. Each specimen was thawed overnight at room temperature prior to preparation. The shoulders were disarticulated at the glenohumeral joint, and the clavicle and scapula were dissected free of all soft tissues, excluding the AC joint capsule, coracoacromial (CA) ligament, and the CC ligament complex. After dissection was complete, the AC joint capsule and CC ligaments were sharply transected to simulate complete AC joint dislocation. Any preexisting lesion of the ligamentous restraints and degenerative changes of the AC joint, including changes resulting in significant bone loss or ligamentous instability, were ruled out by visual inspection.

TABLE 1
Cadaver Demographics and Specimen Characteristics[a]

Specimen	Right	Left	DE Size, mm	Age, y	Sex	BMI, kg/m^2
1	DE	DB	40	65	Male	17.6
2	DE	DB	35	45	Male	27.0
3	DE	DB	45	54	Male	24.1
4	DB	DE	35	79	Male	29.8
5	DB	DE	30	83	Male	14.0
6	DB	DE	30	80	Male	22.3

[a] BMI, body mass index; DB, dog bone button; DE, double Endobutton.

One side of each pair was assigned to the double Endobutton (DE) group and other side the dog bone button (DB) group. Although the hand dominance of each cadaver was unknown, each group was composed of 3 right and 3 left shoulders to limit the confounding effect of handedness (Table 1).

Surgical Technique

Double Endobutton Group. Specimens in the DE group underwent AC joint reconstruction utilizing the previously described continuous-loop DE technique.[24] This method employed the Endobutton CL system (Smith & Nephew), including 2 cortical buttons connected by a continuous loop of high-strength braided suture (No. 5 Ethibond; Ethicon), to reproduce the anatomic course of the conoid bundle of the CC ligament through a 4.5-mm tunnel drilled through the clavicle and coracoid. An auxiliary stitch, again using a high-strength braided suture (No. 5 Ethibond), passed through a separate 2.5-mm clavicular drill hole, was used to replicate the trapezoid bundle. The size of the continuous suture loop was determined with the joint reduced by measuring the channel length from the superior surface of the clavicle to the inferior surface of the coracoid with a depth gauge. The continuous loop comes in 5-mm increments. The size of the Endobutton loops used in each specimen varied to most closely approximate the native anatomy and can be found in Table 1. Figure 1A demonstrates the final DE construct.

Dog Bone Button Group. Specimens in the DB group underwent AC joint reconstruction using a commercially available cortical button system (Dog Bone Button; Arthrex). This construct consists of 2 precontoured titanium cortical buttons connected by 2 loops of 2-mm suture tape (FiberTape and TigerTape; Arthrex). Care was taken to drill the cortical tunnels in the identical location in both the DE and DB groups—well centered in the coracoid and clavicle and positioned over the footprints of the conoid bundle of the CC ligament—using a 3.0-mm cannulated drill bit. Once the suture tape was passed through the coracoid and clavicle, the joint was anatomically reduced and the limbs are over the superior button with 4 alternating half-hitches. Figure 1B includes an illustration of the final DB construct.

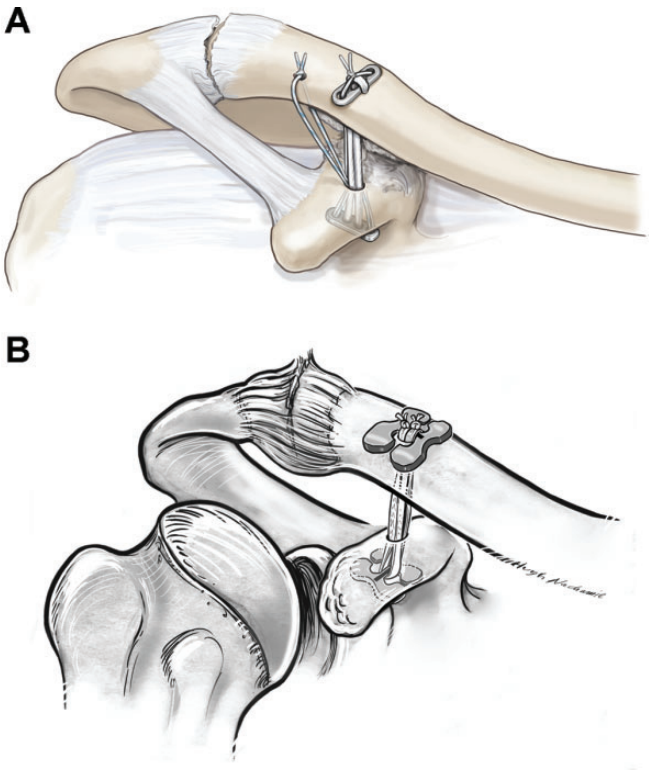

Figure 1. Illustrations depicting 2 acromioclavicular joint reconstruction techniques: (A) continuous-loop double Endobutton construct and (B) dog bone button fixation construct.

Biomechanical Testing

The posterior scapula was mounted on an aluminum plate and fixed with bolts and washers positioned at 3 separate landmarks. A bracket on the base of this plate was held in a dual angle vise. Adjustments of the vise permitted the proximal clavicle to be vertically oriented in its neutral anatomic position relative to the scapula. This orientation permitted sequential loading in the plane along the axis of the AC joint and perpendicular to the AC joint line. A transverse hole was drilled in the clavicle 4 cm proximal to the surgical construct, and the clavicle was fixed to 2 plates using a pin. The vise and plates were then attached to a materials testing machine (MTS Systems, Inc). Marking pins were inserted at 3 osseous landmarks (acromion, clavicle, and coracoid) adjacent to the construct and fixed in place with cyanoacrylate glue to provide reference sites for measurement. The testing rig and setup is demonstrated in Figure 2.

Biomechanical testing was performed at room temperature with the specimens kept moist using saline solution to prevent desiccation. A static superior preload was applied to the clavicle immediately anterior to the fixation construct using a cord, pulley, adjustable ring stand, and 5-N free weight to maintain consistent superior tension on the construct throughout testing. The construct was then subjected to sequential axial loads. First, a 5-N axial load was applied to the clavicle, and distances between marking pins were measured to establish the initial reference (starting point). All translational distances were measured using a digital caliper with an error of 0.005 mm. A 70-N axial load was then applied to the clavicle, and the initial displacement was again measured in the same fashion. A 70-N load has been used in several recent studies[5,6,13,16,18,20,27,28] as it is below the threshold at which significant osseous bending occurs[5,13,20,29] and simulates the stresses of a mild physical therapy rehabilitation protocol.[27,28]

Cyclical axial loading from 20 to 70 N was applied sinusoidally at 1 Hz. After 10, 100, 1000, and 5000 cycles, the axial load was reduced to the static 5-N preload, and axial and superior displacements were measured and recorded. After cyclical loading, the specimens were reoriented, load-to-failure testing was performed at a rate of 1 mm/s in the superior direction, and load-displacement curves were obtained. Stiffness was defined as the regression slope from the linear segment of the load-displacement curves obtained during load-to-failure testing. Failure was defined as a 10-mm superior displacement or any fracture, insufficiency, or material incompetence. Final load at the time of construct failure was recorded. Failed specimens were removed from the mount and visually examined to determine the precise mode of failure.

Statistical Analysis

The Student paired t test was used to compare differences in continuous variables between study groups. The Fisher exact test was employed to compare differences in nominal variables. All statistical analysis was performed using the SPSS statistical software package (version 20; IBM Corp). The level of significance was set at $P < .05$. Data are expressed as mean ± standard deviation. Post hoc power analysis revealed that a sample size of 19 specimens in each group would be required to achieve statistical significance in displacement after cyclical loading.

RESULTS

Cyclical Loading

The mean initial displacement at 5 N of axial load was greater for the DE group (3.3 mm) compared with the DB group (1.8 mm; $P = .03$). The results for axial displacement and superior displacement at 100, 1000, and 5000 cycles are displayed in Table 2. There was no statistically significant difference in mean axial and superior displacement for the DB group compared with the DE group at any point. The only exception was at 100 cycles, when the mean superior displacement was greater for the DE group than the DB group (0.2 vs 0.3 mm).

Load to Failure

The results for load-to-failure testing are demonstrated in Table 3. No statistically significant difference in mean load at failure was detected between groups. Failure loads ranged from 300 to 800 N for all specimens, regardless of

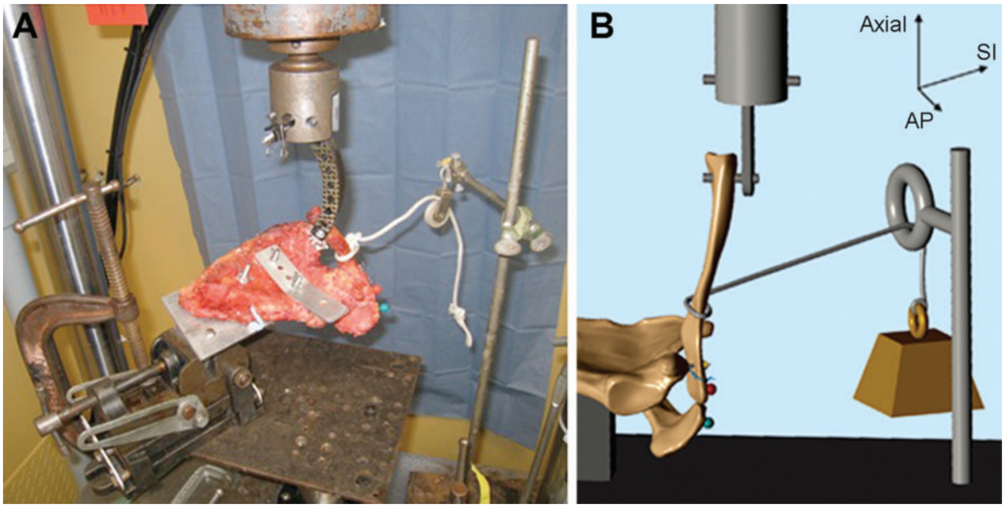

Figure 2. (A) Testing rig. Position of the scapula in the vise, vise angles, and position were adjusted so that scapula was anatomically positioned and vertically oriented. The ring stand position and pulley were adjusted to apply a static perpendicular superior load to the clavicle anterior to the fixation construct. Two marking pins can be seen. (B) Artist depiction of testing rig. AP, anterior-posterior plane; SI, superior-inferior plane.

TABLE 2
Cyclical Loading Results for 100, 1000, and 5000 Cycles[a]

	Axial Displacement, mm			Superior Displacement, mm		
Group	100	1000	5000	100	1000	5000
DB group	0.3 ± 0.1	1 ± 0.5	1.7 ± 0.6	0.2 ± 0.1	0.5 ± 0.3	1.1 ± 0.8
DE group	0.4 ± 0.1	0.8 ± 0.1	1.2 ± 0.2	0.3 ± 0.1	0.5 ± 0.2	0.7 ± 0.2
P value	.75	.63	.19	.01[b]	.69	.32

[a] Data are expressed as mean ± SD. DB, dog bone button; DE, double Endobutton.
[b] Statistically significant.

TABLE 3
Load-to-Failure Results[a]

	Load at Failure, N	Stiffness, N/mm
DB group	552 ± 205	21.1 ± 6.5
DE group	558 ± 70	17.9 ± 3.4
P value	.96	.42

[a] Data are expressed as mean ± SD. DB, dog bone button; DE, double Endobutton.

group. In the DB group, modes of failure included fixation pull-out in 3 specimens, suture cutting through the clavicle in 2 specimens, and fracture of the scapula at the mount in 1 specimen. In the DE group, modes of failure included fixation pull-out in 3 specimens, suture loop stretching in 2 specimens, and clavicle fracture through the drill hole in 1 specimen.

DISCUSSION

Axial plane cyclic testing of both constructs demonstrated excellent stability in all specimens. Within the DE group, after 5000 cycles, mean displacement was 1.2 mm in the axial plane and 0.7 in the SI plane. Within the DB group, mean displacement was 1.7 mm in the axial plane and 1.1 mm in the SI plane. There was no statistically significant difference between final mean displacement for each construct in either plane.

The mean initial displacement with an initial 5-N axial load was greater for the DE group than the DB group by 1.5 mm. This initial laxity was likely due to differences between the 2 techniques. In the DB technique, sutures are tied to secure the construct in position once the AC joint has been reduced. In the DE group, however, the continuous loop comes in 5-mm increments, such that reduction of the AC joint may be up to 2.5 mm off depending on which loop size is selected. This small mismatch likely accounts for the displacement found after application of a small initial load. Using a larger button (eg, Xtendonbutton; Smith & Nephew) or different button and washer configurations allows consistent and accurate reduction of the AC joint to within 1 mm of the native anatomy.[25] Furthermore, the statistically significant difference after 100 cycles of axial load was only 0.1 mm and therefore would not be clinically relevant.

This experiment represents the first study to report on biomechanical testing on either suture-button or tendon constructs using cyclical testing in the axial plane. In AC joint injury, not only is the typical mechanism of injury (fall on the point of the shoulder) a deformation in primarily the axial plane, but routine activities of daily living place significant axial forces across the joint. Oki et al[19] demonstrated that simple abduction of the arm transmits large axial forces, up to 34 N, across the AC joint. In addition, and perhaps more important, cyclical testing in the axial plane introduces shear forces that are not present in simple SI cyclical testing.[19] Suture rupture has been suspected as a cause of failure by Lim et al[14] and others using the suture-button constructs underscoring the importance of testing cyclical forces in either the axial or AP direction, which will incorporate an element of shear. Shear forces contribute to the risk of not only suture abrasion but also tunnel widening. Although many authors have recently documented the risk of fracture from a larger coracoid drill hole, the risk of suture abrasion from smaller drill holes has not been studied.[12] Cyclical testing in the axial plane may better document the consequences of shear forces that act on suture materials as they pass through the bone tunnel in the coracoid. The ideal size for a drill hole may well represent a balance between fracture risk on the high side and suture abrasion risk on the low side.

Although numerous suture button constructs have demonstrated stability in standard biomechanical testing, the clinical results show that constructs tend to slip and subluxate in a high percentage of cases. This DE construct is unique in that it is knotless, eliminating the possibility of knot slippage or breakage. The potential for knots subjected to cyclical load to either slip or fail has been shown by Abbi et al.[1] Barber et al[2] showed that ultra–high molecular weight polyethylene (UHMPE) sutures show significantly better strength than standard sutures, but because of their frictional properties, have high rates of slippage at loads well below their failure threshold. Ilahi et al[11] also demonstrated that UHMPE sutures tied with 5 square knots showed that 3 mm of slippage occurred at only 60% of the failure load. Indeed, Lim et al[14] suggested that knot slippage was a factor in reporting a 50% slippage rate with the use of a commercially available cortical button UHMPE suture–based fixation device. By comparison, Barrow et al,[3] among others, have demonstrated that the Endobutton, even when tested with cyclic loading of up to 250 N at 4500 cycles, only showed a 1.3-mm change in length. Both author groups concluded the continuous loop was more resistant to creep than both standard knotted systems as well as more recently introduced adjustable knot systems. In addition, there is an even load distribution across the suture material, which is not possible in suture button systems with multiple sutures and multiple knots.

Load at failure for both constructs was similar (DB, 552 N; DE, 558 N), which is consistent with multiple previous studies that indicate that the native CC ligament has an ultimate strength of approximately 500 N.[9,17] Thus, both constructs appear to be of adequate strength in terms of failure from high sudden loads. Within the DE group, failure of the construct was independent of the integrity of the auxiliary stitch. Although the components of the DE construct were not isolated, the auxiliary stitch aims to re-create the trapezoid ligament of the CC ligament complex, which functions to help resist axial compression across the AC joint and rotational forces on the scapula.[19] We suspect that under the testing conditions in the current study, the continuous loop was subjected to greater forces and failed prior to the remainder of the construct. This finding is consistent with design of the implant where the continuous loop is the primary load-bearing component of the construct.

The lack of correlation of biomechanical results with clinical success that has been observed with standard suture-button constructs has not been seen with the closed-loop DE construct. Recent reports by Struhl and Wolfson[25] and others have shown very high clinical and radiographic outcome scores with very low complication rates. Indeed, the mean CC interval only increased by 1.2 mm, which not only confirmed good stability of the construct but correlated extremely well with the current biomechanical study as well as the study by Grantham et al.[8]

The current study was not without limitations. The sample size prevented statistical significance from being achieved. Based on a post hoc power analysis, at least 3 times the number of specimens would be required to detect a statistically significant difference between groups. In addition, load testing to failure was isolated to the SI plane. Additional testing in orthogonal planes may further characterize the stability and strength of the constructs. Last, bone mineral density was not performed prior to testing. Poor bone quality may have contributed to mode of failure. The mean age of cadavers included in the study was greater than the mean age of patients presenting with AC joint dislocations. Although the specimens may not be representative of the population of patients with acute AC joint dislocations, we would expect younger patients with superior bone quality to exhibit even greater resistance to fracture and suture cut out.

CONCLUSION

Cyclical testing in the axial plane confirmed that the closed-loop DE construct provided good stability when subjected to forces that can be expected to be present in the postoperative period. The DE construct showed similar ultimate performance and biomechanical strength relative to a commercially available cortical button system. Greater initial displacement within the DE group was likely due to the inherent laxity of the reduction, but did not affect final displacement results.

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