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Distal-third clavicle fracture fixation: a biomechanical evaluation of fixation

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Background: Approximately 25% of distal clavicle fractures are unstable. Unstable patterns have longer times to union and higher nonunion rates. Stable restoration of the distal clavicle is important in decreasing the nonunion rate in distal clavicle fractures. The purpose of this study was to biomechanically compare operative constructs for the treatment of unstable, comminuted distal-third clavicle fractures in a cadaveric model using a locking plate and coracoclavicular reconstruction. We hypothesized that the combination of coracoclavicular reconstruction and a distal clavicle locking plate is biomechanically superior to either construct used individually.

Materials and methods: An unstable distal clavicle fracture was created in 21 thawed fresh-frozen cadaveric specimens. The 21 specimens were divided into 3 treatment groups of 7: distal-third locking plate, acromioclavicular (AC) TightRope (Arthrex, Naples, FL, USA), and distal-third locking plate and AC TightRope together. After fixation, each specimen was cyclically tested with recording of displacement to determine the stiffness and stability of each construct, followed by load-to-failure testing in tension and compression to determine the maximum load.

Results: The combined construct of the locking distal clavicle plate and coracoclavicular reconstruction resulted in increased stiffness, maximum resistance to compression, and decreased displacement compared with either construct alone.

Conclusion: Greater fracture stability was achieved with the combination of the AC TightRope and locking clavicle plate construct than with either alone, suggesting a possibility for increased fracture-healing rates.

Level of evidence: Basic Science Study, Biomechanics, Cadaveric Model.

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Keywords: Distal clavicle fracture; biomechanical; locking plate; TightRope

Distal-third clavicle fractures account for 21% to 28% of all clavicle fractures and constitute a higher proportion of complications related to clavicle fracture treatment.^{44,51}

Ethical committee: Approved by the Clinical Research Center for use of cadavers (study 08-002C).

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Distal-third clavicle fractures tend to occur mostly in elderly individuals as a result of simple falls.^{19,52} Approximately 25% of distal clavicle fractures are unstable.^{44,51} Stable fracture patterns typically heal well without surgical management; however, unstable patterns have longer times to union and higher nonunion rates. For adequate visualization of a distal clavicle fracture, a Zanca radiograph is often helpful, along with a 10-lb stress view

to analyze for integrity of the coracoclavicular (CC) ligaments.⁵³ Stable fixation of the distal clavicle is essential for proper support of the suspensory mechanism of the upper limb.^{8,39} Historically, open reduction and internal fixation were not recommended, even though most authors have agreed that treatment by external support in adults is associated with several weeks of painful disability, prolonged rehabilitation, and loss of productivity.^{4,8,55,65} Neer^{41,42} found that although these fractures are rare, they account for nearly 50% of clavicle nonunions. Neer classified distal fractures as follows: (1) type I fractures occur lateral to the CC ligaments, usually with minimal displacement; (2) type II fractures occur more medial to the CC ligaments and usually result in significant displacement; (3) type IIa fractures have both the conoid and trapezoid ligaments still attached to the distal fragment; (4) type IIb fractures involve rupture of the conoid ligament with the trapezoid ligament remaining intact; and (5) type III fractures are intra-articular fractures of the acromioclavicular (AC) joint.⁴¹ Type II distal fractures have the highest rate of nonunion,^{41,42,45,54} and the rate of nonunion is high with both nonoperative and operative management.^{52,54} For those fractures requiring surgical care, the operative procedure varies according to the type and location of the fracture.^{17,65} Because there is no agreement on the standard of operative care for these injuries, the orthopedic surgeon continues to deal with a significant dilemma. From a biomechanical perspective, the importance of the CC ligaments in controlling superior migration has been elucidated.^{34,37,38,50,54} Stable restoration of the distal clavicle is important in decreasing the nonunion rate in fractures involving the distal clavicle. Proposed treatments include CC screws,^{4,34,62} tension bands,^{7,10,25,56} Kirschner wires,^{19,31} hook plates,^{20,28} nonlocked plates,²⁹ and locked plates.^{21,24,28,47,64}

Despite multiple methods of fixation for unstable distal clavicle fractures, no single surgical technique has been shown to be superior.^{1,5} Transacromial wire fixation has been associated with high rates of complications including nonunion, AC arthrosis, symptomatic hardware, and Kirschner wire migration into the cervical spine, trachea, vascular structures, lung, and abdomen.^{3,14,26,30,31,33,35,49,59} Tension band techniques have had mixed results.^{11,26} Several case series have reported successful union rates with open reduction and internal fixation of the proximal clavicle fragment to the coracoid process such as with a cannulated screw, but such procedures do require additional surgery for hardware removal before screw failure.^{4,13,16,23,34,62} Satisfactory results have been obtained with use of the Knowles pin placed transacromially, especially with CC ligament repair or reconstruction.^{7,10,15,60} Transacromial fixation with a threaded Knowles pin is more secure than that with a smooth pin and avoids medial pin migration, although there was asymptomatic radiographic lucency around the pin and asymptomatic lateral migration of the pin at the time of removal.¹⁵

Small series have reported successful techniques for CC repair or reconstruction.^{6,9,18,32,43,46,48,56,61,63} These all address the superiorly directed forces. The use of plates has evolved in the care of distal clavicle fractures. Earlier in distal clavicle fracture repair, small locking plates, such as distal radius locking plates, were successfully used to secure the distal fragment without disrupting the AC joint.²⁵ There are now contoured locking plates designed for the distal clavicle. However, the plates do not oppose the superiorly directed forces and can result in complications including periprosthetic fracture, screw loosening, deep infection, and malunion, albeit these are not common.¹ A more common complication is prominent hardware necessitating removal after union.¹ AC hook plates have also been used successfully to treat distal clavicle fractures that are too small for distal screw purchase. In limited series, hook plates have been more successful when compared with other methods of fixation.^{17,22,30} However, these plates have been associated with complications, including acromion fracture, osteolysis of the acromion, and rotator cuff tear.²⁸ The hook plate also commonly requires an additional surgery for removal.^{27,40,57} A systematic review of 425 cases by Oh et al⁴⁷ found no clear evidence for a superior fixation method, but the study noted higher complication rates with K-wires with wire tension band fixation, as well as the hook plate.

To date, although limited data are available, acromial hook plating has the most supportive evidence. Acromial hook plates prevent superior translation of the clavicle while providing stable fixation of the fracture. The downside to the hook plate is related to its position under the acromion, causing osteolysis, fracture, and occasionally, rotator cuff tears. We propose using the TightRope (Arthrex, Naples, FL, USA) to add fixation to the coracoid in addition to a distal clavicle locking plate. This method should both achieve stable fixation of the fracture and oppose the superiorly directed forces on the clavicle while avoiding complications of the subacromial hook.

The purpose of this study was to compare operative constructs for the treatment of unstable, comminuted distal-third clavicle fractures in a cadaveric model. The study has 3 arms: (1) distal-third clavicle superior locking plate (109 mm in length) (Smith & Nephew, Memphis, TN, USA); (2) AC TightRope; and (3) combination of the distal-third locking plate and AC TightRope. We hypothesized that the combination of the AC TightRope and distal clavicle locking plate is biomechanically superior to either construct used individually in the treatment of unstable distal-third clavicle fractures.

Materials and methods

Twenty-one fresh-frozen cadaveric specimens were divided into three groups of seven. Before device implantation and testing, each specimen was allowed to thaw for 24 hours at room temperature, and all soft-tissue attachments were removed. Radiographic evaluation of each specimen was used to ensure the absence of prior

fracture or pathologic lesions that would compromise structural integrity. An unstable fracture was replicated with an osteotomy by use of an oscillating saw on the distal clavicle, 20 mm from the AC joint. The osteotomy was created with a 4-mm gap between the proximal and distal fragments to increase instability, simulating comminution. The CC ligaments were cut to create instability of the medial fragment. The 21 specimens were divided into 3 treatment groups of 7: distal-third locking plate, AC TightRope, and distal-third locking plate and AC TightRope together. The specimens with the TightRope had the TightRope placed before the plate. A 3.5-mm drill, as specified by the TightRope system, was used to create a vertically oriented hole through the clavicle, directly superior to the coracoid, and through the coracoid. The oblong button was placed through the clavicle and coracoid, resting on the inferior surface of the coracoid, with the round button on the superior surface of the clavicle. In the specimens with the plate, the plate was then placed superiorly on the clavicle, over the TightRope, in the best-appearing position for good purchase in the distal fragment and best-fit contour of the proximal fragment. The distal four 2.7-mm locking screw holes were used to secure the distal clavicle fragment, with bicortical locking screws. Of the proximal 3.5-mm screw holes, 4 were chosen that best fit centrally on the clavicle given the contour, while trying to span the largest length of the clavicle, and 4 bicortical nonlocking screws were placed. In the specimens with both the TightRope and locking plate, the distal-most 3.5-mm screw hole was avoided given its proximity to the TightRope drill hole.

Mechanical testing

Biomechanical testing was conducted in an axial compression and torsion biaxial system, the EnduraTEC Smart Test servo-pneumatic test frame (SP-AT 5560/153; EnduraTEC Systems, Minnetonka, MN, USA), by use of WinTest software (Bose Corporation, Eden Prairie, MN, USA; version 2.56) for testing control and data acquisition. At calibration of the testing equipment, the ranges were ± 127 mm for displacement, ± 12.5 kN for load, $\pm 50^\circ$ for rotation, and ± 14 Nm for torque, all with less than 0.5% full-scale variation. During cyclic loading, proximal fixation was achieved with the proximal clavicle secured in the jig proximal to the locking clavicle plate. Distal fixation was achieved with the scapula secured in the distal jig (Fig. 1). The specimen was preloaded at 75 N of tension oriented along the long axis of the clavicle for 5 minutes to remove the initial viscoelastic effect. The cyclic tensile load along the long axis of the clavicle cycled from 10 N to 75 N in a sinusoidal pattern at a rate of 2 Hz. A rotation of 2° of external rotation about the long axis of the clavicle was applied simultaneously in a sinusoidal pattern along with the axial loads. The maximum axial load of 75 N corresponded to full external rotation, and the load of 10 N corresponded to neutral position. This corresponds to normal physiologic motion during arm swinging, performed to more closely simulate the true environment.⁵⁸ Cyclic testing was performed to determine the stability and stiffness of the constructs. Five thousand cycles were applied. There was no evidence on the specimens at the end of testing of motion in the jigs. The torque and displacement were recorded from the beginning of the test to the end of the 5,000 cycles. Displacement was measured through the data acquisition system of the EnduraTEC Smart Test system. Displacement was measured as the axial position of the actuator at the maximum load subtracted from the initial position of the actuator.



Figure 1 Jig for cyclic test and load to failure in tension.

Load-to-failure testing in tension was performed by use of a displacement-driven ramp command. The mechanical setup was identical to the setup for the cyclic testing. The EnduraTEC machine was programmed to increase 0.5 mm/s until the level of force peaked. At this point, the failure was always at the TightRope in the specimens with the TightRope (Fig. 2), and it was only at the AC joint in the specimens without the TightRope. No failure of the plate was shown. Thus, the locking clavicle plate construct was able to be loaded to failure in compression. This simulates the compressive load that the clavicle experiences, physiologically serving as a strut for the suspension of the shoulder complex.^{2,36} Because the TightRope was not present during compressive testing, the test was performed to determine the effects of the previous presence of the TightRope on the locking plates during load to failure. For load-to-failure testing in compression, the proximal gripping was the same; however, distally, the clavicle was disarticulated from the scapula through sharp dissection. The distal clavicle was then set in a depression in a plate of the distal jig to allow bending but not translation, as shown in Figure 3. The load to failure in compression was tested by use of a ramp command of -0.5 mm/s until failure.

Statistical analysis

Analysis of variance was used to compare the 3 groups on outcomes measured on a continuous scale. The least significant difference method was used for follow-up pair-wise comparisons. Inferences were made at the .05 level of significance with no correction for multiple comparisons.

Results

The mean age of subjects at death was 68.3 ± 11.7 years. The radiographic screening of the clavicles did not show

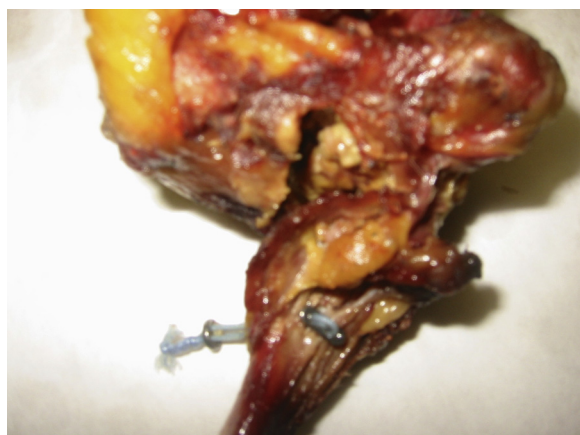


Figure 2 Load-to-failure tensile results (oblong button of TightRope pulled through coracoid).

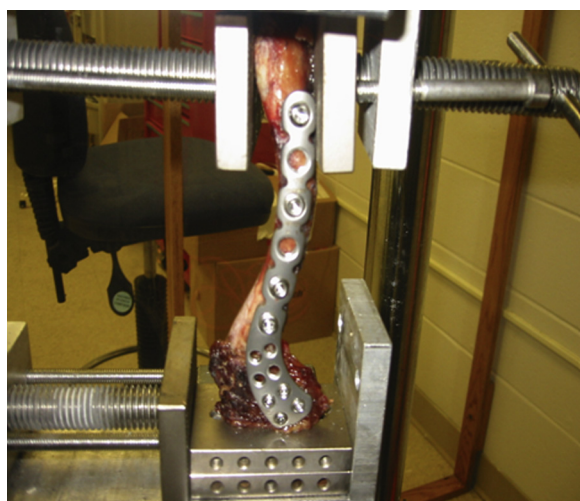


Figure 3 Setup for load to failure in compression. The distal portion (bottom) is recessed to allow bending but not translation.

any pathology. The torsion in all groups was nearly irrelevant, at approximately 2 Nm (Table I), with no difference among groups. The lengths of the clavicles averaged 15.1 cm in the locking plate group (SD \pm 1.7 cm), 14.8 cm in the TightRope group (SD \pm 1.4 cm), and 14.4 cm in the combination group (SD \pm 1.3 cm). No statistical difference was found among groups ($P = .66$).

Table II contains the results for the comparisons of the 3 groups. By use of analysis of variance, the 3 groups differed on load to failure in compression ($P = .024$), stiffness ($P < .001$), and total change in position ($P = .002$) but not load to failure in tension ($P = .19$). However, when we inspect the means for load to failure in tension, there may be a clinically significant difference (combined group, 459 N; locking plate group, 396 N; and TightRope, 312 N). Seventy-five newtons is over twice the force of the average hanging human arm.¹²

For load to failure in compression, the tested construct consisted of only the clavicle and the locking plate after

removal of the TightRope and removal from the scapula (Fig. 3), after the 5,000 cycles. The locking plate in the combined group failed under greater mean compression of 1,491 N compared with the locking plate group, at a mean of 831 N ($P < .024$). In the group with the locking clavicle plate only, failure occurred by permanent plate deformation at the osteotomy site in 4 of the constructs, as shown in Figure 4; 1 of the constructs failed by fracture of the clavicle around the distal screws, and 2 of the constructs failed by both permanent plate deformation at the osteotomy site and fracture of the clavicle around the distal screws. For the group with the TightRope and clavicle plate, during cyclic testing, 5 constructs failed by permanent deformation and 2 by fracture around the distal screws.

The least significant difference post hoc method was used for pair-wise comparisons of the 3 groups. Table II shows that the groups did not differ regarding load to failure under tension. The combined locking plate and TightRope had greater mean stiffness (53 N/mm) than both the locking plate (31 N/mm, $P < .001$) and TightRope (27 N/mm, $P < .001$). The combined locking plate and TightRope had a lower mean change in position (0.30 mm) than both the locking plate alone (0.75 mm, $P < .007$) and TightRope alone (0.91 mm, $P = .001$). Figure 5 is a graphical representation of the average displacement of each construct type throughout cyclical testing.

Discussion

No single surgical technique for fixation of the unstable distal clavicle fracture has been shown to be superior.^{1,5} To date, although limited data are available, acromial hook plating has the most supportive evidence. Acromial hook plates prevent superior translation of the clavicle while providing stable fixation of the fracture. The downside to the hook plate is related to its position under the acromion, possibly causing osteolysis, fracture, and occasionally, rotator cuff tears. It also requires an additional surgery for removal.^{27,40,57}

Similar to our study, other reports used locking clavicle plates augmented with CC repair, reconstruction, and support (eg, with suture anchors).²¹ This approach opposes the superiorly directed forces of the trapezius while avoiding complications from disrupting the AC joint as with the hook plate. The studies showed promising results, though with small study groups.^{4,7,34,62} The study of 16 patients by Klein et al²⁸ yielded good results using a contoured locking plate with coracoid suture augmentation. Several case series have reported successful union rates with open reduction and internal fixation of the proximal clavicle fragment to the coracoid process with a cannulated screw. Screw fixation into the coracoid does require additional surgery for hardware removal before screw failure.^{4,13,16,23,34,62} Satisfactory results have been obtained with use of the Knowles pin placed transacromially, especially with CC ligament repair

Table I Torsion results at 5,000 cycles

	Mean \pm SD			<i>P</i> value (analysis of variance)
	Combined	Locking plate	TightRope	
Torsion (Nm)	2.26 \pm 0.49	2.11 \pm 0.31	2.14 \pm 0.38	.74

Table II Biomechanical results of 3 constructs

	Mean \pm SD			<i>P</i> value*		
	Combined	Locking plate	TightRope	Combined vs locking plate	Combined vs TightRope	Locking plate vs TightRope
Failure in compression (N)	1,491 \pm 656	831 \pm 170		.024		
Failure in tension (N)	459 \pm 171	396 \pm 120	312 \pm 134	.43	.072	.29
Stiffness (N/mm)	53 \pm 12	31 \pm 10	27 \pm 5.0	<.001	<.001	.43
Change in position (mm)	0.30 \pm 0.19	0.75 \pm 0.35	0.91 \pm 0.26	.007	.001	.30

* *P* values were calculated from the least significant difference after analysis of variance, except for the comparison between the combined construct and the locking plate for failure in compression, which was calculated from analysis of variance because this was a 2-group analysis.

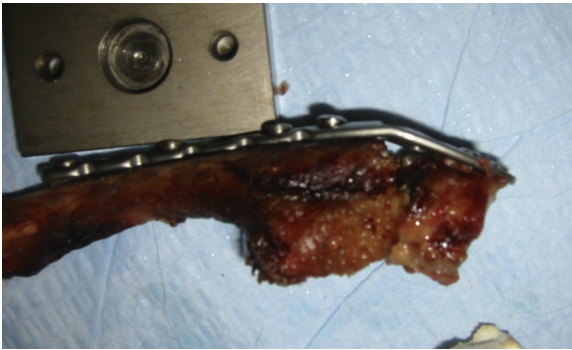


Figure 4 Example of result of load to failure in compression with failure due to bending through overlying screw hole.

or reconstruction.^{7,10,15,60} Extra-articular Knowles pin fixation with CC augmentation by use of Ethibond (Ethicon, Somerville, NJ, USA) resulted in 92% bony union within 12 weeks.⁶⁰ The remaining 8% of patients were non-compliant with postoperative care, including non-active flexion for 6 weeks. At the time of removal, asymptomatic radiographic lucency around the pin and asymptomatic lateral migration of the pin by 1 to 5 mm were reported. In addition, 12% of patients had asymptomatic CC heterotopic ossification.

Several techniques focus highly on CC repair for reconstruction. Arthroscopic techniques for repair or reconstruction of the CC ligament have been described by use of sutures, the TightRope system, or a button device, but limited outcome data exist.^{6,9,46,48} Webber and Haines⁶¹ reported that 11 patients with CC ligament reconstruction using a Dacron graft had a union rate and other clinical outcomes that were satisfactory. Li et al³² showed adequate fixation of type IIb distal clavicle fractures and a 100% union rate with good functional results using titanium cable

cerclage around the clavicle and through a drill hole through the coracoid. Shin et al⁵⁶ had success using suture anchors for CC stabilization, although erosion of the clavicle by the suture material occurred. Yang et al⁶³ performed stabilization with Mersilene tape (Ethicon, Somerville, NJ, USA) around the distal portion of the medial clavicle fragment and the coracoid process with good union results and few complications. Friedman et al¹⁸ had acceptable symptomatic results with suture anchors solely used at the base of the coracoid for fixation of distal clavicle fractures, but 8 of 24 patients had an increased CC distance on final radiography. Cerclage of the clavicle around the coracoid is an option for long oblique fractures but may not provide sufficient fixation against distracting forces and is inadequate for highly comminuted fractures.⁴³ In all, fixation methods that address the superiorly directed forces on the clavicle may increase union rates, although most have their own specific complications.

Our results showed the combination of a locking plate and TightRope to be superior to either method alone. Although the load to failure in compression included only the locking plate, during cyclic testing, the construct that had the AC TightRope and locking plate had greater strength than the group with the locking plate alone. The TightRope likely translates tensile forces directly from the arm and scapula through the coracoid to the proximal fragment of the clavicle. This reduces the forces across the fracture site that the locking plate is required to withstand and, therefore, reduces micromotion about the fracture, plate, and screws. The fact that the combination group failed at a greater compressive load compared with the locking plate-only group supports this observation. We theorize that the added stability of the AC TightRope decreases the wear and fatigue around the locking plate, allowing it to outperform in the load-to-compression testing. This is clinically relevant

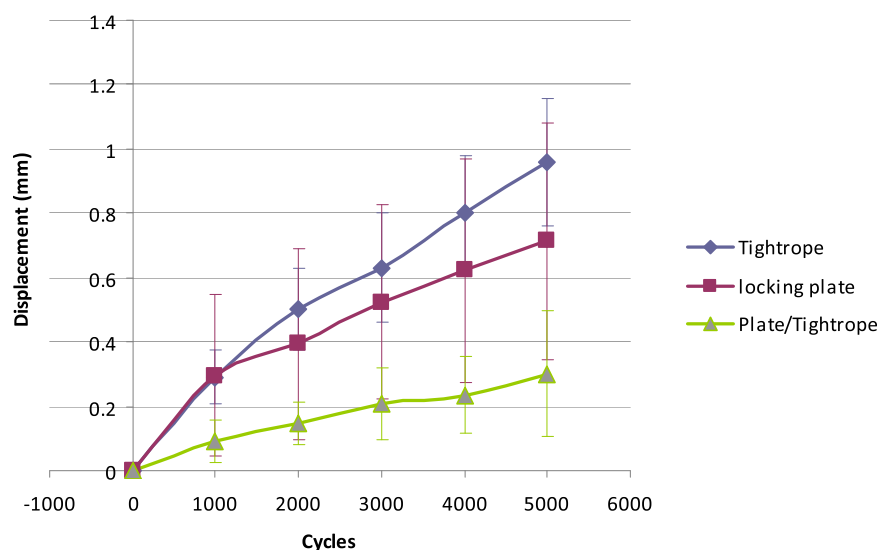


Figure 5 Displacement during cyclic testing: initial displacement and displacement at every 1,000 cycles for the 3 constructs (TightRope, locking plate, and combined locking plate and TightRope). Error bars equal 1 SD.

because the clavicle is thought of as a strut often under compression used to suspend the shoulder complex.^{2,36} This could lead to increased fracture-healing rates as a result of greater construct strength and stiffness.

A disadvantage of the combination technique is the requirement for significant stripping of the bone for placement of the precontoured locking clavicle plate, which is an issue with plates in general. The combination technique may only be indicated for distal clavicle fractures with high-grade comminution where simple plate fixation would not achieve adequate stabilization. Disadvantages of the TightRope include risks associated with dissection around the coracoid, as well as cost and increased operative time. With noncomminuted fractures with a long oblique fracture, the AC TightRope implant alone may provide adequate fixation,⁴³ although implants cutting through the clavicle may be a complication.⁵⁶ By using the AC TightRope implant alone, the approach to the fracture can theoretically be performed with less soft-tissue dissection that would potentially assist in fracture healing.

A limitation of our study is the variance in the size of the clavicles and, therefore, the varied positioning of the proximal screws. However, this likely did not affect the results because there was only 1 failure of the proximal fragment (a specimen in the combined group) around the proximal screws. Another limitation of our study is small sample size and subsequent low power to fully assess the comparison between the locking clavicle plate and AC TightRope. However, because of large differences, we were able to show that the combination construct differed from the 2 single methods in strength, stiffness, and load to failure. Although the locking clavicle plate may be biomechanically superior to the AC TightRope, our study was underpowered to adequately show this difference. A difficulty with simulating clavicle fractures is the multitude of

forces acting on the clavicle. As such, our biomechanical setup is a simplified model. Physiologically, the tension is directed in a more inferior orientation, but this approach was prohibitively difficult to set up in our laboratory. Tension along the long axis of the clavicle still simulates tensile forces across the AC joint and TightRope. Although the exact physiologic forces were not re-created, our setup should be sufficiently similar to adequately test and differentiate these methods of fixation.

Conclusions

When the combination of the AC TightRope and locking clavicle plate construct is used, greater fracture stability was achieved than with either alone, which could lead to increased fracture-healing rates as a result of greater construct strength and stiffness. Variations of this method, such as using suture anchors, would likely show similar advantages. Future clinical studies should report healing rates clinically. With unstable distal clavicle fractures, we recommend the TightRope as an alternative for augmentation of fixation.

Disclaimer

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