



Fixation of distal clavicle fractures with coracoclavicular instability: a comparative biomechanical study in human cadavers

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Background: The need for coracoclavicular (CC) stabilization in the fixation of fractures with CC instability (Neer type IIB and V) was biomechanically demonstrated by higher construct strength than isolated locking plate osteosynthesis. It was the purpose of this study to prove noninferiority of the new cow-hitch suture repair technique compared with the well-established suture tape double-button fixation with regard to overall fixation strength and cyclic loading properties.

Methods: Twelve human cadaver shoulders (7 right and 5 left) were matched for sex and age (mean age: 75 ± 5 years). An oblique parasagittal fracture line 20 mm medial to the acromioclavicular joint line was created, and the CC ligaments were dissected. Six shoulders were reconstructed by a double FiberTape fixation with two suture buttons (group DB), and the remaining six shoulders by a cow-hitch suture repair using a double FiberWire with only coracoid button fixation (group CH). Both reconstruction techniques were tested in a servo-hydraulic material testing machine for cyclic displacement (mm), stiffness (N/mm), and maximum load-to-failure (N) after 500 cycles at 3 mm/s and inferosuperior load between 15 and 70 N. Superior fragment displacement in space was recorded using a MicroScribe digitizer.

Results: There were no statistically significant differences regarding cyclic displacement (group DB: 0.7 mm; group CH: 1.3 mm; $P = .36$), stiffness (group DB: 177 N/mm; group CH: 116 N/mm; $P = .17$), maximum load-to-failure (group DB: 560 N; group CH: 492 N; $P = .59$), and superior displacement in space of the medial fragment (group DB: 3.2 mm; group CH: 1.6 mm; $P = .48$).

Conclusion: Fixation of unstable distal clavicle fractures using a double FiberWire cow-hitch suture repair with isolated coracoid button fixation for stand-alone CC stabilization resulted in similar biomechanical properties to a double-suture button fixation with FiberTapes while avoiding prominent clavicular implants.

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About 15% of all clavicle fractures affect the distal third of the clavicle.²¹ Of these, up to 50% go along with instability of the coracoclavicular (CC) ligament complex owing to rupture or avulsion—corresponding to Neer type IIB or V fractures, respectively.²⁰ Nonoperative treatment of these fractures leads to symptomatic nonunion in 44% of cases.^{23,27,28} Therefore, the relative proportion

of surgically treated unstable distal clavicle fractures is outpacing their overall increasing incidence.^{9,10}

Regarding the preferred type of fracture fixation, the current literature remains controversial as the complication rate for most procedures is high.^{3,23,29}

Clavicle hook plates are very popular owing to their easy applicability and good union rates.²² However, these implants usually need to be removed after bony healing and are not designed to address CC instability but allow CC ligament scarring by fracture reduction and buttressing of the hook under the acromial roof.⁴ Additional associated complications are acromial osteolysis or fracture, hardware dislocation, degenerative changes of the acromioclavicular (AC) joint, subacromial bursitis, and iatrogenic rotator cuff lesions.^{15,22,31,34}

The study was approved by the institutional review board (W 698) at Balgrist University Hospital, University of Zürich, prior to initiation of the study. A waiver of the Cantonal Ethics Committee was obtained (Req-2018-00588) before publication.

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Unlike AC joint dislocations, where the horizontal component of instability is often underestimated and must absolutely be considered during surgical stabilization, there is no need for horizontal stabilization in a distal clavicle fracture with rupture or avulsion of the CC ligaments but intact AC joint capsule.^{6,12,19} Indirect reduction with stand-alone CC screw fixation has been introduced in 1991.² Biomechanically, the importance of CC stabilization to control superior clavicle dislocation has been elucidated.²⁵ Although yet the preferred surgical technique has to be defined, any type of CC stabilization—either stand-alone or as supplement—outperforms isolated locking plate osteosynthesis by a 75 to 100% higher construct strength.^{16,32} Accordingly, isolated CC suture stabilization using coracoid bone anchors or suture button devices yielded union rates and clinical outcomes comparable with those with isolated and/or additional plate fixation.^{7,26,30,33} However, up to 29% of patients report clavicular button irritation, sometimes also requiring secondary implant removal.^{29,33}

In fixation of clavicle fractures, the prominence of implants on the clavicle is often problematic and requires secondary implant removal in up to 29% of cases owing to local irritation.³³ Even when deploying arthroscopic techniques, up to 15% of patients ask for secondary hardware removal.²⁹ The recently introduced cow-hitch fixation technique of distal clavicle fractures offers several clinical advantages, such as the absence of prominent hardware, suture slippage, and a sawing effect in combination with possible interfragmentary compression and distribution of compressive forces due to a larger contact area.^{13,24} The double-strand design of this knot has been shown to be up to three times stronger and significantly stiffer, holds the initially applied tension about a factor of 10 better, and yet has the smallest knot volume compared with conventional knots.¹⁸ In clinical practice, the cow-hitch knots are tied anteroinferiorly and the free suture ends are later used to close the deltoid interval with immersed knots. Owing to the hereby achieved soft-tissue coverage and the deltoid fascia countersunk suture knots below, local irritations can be avoided, as recently shown in a clinical case series.¹³ The purpose of this study is to investigate the biomechanical properties of two CC stabilization techniques. Overall fixation strength and cyclic loading properties of a cow-hitch suture repair with distal only button fixation were compared with those of a well-studied suture tape double-button fixation (Arthrex Dog Bone) in a human cadaver model.^{5,7,8,11,23,32}

The authors hypothesized that there will be no significant difference between the new cow-hitch suture repair technique compared with the well-established suture tape double-button fixation (noninferiority study).

Material and methods

This study was approved by the institutional review board and the local Ethics Committee (Req-2018-00588) before execution.

Specimen preparation

For this biomechanical study, twelve human cadaver shoulders (7 right and 5 left) were matched for sex and age (mean age: 75 ± 5 years) to respect bone mineral density as a possible confounder. All cadavers received a previous computed tomography (CT) scan to rule out fractures or other bone pathologies potentially compromising the specimen. Before testing and dissection, each specimen was thawed for 24 hours at room temperature. All adjacent soft tissue was then removed with exception of the AC and CC ligaments. The glenohumeral joint was disarticulated. All specimens were finally embedded in polymethylmethacrylate cement in an upright position, and the scapula was fixed to the base plate of the

testing machine. The medial end of the clavicle was rigidly secured in the sensor arm of the testing machine using a custom-made jig. After mounting the specimen onto the material-testing machine, an oblique parasagittal fracture line running 20 mm medial to the AC joint line and between the CC ligaments was created using an oscillating bone saw and the CC ligaments were dissected. Two superficial markings were placed close to the fracture line and were used as reference points for three-dimensional measurement of the fragment dislocation on both clavicle fragments.

Surgical techniques

Group DB (double FiberTape and Arthrex Dog Bone Button)

A clavicular 3.2-mm bone tunnel was drilled approximately 30 mm medial to the AC joint line and 10 mm medial to the future fracture line, pointing toward the coracoid base with aid of an aiming device.⁷ A second 3.2-mm drill hole was placed close to the coracoid base between the conoid and trapezoid ligament insertion. A titanium suture button device (Arthrex Dog Bone Button, Naples, Florida, USA) was preloaded with two FiberTapes, which were shuttled retrogradely through the transcoracoid-transclavicular bone tunnel. The FiberTapes were tied over the clavicular Dog Bone button with six alternating half hitches. Tensioning of the tape was performed under visual control, with the aim of anatomical alignment of the two fragments.

Group CH (double FiberWire and cow-hitch technique)

Two clavicular 2.5-mm bone tunnels were drilled in the shaft center of the clavicle approximately 30 and 45 mm medial to the AC joint line, pointing toward the coracoid base. Likewise, a coracoid 3.2-mm drill hole was placed close to the coracoid base. A suture button device (Arthrex Dog Bone Button, Naples, FL, USA) was previously loaded with two No. 5 FiberWire sutures and then placed inferiorly at the coracoid base. One suture limb of each suture was then shuttled through one respective drill tunnel in a loop configuration, and cow-hitch knots were tied (Fig. 1). A detailed instruction of this technique has been published recently¹³ (Suppl. 1). Both cow-hitch knots were secured by three alternating half hitches again under visual control of fracture reduction.

Biomechanical testing

A servo-hydraulic material testing machine (Zwick Z1456, ZwickRoell GmbH & Co. KG, Ulm, Germany), equipped with a 20-kN tension-compression load cell, was used. The specimen was oriented corresponding to the typical traumatic force vector from inferior to superior. After dissection and surgical fixation, the specimen was mounted to the material testing machine and the position of both fragments in space was registered using a three-dimensional digitizer (MicroScribe MX, Revware Inc., Raleigh, NC, USA). For all test runs, the position-controlled testing mode was used to determine fragment motion. To eliminate creep of the suture material, a preconditioning run was performed for 10 cycles at 25 N of load at 0.5 mm/s. The position of both fragments was then recorded using the MicroScribe digitizer, and their net displacement was calculated in relation to their position after preconditioning (Fig. 2). After preconditioning, the force measurement was zeroed. Cyclic testing was then performed with 500 cycles at a constant velocity of 3 mm/s and inferosuperior load between 15 and 70 N.¹⁷ After cyclic testing, fragment position in space was again registered using the MicroScribe digitizer. Finally, load-to-failure testing was conducted in superior direction at a velocity of 1 mm/s. Failure was defined as the first significant load decrease on the load-displacement diagram. The failure was video recorded, and the failure mode was documented. Stiffness (N/mm) of both

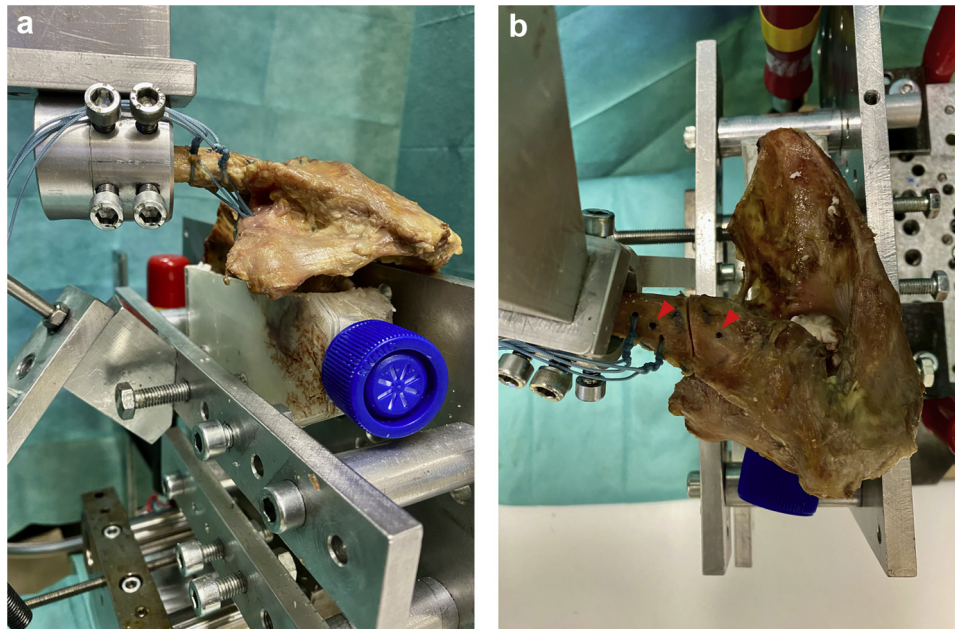


Figure 1 Frontal (a) and Top (b) view of the cow-hitch suture repair. The red arrowheads mark the scanning points for Microscribe measurements of 3-dimensional displacement.

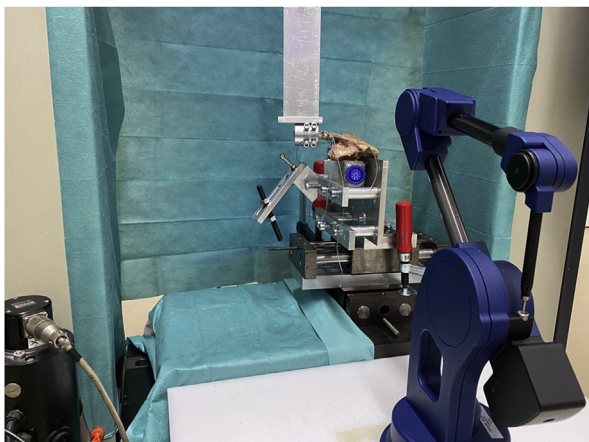


Figure 2 Biomechanical testing setup with 3-dimensional digitizer in front.

reconstruction techniques was calculated from the gradient of the linear portion of the load-displacement curve (40–80 N).

Statistical analysis

Statistical analysis was performed using Prism (version 8.4.2, GraphPad Software, San Diego, CA, USA). All data are reported as mean \pm standard deviation (SD). Displacement values were compared using unpaired t-tests with Holm-Sidak correction. Each value was analyzed individually, without assuming a consistent SD. The statistical significance level was set at $P < .05$.

Results

Owing to distorted, noninterpretable load-displacement curves, three consecutive specimens (2 DB and 1 CH) had to be excluded from cyclic displacement and stiffness calculations and were only considered for maximum load-to-failure analyses.

There were no statistically significant differences regarding cyclic displacement (group DB: 0.7 mm; group CH: 1.3 mm; $P = .36$), stiffness (group DB: 177 N/mm; group CH: 116 N/mm; $P = .17$), and maximum load-to-failure (group DB: 560 N; group CH: 492 N; $P = .59$) (Table 1). Also, no significant differences regarding superior-inferior displacement in space of the medial (group DB: 3.2 mm; group CH: 1.6 mm; $P = .48$) and lateral fragment (group DB: 2 mm; group CH: 0.3 mm; $P = .24$) was observed during cyclic loading. At ultimate construct failure, the overall displacement was 14.5 mm for group DB and 13.1 mm for group CH, respectively ($P = .82$) (Fig. 3).

The failure modes in group DB were 2 clavicle fractures, 2 medial clavicle fractures at the fixation site, and 2 coracoid fractures, one of these with transcoracoid button migration. In group CH, all but one specimen failed owing to coracoid fractures with implant migration and the remaining specimen fractured at the clavicular fixation site.

Discussion

In this biomechanical cadaver study, the cow-hitch suture repair using a double FiberWire with single coracoid button fixation for stand-alone CC stabilization in the context of unstable distal clavicle fractures resulted in similar construct properties as the well-established double button fixation technique with FiberTapes.

In comparison with previous studies, the reference fixation technique in the present study using two cortical suture buttons showed slightly superior values in terms of maximum pull-out strength and cyclic displacement.^{1,32} This also resulted in a comparably high construct stiffness. However, the opposed fixation technique using only a coracoid suture button also showed a comparably high construct strength.³² The present results are even more supported when considering the remarkably higher age of the cadavers compared with the literature and the presumably reduced bone density.^{1,32}

In this series, 75% of constructs failed owing to a fracture elsewhere than at the fixation site, underlining the construct strength of both techniques. The present failure pattern differs clearly from previous biomechanical studies with a higher incidence of fractures

Table 1
Summary of results (mean ± SD).

	Group DB	Group CH	P value
Cyclic displacement (mm)	0.7 ± 0.1	1.3 ± 1.3	.36
Stiffness (N/mm)	177 ± 75	116 ± 43	.17
Max. load-to-failure (N)	560 ± 199	492 ± 217	.59
Z-displacement of medial fragment (mm)	3.2 ± 4.6	1.6 ± 1.2	.48

SD, standard deviation.

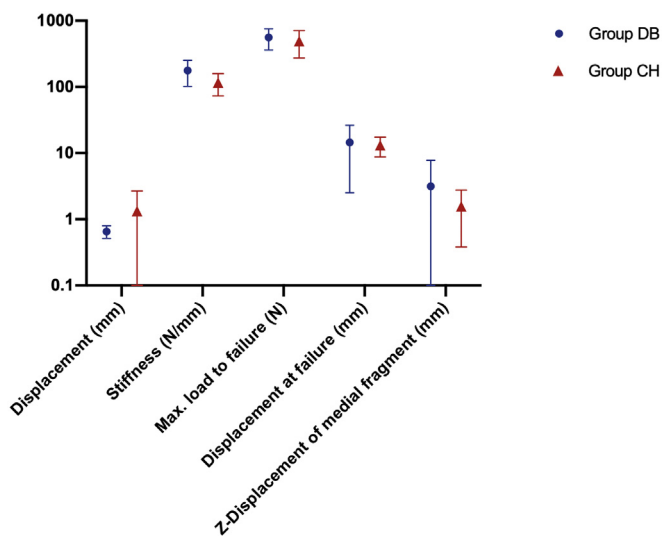


Figure 3 Diagram comparing the results of both treatment groups (mean ± SD). SD, standard deviation.

not related to potting or fixation to the sensor arm.³² In view of higher overall construct strengths despite the older age of the specimen in this study, it can be assumed that a stronger specimen fixation allowed for higher testing loads with the ultimate failure being more often fractures not related to the fixation site than in other studies.³² This reduces artifacts and facilitates biomechanical testing of the surgical reconstruction itself irrespective of the experimental setup.

Complementary to a clinical case series,¹³ the present study now also provides biomechanical evidence that the use of the occasionally irritating clavicular button is dispensable when using the cow-hitch suture technique and, thus, the number of secondary surgeries can be reduced in patients with distal clavicle fractures.

From a health economic view, suture button devices have shown better cost-effectiveness than hook or locking plate fixation for Neer type II distal clavicle fractures owing to both lesser implant costs and better effectiveness with a high uneventful healing rate of 96%.⁸ The implant costs of the cow-hitch fixation amount to 212 USD (1 Dog Bone Button at 174 USD, 2 FiberWire No. 5 sutures at 38 USD), thus being even less expensive than the DB technique with about 850 USD (1 Dog Bone kit at 669 USD, 1 additional FiberTape suture at 189 USD). Despite varying market prices and surgeon's preferences, the higher expenses of the DB technique—than plate fixation which is already cost-effective—need to be taken into consideration when choosing between two biomechanically equivalent techniques.

There are some limitations in this study. In this analysis with human cadavers, bone quality was poor according to clinical impression and consistent with age of the cadavers. Correspondingly, none of the samples showed a comminuted fracture pattern as failure mode. This limits the applicability of the results to the

usually younger and active patient population of these injuries. To improve the comparability of both groups, the specimens were matched by age and gender after fracture exclusion on CT scans.

In three consecutive test runs, the load-displacement curve showed a substantially different shape in comparison and could be used for maximum load-to-failure calculations only. Considering the total number of twelve cadavers, this is a significant dropout. However, the maximum load-to-failure analysis with all 12 cadavers also showed no significant difference, thus also demonstrating noninferiority of the cow-hitch suture repair. The results may be affected by the limited number of samples. However, mechanical complications are rare in clinical practice, so the possible differences would most likely be in the supraclinical range.

Compared with the original description,¹⁴ the cow-hitch technique was later modified by using a suture button to combat the risk of anchor pullout through a larger and cortical rather than cancellous implant-bone interface and avoid the risk of suture breakage at the anchor eyelet.⁶ In addition, fixation in this manner is assumed to be more independent of bone quality.

Different from the cow-hitch technique, the dog bone technique used a 3.2-mm drill hole owing to the difficulty of sliding two doubled and more voluminous suture tapes through the 2.5-mm drill hole. Moreover, insufficient tensioning of the suture tapes due to an overstuffed drill hole with potentially reduced stiffness as a result had to be avoided.

Furthermore, a double clavicle tunnel technique in the CH group was opposed to a single clavicle tunnel technique in the DB group. The use of multiple drill holes brings up the concern of weakening the clavicle. However, thinner drill holes with a distance of about 15 mm were chosen in the double tunnel technique. In the present study, no construct with the CH technique showed a clavicle fracture outside the fixation site. In contrast, in the DB group with one 3.2-mm drill hole, two specimens failed at the clavicle independently of the fixation site. This indicates a possible advantage of load distribution due to a longer working length at the clavicular fixation using the CH technique. However, the spacing between the two drill holes was chosen based on the anatomy of the CC ligaments and has not been studied biomechanically so far.

This study tested Neer type IIB distal clavicle fractures with complete dissection of the CC ligaments. Thus, the created fractures correspond functionally to the second most common unstable fractures with bony avulsion of the CC ligamentous complex (Neer type V). In these fractures, the cow-hitch configuration is assumed to be particularly beneficial owing to its interfragmentary compression which promotes anatomical healing of the injury. In this context, the biomechanical properties of the cow-hitch repair remain to be investigated.

However, the semicircumferential loop configuration could also be a disadvantage of the cow-hitch technique, as it potentially compromises periosteal perfusion at the fracture site. On the other hand, the comminuted fracture zone at the distal clavicle is not necessarily exposed and the fracture hematoma may be preserved in favor of fracture healing.

Conclusion

Fixation of unstable distal clavicle fractures using a double FiberWire cow-hitch suture repair with single coracoid button fixation for stand-alone CC stabilization resulted in similar biomechanical properties as a double suture button fixation with FiberTapes while avoiding prominent clavicular implants. Therefore, the cost-effective cow-hitch technique has become the treatment of choice in our institution for distal clavicle fractures with CC instability.

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Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jseint.2021.08.003>.

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