



Biomechanical testing of three coracoclavicular ligament reconstruction techniques with a 3D printing navigation template for clavicle-coracoid drilling

Ji Qi^{1,2,3,4#^}, Shijie Fu^{5,6,7,8#}, Ruiyue Ping^{1,3#^}, Kai Wu^{9#}, Ziyu Feng¹⁰, Yanxiao Xu¹¹, Xiaoguang Guo⁵, Dingkun Lin^{1,3}, Lei Zhang^{5,6,7,8^}

¹Department of Orthopaedics, Guangdong Provincial Hospital of Chinese Medicine, Guangzhou, China; ²Wang Jing Hospital of China Academy of Chinese Medical Sciences, Beijing, China; ³The Second Clinical College of Guangzhou University of Chinese Medicine, Guangzhou, China; ⁴Postdoctoral Research Station, Guangdong Provincial Hospital of Chinese Medicine, Guangzhou, China; ⁵Department of Orthopaedics, Affiliated Traditional Chinese Medicine Hospital of Southwest Medical University, Luzhou, China; ⁶Center for Orthopaedic Diseases Research, Affiliated Traditional Chinese Medicine Hospital of Southwest Medical University, Luzhou, China; ⁷Clinical Base of Affiliated Traditional Chinese Medicine Hospital of Southwest Medical University, Guangdong Province Medical 3D Printing Application Transformation Engineering Technology Research Center, Luzhou, China; ⁸Expert Workstation in Luzhou, Luzhou, China; ⁹The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, China; ¹⁰Southern Medical University, Guangzhou, China; ¹¹Suzhou Yongding Hospital, Suzhou, China

Contributions: (I) Conception and design: J Qi, S Fu, R Ping, K Wu, D Lin, L Zhang; (II) Administrative support: D Lin, L Zhang; (III) Provision of study materials or patients: Z Feng, Y Xu, X Guo; (IV) Collection and assembly of data: J Qi, S Fu, R Ping, K Wu, Y Xu, X Guo; (V) Data analysis and interpretation: Z Feng, X Guo; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Dingkun Lin. Professor, Department of Orthopaedics, Guangdong Provincial Hospital of Chinese Medicine, No. 111 Dade Road, Yuexiu District, Guangzhou, China. Email: lindingkun@126.com; Lei Zhang, PhD. Department of Orthopaedics, Affiliated Traditional Chinese Medicine Hospital of Southwest Medical University, No. 182 Chunhui Road, Longmatan District, Luzhou, China. Email: zhanglei870722@126.com.

Background: The identification and precise clavicle-coracoid drilling during coracoclavicular (CC) ligament reconstruction for acromioclavicular (AC) joint dislocation require a high level of experience and surgical skills. Furthermore, the improvement of flexible fixation, such as Endobutton techniques for CC ligament reconstructions is ongoing. We have developed a 3D printing technique navigation template for clavicle-coracoid drilling and a novel implant for the reconstruction. This study aimed to determine the efficiency of the navigation template for clavicle-coracoid drilling and to evaluate the biomechanical performance of the novel CC ligament reconstruction technique.

Methods: A total of 24 fresh-frozen human cadaveric shoulders were randomly assigned to 1 of 3 reconstruction groups or a control group: TightRope, Triple Endobutton, and the Adjustable Closed-Loop Double Endobutton technique. Computed tomography scans, navigation template designs, and 3D printing were performed for the shoulders. Then, AC joint dislocation was simulated in the reconstruction groups, and 3 CC ligament reconstruction techniques were operated via the 3D printing template separately. Furthermore, biomechanical protocols including the translation test (load from 5 to 70 N) and the load-to-failure test were performed to characterize the behaviors and strengths. One-way ANOVA test analyzed differences in displacement under the translation load and the load at failure.

Results: CC ligament reconstructions were performed successfully along with the 3D printing navigation template in the 3 reconstruction groups. During the translation test, no significant difference was found in displacements among the 4 groups. Meanwhile, the mean load of all reconstruction groups at failure (Adjustable Closed-Loop Double Endobutton, 722.1620 N; TightRope, 680.4020 N; Triple Endobutton,

[^] ORCID: Ji Qi, 0000-0002-2267-532X; Ruiyue Ping, 0000-0002-9528-9251; Lei Zhang, 0000-0002-7834-4693.

868.5762 N) was significantly larger than the control group (564.6264 N, $P < 0.05$). The Triple Endobutton group had the maximum load at failure ($P < 0.05$), however, no significant difference was noticed between the other 2 reconstruction groups ($P > 0.05$).

Conclusions: The 3D printing navigation template may become helpful and reliable for AC joint dislocation surgery. Among the 3 CC ligament reconstruction techniques, the Triple Endobutton technique has the best strength in terms of biomechanics, while the biomechanical strength of the Adjustable Closed-Loop Double Endobutton technique is reliable in comparison with the TightRope technique.

Keywords: Acromioclavicular joint dislocation; coracoclavicular ligament reconstruction; 3D printing; Endobutton; biomechanics

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Introduction

Acromioclavicular (AC) joint dislocation is a common injury occurring in the shoulder. In the condition of Rockwood type IV-VI AC joint dislocation, the coracoclavicular (CC) and AC ligaments are completely torn, and patients may suffer from considerable pain and shoulder dysfunction, requiring reconstruction (1-3). There are over 60 types of techniques for treating AC joint dislocations (4), and implant choice for fixation is one of the most critical management controversies. Rigid fixations in the form of pins, CC screws and hook plate were first developed and are still widely applied in general AC surgeries (5-7), due to their relatively convenient surgical procedures and biomechanical strength. However, such fixations require a second removal procedure, and potential complications may occur, including pain, excessive surgical injuries, osteolysis, and subacromial impingement syndrome (8-11). With the rapid development of sports medicine, clinical evidence has demonstrated that surgical reconstruction by flexible fixation seems to provide a better quality of life for postoperative patients with AC injury (12). Nowadays, it is gradually accepted that the ideal surgical treatment for AC joint dislocation should not only restore its static anatomy, but also flexible fixations (13). Since the CC ligament plays a vital role in the physiological function of the AC joint, CC ligament reconstruction has been considered as a practical choice to provide flexible fixation.

The Endobutton technique has become common in CC ligament reconstruction. The primary purpose of this procedure is to achieve flexible fixation with fewer surgical injuries. By applying 2 or 3 titanium-alloy buttons connected by a polyester loop within the distal clavicle and coracoid

process, the distance of the CC interval is narrowed, allowing self-restoration of CC ligaments (14). In pursuit of minimal invasiveness and suitable implants, this procedure can also be operated under arthroscopy. Therefore, the technique has gained preference in AC joint repairing surgery (2,15). However, it cannot be ignored that the accuracy of clavicle-coracoid tunnel drilling is of great importance for reconstruction success. To date, it is still one of the difficulties in treating severe injury, especially for inexperienced surgeons. The three-dimensional (3D) printing technique has been popular in surgery (16-19). It may overcome many of the limitations of two-dimensional imaging by generating a graspable 3D object, and offers better pre-operative planning and accurate navigation during surgery. However, its application in clavicle-coracoid drilling is rare.

Numerous Endobutton techniques such as TightRope (TR) and Triple Endobutton (TE) have been reported in the treatment of AC joint dislocation (20-23). The TE technique exhibited stronger fixation but a more complex surgical process and more significant cost (22,23). The TR technique is easier to perform with less time and cost (20). However, both open-loop design techniques require knotting to achieve the suitable length of the loop, and the reconstructions are prone to failure due to suture breakage. In order to simplify surgical procedures and reduce complications, the closed-loop Endobutton technique has been previously attempted (24).

Meanwhile, the difficulty in adjusting the length of loops has raised more concern. Then, our research team designed another novel modification, namely the Adjustable Closed-Loop Double Endobutton technique (ACLDE). Conveniently, the length of the continuous closed-loop

could be adjusted by screw rotation above the superior plate without the knotting procedure (25). As one kind of modified technique, the biomechanical performance of ACLDE technique is of vital importance for clinical application in the future. Since the design is similar to the TR and TE techniques and aims to replace the techniques, it is essential to determine whether the ACLDE technique has sufficient biomechanical strength than the other 2 kinds of flexible fixations.

Therefore, this study aimed to design a 3D printing navigation template to assist accurate clavicle-coracoid drilling during reconstructive surgery. Moreover, via biomechanical tests on cadaveric specimens, the biomechanical performance of ACLDE was evaluated compared to the TR and TE techniques.

We present the following article in accordance with the MDAR reporting checklist (available at <https://dx.doi.org/10.21037/atm-21-737>).

Methods

Ethics statement

All procedures performed in this study involving human participants were following the Declaration of Helsinki (as revised in 2013). The procedures were approved by the Medical Ethics Review Board of Affiliated Traditional Chinese Medicine Hospital of Southwest Medical University (No. KY2018032). Written informed consent was obtained from all donors and preserved by the Department of Anatomy, Southern Medical University.

Specimens and grouping

This study used 24 fresh-frozen shoulder specimens with native clavicle and scapula from deceased donors. Specimens with obvious deformities or fractures were excluded. A total of 8 female and 16 male donors had a mean age of 43 years (range, 28–60 years). All cadavers were provided by the Department of Anatomy, Southern Medical University, which abides by the local rules of ethics. All specimens were randomly divided into 4 groups: the ACLDE group (n=6), the TR group (n=6), the TE group (n=6), and the control group (n=6).

Design and 3D printing of the navigation template

Before reconstruction, a thin-slice computed tomography

(CT) scan (Siemens 64-slice spiral CT) was performed for each specimen. The slice thickness was 0.6 mm, in order to ensure the accuracy of 3D reconstructions. The scan results were saved as data imaging and communications in medicine (DICOM) format files. Then, the navigation template was designed via the MedCAD/cylinder order in Geomagic Studio 2017 (Geomagic, Inc., Cary, North Carolina, USA) and Mimics 21.0 (Materialise, Belgium), following previously reported methods (18,26,27). Firstly, CT data were imported, and the threshold was set to 226–1,688 HU. After separation of bone tissue via the thresholding tool, the 3D models of the AC joint with intact clavicle and scapula were reconstructed via the Calculate 3D tool. 3D models were exported as Standard Triangulation Language (STL) format files. Secondly, cutting bone plane was performed on the 3D models to obtain a 5-mm-thick card template fit for the morphology of upper edge of the distal clavicle. Thirdly, the virtual bone tunnels of reconstruction surgery were copied on the models. For the ACLDE and TR groups, one tunnel was drawn from the distal clavicle to the basal part of the coracoid process.

In contrast, for the TE group, the same tunnel and another lateral tunnel were drawn. Each tunnel was set with a 2.75-mm radius column and a 1.5-mm radius inside the channel. Next, Boolean operations (card template + tunnel support column) - (tunnel channel) were implemented to obtain the navigation template (*Figure 1*).

The final navigation template was output to Makerware via an STL file, and the real-size template was printed by a 3D printing machine (Replicator 2, Makerbot Industries, US). The printer used polylactic acid (PLA), a type of thermoplastic polyester, to extrude the plastic on a build platform where it solidifies. The standard settings were as follows: extruder temperature 215 °C, chamber temperature 24 °C, primary layer height 0.2 mm, infill 2%, support infill 20%, and maximum overhang without support 60%. The printed navigation plate was well-positioned and fixed on the prepared specimen, to assist the clavicle-coracoid drilling (*Figure 2*).

Specimen preparation and surgical procedures

Each specimen was thawed at room temperature for 24 hours and free from soft tissue by dissection. The AC joint, CC ligaments, and bony architecture of the scapula and clavicle were left intact. Furthermore, the specimen was confirmed to be free of previous fractures or injuries, and the initial distance of the CC interval was recorded for

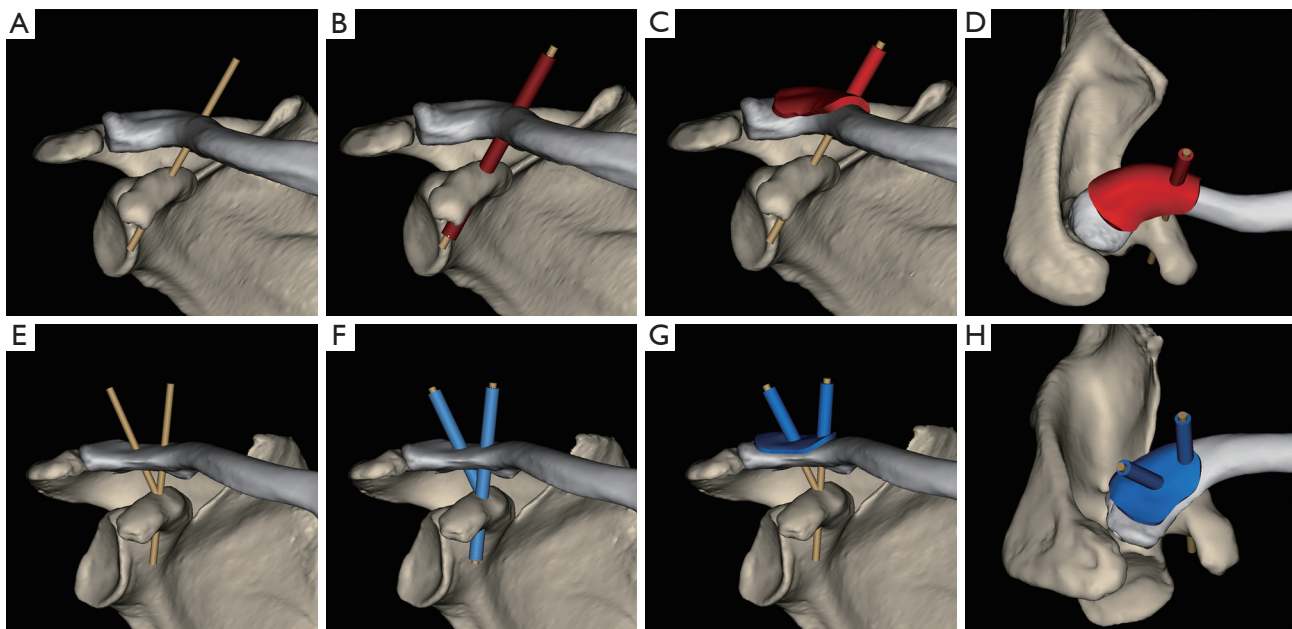


Figure 1 Digital design of the 3D printing navigation template for clavicle-coracoid drilling. (A) A tunnel (1.5 mm in radius) passing through the center of the distal clavicle (3.5 cm inside the distal) and the center of the basal part of the coracoid process; (B) column (2.75 mm in radius) connecting the clavicle and coracoid; (C,D) a 5-mm-thick card template fit for the morphology of the upper edge of the distal clavicle and one-tunnel navigation; (E) double tunnels (1.5 mm in radius) originating from the center of the distal clavicle (2.5 and 3.5 cm inside the distal separately) up to the center of the basal part of the coracoid process; (F) double columns (2.75 mm in radius) connecting the clavicle and coracoid; (G,H) a 5-mm-thick card template fit for the morphology of the upper edge of the distal clavicle and double-tunnel navigation.

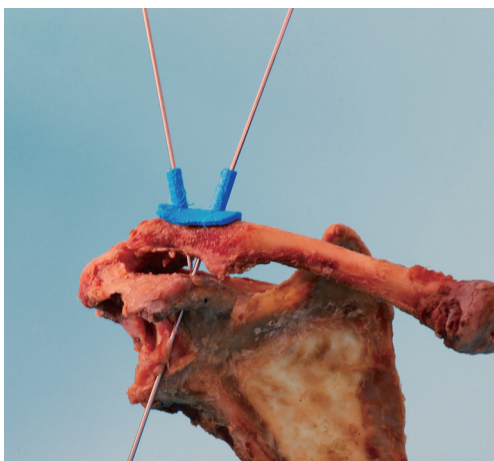


Figure 2 Clavicle-coracoid drilling via the 3D printing navigation template.

reproduction in the subsequent reconstruction. Following previously described methods (28), the AC ligaments and CC ligaments were transected to simulate a complete AC joint dislocation in the ACLDE, TR, and TE groups, and then reconstructed with the 3 techniques separately. The same surgeon performed the procedures.

The ACLDE device consists of one piece of Endobutton titanium-alloy plate, another modified button titanium-alloy plate, and a polyester loop connected together (Delta Medical, Beijing, China; approval by State Intellectual Property Office of the People's Republic of China, CN209122408U). The materials of plates and loop were the same as TR and TE (Figure 3). In the ACLDE group, after the navigation template was well-positioned and fixed, a Kirschner wire (K-wire, ϕ 1.5 mm) was inserted into the

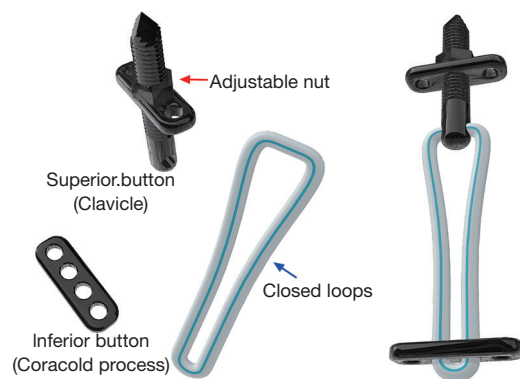


Figure 3 The Adjustable Closed-Loop Double Endobutton (ACLDE) technique. With the closed polyester loop (blue arrow), the titanium-alloy button plates are connected together. Lengthening and shortening of the loop can be performed by nut rotation (red arrow) above the superior plate.

template, drilling from the clavicle to the coracoid process under navigation. Then, the navigation template was pulled out, and the K-wire was fixed as the guide, followed by the second drilling through a hollow drill (\varnothing 4.0 mm). Next, via lead sutures, the implant was inserted into the tunnel, from the clavicle to the coracoid process. After the inferior sub-coracoid button was flipped, another plate was left above the clavicle. Finally, the length of the loop was adjusted to fix the joint, by twisting the nut on the superior plate (*Figure 4A,B,C*).

In the TR group, after CC drilling like the ACLDE group, the reconstruction by the single-bundle TR system (Arthrex GmbH, Munich, Germany) was performed as previously described (29) (*Figure 4D,E,F*). In the TE group, double bone tunnels needed to be drilled in priority under a specific navigation template, and then the TE system (Arthrex GmbH, Munich, Germany) was inserted as previously described (22,23) (*Figure 4G,H,I*).

Biomechanical protocol

All biomechanical tests were routinely conducted using the Servo-hydraulic Material Testing System (MTS) and the Win Test Digital Control System (Bose Electro Force 3520-AT; Bose, MN, USA). Throughout all phases of preparation and testing, the specimens were tested at room temperature, and kept moist with 0.9% saline

solution. To evaluate the stability of the primary and reconstructed joints, the translation test was performed in anterior, lateral and superior directions (28). The reference position of the translation test was the acromion adjacent to the AC joint. Firstly, all specimens were conditioned for 10 cycles to 20N in anterior, lateral and superior testing to eliminate the creep phenomenon. The translation test (load from 5 N to 70 N) was applied at a rate of 10 N/s, following the previous method (30). The specimens were then loaded to 70 N in anterior, lateral, and superior directions, separately (*Figure 5*). To evaluate the stiffness, the displacements (5 N, 20 N, 40 N, 60 N) measured by the system were compared among the 4 groups, with an accuracy of 0.0001 mm.

Finally, all specimens were loaded to failure in the superior direction at a constant distraction rate of 1 mm/s to assess the maximal tensile loading capacity and the displacement to failure of each group (*Figure 5*). In addition, no less than a 2-minute interval was maintained before each loading test. Each specimen was preloaded to tighten every laxity in the system and to stretch the construct to a uniform load before measurements began. No specimen was used twice. Thus, each specimen that was reconstructed once was loaded to failure. Failure was defined as rupture of the CC ligament, internal fixation failure, or avulsion fracture (30). Ultimate load at the time of construct failure was record, and the failure mode was visually analyzed. The MTS frame has an accuracy of 0.1%, so the displacement rate of all tests was consistent.

Statistical analysis

Data were presented as mean and standard deviation (SD). Normal distribution within each group was tested with the Kolmogorov-Smirnov test. For the detection of differences among the 4 groups regarding the displacement under translation load and the ultimate load at failure, one-way ANOVA with Bonferroni post hoc multiple comparisons were used. Analysis was performed by SPSS software (version 20, IBM Corp). A power analysis (a value of 0.05 and power of 0.80), based on the estimated load at failure from pilot data and the previous study, showed that a minimum of 6 specimens was required for testing. All statistical tests were two-sided, and the level of statistical significance was set at two-sided $P < 0.05$.

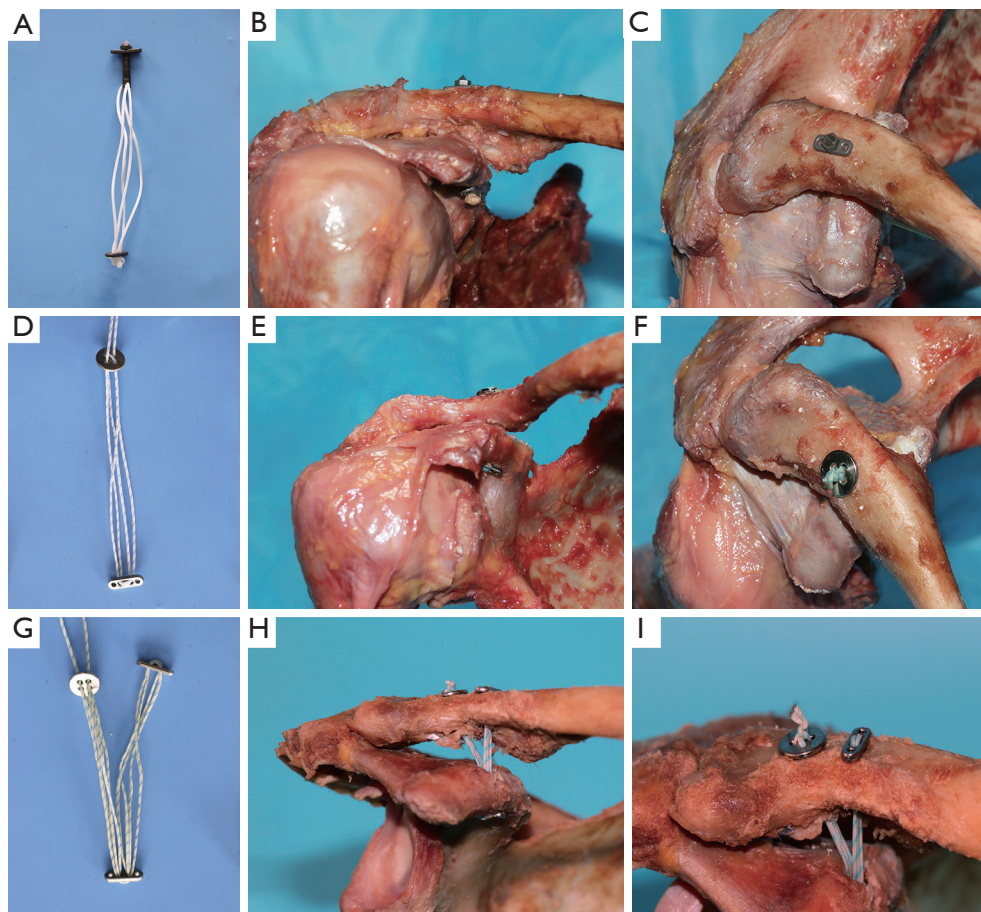


Figure 4 Three coracoclavicular (CC) ligament reconstruction techniques. (A) The Adjustable Closed-Loop Double Endobutton (ACLDE) device; (B) anterior view of the reconstructed acromioclavicular (AC) joint with ACLDE; (C) superior view of the reconstructed AC joint with ACLDE; (D) the TightRope (TR) device; (E) anterior view of the reconstructed AC joint with TR; (F) superior view of the reconstructed AC joint with TR; (G) the Triple Endobutton (TE) device; (H) anterior view of the reconstructed AC joint with TE; (I) superior view of the reconstructed AC joint with TE.

Results

Clavicle-coracoid drilling

A total of 24 templates were made via 3D printing. In 3 reconstruction groups, bone tunnels were drilled successfully through the specially printed templates as previously designed, without any fracture during the drilling procedure.

Translation test

In the displacements following the anterior, lateral, and superior directions, no significant difference was found among the 4 groups, under the load of 5, 20, 40 and 60 N,

respectively ($P > 0.05$; *Table 1*).

Load-to-failure test

In the TR group, failure occurred with loop rupture in 2 specimens, clavicle tunnel fracture in 1 specimen, and coracoid process fracture in 3 specimens. In the ACLDE group, failure occurred with loop rupture in 2 specimens, and coracoid process fracture in 4 specimens. In the TE group, failure occurred with coracoid process fracture in 5 specimens, and scapula fracture in 1 specimen.

There was a significant difference in the ultimate load at failure among the 4 groups ($F = 13.850$, $P = 0.00004$; *Table 2*). The maximum load was found in the TR group ($P = 0.006$

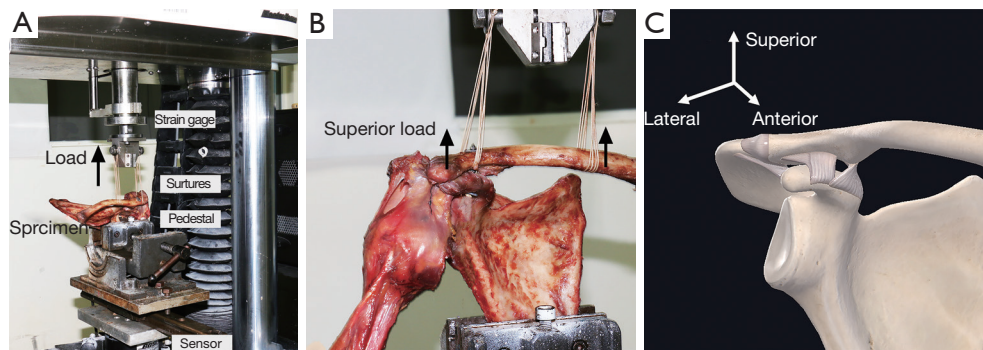


Figure 5 Biomechanical protocols. (A) Tests were conducted using the Bose Electro Force 3520-AT Material Testing System (MTS); (B) load-to-failure: the clavicle was hung by 2 pieces of equidistant ETHIBOND Excel Polyester Sutures (Ethicon, LLC, USA), and the scapular was fixed at the pedestal of MTS at the same time; then, superior load was gradually applied on the specimens until failure; (C) a diagram of the translation test of the acromioclavicular joint in 3 directions (anterior, superior, and lateral), and the load was controlled as no more than 70N.

Table 1 Difference in anterior, lateral and superior displacement of acromioclavicular joint under translation test among four groups (mean \pm standard deviation)

Direction	Load	Displacement (mm)				F	P
		ACLDE	TR	TE	control		
Anterior	5 N	0.1799 \pm 0.1804	0.0883 \pm 0.0522	0.2565 \pm 0.2431	0.2930 \pm 0.2676	1.188	0.339**
	20 N	0.8067 \pm 0.6437	0.6053 \pm 0.4512	0.9733 \pm 0.6834	1.1681 \pm 0.8261	0.780	0.519**
	40 N	1.5922 \pm 0.8813	1.8906 \pm 1.7496	2.1057 \pm 1.0672	2.9387 \pm 1.7743	0.986	0.419**
	60 N	2.3531 \pm 1.0898	2.9606 \pm 2.4038	3.3694 \pm 1.2331	5.6786 \pm 3.4866	2.456	0.093**
Lateral	5 N	0.5710 \pm 0.4267	0.6453 \pm 0.9737	0.1369 \pm 0.0564	0.6232 \pm 0.9597	0.674	0.578**
	20 N	1.8690 \pm 1.3491	1.4520 \pm 1.9341	0.7612 \pm 0.3573	1.7640 \pm 1.7654	0.680	0.575**
	40 N	3.0670 \pm 1.8890	2.3671 \pm 2.4020	1.6780 \pm 0.7518	3.1289 \pm 2.0161	0.799	0.509**
	60 N	4.0685 \pm 2.0360	3.1734 \pm 2.6271	2.6202 \pm 1.0154	4.5440 \pm 1.9488	1.077	0.381**
Superior	5 N	0.0893 \pm 0.0336	0.1639 \pm 0.2741	0.0895 \pm 0.0496	0.2626 \pm 0.2456	1.163	0.348**
	20 N	0.4320 \pm 0.1228	0.5912 \pm 0.5592	0.3611 \pm 0.1333	0.8480 \pm 0.4907	1.908	0.161**
	40 N	0.9250 \pm 0.2280	1.1517 \pm 0.6777	0.7613 \pm 0.2391	1.4629 \pm 0.6168	2.338	0.104**
	60 N	1.4641 \pm 0.4160	1.7420 \pm 0.7443	1.2115 \pm 0.3287	2.0480 \pm 0.7104	2.324	0.106**

**P>0.05. ACLDE, Adjustable Closed-Loop Double Endobutton; TR, TightRope; TE, Triple Endobutton.

vs. ACLDE group; P=0.001 *vs.* TR group; P=0.000003 *vs.* control group), while the minimum load in the control group (P=0.004 *vs.* ACLDE group; P=0.025 *vs.* TR group; P=0.000003 *vs.* TE group). However, no significant difference was observed comparing the ACLDE and TR groups (P=0.392).

Discussion

The main advantage of CC reconstruction with Endobutton techniques is achieving flexible fixation, and decreasing the surgical trauma as far as possible. Moreover, the techniques can not only be operated with an open approach, but

Table 2 Ultimate load (N) at failure of each group

Trial	ACLDE	TR	TE	Control
1	824.5644	740.2265	829.0353	543.1532
2	665.3798	517.5176	820.5664	566.0421
3	834.2998	732.9020	918.0731	456.6088
4	733.8176	830.8664	920.3620	568.3310
5	609.3020	643.1532	814.5031	627.1554
6	665.6086	617.7465	908.9175	626.4678
Mean \pm SD	722.1620 \pm 92.0401 ^{a,c}	680.4020 \pm 110.2899 ^{a,c}	868.5762 \pm 52.0605 ^{a,b}	564.6264 \pm 63.0537

^aP<0.05 vs. Control group; ^bP<0.05 vs. TR group; ^cP<0.05 vs. TE group. ACLDE, Adjustable Closed-Loop Double Endobutton; TR, TightRope; TE, Triple Endobutton.

also under arthroscopy. Under the limited surgical view, the difficulty of accurate clavicle-coracoid drilling would increase. Also, the fracture of the clavicle or coracoid process along with the inaccurate drilling tunnel may raise concerns. To date, the application of 3D printing technology in the clinical treatment of AC joint injuries has been rare. Whether it may improve the accuracy of drilling and simply the operation remains unknown. In this study, the special 3D printing navigation template was attempted. Finally, the results revealed that the actual tunnel was accurate as with the former digital design, and the CC ligament reconstructions were performed successfully along with the drilling tunnel in the 3 groups. In addition, the size of the template was suitable for arthroscopic surgery. The important finding indicates that 3D printing navigation template may be helpful in the future treatment of AC joint dislocations. However, for high-grade AC dislocation, it would be difficult to design the drilling navigation template before surgery. Aiming to solve this problem, we suggested designing the navigation template based on the uninjured side of the anatomical structure.

Of the 3 CC ligament reconstruction techniques used in this study, both the TR and TE techniques have been applied in the clinical treatment of AC dislocation for several years. Such techniques are gaining importance to ensure a lower risk of stiffness, infection, soft tissue morbidity and hardware irritation in postoperative management (31). Numerous biomechanical studies in recent years have found that double-bundle reconstructions such as the TE technique seems to have the advantage of restoring natural biomechanics as far as possible (4,23). Yet, relatively difficult surgical procedures, long operation time, and the higher cost limit more widespread use of the implant. Therefore, TR

and other single-bundle reconstructions are well accepted in the clinic. In recent years, numerous biomechanical and clinical studies have accelerated the development of single-bundle reconstructive techniques that are applied to stabilize the AC joint with fewer steps, lower surgical trauma, and more adjustable functions to meet the needs of different patients. The ACLDE device was one of the modified single-bundle devices created by several surgeons. The device's overall design is similar to TR, and the main modification was the adjustable and continuous closed-loop connected with double button plates. When it is fixed on the injured AC joint, the length of the closed-loop can be easily adjusted to meet different needs in a surgical operation via a rotatory screw nut above the superior button plate rather than knotted way. In this way, the implant would increase the convenience of the operation. However, to realize the clinical translation of this technique, biomechanical tests are essential to determine whether the ACLDE system has sufficient biomechanical strength compared with other flexible fixations.

The AC joint has a multidimensional flexible stabilization which is vital to its functioning (32). Considering such biomechanical characteristics, it seemed to be difficult to evaluate the biomechanical behavior of the primary AC joint and reconstructed joint. Previously, tests under the superior-inferior and anterior-posterior dimensional loads were often the focus (28,29), while lateral-medial displacement in the translation test has been rarely investigated. Therefore, this experiment aimed to analyze the displacements under corresponding loads in all 3 dimensions first. During the translation test, to determine the stabilization of internal fixation in the 3 dimensions, the loads were performed on the specimens with no more than 70N according to former

reported methods (22,30). Oki *et al.* (33) demonstrated that simple abduction of the arm transmitted large axial force, which was up to 34 N across the AC joint. Previous studies demonstrated that up to 70 N loading on the specimens was able to simulate the physiological mechanical behavior of the AC joint, and did not affect results during loading in other directions (30). Through the translation test, this study revealed no statistically significant differences in the translation of the AC joint at 70 N in the superior, anterior, and lateral directions among the ACLDE, TR, TE reconstructions and the intact state. Therefore, it can be demonstrated that the reconstructed AC joint with ACLDE, TR, and TE devices was similar in terms of biomechanical behavior under physiological load. In addition, the 3 types of reconstructions showed similar translation behavior as the control group with an intact AC joint.

Although flexible stabilization of the AC joint was multidimensional, AC joint dislocation occurred mostly in the superior dimension, showing the sticking up distal clavicle on the injured side (30). As a result, this experiment further performed load-to-failure tests in the superior direction, to determine the ultimate strengths of the 3 types of reconstructions and the intact joint. Previously, it has been confirmed that the normal AC joint with native CC ligaments can withstand superior tensile forces up to 500 N (34). In this study, the results of load-to-failure tests revealed that the mean load at failure of the native AC joint was 564.6264 N, which was in agreement with relevant findings. In contrast, the mean failure load of the AC joint reconstructed by the ACLDE, TR, and TE devices was 722.1620 N, 680.4020 N and 868.5762 N, respectively. These results demonstrated 2 key findings. Firstly, among the 3 reconstructions, the ultimate load of the TE group was significantly higher than the others, indicating that the double-bundle reconstruction would be stronger in ultimate biomechanics than single-bundle reconstruction. In other words, for AC joint dislocation, in comparison with ACLDE and TR devices, CC ligament reconstruction with TE may have lower risk of re-dislocation. Secondly, the study was also aimed at evaluating the ultimate strength of such modified devices as the ACLDE. The results indicated that the superior-inferior biomechanical strength of the ACLDE was better than the normal AC joint. The biomechanical data proved that CC ligament reconstruction with ACLDE technique was reliable in strength.

Moreover, the biomechanical strength was no less than other single-bundle reconstructive devices such as the TR. That is, when single-bundle CC ligament

reconstruction for AC joint dislocation was operated in clinical practice, both the ACLDE and TR techniques were practical choices. Because of the simple operating process of ACLDE without knotting, based on the findings, the study suggests the preferential application of the ACLDE technique. Altogether, the above findings provided basic data of ACLDE devices in biomechanics, suggesting that it would be helpful for clinical application. However, the long-term clinical efficiency and complications remain to be investigated in the future.

Apart from the biomechanical performance, the reasons for the failure of flexible fixations have raised far more concerns. Multiple reasons may induce failure after AC joint reconstruction in clinical practice, such as loop rupture and drill-hole fracture, among others. In biomechanical testing, the failure mode is of high importance for evaluating the performance of a reconstructive technique or device. Thus, it was also recorded in this study. In the ACLDE, TR and TE groups, it was found that the most common mode of failure was a fracture that occurred in the coracoid process, most likely indicating that the relatively vulnerable part of the reconstructions and stress concentration were located on the site of the drilling hole and the inferior sub-coracoid button.

However, there still exist some limitations in this study. Firstly, due to the lack of funding and the limitation of objective conditions, the fresh-frozen shoulder specimens were not all paired, and individual differences might have caused bias in the final results. Secondly, the bone density of relevant cadaveric AC joint structures was undetermined in the study, which leaves room for further improvement of the load-to-failure test. Thirdly, this biomechanical study on cadaveric material could not account for progressive healing of the ligaments. Therefore, it cannot be ignored that the differences among the 4 groups in the study might be less significant *in vivo*. Fourthly, the study was aimed to determine the strength of the normal and reconstructed joint, but the elasticity was relatively ignored. Lastly, no cycling load was performed to determine the strength of reconstructions, and more biomechanical tests need to be performed in further studies, to characterize more mechanical behaviors of the constructive techniques and implants. Furthermore, the small sample size in this study limits the ability to draw firm conclusions, and these preliminary results will need to be validated in larger studies.

Conclusions

For the treatment of AC joint dislocation, a 3D printing

navigation template may be helpful to improve the accuracy of clavicle–coracoid drilling and reduce the difficulty of operations. Moreover, CC ligament reconstruction with the ACLDE, TR, and TE devices have similar biomechanical behaviors as the intact joint under physiological translation load. Among the 3 types of reconstructions, the strength of the TE device was superior to the ACLDE and TR devices in terms of biomechanics. Despite this, the biomechanical strength of the ACLDE device was no less than that of the TR device and the normal joint. Therefore, from a biomechanical perspective, the ACLDE device may become a valid alternative in the clinical treatment of AC joint dislocation. Furthermore, modification of the technique remains to be performed focusing on the inferior sub-coracoid button and bone tunnel site.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study involving human participants were following the Declaration of Helsinki (as revised in 2013). The Medical Ethics Review Board of Affiliated Traditional Chinese Medicine Hospital of Southwest Medical University approved this study (No. KY2018032). Written informed consent was obtained from all donors and preserved by the Department of Anatomy, Southern Medical University.

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