

# Reconstruction

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# Reconstruction Alone Versus Hardware-Augmented Reconstruction in Chronic High-Grade AC Joint Dislocation: A Systematic Review of Treatment Outcomes

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## Abstract

**Background** Acromioclavicular joint dislocation is a common shoulder injury, with chronic high-grade cases often requiring surgical intervention to restore stability. While reconstruction techniques are the standard approach for managing chronic dislocations, the role of hardware augmentation remains controversial. This systematic review compares the clinical outcomes of reconstruction alone versus hardware-augmented reconstruction in patients with chronic high-grade acromioclavicular joint dislocation.

**Methods** We searched Cochrane Library, EMBASE, and Pubmed databases using the keywords “acromioclavicular joint,” “dislocation,” and “surgery” according to the MeSH index for English-language studies. We performed a systematic review using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.

**Results** Two authors independently reviewed 915 articles. 36 met the inclusion criteria, comprising 1013 patients who underwent reconstruction surgery and 57 patients who underwent reconstruction with hardware-augmented reconstruction surgery. The reconstruction group demonstrated higher Constant–Murley (88.2 vs. 85.6) and Subjective Shoulder Value scores (84.1 vs. 70) compared to the combination group. However, the combination group had a superior American Shoulder and Elbow Surgeons score (93 vs. 82). The complication rate was higher in the reconstruction group (16% vs. 12%). In comparison, the combination technique had a lower revision rate (4.5% vs. 5.86%).

**Conclusion** This study compared treatment outcomes between reconstruction alone and hardware-augmented reconstruction, and it revealed that reconstruction alone is superior in functional outcomes. However, reconstruction augmented with a hardware-augmented reconstruction approach is superior in terms of lower complications and revision rates.

**Keywords** Acromioclavicular joint · Chronic · High-grade · Reconstruction · Hardware fixation · Dislocation · Shoulder

## Introduction

AC (acromioclavicular) joint dislocation is a common injury caused by direct trauma to the shoulders, accounting for 9% of shoulder girdle injuries [1]. It is associated with injuries to the acromioclavicular (AC) and coracoclavicular (CC) ligaments [2]. The most commonly used criterion for AC dislocation is the Rockwood classification. The current guideline is that Rockwood grades I and II are treated conservatively, whereas high-grade injuries (grades III–VI) are treated surgically [3]. However, since no explicit treatment algorithm exists, whether immediate operative, delayed, or

conservative treatment is appropriate for Grade III remains debatable. A recent study suggests surgery is often recommended for patients with high shoulder activity, such as workers, athletes, or soldiers who frequently engage in shoulder movement [4].

In chronic AC joint dislocations (> 3 weeks after injury), surgical treatment is required to heal the torn structures and maintain shoulder stability [5]. Various surgical techniques have been documented in the literature and categorized into four groups: (a) nonbiological fixation between the coracoid and clavicle, including suture loops and synthetic ligaments (polydioxanone (PDS), the Gore-Tex, Dacron, carbon fiber and Mersile<sup>®</sup> tape, the TightRope, the Lockdown, the Surgilig, and the ligament augmentation and reconstruction system (LARS); (b) biological reconstruction of

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the CC ligaments, including allograft or autograft tendon reconstruction (hamstring or palmaris longus autograft); (c) ligament and/or tendon transfer, such as the Weaver–Dunn and Dew procedures; and (d) hardware-augmented reconstruction with Kirschner wires (Phemister technique), a hook plate, or other extra-articular techniques (Bosworth screw fixation) [4].

This systematic review aims to evaluate and compare the clinical outcomes of reconstruction alone versus hardware-augmented reconstruction fixation for treating high-grade AC joint dislocations, as classified by the Rockwood criteria. The secondary objective is to compare the complications and revision rates of these two treatment approaches. The findings will guide clinical decision-making and optimize patient outcomes.

## Methods

This study was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. This study used the PICO (population, intervention, comparison, and outcomes) model; the study population included patients with chronic high-grade AC joint dislocation (III–VI); the intervention was any of the two surgical treatments (reconstruction with and without hardware fixation); no comparison group; and the outcomes were the functional score, revision rates, and complications rates.

## Search Strategy

A literature search for eligible studies was conducted on August 28, 2024, using the Cochrane Library, EMBASE, and PubMed databases. The search engines were used to locate studies with the combination of “acromioclavicular joint,” “dislocation,” and “surgery.” The search in PubMed was conducted using (“acromioclavicular joint”[MeSH Terms] OR (“acromioclavicular”[All Fields] AND “joint”[All Fields]) OR “acromioclavicular joint”[All Fields]) AND (“dislocate”[All Fields] OR “dislocated”[All Fields] OR “dislocates”[All Fields] OR “dislocating”[All Fields] OR “dislocator”[All Fields] OR “dislocators”[All Fields] OR “joint dislocations”[MeSH Terms] OR (“joint”[All Fields] AND “dislocations”[All Fields]) OR “joint dislocations”[All Fields] OR “dislocation”[All Fields] OR “dislocations”[All Fields]) AND (“surgery”[MeSH Subheading] OR “surgery”[All Fields] OR “surgical procedures, operative”[MeSH Terms] OR (“surgical”[All Fields] AND “procedures”[All Fields] AND “operative”[All Fields]) OR “operative surgical procedures”[All Fields] OR “general surgery”[MeSH Terms] OR (“general”[All Fields] AND “surgery”[All Fields]) OR “general surgery”[All Fields]

OR “surgery s”[All Fields] OR “surgeries”[All Fields] OR “surgeries”[All Fields]

## Study Selection

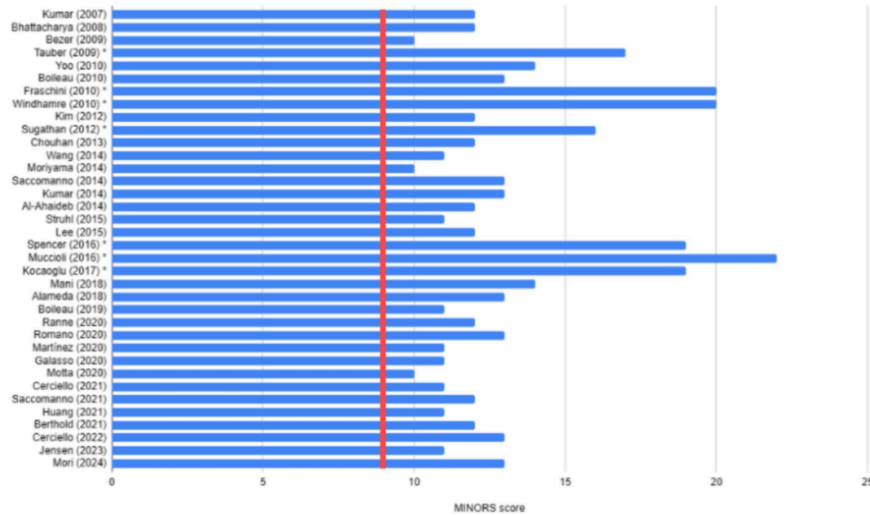
All included studies contained original data, were published in English, and had at least 12 months of follow-up. Studies involving adjuvant surgery, additional surgical methods, or patients with previous AC joint surgery were excluded. The authors resolved any discrepancies in the final list of studies by consensus. Reference lists were also reviewed to identify additional studies.

## Quality Assessment and Risk of Bias Assessment

Two authors (M and KSG) independently reviewed the search results. Studies were initially screened by title and abstract, with full texts of the relevant articles obtained and independently reviewed by both the authors. Disagreements between the two authors were resolved through consensus and discussion with a third author (EK). The risk of bias was assessed using the Methodological Index for Non-Randomized Studies (MINORS) score for non-randomized studies and the Cochrane Risk of Bias 2 assessment tool for randomized studies. The MINORS score allows 16 points for non-comparative studies and 24 points for comparative studies. High-quality studies were defined as those with scores above 60%—9 out of 16 for non-comparative studies and 14 out of 24 for comparative studies. According to the Cochrane assessment, the risk of bias was categorized as high, low, or unclear. The 39 non-randomized studies comprised 29 non-comparative and seven comparative studies (Fig. 1). These studies are considered high-quality studies according to MINORS criteria.

## Data Extraction and Analysis

Data were extracted from each study’s text, figures, tables, and supplementary files. The extracted data included (1) study and patient characteristics; (2) mean follow-up time; (3) mean AC joint dislocation onset (4) pain visual analog scale (VAS) score; (5) functional scores, revision, and complication rates. The primary outcome was the functional score (e.g., Constant, Disabilities of the Arm, Shoulder and Hand (DASH), Simple shoulder test (SST) score, The University of California at Los Angeles (UCLA) score, Larsen, Acromioclavicular Joint Instability Score (ACJI)). The Constant–Murley score was rated as poor (0–55), fair (56–70), good (71–85), and very good (86–100) [6, 7]. Secondary outcomes included revision and complication rates. The process of study selection is detailed in Fig. 2. The initial search identified 460 studies, with 418 studies excluded due to duplication or not meeting the criteria. After screening,



**Fig. 1** MINORS quality assessment of the 29 studies was non-comparative, and seven studies (indicated with asterisks) was comparative. The vertical red line represents the cutoff point for non-comparative

studies considered high quality. MINORS, methodological index for non-randomized studies

41 were eligible for review. Four studies were excluded due to incomplete demographic data, and one was excluded because the study was unfinished, resulting in a small sample size [8–12]. Thirty-six studies are included in this systematic review [4, 5, 13–46]. Given the various surgical techniques used in this study, we categorized them into two methods: reconstruction surgery only and reconstruction surgery combined with hardware-augmented reconstruction. Due to the heterogeneity of the patient populations and variations in treatment approaches across the included studies, conducting meaningful quantitative analyses proved challenging. Therefore, a qualitative approach was adopted. A narrative synthesis of the data was provided, offering detailed descriptions of patient demographics, treatment modalities, and outcomes to highlight trends and commonalities across the studies.

**Result**

**Characteristics and Demographics**

1070 with chronic high-grade AC joint dislocation cases were included in this study. The mean age of patients was  $37.8 \pm 5.6$  years. The chronic high-grade AC joint

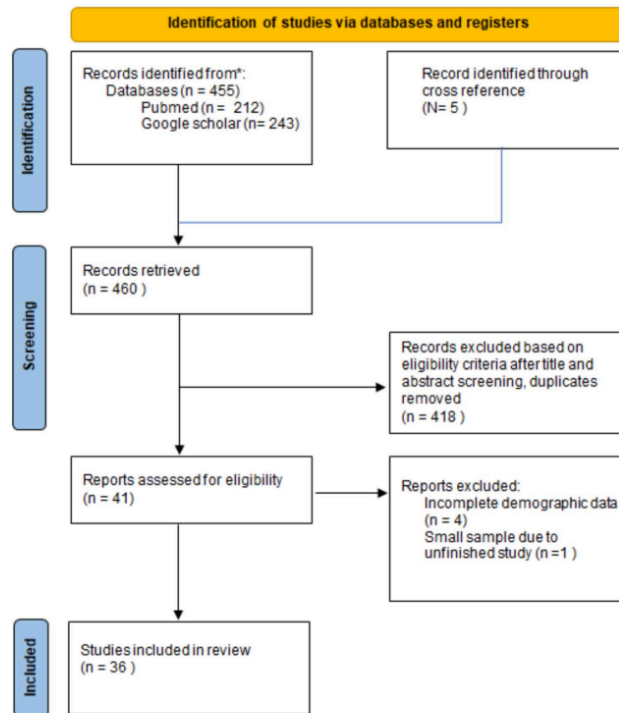
dislocation cases were followed up for  $37.2 \pm 22.8$  months. 1013 patients underwent reconstruction surgery, and the remaining 57 patients underwent hardware-augmented reconstruction surgery. This study only included 5 studies that treated grade VI chronic AC joint dislocation [18, 21, 34, 38, 41].

The detailed characteristics, demographics, and treatment techniques are provided in Table 1.

**Outcome Measurement and Result**

Table 2 summarizes various functional outcomes from the included studies. The Constant–Murley score was reported in 25 studies for the reconstruction group (mean score: 88.2 (Good)) and in two studies for the combination group (mean score: 85.6 (Good)). Three studies in the reconstruction group and one in the combination group reported the Subjective Shoulder Value (SSV), with scores of 84.1 and 70, respectively. The American Shoulder and Elbow Surgeons (ASES) Shoulder Score was reported in five studies from the reconstruction group (mean score: 82 (Good)) and one study in the combination group (93 (Good)). Additional outcomes include the Oxford score, modified UCLA Shoulder Score, DASH score, UCLA, and JOA functional outcome scores.

**Fig. 2** Preferred reporting items for systematic review and meta-analysis diagram



All patients experienced mild pain as assessed by the VAS score. The reconstruction group included 136 patients with an average follow-up of 44.1 months, whereas the combination group had 57 patients with an average follow-up of 48.5 months.

One study with 22 patients in the combination technique group had a lower revision rate than the reconstruction technique group, which included ten studies with 44 patients (4.5% vs. 5.86%). It also had a more extended follow-up period (43 vs. 36.9 months).

146 patients (16%) in the reconstruction group experienced a complication, with a mean time to follow-up of 34 months. The combination group reported complications in 6 patients (12%) with a mean follow-up time of 57.5 months. The implant-related complication rate was 23.3% in the reconstruction group and one participant (16.7%) in the combination group. Non-implant related complication rates were 76.7% and 83.3% in the reconstruction and

combination group, consecutively. Table 3 provides detailed information on specific complications in each group.

## Discussion

This systematic review of chronic AC joint dislocation found that the reconstruction group had a better functional outcome than the combination group (reconstruction augmented with hardware fixation). Still, the combination group had lower complication and revision rates. However, it must be highlighted that only four out of the 36 studies included were combination groups [13–16].

The reconstruction group had a better Constant–Murley score and SSV score than the combination group. This finding is in line with a study by Windham et al. that compared Weaver–Dunn (WD) augmented with PDS-braid and WD augmented with a hook plate and found no significant

**Table 1** Characteristics and demographics of the studies

No.	Study (year)	Design	Level of study	Surgical technique	Type of surgery	Sample size (M/F)	Age (years)	Follow-up (months)	Type of AC joint injury according to Rockwood type
1	Windhamre (2010) [13]	Retrospective	III	Weaver–Dunn augmented with PDS	Reconstruction	23 (N/A)	39.5	114	III, IV, and V
2	Chouhan (2013) [14]	Prospective	II	Weaver–Dunn with temporary hook plate Artificial braided polyester ligament prosthesis + K-wire	Reconstruction + hardware fixation Reconstruction + hardware fixation	22 (N/A) 8 (8/0)	38 33	43 46	III
3	Moriyama (2014) [15]	Case series	IV	Modified Cademat procedure (Suture CA ligament + K-wire)	Reconstruction + hardware fixation	6 (5/1)	49.3	72	III
4	Wang (2014) [16]	Retrospective	III	Coracoid process transfer augmented with a hook plate fixation	Reconstruction + hardware fixation	21 (20/1)	41.6	33	III and V
5	Kumar (2007) [17]	Retrospective	III	Modified Weaver–Dunn technique	Reconstruction	15 (N/A)	42	27	III
6	Bhattacharya (2008) [18]	Prospective	II	Surgling Nottingham	Reconstruction	11 (10/1)	35.1	24	III, IV, V, and VI
7	Bezer (2009) [19]	Prospective	II	Weaver–Dunn	Reconstruction	29 (21/8)	29.8 ± 8.3	69.5	III
8	Tauber (2009) [20]	Prospective	II	semitendinosus tendon graft vs. modified Weaver–Dunn	Reconstruction	16 (10/6)	41.4	37	III, IV, and V
9	Fraschini (2010) [21]	Retrospective	III	Dacron vascular prosthesis vs LARS I (ligament advanced reinforcement System, surgical implants and devices, Arc-sur-Tille, France)	Reconstruction	90 (84/6)	31.5	15	III, IV, V, and VI
10	Boileau (2010) [22]	Prospective	II	Weaver–Dunn + double-button	Reconstruction	10 (8/2)	41	12.9	III and IV
11	Yoo (2010) [23, 24]	Retrospective	III	Semitendinosus auto-graft	Reconstruction	5 (4/1)	33	33	III
12	Sugathan (2012) [24]	Retrospective	III	Weaver–Dunn	Reconstruction	11 (8/3)	31.7	72	III
13	Kim (2012) [25]	Retrospective	III	Lateral half conjoint tendon and coracoacromial ligament transfer	Reconstruction	12 (12/0)	37.3 ± 7.7	31.2 ± 9.5	V

Table 1 (continued)

No.	Study (year)	Design	Level of study	Surgical technique	Type of surgery	Sample size (M/F)	Age (years)	Follow-up (months)	Type of AC joint injury according to Rockwood type
14	Kumar (2014) [26]	Retrospective	III	Modified Weaver–Dunn/Surgilig synthetic ligament	Reconstruction	55 (N/A)	42	40	III, IV, and V
15	Saccomanno (2014) [27]	Prospective	II	Semiteninosus grafting	Reconstruction	18 (17/1)	27.5 ± 8.2	26.4 ± 2.3	III, IV, and V
16	Al-Ahaidib (2014) [28]	Retrospective	III	Weaver–Dunn + tightrope	Reconstruction	9 (N/A)	38.6	20	III
17	Lee (2015) [29]	Retrospective	III	Double-bundle CC reconstruction surgery using the CA ligament and the conjoined tendon	Reconstruction	18 (14/4)	36.5	35.3	III, IV, and V
18	Strahtl (2015) [30]	Case series	IV	Continuous loop double endo button	Reconstruction	26 (23/3)	41.2	50.4	III, IV, and V
19	Muccioli (2016) [31]	Prospective	II	Ligament augmentation and reconstruction system (LARS)	Reconstruction	43 (43/0)	30	28.2 ± 7.3	III, IV, and V
20	Spencer (2016) [32]	Retrospective	III	(1) Modified Weaver–Dunn (2) Allograft fixed through coracoid and clavicular tunnels (3) Allograft loop coracoclavicular fixation (4) Combined allograft loop and synthetic cortical button fixation	Reconstruction	167 (N/A)	38.1 ± 14.7	15.7 ± 16.2	III, IV, and V
21	Kocaglu (2017) [33]	Retrospective	III	Palmaris longus tendon graft vs modified Weaver–Dunn	Reconstruction	32 (27/5)	39.7	44.9	III, IV, and V
22	Mami (2018) [34]	Case series	IV	Modified Weaver–Dunn	Reconstruction	40 (29/11)	36.5 ± 11.1	12	IV, V, and VI
23	Alamedd (2018) [35]	Retrospective	III	Modified Weaver–Dunn	Reconstruction	28 (24/4)	34.9 ± 9.7	12	III
24	Boileau (2019) [36]	Prospective	II	Arthroscopic modified Weaver–Dunn procedure with CC suture button fixation (Twinbridge)	Reconstruction	57 (49/8)	42	36	III and V

Table 1 (continued)

No.	Study (year)	Design	Level of study	Surgical technique	Type of surgery	Sample size (M/F)	Age (years)	Follow-up (months)	Type of AC joint injury according to Rockwood type
25	Galasso (2020) [37]	Retrospective	III	Modified Weaver–Dunn	Reconstruction	27 (24/3)	50.5 ± 14.6	12	III
26	Martinez (2020) [38]	Retrospective	III	Twin tail tightrope	Reconstruction	21 (19/2)	30.7 ± 11.7	49.7 ± 17.1	III, IV, V, and VI
27	Romano (2020) [4]	Retrospective	III	Infinity-lock button system	Reconstruction	15 (15/0)	32	18	III
28	Ranne (2020) [39]	Retrospective	III	Autogenous semitendinosus graft	Reconstruction	58 (54/4)	36.4 ± 13.3	24	III and V
29	Meta (2020) [40]	Case series	IV	Graftrope technique	Reconstruction	12 (N/A)	36	91	IV
30	Cerciello (2021) [5]	Retrospective	III	Semitendinosus/peroneus longus allograft tendons	Reconstruction	42 (34/8)	42.7 ± 12.8	45.6 ± 37.2	III and V
31	Berthold (2021) [41]	Retrospective	III	Semitendinosus/peroneus longus allograft tendons	Reconstruction	24 (22/2)	44.7 ± 13.4	37 ± 35	III, IV, V, and VI
32	Huang (2021) [42]	Retrospective	III	Duo-figure-8 autogenic graft wrapping technique	Reconstruction	7/3 (10)	47.0 ± 13.8	26.3	III and V
33	Sacomanno (2021) [43]	Prospective	II	Semitendinosus tendon graft	Reconstruction	30 (28/2)	28.9 ± 8.3	28.1 ± 2.4	III, IV, and V
34	Cerciello (2022) [44]	Prospective	II	Primary fixation with a suspensory system Coracoclavicular ligaments reconstruction with a double loop of autologous Gracilis Acromioclavicular ligament reconstruction with autologous Coracoclavicular ligament	Reconstruction	22 (19/3)	34.4 ± 9	49.9 ± 11.8	III, IV, and V
35	Jensen (2023) [45]	Retrospective	III	Graft rope + horizontal tendon augmentation	Reconstruction	16 (14/2)	44.4	13	III and V
36	Mori (2024) [46]	Retrospective	III	Dog button + autosemitendinosus tendon graft	Reconstruction	21 (16/5)	40	31.7	III, IV, and V
						Mean ± SD	37.8 ± 5.6	37.2 ± 22.8	

WD Weaver–Dunn technique, CC coracoclavicular, CA coracoclavicular, LARS ligament advanced reinforcement system, PDS polydioxanone



**Table 2** Functional outcome following AC joint reconstruction versus hardware-augmented reconstruction

Functional outcome	Reconstruction group (interpretation)	Combination group (interpretation)
Constant–Murley score	88.2 [4, 5, 13, 17–20, 23, 27–31, 33, 36–40, 42–46]	85.6 [13, 14, 16]
SSV	84.1 [13, 22, 36]	70 [13]
ASES shoulder score	82 [5, 20, 30, 33, 41, 42, 44, 46]	12 [14]
Oxford score	46.6 [12, 14, 19, 22, 23]	N/A
Modified UCLA shoulder score	20.3 [21, 22, 25, 29]	N/A
DASH score	9.3 [27, 35, 43]	N/A
UCLA shoulder score	29.3 [23, 30]	N/A
Nottingham score	86.7 [26, 34]	N/A
JOA	N/A	94.1 [15]

SSV subjective shoulder value, ASES American shoulder and elbow surgeon, UCLA University of California, Los Angeles, DASH disabilities of the arm, shoulder, and hand, JOA Japanese Orthopaedic Association

**Table 3** The complications following AC joint reconstruction versus hardware-augmented reconstruction

Complication	Reconstruction group	Combination group
Total (%)	146 (16%)	6 (12%)
N total	911	36
Mean follow-up (months)	34	57.5
Implant related	23.3%	16.7%
Loosening	9 (6.2%) [18, 21, 32]	N/A
Intraoperative fracture (clavicle + coracoid)	6 (4.1%) [5, 21, 31, 41]	N/A
Migration	3 (2.1%) [22, 35]	N/A
Discomfort	16 (10.9%) [17, 34, 38, 45]	1 (16.7%) [13]
Non-implant related	76.6%	83.3%
Graft problem	6.8%	N/A
Rupture, dislodge	10 (6.8%) [18, 21, 34]	N/A
Skin	26%	66.6%
Superficial infection	31 (21.2%) [13, 20, 22, 26, 29, 31–36, 38, 39, 43–45]	4 (66.6%) [13, 14]
Fistula	2 (1.4%) [38]	N/A
Hypertrophic scar	5 (3.4%) [27]	N/A
Bone and joint	43.8%	16.7%
Deep infection	1 (0.7%) [39]	N/A
Arthrosis	16 (10.9%) [20, 24, 33, 39]	1 (16.7%) [15]
Stiffness	9 (6.2%) [17, 32, 34, 42]	N/A
HO and ossification	21 (14.3%) [5, 37, 41, 44, 45]	N/A
Chronic pain	9 (6.2%) [24, 34, 43, 44]	N/A
Radiographic failure	8 (5.5%) [32]	N/A

HO Heterotrophic ossification, N/A Not available

difference in Constant–Murley score but higher in WD augmented with PDS-braid or reconstruction group (85 vs. 71). A better ASES score is found in the combination group. A study by Wang et al. reported on 21 patients who underwent coracoid transfer augmented with hook plate fixation, showing improved functional scores, with all patients returning to their original sports activities within 3.7 months postoperatively [16]. A similar study utilizing the modified Cadenat

technique with hook plate fixation demonstrated improved functional scores [15]. In our opinion, this can be due to the components of the ASES score, which are pain and function. Using hardware fixation to hold fixation and temporary stabilization can improve function and even allow early mobility.

In our study, the complication rate was higher in the reconstruction group, with a reported rate of 16%. The

most common complication in both groups was superficial infection. The higher incidence of disease in the reconstruction group may be attributed to specific reconstruction techniques that involve the placement of bulky knots over the superior (clavicular) button, potentially increasing the risk of local irritation and subsequent infection [22]. Large knots can cause skin irritation, eventually leading to skin erosion and localized infection [47]. The combination technique mainly uses a hook plate as an adjunct to the reconstruction procedure. In our combination group, a higher rate of discomfort was observed, likely due to the hook plate causing chronic irritation in the subacromial space, leading to persistent pain [13]. While the hook plate protects the reconstructed ligament, limits vertical and horizontal displacement, and mitigates anteroposterior instability, our findings indicate that it does not significantly reduce the incidence of recurrent subluxation of the lateral clavicle [16]. Rigid protection of the reconstructed ligament failed to prevent elongation of the transferred ligament over time, likely due to premature removal of the hook plate. In addition, according to Boström et al., reconstruction augmented with a hook plate resulted in increased pain during movement, no improvement in functional outcomes, and required removal of the hook plate, necessitating an additional surgical procedure [13].

To our knowledge, no studies analyze the revision rate in reconstruction combined with a hardware for chronic high-grade AC joint dislocation. Our study observed a lower revision rate in the combination group. Windhamre et al. also found the same result. This may be attributed to the hardware providing more excellent initial mechanical stability, thereby reducing the risk of failure caused by graft elongation or loosening [13]. In addition, the hardware creates a supportive environment during the crucial graft healing period [48].

Our study represents the first systematic review to identify the optimal treatment approach for chronic high-grade AC joint dislocations. It is characterized by well-defined inclusion and exclusion criteria and a highly systematic approach to study selection. A minimum follow-up duration of >1 year was established as a criterion to ensure an accurate assessment of functional outcomes, complications, and revision rates. Moreover, we included recent publications, ensuring they reflect current conditions and are generalizable to clinical settings. The limitation of this study is that it is a systematic review, which inherently includes studies with varying surgical techniques and outcome measures. Consequently, the functional outcome scores reported are highly variable, potentially affecting the generalizability of the findings. In addition, the combination techniques or hardware-augmented reconstruction evaluated in our study were limited to only four studies that may influence the results.

## Conclusion

The current systematic review revealed that reconstruction alone is superior in functional outcomes. However, hardware-augmented reconstruction approach is superior in terms of lower complications and revision rates. While this review provides insight into potential differences between the two approaches, the qualitative nature of the analysis, along with variations in study design, outcome measures, and the number of included studies, suggests that these findings should be interpreted with thoughtful consideration.

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**Data availability** This systematic review is based on previously published studies. All data generated or analyzed during this study are included in the published articles cited in the references.

## Declarations

**Conflict of interest** All the authors declare that they have no conflict of interest.

**Ethical approval** Ethical clearance was not required.

**Informed consent** For this type of study, informed consent is not required.

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