



Infinity-Lock™ Button System Clinical Summary

Compilation of publications on the Infinity-Lock Button System

Introduction

Recent publications suggest that the Infinity-Lock Button System (ILBS) for acromioclavicular separation, involving disruption of the coracoclavicular ligaments, effectively restores shoulder anatomy and function, reduces pain, and facilitates a return to normal daily activities.

Publications

Pradhan et al (2024)

- Data prospectively collected from 28 patients with distal clavicle injuries and coracoclavicular ligament (CCL) disruption, treated using the ILBS over a period of 7 years.
- Only patients over the age of 18 who sustained a lateral end clavicle (LEC) fracture or acromioclavicular joint (ACJ) dislocation and had fully accessible medical and radiological records were included.
- Patients divided into two groups: Group A consisted of 14 patients with LEC fractures (Neer type II and type V); Group B included 14 patients with traumatic ACJ dislocations (Rockwood type III, IV, and V).
- Mean time to surgery was 75.8 days (range 3–619 days). Meanean follow-up period was 38.6 months (range 8–68 months).
- Statistically significant improvement in all patient-reported outcome measures (Q-DASH, VAS, and OSS) between preoperative and postoperative scores. No statistically significant difference in patient-reported outcomes noted when comparing the 2 groups at postoperative follow-up.
- No intraoperative complications reported.
- Post-fixation, 23/28 patients (>80%) achieved full restoration of range of motion (ROM), while 5 patients (17.9%) experienced some limitations in ROM, described as subjective limitations in abduction and forward flexion movements only.
- Twenty-six patients (92.9%) returned to their pre-injury level of activity, and 25 patients (89.7%) reported subjective satisfaction with the surgical intervention as either 'good' or 'excellent.' No patients reported clinical symptoms or signs of ACJ instability.
- No patient required revision surgery for instability; none underwent implant removal or any further procedures.
- Only 2 patients in Group B had postoperative symptoms of complex regional pain syndrome, which did not require further surgical intervention.
- Most patients had full restoration of their pre-injury ROM and were able to accomplish ADLs, hobbies, and occupational work without hindrance
- The study demonstrates the positive impact of using the ILBS on patient-reported outcome measures (PROMs).

Table 1. Results summary for Pradhan et al (2024)

Scores	Pre-operative (mean, SD)	Follow-up (mean,SD)	P value
VAS (combined results)	66.71 (9.19)	16.96 (12.12)	< 0.001
OSS (combined results)	18.50 (6.56)	44.14 (3.39)	< 0.001
Q-DASH (combined results)	69.03 (17.56)	7.16 (7.29)	< 0.001

Romano et al (2020)

- Study retrospectively analysed 15 patients who underwent surgical stabilization of ACJ dislocation (Grade III) using the ILBS. All patients evaluated pre-operatively, at 2 weeks, 4 weeks, 8 weeks, 3 months, 6 months, and annually postoperatively
- Inclusion criteria: (1) patients with primary AC dislocation classified as Rockwood grade III, (2) time elapsed since trauma $\geq$ 6 weeks, and (3) patients under 60 years old. Exclusion criteria:(1) revision surgery, (2) glenohumeral osteoarthritis, (3) rotator cuff tear, (4) glenohumeral instability, and (5) fracture-dislocation
- Minimum follow-up period was 12 months, with an average duration of follow-up of 18 months (range 12 to 24 months).

- Minimum follow-up period was 12 months, with an average duration of follow-up of 18 months (range 12 to 24 months).
- Twelve patients rated their outcome as very good, and three rated it as good; no patients were dissatisfied with the surgery.
- Average Constant score, SACS score, forward flexion, and external rotation all improved significantly.
- No intraoperative or postoperative complications were recorded.
- No clinical or radiographic loss of AC joint reduction was found at the last follow-up
- The authors concluded that the described technique is effective for treatment of chronic grade III ACJ dislocation, resulting in elevated satisfaction ratings and predictable outcomes. Nevertheless, further longer-term follow-up studies are required.

Table 2. Results Summary For Romano et al. (2020)

	Pre-operative (mean, sd)	Post-operative (mean, sd)	P - value
Forward Flexion	70 ± 28	162 ± 8	<0.05
External rotation with elbow at side	15 ± 5	35 ± 10	<0.05
External rotation at 90° of abduction	46 ± 9	84 ± 5	<0.05
Active internal rotation hand level	5 ± 3	9 ± 1	NS
Internal rotation at 90° of abduction	38 ± 9	88 ± 1	<0.05
SACS	52 ± 15.7	10 ± 8.2	<0.00001
Constant Score	38 ± 15	95 ± 3	<0.00001

Dupley et al (2017)

- The authors present the early results of coracoclavicular reconstruction for ACJ dislocation
- using the ILBS in a Lark's foot method.
- Mean follow-up time was 26 weeks (range: 12 to 70 weeks).
- No complications were reported at the 12-week follow-up.
- All patients reported satisfaction with the procedure and stability in the shoulder.
- Patient-reported outcome measures (PROMs) showed improvement, although normal function was not fully recovered by week 26.
- All patients had an improved radiographic outcome. Only two had a postoperative CC:clavicle ratio higher than 1:1 (1.6:1 and 1.3:1); these were the two patients with the largest preoperative ratios (3.1:1 and 2.2:1, respectively).
- Authors conclude that initial results appear promising in holding the reduction of the ACJ at the time of the surgery to the time of post-op radiographic review. Initial Patient reported outcomes are promising with all patients "happy" with the results and all felt "stable". The bigger the pre-op deformity the more difficult to restore normal radiographic anatomy – but nevertheless all 12 patients satisfied. Longer-term radiographic and clinical follow up required.

Table 3. Results Summary for Dupley et al (2017)

PROMS	Post-op mean (range)	Contralateral mean (range)
ASES Score	76 (63 - 98)	99 (90 - 100)
Nottingham Clavicle Score	80 (72 - 92)	96 (92 - 100)
Radiographic Outcomes	Pre-op (range)	Post-op (range)
CC Distance (mm)	20.1 (8-34.2)	12.7 (4 - 21)
CC:Clavicle Ratio	1.7:1.0 (0.7-3.2:1.0)	90 (80 - 99)
Questionnaire	Yes	No
Are you happy with your shoulder	100%	0%
Does it feel stable?	100%	0%

Chowdhury et al (2019)

- Data were collected retrospectively from 15 patients to determine the outcomes of using the ILBS in the management of ACJ separation.
- Preoperative and postoperative PROMs (including DASH and OSS) were compared, and radiological outcomes were assessed.
- The ILBS resulted in improved radiological and clinical outcomes in cases of ACJ disruption.
- The mean reduction in the CC distance was 8.22 mm, while the mean reduction in the CC ratio was 0.6.
- Reported complications included one case of postoperative paraesthesia (self-limiting) and one case of fixation failure, which required revision surgery.
- The authors concluded that the ILBS results in improved radiological and clinical outcomes in AC joint disruption and is an effective technique in the management of this condition

Table 4. Results Summary for Chowdhury et al (2019)

PROMs	Pre-op mean (SE)	Post-op mean (SE)	Wilcoxon Signed-Rank Test
DASH	69.7 (5.34)	23.3 (6.00)	p=0.00148
Oxford Shoulder Score	16.2 (3.20)	40.5 (3.09)	p=0.00148

Loukovitis et al (2019)

- This study describes the early results of a comparison between two techniques for the reconstruction of the coracoclavicular ligament following acromioclavicular joint dislocation.
- Patients included had ACJ dissociation classified as Rockwood grade III, IV, or V. Grade III patients had chronic instability, while grades IV and V followed an acute event.
- Fifteen patients were treated using the ILBS with a Lark's foot technique (Group 1), while another fifteen patients received an established synthetic tape with fixation in the clavicle using an AP screw (Group 2).
- Follow-up was conducted at a minimum of 3 months.
- The mean improvement in CC distance was 7.4 mm for Group 1 and 5.5 mm for Group 2.
- Comparison of both techniques suggested better early outcomes with the ILBS in terms of both radiographic and clinical results.

Table 5. Results Summary for Loukovitis et al (2019)

Radiographic outcomes	Group 1 ILBS with Lark's foot technique	Group 2 Synthetic Tape with AP screw
Pre-op CC distance (mean)	20.1 mm	22.3 mm
Post-op CC distance (mean)	12.7 mm	16.8 mm
Mean CC:Clavicle ratio	0.9:1	1.4:1



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Post-op ASES score	76	77
Post-op Nottingham score	80	69

Conclusions from the recent studies

- Surgical treatment of the disrupted AC joint using the Infinity-Lock Button System is safe and effective in restoring shoulder function and reducing pain in the shoulder. Data suggest better early outcomes compared to other techniques.
- High levels of patient satisfaction are achieved with treatment using the Infinity-Lock Button System. The Infinity-Lock Button System is effective in providing anatomic shoulder reduction, restoring the ACJ to the normal position and thereby provide cosmetic improvement to the appearance of the shoulder.
- It enables patients to return to sports activity, potentially at a level comparable to that before the injury.

Abbreviations

AC:	Acromioclavicular
ACJ:	Acromioclavicular Joint
ADL:	Activities of Daily Living
AP:	Anterior-Posterior
ASES:	American Shoulder and Elbow Surgeons Shoulder Score
CC:	Coracoclavicular
CCL:	Coracoclavicular Ligament
CS:	Constant Score
DASH:	Disability of the Arm, Shoulder and Hand Score
ILBS:	Infinity-Lock Button System
LEC:	Lateral End Clavicle
OSS:	Oxford Shoulder Score
PROM:	Patient Reported Outcome Measure
Q-DASH:	Quick-Disability of the Arm, Shoulder and Hand Score
ROM:	Range of Motion
SACS:	Specific Acromioclavicular Score
SE:	Standard Error
SD:	Standard Deviation
VAS:	Visual Analogue Score

Study Citations

Chowdhury, A., S. Kohli, A. Taiwo, S. Sampalli and A. Elmorsy (2019). Clinical and Radiological Outcomes of the Xiros **Infinity-Lock** Button System, a Novel Suture Button Technique for the Management of Acromioclavicular Joint Disruption. EFORT. Lisbon.

Dupley, L., R. Heasley and N. Jain (2017). Radiographic and Patient Reported Outcomes of CoracoClavicular Reconstruction for Acromioclavicular Joint Dissociation - The Results of a New Synthetic Tape. Presentation at BOSTAA 2017.

Loukovitis, K., L. Dupley, S. Sharma, R. Heasley and N. Jain (2019). A comparison study of the clinical and radiographic outcomes of two techniques of coraco-clavicular ligament reconstruction. EFORT. Lisbon.



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Pradhan A, Akhtar M, Pulavarti R (May 23, 2024) Early to Mid-term Results of Coracoclavicular Ligament Reconstruction Using the **Infinity-Lock** Button System in the Management of Traumatic Acromioclavicular Joint Dislocations and Lateral End of Clavicle Fractures. Cureus 16(5): e60936.

Romano, A. M., P. Casillo, M. De Simone, G. Nastrucci, D. Risorto, M. Susanna, A. Di Giunta and F. Ascione (2020). "The Infinity-Lock System for Chronic Grade III AC Joint Dislocation: A Novel Technique, Rehabilitation Protocol and Short Term Results." J Clin Med 9(8)

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