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Original article

Functional recovery following early mobilization after middle third clavicle osteosynthesis for acute fractures or nonunion: A case-control study

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ABSTRACT

Background: Good outcomes have been reported after surgical treatment for acute or nonunion of displaced midshaft clavicle fractures. However, the postoperative rehabilitation and timeline for a complete functional recovery are poorly documented. The purpose of the current study was to evaluate the efficacy of an immediate motion protocol following plate fixation of a midshaft clavicle fracture and to compare functional recovery between acute and nonunion cases.
Methods: Between October 2011 and July 2015, all patients above the age of 18, having either an acute or a nonunion of the midshaft clavicle fracture, were considered as potentially eligible for inclusion in this prospective case-control study. Postoperatively, no immobilization was recommended and patients were to undergo rehabilitation protocol consisting of hourly stretching.
Results: Forty-two patients were included (31 with acute and 11 with delayed fixation) at a mean follow-up of 33 months (range, 12 to 78 months). Surgical complications consisted of one transient frozen shoulder, one delayed union, and two superficial infections. All patients returned to work, retrieved full shoulder range of motion (ROM), and returned to heavy sports and activities. Function returned faster in the acute group compared to the nonunion group based on the SANE score at 2 weeks (73 ± 21 vs. 45 ± 26 respectively, $P = 0.01$), SANE score at 6 weeks (89 ± 15 vs. 66 ± 23 respectively, $P = 0.01$), SANE score at 3 months (96 ± 10 vs. 85 ± 14 respectively, $P = 0.03$), and based on return of full ROM (17 ± 25 vs. 44 ± 31 days respectively, $P = 0.01$). A trend was observed for nonunion cases needing more time to return to work and sports activities.
Conclusion: Functional outcome is excellent following the treatment of both acute and non-united clavicle fractures, but recovery occurs earlier following acute treatment. An early mobilization rehab protocol can be safely recommended for both types of conditions and may result in substantial healthcare cost-savings, without increasing complication rate and decreasing patient satisfaction.
Level of evidence: Level III; case-control study; treatment study.

1. Introduction

The clavicle is one of the most common fractured bones, accounting for approximately 2.5 to 10% of all fractures [1,2]. Fractures of the midshaft represent approximately 80% of the clavicle fractures, with a clear preponderance in males [1,2]. The benefits of surgical management over conservative is clearly demonstrated in displaced fractures, with surgical treatment resulting in earlier healing, a lower nonunion or malunion rate, improved final functional outcome [3–6]. This fast-track rehabilitation protocol may therefore lead to cost savings by decreasing work absenteeism and the need for physiotherapy [7].

In recent years, increased emphasis has been placed on value in health care. In addition to implant cost, potential areas of cost savings include length of stay, complication and readmission rate,

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return to work, and postoperative rehabilitation center or physical therapy utilization. The authors believe that open reduction and internal fixation (ORIF) with superior locking compression plate (LCP), allows immediate post-surgical mobilization. This fast-track rehabilitation protocol may therefore lead to cost savings by decreasing work absenteeism and the need for physiotherapy. However, the effects of immediate mobilization after clavicle osteosynthesis are poorly documented in the literature.

The primary purpose of this study was to evaluate the efficacy of immediate mobilization following ORIF of a midshaft clavicular fracture with a LCP plate. The secondary purpose was to evaluate the speed of functional recovery between acute and nonunion cases. The hypothesis was that immobilization and physiotherapy are not required following either acute or delayed fixation of a midshaft clavicle fracture.

2. Methods

2.1. Design and patients

A retrospective review of prospectively collected data was performed of clavicle fractures treated by a single surgeon (A.L. Blinded for purpose review) between October 2011 and July 2015. Inclusion criteria included:

- age ≥ 18;
- either an acute midshaft clavicle fracture with 100% or greater displacement [4];
- or nonunion midshaft clavicle fracture treated surgically;
- a minimum follow-up of 1 year.

An acute fracture was defined as surgical treatment within 4 weeks of injury. Exclusion criteria included polytrauma, nonadherence to the rehabilitation protocol, pre-existing ipsilateral upper extremity condition affecting recovery, and revision surgery. The study protocol was approved by our institutional Ethics Committee (AMG: 12–26 blinded for review purpose) and all patients gave written informed consent.

2.2. Study variables

The outcome of interest was the timeline of functional recovery. In order to evaluate outcomes of interest, the following parameters were evaluated: timelines for full range of motion (ROM) (defined as equal to the opposite arm) and return to light sports activity or to heavy load work/sports activity, and single shoulder numerical assessment (SANE) at 2, 6, 12 weeks, and 1 year postoperative [8]. The SANE score is a single response expressed as the percentage of the shoulder from 0 to 100 with 100 being normal. The following baseline clinical characteristics were collected: age, sex, side, limb dominance, type of work (heavy or not), salaried or self-employed status, tobacco smoking, delay between initial trauma and surgery, acute or nonunion treatment, scar length, use of osseous autograft, need for physical therapy, days off work, surgical complications, and the need for hardware removal.

2.3. Surgical approach

A transverse incision was made along the superior aspect of clavicle under general anesthesia. Exposure was performed with minimal periosteal stripping. In acute cases, one to two 2.7 or 3.5 mm screws were used to fix the inter-fragment bone according to fracture configuration. In cases with small comminuted fragments not amenable to lag screw fixation, 1 or two 2 cerclage sutures were used for temporary fixation.

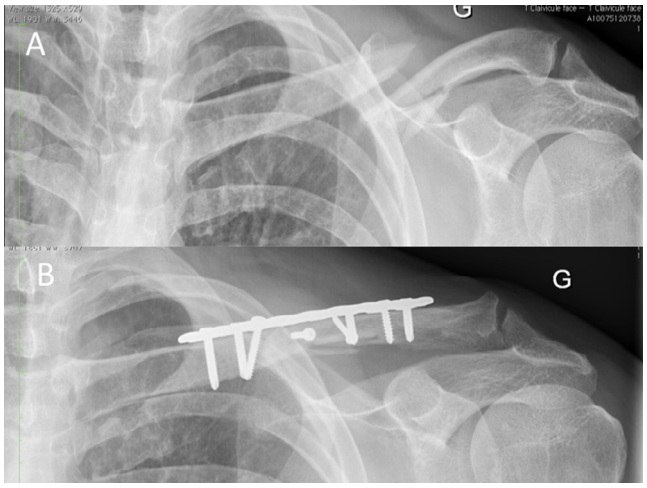

Fig. 1. A. Anteroposterior X-ray of an acute left clavicular fracture. B. Two 2.7 mm screws were used to fix the inter-fragment bone before superior stabilization by a straight 3.5 mm LCP plate.

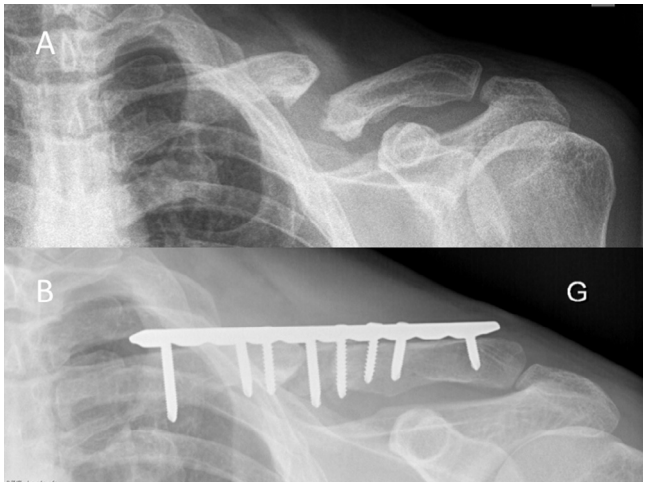

Fig. 2. A. Nonunion of a left clavicular fracture with a segmental defect in a 50-year-old patient. B. A tricorticaliliac crest autograft followed by compression with a plate and lag screws were used. Two screws stabilized the graft.

Nonunions with a segmental defect were treated with a tricortical iliac crest autograft previously harvested in conformity with preoperative planning performed [9]. Nonunion without segmental defect were treated with autograft from the ipsilateral olecranon, followed by compression with a plate and lag screws if possible.

After anatomical reduction was achieved, both the acute and nonunion cases were then stabilized superiorly by a straight 3.5 mm LCP plate (DePuy Synthes, Oberdorf, Switzerland), with a combination of compression and stabilization screws (Fig. 1). One or two screws were then used to stabilize the graft in case of segmental defect (Figs. 2 and 3). Double or wave plates were not employed. At the end of the procedure, the platysma were sutured together in order to recover the plate (Fig. 4) [10]. Postoperatively, nonsteroidal anti-inflammatory drugs were avoided because of their possible influence on bone-healing, even if there is no consensus regarding its safety [11]. Paracetamol and opioids were prescribed for pain control.

No postoperative immobilization or formal physical therapy was initially prescribed. Patients were allowed immediate active ROM and return to daily activities. The patients were asked to avoid any weight bearing activity engendering pain equal or superior to 4 on a scale of 10 (0 = no pain, 10 = maximal pain). Full

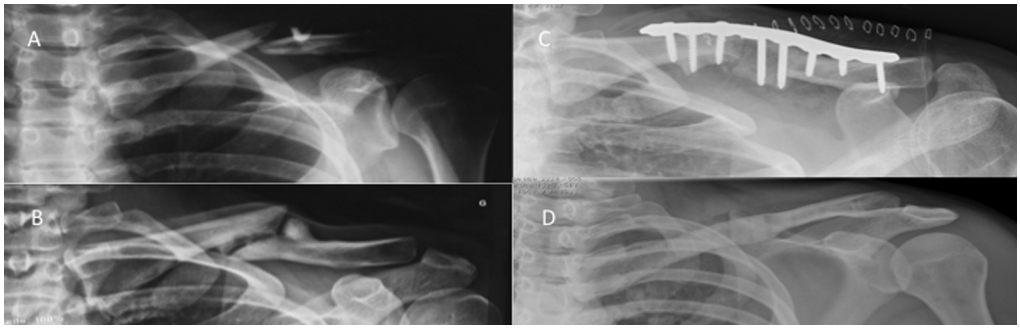

Fig. 3. A. Acute left middle-third clavicle fracture in a 25-year-old woman with development at 6 months of a nonunion (B). C. Stabilization with a 3.5 LCP plate and a 2.7 cm long tricortical iliac crest autograft. D. X-ray after hardware removal 18 months later.

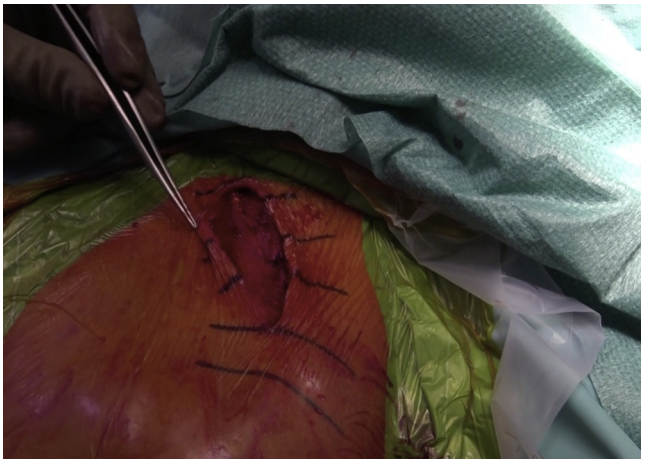

Fig. 4. At the end of the procedure, the platysma is sutured together in order to recover the plate and to avoid direct contact between the plate and the subcutaneus plane.

weight bearing was allowed at 6 weeks postoperative. Physical therapy was only prescribed if complete ROM and strength were not acquired at 6 weeks postoperative.

2.4. Statistical analysis

Statistical analysis was performed with "R" software (version 3.1.1, Vienna, Austria). Baseline clinical characteristics were compared between groups with Chi-squared test, Student *t*-test, or Wilcoxon test, as appropriate. Similarly, functional recovery delays for parameters of interest and SANE scores at different time points were described and compared between groups with Student tests. Two-tailed *P* values less than .05 were considered statistically significant. Furthermore, their influence on SANE score at 6 weeks was analyzed with the appropriate statistical test (Student test or correlation test). A post hoc power analysis showed that this study had a 90% power to detect a 20% difference in the SANE score between the acute repair and nonunion groups.

3. Results

Of the 43 eligible patients, one was excluded because he sustained a polytrauma. The 42 remaining patients were available for follow-up at a mean of 33 months postoperative (range, 12 to 78 months). There were 31 patients in the acute group and 11 in the nonunion group. None of the initial fractures in the nonunion group presented with 100% or greater displacement on initial radiographs. Baseline characteristics are summarized in Table 1.

Table 1
Baseline clinical characteristics.

	All patients ($n=42$)	Acute repair ($n=31$)	Nonunion cure ($n=11$)	*P*
Age, y	42 ± 13	43 ± 14	38 ± 9	0.15
Sex (male)	35 (83%)	27 (87%)	8 (73%)	0.53
Dominant side	18 (43%)	14 (45%)	4 (36%)	0.88
Tobacco use	8 (19%)	6 (19%)	2 (18%)	1
Associated fracture, *n*	3 (7%)	1 (3%)	2 (18%)	0.33
Delay trauma-surgery, days	119 ± 221	8 ± 5	431 ± 232	<.001
Bony graft	9 (21%)	0 (0%)	9 (82%)	–
Surgical complications	4 (10%)	1 (3%)	3 (27%)	0.08
LCP plate ablation	25 (81%)	18 (78%)	7 (88%)	0.96
Scar length (cm)	11 ± 1	11 ± 1	11 ± 2	0.39
Workheavy	7 (17%)	3 (10%)	4 (36%)	0.12
Work as independent	6 (14%)	5 (16%)	1 (9%)	0.94

Mean ± standard deviation *or* absolute number (percentage).

Table 2
Functional outcomes.

	All patients ($n=42$)	Acute ($n=31$)	Nonunion ($n=11$)	*P*
Work absenteeism, days	43 ± 44	32 ± 33	70 ± 58	0.06
Full ROM, days	24 ± 29	17 ± 25	44 ± 31	0.02
Return to light sports, days	39 ± 32	34 ± 33	52 ± 27	0.09
Return to heavy sports, days	73 ± 45	62 ± 32	101 ± 64	0.08
SANE score at				
2 weeks	66 ± 25	73 ± 21	45 ± 26	0.01
6 weeks	83 ± 20	89 ± 15	66 ± 23	0.01
12 weeks	93 ± 12	96 ± 10	85 ± 14	0.03
1 year	99 ± 4	100 ± 1	97 ± 6	0.17

Mean ± standard deviation; ROM: range of motion.

Bending of the lateral side of plate was used in 81% (31 of 42) of cases. Surgical complications consisted of one frozen shoulder, which recovered non-operatively, one delayed union in the nonunion group which took 6 months to unite, and 2 superficial infections which resolved with oral antibiotics. Twenty-six percent of the patients from the acute group and 55% of the nonunion group required physical therapy.

All patients returned to work, achieved full shoulder ROM, and returned to heavy sports and activities. At 3 and 12 months, all patients were satisfied and would recommend the surgery. A trend was observed in the nonunion group that it took more time in order to return to functional activities (Table 2). The SANE score was significantly lower in the nonunion group at 2 weeks, 6 weeks,

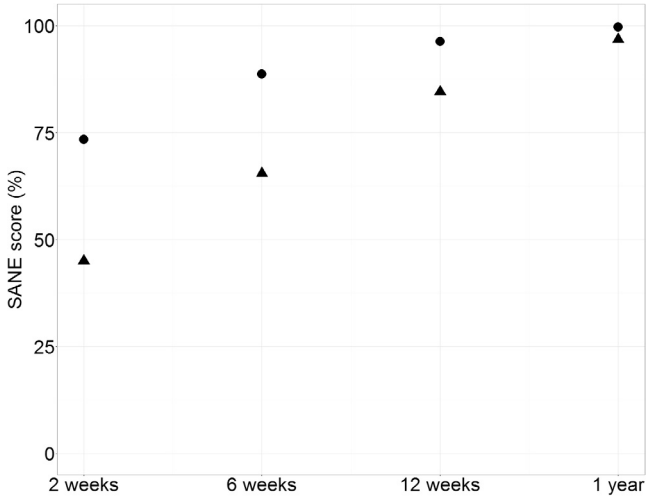

Fig. 5. SANE score at different time points. *Dots*, acute fixation. *Triangles*, delayed fixation.

and 12 weeks, but not at one postoperative (Table 2 and Fig. 5). Regarding the influence of baseline characteristics on SANE score at 6 weeks (Table 3), surgical complications and the use of structural bone graft had a significantly deleterious effect. In the 9 of 11 patients with a bony graft, the mean SANE score was 59%, compared to 95% in the 2 of the 11 patients without bony graft. The rate of re-intervention for hardware removal was 81% at last follow-up.

Table 3
Influence of selected baseline clinical characteristics on SANE score at 6 weeks.

	P
Age	0.71
Sex (male)	0.52
Dominant side	0.36
Tobacco use	0.47
Associated fracture	0.36
Delay trauma-surgery (for acute repair only)	0.84
Delay trauma-surgery (for nonunion fixation only)	0.4
Bony graft (for nonunion fixation only)	0.01
Surgical complications	0.03

4. Discussion

Osteosynthesis with LCP plate is a reliable option for both acute [3,5,6] and non-united mid-shaft clavicle fracture [12]. Surgery allows anatomical reduction of the clavicle, avoiding a long period of immobilization and even malunion with subsequent pain, fatigue, and scapulothoracic dyskinesia [4,13,14]. The goal of surgery is to facilitate an accelerated rehabilitation protocol with a fast return to activities, minimal rehabilitation costs and time away from work.

Most previous studies have recommended sling immobilization and physical therapy following operative treatment of a clavicle fracture, using arm sling protection for two to six weeks after osteosynthesis [15–17]. Conversely, the present series demonstrates that postoperative immobilization seems unnecessary in either group, confirming one of our hypotheses. Previous authors have also recommended physical therapy in all cases [15,16]. In the present series, only 26% of the patients from the acute group and 55% of the nonunion group required physical therapy, resulting in an economic savings compared to the aforementioned study protocols. We believe that systematic prescription of physical therapy in the postoperative period leads to over-treatment compared to adopting a wait-and-see approach. Nevertheless, physical therapy remains beneficial after 6 weeks in some patients, partially invalidating our second hypothesis. This mainly occurs in the nonunion group, probably due to the longer period of shoulder deconditioning. Physiotherapy was usually necessary during a limited period of time, similarly as if began without delay.

Concerning functional recovery, a prompt and complete functional recovery has been observed in the whole sample, with a return to work and heavy sports and activities in all cases, confirming the efficacy of operative treatment [3]. However, the functional recovery was globally significantly slower in the patients with nonunions, even though a trend between the two groups was observed concerning return to sports and work. Potter et al., in a retrospective study of 30 patients compared immediate osteosynthesis and delayed osteosynthesis with autograft, after a mean follow-up of 29 months (range, 12 to 72 months). They reported no statistically significant differences in ROM, abduction endurance, DASH score, or patient satisfaction. However, in the delayed reconstruction group, the Constant score (acute, 95; delayed, 89; $P = 0.02$), and flexion endurance (acute, 109%; delayed, 80%; $P = 0.05$) were significantly lowered [18]. Davids et al. reported a case series of 14 patients with delayed osteosynthesis with autograft, after a mean follow-up of 60 months (range, 16 to 101 months), in which postoperative mobilization started after one week [10]. All patients were asymptomatic after 10 weeks and had a normal range of shoulder motion.

Two complications occurred, including a nearly infection which was managed without plate removal, and a repeat clavicle fracture one year after plate removal at the site of a screw hole which occurred during sports activities. Overall, these results are comparable with nonunion group, with full ROM recovery in all patients, 100% patient satisfaction, and good clinical scores at final follow-up. To the best of our knowledge, time loss from work was not reported in case of operative treatment for a clavicle nonunion in previous studies.

The main strengths of this study include the prospective data collection and 100% follow-up. This allowed us to determine the rate of recovery and healing and closely monitor the impact of an accelerated rehabilitation protocol. However, this study has limitations that warrant discussion. First, its design comes with all of the obvious limitations, such as the inability to determine the rationale to proceed to operative fixation, which could have led to treatment bias. Additional reasoning in the decision-making process, like measures of objective shoulder functioning or a prospective design, seem important factors that were not accounted for. Second, we found a high rate of hardware removal (81%). Fridberg et al. reported 31 cases among 105 fractures (30%) of plate removals due to discomfort [19]. Recently, Hulsmans et al. described a percentage of around 40% of implant removals because of implant irritation [20]. One could argue that our higher incidence is related to consequent thickness and superior position of the plate [21]. The use of low profile precontoured plates could have theoretically reduced the incidence of postoperative hardware prominence and potentially decreased the need for subsequent surgery to remove the implant. However, the biomechanical superiority of a LCP has been demonstrated over a classical dynamic compression plate [22,23], thinner plates (Fig. 6) [24], or plates with lower strength [25]. Moreover, it seems that proportion of plate removal in patients with clavicular fractures undergoing plate fixation by an anteroinferior or superior approach is similar [20,26]. Reimbursement, body mass index and gender may be other factors that influence the rate of hardware removal [17]. Another reason could be culture-specific beliefs; in our country many patients feel that plate removal is a part of the normal healing process. A final limitation of the current study is that we did not evaluate the costs or number of physical therapy visits. While we believe that overall usage and cost were lower based on the few numbers of patients who required

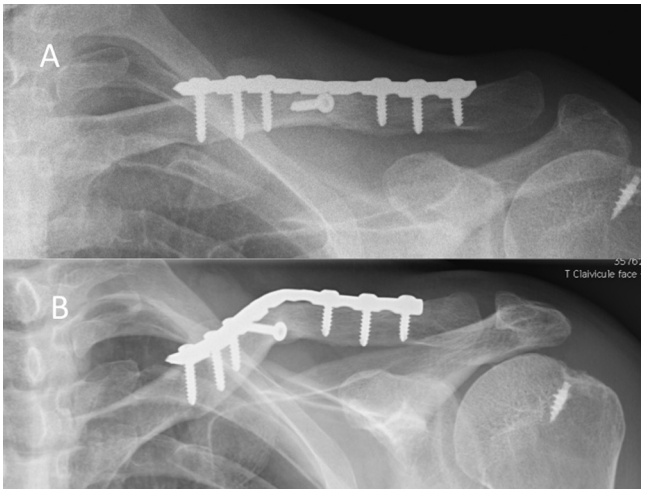

Fig. 6. A. A 52-year-old male sustained a midshaft clavicular fracture. The fracture was fixated in another center with a non-locking reconstruction plate and a lag screw. B. Four months after, the patient felt pain following a minor trauma. A plate bending is seen on X-rays. Since the patient had reasonable function and few pain, this was treated conservatively.

treatment, we are unable to provide specific cost data. Additional study is needed to further define the cost savings and value our rehabilitation protocol.

5. Conclusion

Functional outcome is excellent following treatment of both acute and nonunited clavicle fractures, but recovery occurs earlier following acute treatment. An early mobilization rehab protocol can be safely recommended for both types of conditions and may result in substantial healthcare cost-savings, without increasing complication rate and decreasing patient satisfaction.

Funding

None.

Ethical committee approval

This study was approved by local ethical committee (Switzerland, Geneva regional board; protocol nº 12-26).

Disclosure of interest

P.J.D. is a paid consultant for Arthrex.

A. Lädermann, S. Abrassart, J. Tirefort, A. Nowak, A.J. Schwitzguebel declare that they have no competing interest.

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