

Two-Year Functional Outcomes of Operative vs. Non-Operative Treatment of Completely Displaced Midshaft Clavicle Fractures in Adolescents: Results from a Prospective, Multicenter, Level 2 Study

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Purpose: To investigate the two-year functional outcomes and complications following operative vs. non-operative treatment of completely displaced midshaft clavicle fractures in adolescents.

Methods: All patients 10-18 years old treated for a midshaft clavicle fracture between August, 2013 and August, 2018 at one of 8 geographically diverse, high-volume, tertiary-care pediatric centers were enrolled, with independent treatment decisions determined by individual providers. The sub-population of patients with completely displaced fractures was prospectively followed for over 2 years. Clinical course, complications, validated patient-reported outcome measures (PROs), quality of life metrics, and satisfaction scores were analyzed. To address the ceiling effect of the PRO/satisfaction data following clavicle injuries, a priori thresholds for ‘suboptimal’ scores were established (ASES scores <90, QuickDASH scores >10, EQ-5D <0.80). According to ‘intention to treat’ statistical principles, one post-operative complication (and a subsequent secondary operation) was analyzed within the non-operative cohort, given that the patient represented a ‘crossover’ from the non-operative to the operative treatment group.

Results: Of the 909 patients enrolled in the prospective study, 417 patients (45.9%) demonstrated completely displaced fractures and maintained enrollment over the study period, 277 (66%) of whom had reached two-year follow up, and 151 of whom provided adequate PRO data, representing a 55% response rate. Of these patients, 55 (36%) underwent operative treatment, while 96

(64%) were treated non-operatively. Those treated surgically showed no difference in gender distribution (76% males, $p=0.43$), athletic participation ($p=0.76$), or fracture pattern ($p=0.18$), but were older (mean age 15.3 vs. 13.5 years, $p<0.001$) and had greater shortening ($p<0.001$) than those treated non-operatively. Within the subset with adequate complication data, listed in Table 1, complications were less common in non-surgical than surgical patients ($p=0.0003$), but this difference did not reach significance when sensory deficits were excluded ($p=0.17$). There was no difference in secondary surgeries ($p=0.43$). While greater percentages of operative than non-operative patients reported suboptimal PRO/satisfaction scores (ASES: 15% vs. 5%, QuickDASH 11% vs. 5%, satisfaction 11% vs. 5%), these differences did not reach significance ($p=0.07$, 0.20, 0.06, respectively).

Conclusion: At eight large pediatric centers with many surgeons making independent treatment decisions, non-operative treatment of adolescent clavicle fractures demonstrated lower complication rates and similar satisfaction and functional outcomes.

Significance: These data establish a comprehensive functional assessment of adolescents treated for clavicle fractures, which represents the epidemiological sub-population most affected by this condition. Unlike several adult studies demonstrating superiority in operative treatment, this adolescent study demonstrates equivalent function and fewer complications associated with non-operative treatment.

Table 1. Complications of Completely Displaced Midshaft Clavicle Fractures with 2-Year Follow-Up

Complication	Surgical (N=53)	Clinical Outcome	Non-Surgical (N=87)	Clinical Outcome	p-value
	n (%)		n (%)		
Hardware pain/irritation	5 (9.4%)	2 out of 5 (40%;3.8% overall): ROH surgery (mean 21.5 months post-op) [§]	1 (1.1%)	'Crossover' patient: ORIF 2 months post-injury → ROH surgery 10 months post-op	0.03
Sensory symptoms	13 (24.5%)	Numbness distal to incision (resolution reported in 5 out of 13, 38%, mean 6 months post-op)	1 (1.1%)	Occasional paresthesias (6mo post-op) → spontaneous resolution	<0.0001
Superficial Infection	0 (0.0%)		0 (0.0%)		n/a
Deep Infection	0 (0.0%)		0 (0.0%)		n/a
Delayed Union	2 (3.8%)	Patient 1: bone stimulator (6 months post-op) → healing Patient 2: Revision ORIF → healed	2 (2.3%)	Both patients: non-operative treatment → healed	n/a
Non-union	0 (0.0%)		0 (0.0%)		n/a
Symptomatic Malunion	0 (0.0%)		2 (2.3%)	Patient 1: PT → improvement Patient 2: operative exostosis for bony prominence → resolution	n/a
Refracture	1 (1.9%)	2 wks following ROH → healed w/ non-operative tx	2 (2.3%)	Both patients: non-operative treatment → healed	n/a
Other (described below)	3 (5.7%)		0 (0.0%)		n/a
Atlanto-axial rotatory subluxation (immediately post-operative)	1 (1.9%)	Unresponsive to halo traction → C1-2 fusion	0 (0.0%)		n/a
Intra-operative blood loss (1 liter) → urgent vascular surgery consultation	1 (1.9%)	Ligation of cephalic vein branch	0 (0.0%)		n/a
Development of acromioclavicular (AC) joint ganglion cyst (4 mo post-op)	1 (1.9%)	US-guided AC joint aspiration, injection (7 mo post-op) [#]	0 (0.0%)		n/a
Any secondary operation	4 (7.5%)		3 (3.4%)		0.43
Any Complication	19 (35.8%)		8 (9.2%)		0.0003
Any Complication (excluding 'Sensory')	9 (17.0%)		7 (8.0%)		0.17

[§] ROH = removal of hardware

* PT = physical therapy

[#] US = ultrasound