VIDEO Abstract

Two-Year Functional Outcomes of Operative vs Nonoperative Treatment of Completely Displaced Midshaft Clavicle Fractures in Adolescents

Results From the Prospective Multicenter FACTS Study Group

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Investigation performed at Boston Children's Hospital, Boston, Massachusetts, USA

Background: The optimal treatment of midshaft clavicle fractures is controversial. Few previous comparative functional outcome studies have investigated these fractures in adolescents, the most commonly affected epidemiologic subpopulation.

Purpose/Hypothesis: The purpose was to prospectively compare the outcomes of operative versus nonoperative treatment in adolescents with completely displaced midshaft clavicle fractures. The study hypothesis was that surgery would yield superior outcomes.

Study Design: Cohort study; Level of evidence, 2.

Methods: Patients aged 10 to 18 years treated for a midshaft clavicle fracture over a 5-year period at 1 of 8 pediatric centers were prospectively screened, with independent treatment decisions determined by individual musculoskeletal professionals. Demographics, radiographic clinical features, complications, and patient-reported outcomes (PROs) were prospectively recorded for 2 years. Regression and matching techniques were utilized to adjust for potential age- and fracture severity–based confounders for creation of comparable subgroups for analysis.

Results: Of 416 adolescents with completely displaced midshaft clavicle fractures, 282 (68) provided 2-year PRO data. Operative patients (n = 88; 31%) demonstrated no difference in sex (78% male) or athletic participation but were older (mean age, 15.2 vs 13.5 years; $P < .001$), had more comminuted fractures (49.4% vs 26.3%; $P < .001$), and had greater fracture shortening (25.5 vs 20.7 mm; $P < .001$) than nonoperative patients (n = 194; 69%). There was no difference in mean PRO scores or rates of ''suboptimal'' scores (based on threshold values established a priori) between the operative and nonoperative treatment groups (American Shoulder and Elbow Surgeons, 96.8 vs 98.4; shortened version of the Disabilities of the Arm, Shoulder and Hand, 3.0 vs 1.6; EuroQol [EQ] visual analog scale, 93.0 vs 93.9; EQ–5 Dimensions index, 0.96 vs 0.98), even after regression and matching techniques adjusted for confounders. Operative patients had more unexpected subsequent surgery (10.4% vs 1.4%; $P = .004$) and clinically significant complications (20.8% vs 5.2%; $P = .001$). Overall, nonunion (0.4%), delayed union (1.9%), symptomatic malunion (0.4%), and refracture (2.6%) were exceedingly rare, with no difference between treatment groups.

Conclusion: Surgery demonstrated no benefit in patient-reported quality of life, satisfaction, shoulder-specific function, or prevention of complications after completely displaced clavicle shaft fractures in adolescents at 2 years after injury.

Registration: NCT04250415 (ClinicalTrials.gov identifier).

Keywords: clavicle fracture; adolescent; upper extremity; trauma; functional outcomes

There has been an evolution in the treatment of displaced diaphyseal clavicle fractures over the past quarter century. The historical approach of sling or brace use and expectant healing shifted radically by 2010 toward operative treatment, in part because of a small number of impactful studies,[5,10,17] particularly a randomized controlled trial (RCT)

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published by the Canadian Orthopaedic Trauma Society in 2007,[5] which reported superior shoulder function with surgery. This trend has continued despite a number of subsequent adult RCTs[28,37,41,45] showing no difference in long-term function with nonoperative treatment but consistently lower nonunion rates with surgery.

While controversy remains regarding the optimal treatment for displaced clavicle shaft fractures, meta-analyses and systematic reviews of adult clavicle fracture studies[18,34,40,44,46] have made clear that the 2 most clinically significant risks of nonoperative treatment are nonunion and symptomatic malunion, which arise in approximately 15% and 10% of adult patients, respectively. Meanwhile, the most clinically significant risk of operative treatment appears to be painful implants requiring unexpected additional surgery for removal, which occurs in 15% to 20% of surgical patients.[13,18]

Importantly, the majority of the methodologically robust clavicle fracture studies in the literature have been performed in adult populations, the findings of which may be inappropriate to translate to younger age groups. In part because of the ongoing growth of the clavicle that occurs during and beyond the adolescent years, fracture healing and remodeling in this patient group are likely to be quite distinct from those in adults.[12] While adolescent clavicle fracture studies have consisted of small case series, they have established surgery as a relatively safe treatment for this age group, with symptomatic implant removal rates comparable with or greater than those in adults.[19,20,27,39] One retrospective adolescent study cited several instances of symptomatic malunion in patients with greater fracture shortening.[39] However, in one of the largest cohorts of nonoperatively treated adolescents, only 1 case each of nonunion and symptomatic malunion was reported in 185 patients, suggesting rates substantially lower than those in adults.[27] Additionally, criteria of comminution and fracture shortening, which may contribute to nonunion and symptomatic malunion in adults, do not appear to adversely influence outcomes in adolescents; good strength and functional outcome scores have been noted in adolescents despite severely shortened healed fractures.[2,22,31] Studies in adolescents have demonstrated equivalent patient-reported outcomes (PROs) and significantly higher complication rates with surgery when compared with no surgery.[9,15] Nevertheless, multiple studies have shown significant increases in the rates and volume of adolescent patients being treated with fixation.[6,36,47]

With the purpose of gathering prospective comparative data to improve the level of evidence for adolescent diaphyseal clavicle fracture treatment, a study group of surgeons from 8 pediatric centers was established. The current study was designed to investigate the outcomes of completely displaced fractures in operative and nonoperative cohorts, with the hypothesis that surgery would be associated with superior outcomes.

METHODS

All patients 10 to 18 years old treated for a clavicle shaft fracture between August 2013 and August 2017 at 1 of 8 geographically diverse tertiary care pediatric trauma centers were screened for inclusion. Any middiaphyseal fracture without extension into the proximal or distal ligamentous insertions was considered eligible. The current article represents an analysis of the subpopulation of patients with completely displaced fractures. Patients were excluded for inability to complete PROs (patient or guardian), planned follow-up at nonstudy sites, or underlying disorders (cognitive, neurologic, neuromuscular, or metabolic bone). All participants gave informed consent, and the study was approved by an institutional review board at each center.

Patients were subject to primary treatment decisions by 1 of 68 treating musculoskeletal professionals—orthopaedic surgeons and nonoperative musculoskeletal professionals—with an observational research study design, without randomization or established parameters for treatment. Caregivers had been oriented to the standard protocol, with clinical and radiographic follow-up 2 weeks, 6 weeks, and 3 months after injury (or postoperatively).

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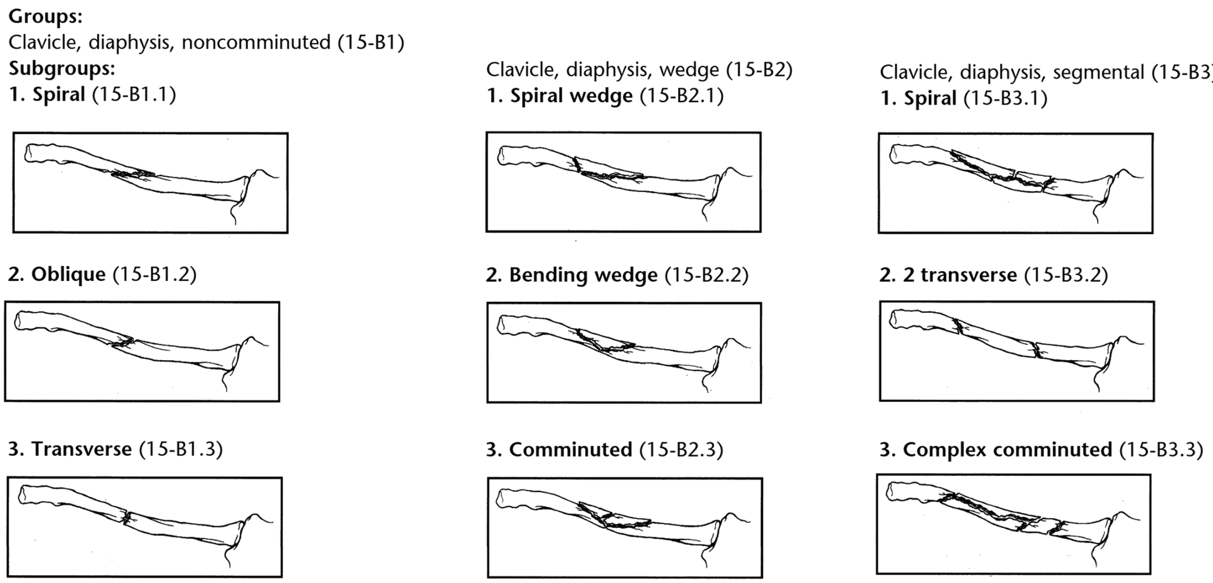

Figure 1. The AO classification system for clavicle fractures. Reprinted with permission from Marsh JL, Slongo TF, Agel J, et al. Fracture and dislocation classification compendium - 2007: Orthopaedic Trauma Association Classification, Database and Outcomes Committee. *J Orthop Trauma*. 2007;21(10):S1-S133. © 2007 Lippincott Williams & Wilkins. https://journals.lww.com/jorthotrauma/Citation/2007/11101/CLAVICLE.9.aspx)

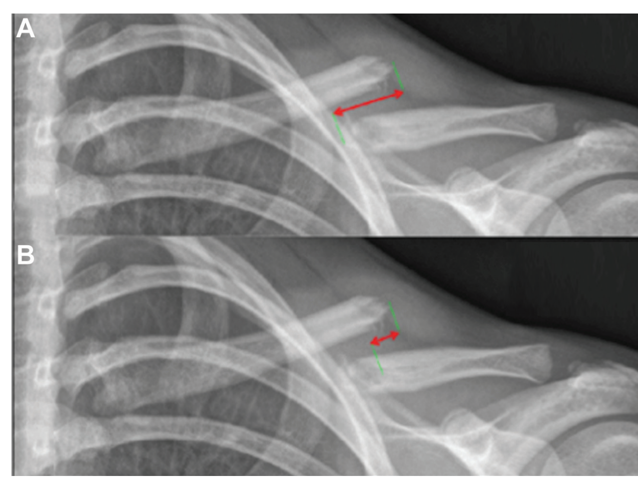

Figure 2. (A) End-to-end shortening is measured (arrow) from the ends of the fracture fragments (lines) that are at the greatest distance from each other, with adjustments for segmental comminution when applicable. (B) ''Cortex to corresponding cortex'' shortening is measured (arrow) from the ends of the fracture fragments (lines) that would be apposed if the fracture were reduced.

Radiographs at each visit until union included an anteroposterior view and cephalad view (15°-30° cephalad). Fracture classification, pattern, shortening, superior displacement, and healing were assessed radiographically by a single principal investigator from each site (B.E.H., A.T.P., Y.L., H.B.E., D.D.S., J.J.N., C.A.P., N.K.P.). Completely displaced fractures were defined by complete cortical discontinuity and/or no contact between fracture ends. Fracture pattern was determined by the AO classification system (Figure 1).

Fracture shortening was measured through 2 methods[14] with established intra- and interrater reliability: end-to-end shortening and "cortex to corresponding cortex" shortening (Figure 2). Healing was categorized as "no callus," "healing," or "healed." Delayed union was defined by absence of a healed fracture by 3 months; nonunion was defined by absence of a healed fracture by 6 months. Symptomatic malunion was defined by the presence of any symptoms (pain, fatigue, weakness, scapular dyskinesis, or shoulder dysfunction) reported ≥3 months after injury with a healed fracture.

The following data were collected: descriptive (age, sex, fracture laterality, hand dominance, and athletic participation), clinical (injury activity, mechanism of injury, and treatment approach), and surgical (fixation technique, implant type, and approach to sensory nerve dissection). Clinical course, complications (delayed union, nonunion, symptomatic malunion, refracture, infection, sensory deficit, implant-related symptoms, and other), and unexpected surgery were analyzed over time. Complications were reviewed by all principal investigators to develop agreement on characterization and classification utilizing the nominal group technique of consensus. The Clavien-Dindo complication classification[7] was modified for clavicle fractures (Table 1).[33] Complications were updated at each time point as "ongoing" or "resolved" based on symptoms.

Validated shoulder-specific functional outcome measures and activity surveys included the American Shoulder and Elbow Surgeons (ASES) score,[30] shortened version of the Disabilities of the Arm, Shoulder and Hand (QuickDASH) score,[1] and Marx shoulder activity score.[4] Other measures included one for global health, the EuroQol

TABLE 1
Modified Clavien-Dindo Classification for Clavicle Fractures[a]

Grade	Description	Clavicle Fracture Examples
1	A complication that requires no treatment and has no clinical relevance; there is no deviation from routine follow-up during the postoperative period; allowed therapeutic regimens include observation, antiemetics, antipyretics, analgesics, diuretics, electrolytes, antibiotics, and physical therapy	• Sensory signs (eg, numbness, decreased sensation, hypoesthesia, hypersensitivity to touch) around fracture site/incision or in upper extremity (as assessed/reported by clinician on physical examination) but no active patient complaint or clinical significance • Wound finding not requiring a change in postoperative care • Postoperative fever • Nausea • Constipation
2	A complication that leads to a deviation from the normal postoperative course (including unplanned clinic visits) or requires outpatient treatment, either pharmacologic or close monitoring	• Sensory symptoms (eg, tingling, paresthesias, hyperesthesias, dysesthesias) around fracture/incision site or in upper extremity (reported as a complaint by the patient) • Superficial wound infection (oral antibiotics, additional clinic visits) • Symptomatic malunion (eg, pain, scapular dyskinesis, fatigue, weakness at >3 mo) that requires extra analgesia, extra imaging (radiograph or CT), extra visits, or PT but does not require/undergo surgery • Symptomatic hardware (≥3 mo postoperatively) that does not require/undergo surgery • Refracture that does not require/undergo surgery • Delayed union (unhealed between 3 and 6 mo) that does not require/undergo surgery; standard of care is follow-up with extra radiographs and visits • Motor nerve palsy requiring bracing and/or close observation (ultimately achieves complete resolution)
3	A complication that is treatable but requires surgical or radiographic interventions or an unplanned hospital admission	• Symptomatic hardware (≥3 mo postoperatively) that requires/undergoes surgical treatment • Symptomatic malunion (eg, pain, thoracic outlet syndrome) that requires/undergoes surgical treatment • Clavicle refracture that requires/undergoes surgical treatment • Clavicle nonunion (unhealed >6 mo); standard of care is surgical treatment • Deep infection; standard of care is surgical treatment • Surgical hematoma that requires/undergoes surgical treatment • Peri-incisional neuroma that requires/undergoes surgical treatment • Deep vein thrombosis; standard of care is anticoagulation ± admission
4	A complication that is life threatening, requires ICU admission, or has the potential or likelihood of permanent disability; a complication that requires organ resection	• Permanent nerve injury (eg, brachioplexus) • Major vascular injury (eg, subclavian vein/artery) • Claviculectomy • Pulmonary embolism • CNS complication • Organ dysfunction
5	Death	

[a]CNS, central nervous system; CT, computed tomography; ICU, intensive care unit; PT, physical therapy.

visual analogue scale (EQ-VAS), one for quality of life, the EuroQol 5-Dimensions index (EQ-5D)[11] and one for general satisfaction (a 5-point score) (Figure 3). All measures were obtained at 6, 12, and 24 months via clinical follow-up and, when that was discontinued, via an institutional review board–approved sequence of emailed surveys, mailed surveys, and telephone calls, depending on patient completion. This process was standardized across all sites, with the central study institution approved to assist secondary sites with patient outreach.

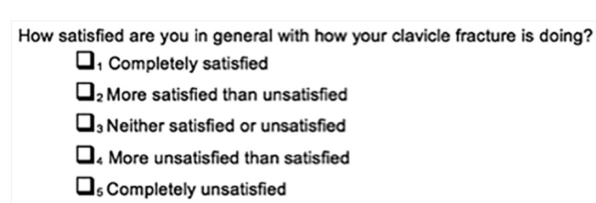
How satisfied are you in general with how your clavicle fracture is doing?
☐1 Completely satisfied
☐2 More satisfied than unsatisfied
☐3 Neither satisfied or unsatisfied
☐4 More unsatisfied than satisfied
☐5 Completely unsatisfied

Figure 3. Question on the patient-reported outcome form regarding general satisfaction with the injured shoulder/clavicle after treatment.

Statistical Analysis

All PROs were analyzed according to proprietary scoring guidelines. Interim analysis revealed severely skewed distributions of PRO scores in all metrics, with clear ceiling and floor effects, making standard t test analyses of mean scores statistically invalid. Therefore, to adjust for these

TABLE 2
Demographic Features and Fracture Characteristics Among Patients With 2-Year Patient-Reported Outcomes by Treatment Group[a]

Variable	Nonadjusted			Propensity Score–Matched Subgroups		
	Nonoperative (n = 194)	Operative (n = 88)	*P* Value	Nonoperative (n = 75)	Operative (n = 75)	*P* Value
Age at surgery, y	13.5 (12.1-15.1)	15.2 (14.4-16.6)	<.001	15.2 (13.9-16.7)	15.0 (14.2-16.3)	.82
Sex			.44			.44
Male	148 (76.3)	71 (80.7)		55 (73.3)	60 (80)	
Female	46 (23.7)	17 (19.3)		20 (26.7)	15 (20)	
Sports participation	160 (87.0)	75 (92.6)	.21	64 (85.3)	70 (94.6)	.10
Hand dominance			≥.99			.78
Right	176 (91.6)	80 (92.0)		69 (92.0)	67 (90.4)	
Left	16 (8.3)	7 (8.0)		6 (8.0)	7 (9.5)	
Shortening (end to end), mm	20.7 (15.0-26.0)	25.5 (19.0-31.3)	<.001	23.9 (19.0-29.0)	24.7 (18.0-30.1)	.67
Superior displacement, mm	12.1 (9.3-16.3)	16.0 (13.0-21.0)	<.001	15.6 (12.0-19.4)	16.0 (12.5-20.0)	.55
Comminution	51 (26.3)	43 (49.4)	<.001	32 (42.7)	36 (48.0)	.62

[a]Values are presented as median (interquartile range) or No. (%).

ceiling/floor effects, outcomes were dichotomized a priori by a statistician and investigator (including B.E.H.) blinded to the interim scores. Cutoffs were established at the ceiling (or floor) minus a value approximately equal to the minimal clinically important difference (MCID) derived from previous literature.[16,21,23,25,35,38,42,43] Thus, thresholds for "suboptimal" scores were established and comparatively analyzed between groups: ASES <90, QuickDASH >10, EQ-VAS <0.80, EQ-5D <0.80, general satisfaction >2. Overall group sample sizes of 182 (nonoperative) and 85 (operative) were found to achieve 80% power to detect a difference between group proportions of 0.11 (or 11%) on a 100-point survey scale at a .05 significance level. The proportion in the operative group was assumed to be 0.045 under the null hypothesis and 0.155 under the alternative hypothesis. This level of power was sufficient to capture the referenced MCIDs for the study PROs. The test statistic used was the 2-sided Fisher exact test. All tests were 2-sided, and $P < .05$ was considered statistically significant. This level of power was sufficient to capture the referenced MCIDs for the study PROs.

Preliminary analysis of the demographic and radiographic features of the 2 treatment groups revealed the presence of several differences that would serve as confounders to treatment group comparisons. Two statistical approaches were utilized to adjust for these confounders, based on previously described techniques.[3,26,48] First, propensity score matching analysis was performed to generate subgroups with equal distribution of the 4 confounders: age, shortening, superior displacement, and comminution. Study participants were randomly matched 1:1 based on propensity scores (within <1.0 standardized mean difference) to allow for those with equivalent baseline covariates to be compared in the 2 treatment groups. This resulted in 75 matched pairs. Second, logistic regression analysis was utilized for adjusted modeling and as a measure of association, where appropriate. For all statistical analyses, SAS software (Version 9.4; SAS Institute) was used.

RESULTS

A total of 416 adolescent patients with completely displaced midshaft fractures were enrolled and included in the current study (Figure 4). Of these, 282 (68%) provided adequate 2-year minimum after-injury PRO data, with no difference between operative (70%) and nonoperative (67%) groups. Of 2-year PRO patients, 88 (31%) underwent operative treatment, while 194 (69%) were treated nonoperatively. When demographic and fracture variables were compared (Table 2), those treated operatively showed no difference in sex or athletic participation but were older, had more comminuted fractures, and had greater fracture shortening than those treated nonoperatively.

Mean 2-year PROs were similar between the nonoperative and operative treatment groups, and there was no significant difference in the rates of suboptimal PROs, as established by a priori MCID thresholds (Table 3). Propensity score–matched subgroups—matched on age, shortening, superior displacement, and comminution—showed no significant differences for any of the PRO parameters (Table 4). In the regression analysis, treatment group was not found to have an association with any of the PRO scores when controlling for the 4 identified confounders (Table 5).

Complications were assessed in the overall cohort and compared between operative and nonoperative treatment groups (Table 6). Complications were significantly less common in nonoperative patients (5.5%) than operative (43.2%, $P < .001$), a difference that was maintained when sensory deficits were excluded (all of which were Clavien-Dindo level 1 complications; 5.2% vs 20.8%; $P = .001$). There were significantly more cases of unexpected additional surgery in the operative group (10.4%) than the nonoperative group (1.4%; $P = .004$). Overall, nonunion (0.4%), delayed union (1.9%), symptomatic malunion (0.4%), and refracture (2.6%) were exceedingly rare, and were not different between treatment groups.

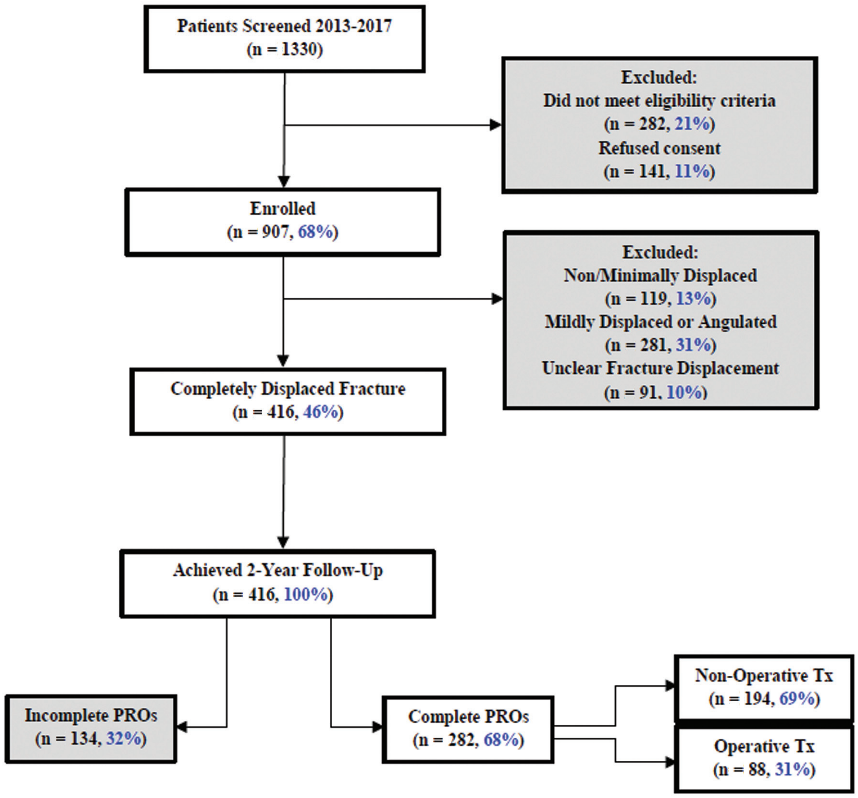

Figure 4. Study inclusion flowchart. PRO, patient-reported outcome; Tx, treatment.

TABLE 3
Distribution of 2-Year PROs by Treatment Group[a]

PRO: Statistical Metric	Nonoperative (n = 194)	Operative (n = 88)	*P* Value[b]
ASES			
Mean (SD)	98.4 (6.2)	96.8 (7.7)	
Suboptimal score (<90), No. (%)	9 (4.7)	8 (9.1)	.18
QuickDASH			
Mean (SD)	1.6 (6.2)	3.0 (7.9)	
Suboptimal score (>10), No. (%)	10 (5.2)	6 (6.8)	.58
EQ-VAS			
Mean (SD)	93.9 (8.4)	93.0 (8.2)	
Suboptimal score (<80), No. (%)	8 (4.2)	6 (6.8)	.38
EQ-5D			
Mean (SD)	0.98 (0.08)	0.96 (0.09)	
Suboptimal score (<0.80), No. (%)	8 (4.2)	6 (6.8)	.38
General satisfaction			
Mean (SD)	1.3 (0.7)	1.3 (0.8)	
Suboptimal score (>2), No. (%)	15 (7.9)	7 (8.1)	≥.99

[a]Because of a severely skewed distribution of PRO scores seen on interim analyses, thresholds were established for dichotomized score adjustments for ceiling effects (ASES, EQ-VAS, EQ-5D) and floor effects (QuickDASH, general satisfaction). ASES, American Shoulder and Elbow Surgeons; EQ-5D, EuroQol 5-Dimension index; EQ-VAS, EuroQol visual analog scale; PRO, patient-reported outcome; QuickDASH, shortened version of the Disabilities of the Arm, Shoulder and Hand.

[b]*P* values were calculated for the distribution of patients with suboptimal scores rather than for mean scores.

The most common clinically significant complication was implant pain or irritation, which occurred in 8.8% of operative patients, with 4.8% undergoing unexpected additional surgery for implant removal. Of note, no patients in the current cohort underwent a planned secondary procedure; in all instances, implant removal surgery was performed to address unexpected implant-related symptoms. One patient in the nonoperative group was a crossover

TABLE 4
Adjusted Analysis of 2-Year PROs: Propensity Score–Matched Subsamples[a]

PRO: Statistical Metric	Nonoperative (n = 75)	Operative (n = 75)	P Value[b]
ASES			
Mean (SD)	98.0 (6.4)	96.8 (7.9)	—
Suboptimal score (<90), No. (%)	4 (5.6)[c]	6 (8.0)	.74
QuickDASH			
Mean (SD)	1.9 (6.8)	2.9 (7.5)	—
Suboptimal score (>10), No. (%)	5 (6.8)[d]	5 (6.8)[d]	≥.99
EQ-VAS			
Mean (SD)	94.3 (6.8)	92.6 (8.4)	—
Suboptimal score (<80), No. (%)	3 (4.0)	6 (8.1)[d]	.33
EQ-5D			
Mean (SD)	0.97 (0.1)	0.96 (0.1)	—
Suboptimal score (<0.80), No. (%)	5 (6.7)	5 (6.8)[d]	≥.99
General satisfaction			
Mean (SD)	1.4 (0.7)	1.3 (0.7)	—
Suboptimal score (>2), No. (%)	6 (8.1)[d]	5 (6.8)[d]	≥.99

[a]Because of a severely skewed distribution of PRO scores seen on interim analyses, thresholds were established for dichotomized score adjustments for ceiling effects (ASES, EQ-VAS, EQ-5D) and floor effects (QuickDASH, general satisfaction). ASES, American Shoulder and Elbow Surgeons; EQ-5D, EuroQol 5-Dimension index; EQ-VAS, EuroQol visual analog scale; PRO, patient-reported outcome; QuickDASH, shortened version of the Disabilities of the Arm, Shoulder and Hand.
[b]*P* values were calculated for the distribution of patients with suboptimal scores rather than for mean scores.
[c]n = 73.
[d]n = 74.

TABLE 5
Regression Modeling Analysis of 2-Year PROs: Unadjusted and Adjusted for Potential Confounders[a]

PRO	Unadjusted Model, OR (95% CI)	P Value	Adjusted Model, OR (95% CI)	P Value
ASES (n = 280)	0.69 (0.50 to 1.68)	.17	0.64 (–0.47 to 1.75)	.26
QuickDASH (n = 280)	0.29 (–0.76 to 1.33)	.59	0.21 (–0.96 to 1.38)	.73
EQ-VAS (n = 280)	0.52 (–0.57 to 1.61)	.35	0.92 (–0.37 to 2.20)	.16
EQ-5D (n = 281)	0.53 (–0.56 to 1.62)	.34	0.42 (–0.79 to 1.63)	.50
General satisfaction (n = 278)	0.01 (–0.93 to 0.94)	.99	–0.27 (–1.36 to 0.83)	.63

[a]Potential confounders: age, comminution, shortening, and superior displacement. ASES, American Shoulder and Elbow Surgeons; EQ-5D, EuroQol 5-Dimension index; EQ-VAS, EuroQol visual analog scale; OR, odds ratio; PRO, patient-reported outcome; QuickDASH, shortened version of the Disabilities of the Arm, Shoulder and Hand.

who had demonstrated incomplete healing 2 months after injury and underwent plate fixation. This participant was analyzed in the nonoperative cohort based on the intention-to-treat statistical principle. This patient developed implant-related symptoms prompting removal surgery 10 months postoperatively. Decreased sensation or loss of sensation around the clavicle region was reported in 22.4% of operative patients, with 1 nonoperative patient reporting chest wall paresthesias that resolved by 6 months after injury. Rates of nonunion, delayed union, and refracture were not significantly different between treatment groups (Table 6). Two nonoperative patients (0.7%) developed nonunion: the first underwent nonunion takedown and plate fixation surgery at 6 months after injury, and the second was an 11-year-old boy with a fibrous nonunion who remained asymptomatic throughout the 2-year follow-up period, having played 3 seasons of baseball. Symptomatic malunion was detected in 2 nonoperative patients (0.7%), with 1 patient's symptoms resolving with physical therapy and the other patient undergoing an operative ostectomy, or "bumpectomy," for a bony prominence approximately 1 year after injury. Refracture occurred in 6 patients in the nonoperative group (2.1%), all of whom healed with additional nonoperative treatment. In the subset of 5 operative patients who sustained refractures (4.0%), 3 underwent additional surgery: 2 operations addressed peri-implant fractures, and the other addressed fracture through a screw hole after implant removal. Six patients in the operative group sustained "other" complications, 2 of which were associated with 3 unexpected additional operations. Of 2 patients with wound dehiscence, 1 underwent operative irrigation/debridement and closure. One patient cited severe neck pain immediately after plate fixation surgery, with imaging revealing atlantoaxial rotatory subluxation. After failed resolution with nonoperative measures and halo traction surgery, she underwent C1-2 cervical fusion

TABLE 6
Complications of Completely Displaced Midshaft Clavicle Fractures: Operative Versus Nonoperative Cohorts With 2-Year Follow-up[a]

	Nonoperative (n = 291)		Operative (n = 125)		
Complication	No. (%)	Clinical Outcome	No. (%)	Clinical Outcome	*P* Value
Hardware pain/irritation	1 (0.34)	Crossover Pt: ORIF 2 mo after injury ⟶ ROH surgery 10 mo postoperatively	11 (8.8)	6 of 11 (55%, 4.8% overall): ROH surgery (mean, 22 mo postoperatively)	<.0001
Sensory symptoms	1 (0.34)	Occasional paresthesias ⟶ spontaneously resolved 6 mo after injury	28 (22.4)	Peri-incisional numbness (resolved in 6 of 28, 21.4%; mean, 4.3 mo postoperatively)	<.0001
Superficial infection	0 (0.0)		0 (0.0)		
Deep infection	0 (0.0)		0 (0.0)		
Delayed union	4 (1.4)	Pts 1-3: nonoperative tx ⟶ healed Pt 4: no callus 2 mo after injury ⟶ ORIF	4 (3.2)	Pt 1-3: bone stimulators ⟶ healed 6 mo postoperatively Pt 4: observation ⟶ healed 5 mo postoperatively	.43
Nonunion	2 (0.7)	Pt 1: Asymptomatic Pt 2: ORIF 6 mo after injury	0 (0.0)		≥.99
Symptomatic malunion	2 (0.7)	Pt 1: Physical therapy ⟶ resolved Pt 2: Bump (exostosis) ⟶ resolved	0 (0.0)		≥.99
Refracture	6 (2.1)	Pts 1-6: nonoperative tx ⟶ healed	5 (4.0)	Pts 1-2: Post-ROH trauma ⟶ 1 nonoperative tx ⟶ healed; 1 re-ORIF Pt 3-5: Peri-implant fx ⟶ 2 re-ORIF; 1 nonoperative tx ⟶ healed	.32
Other	0 (0.0)		6 (4.8)		.0007
Atlantoaxial rotatory subluxation (immediately postoperative)	0 (0.0)		1 (0.8)	Unresponsive to halo traction ⟶ C1-2 fusion	
1-L estimated blood loss ⟶ urgent vascular surgery consultation	0 (0.0)		1 (0.8)	Ligation of subclavian vein branch	
AC joint ganglion cyst (4 mo postoperatively)	0 (0.0)		1 (0.8)	Ultrasound-guided AC joint aspiration, cortisone injection (7 mo postoperatively) ⟶ resolved	
Wound dehiscence	0 (0.0)		2 (0.8)	Pt 1: Irrigation/debridement and closure Pt 2: Wound care	
Horner syndrome	0 (0.0)		1 (0.8)	Resolved	
Any unexpected additional surgery	4 (1.4)		13 (10.4)		.004
Any complication	16 (5.5)		54 (43.2)		<.001
Any complication (excluding "sensory")	15 (5.2)		26 (20.8)		.001
Complications[b]					
Level 2	11 (3.8)		13 (10.4)		
Level 3	4 (1.4)		13 (10.4)		

[a]AC, acromioclavicular; fx, fracture; ORIF, open reduction and internal fixation; Pt, patient; ROH, removal of hardware; tx, treatment.
[b]Modified Clavien-Dindo classification (Table 1).

surgery, with eventual resolution of neck pain and near-normal range of motion, with some limitations in athletic participation.

DISCUSSION

In a large prospective cohort study of adolescent clavicle fractures at 8 pediatric trauma centers across the United States, operative treatment for completely displaced clavicle fractures demonstrated no benefit over nonoperative treatment in terms of 2-year validated shoulder and upper extremity functional outcomes, global health, quality of life, patient satisfaction, or prevention of complications. Complications and unexpected additional surgery were significantly more common in the operative cohort. Given the inherent differences in age and fracture severity that emerged in the treatment groups, 2 statistical methods were applied to ensure comparability between analyzed subcohorts. Regression and matching techniques revealed no difference in PROs between treatments and no significant influence of treatment selection on outcome scores, even when controlling for confounding factors.

Nonunion is the most significant complication and cause of suboptimal function after nonoperative treatment in adults and was exceedingly rare in the adolescent study population. When compared with the meta-analysis of 6 RCTs studying adult populations by McKee et al,[18] in which 14.5% of 200 patients developed nonunion, the current prospective study detected only 2 adolescent patients with nonunions out of 292 treated nonoperatively, for a rate <1%. A previous retrospective multicenter study from 9 pediatric referral centers also demonstrated the rarity of this complication in this age group. Only 25 adolescent midshaft clavicle nonunions were reported over an 11-year period, suggesting a rate of 0.25 cases per year among all the clavicle fractures seen at each center.[24] In the current cohort, 1 patient underwent nonunion takedown and open reduction and internal fixation (ORIF), and the other patient with a nonunion remained asymptomatic, with no interventions requested during the >2 years of close follow-up and with normal activity scores, normal function scores, and full participation in competitive sports. This course suggests that a subset of patients may exist who tolerate clavicular nonunion better than expected. This notion is supported by an adult patient RCT from Finland, in which a 24% nonunion rate in a nonoperatively treated cohort of 32 patients did not influence 1-year functional outcome scores enough to show a difference, as compared with 8 operatively treated patients.[41]

Delayed union is another complication that may be particularly relevant to the adolescent subpopulation. These patients often have higher baseline activity levels than their adult counterparts, and they are often eager to return to sports and full activity soon after injury. There was no difference in the rate of delayed union between treatment groups, although 1 nonoperative patient underwent ORIF 2 months after injury because of slow healing. While not meeting initial study criteria because of delayed union, which was defined as failure to heal between 3 and 6 months, this patient was categorized as an "impending" delayed union to avoid underreporting this complication.

Historically, symptomatic malunion has represented the other concerning complication of nonoperative treatment of clavicle fractures. In addition to several studies of adults,[17,32] 1 retrospective series described 4 of 15 adolescent patients with completely displaced fractures who were initially treated nonoperatively but later underwent osteotomy and plate fixation for symptomatic malunions. No functional outcome measures were obtained in either treatment group, and no statistical comparison was made with the operative group, 16% of whom underwent secondary surgery for hardware removal. The current prospective study demonstrated a 0.7% rate of symptomatic malunion, with 1 of the 2 identified patients undergoing an ostectomy to treat a symptomatic bony prominence. If the true rate of symptomatic malunion was higher than that detected by the current study methods, an adverse effect on shoulder-specific functional outcome measures might be expected. Instead, no statistically significant differences in PROs were detected. This remained true even after controlling for differences in age and fracture severity. The current study does not clearly show what factors contributed to this significantly lower rate of symptomatic malunions in adolescents, as compared with that seen in a previous single retrospective study of 15 adolescent patients and previous studies of adults. Not only does ongoing fracture remodeling occur in this younger patient group, but the growing shoulder may have more accommodating muscular and kinematic function that normalizes and rehabilitates to a greater or faster degree than that of the mature shoulder girdle.

The significantly higher rate of unexpected additional surgery and complications in the operative group, which remained higher even when sensory changes related to clavicle incisions were excluded, is notable for a 2-year follow-up study. While additional patients from the current cohort may have complications of nonoperative treatment, the subset of patients with hardware-related symptoms or complications may increase. For example, Leroux et al[13] reported a hardware removal rate of 18.8% in an adult population, whose activity level would be assumed to be lower than the current adolescent cohort. The instances of peri-implant fracture in the current series, 2 of 3 of which required unexpected additional surgery, may also stem from a relatively active, largely male subpopulation, whose involvement in contact sports is not frequently seen in less active adult populations. Other studies have shown similar findings. In a study of 36 adolescent patients treated operatively, Li et al[15] cited 59% plate prominence/irritation and 42% secondary plate removal, as well as several cases of wound dehiscence, peri-implant fracture, and refracture after removal.

While the current study does not identify a subgroup of adolescents who clearly benefit from surgery as compared with nonoperative treatment, separate ongoing investigations of specific subpopulations, such as older adolescent athletes and severely comminuted *z*-type fractures, are being performed to identify potentially robust surgical indications. However, until such additional studies can identify clear groups that may benefit from surgical treatment, the current data—including complications such as the case of atlantoaxial rotatory instability that may have been related to head positioning during clavicle fracture fixation surgery[29]—may represent a caveat against the documented increasing trend of surgical treatment in children without literature-based support.[8]

A limitation of the current study is the absence of robust early follow-up data, such as consistent time to radiographic healing, return to sports, and early PROs (3, 6, and 12 months). Because study design allowed multiple noninvestigator caregivers to independently manage care, lower rates of early follow-up were achieved than anticipated, despite a regimented follow-up schedule. This is reflective of current variation in management, which the study investigators hope to improve with more research, and the speed with which adolescent patients recover from this injury, regardless of treatment. While the 2-year PRO response rate was 68%, which may introduce some response bias, it was approximately equivalent in the operative and nonoperative treatment groups. Similarly, while 2-year follow-up may be considered adequate in providing an understanding of the natural history of adolescent shoulder function after a clavicle fracture, the current study does not capture the perspective that a 5- or 10-year follow-up study might provide, in which shortening or clavicle implants might influence longer-term function. Another limitation is the previously described differences in treatment groups. While standard statistical methods—propensity score matching and regression techniques—were utilized to control for potential confounders and analyze comparable subgroups, there remains underlying selection bias in the operative group toward older patients with more severe fractures. Randomized controlled trials are designed to eliminate such differences and may be warranted for the adolescent subpopulation in the future. Another limitation of the study design is the lack of standardization of operative techniques—such as the use of different dissection techniques, plate types, or plate positions—and nonoperative treatment methods—such as the timing of sling care, the sling type, or the use of physical therapy. However, these are more reflective of existing practice variation, with more generalizable results.

CONCLUSION

At 8 large pediatric centers with many caregivers making independent treatment decisions, surgery for completely displaced clavicle shaft fractures in adolescents yielded no increased benefit in patient-reported quality of life, shoulder-specific functional outcomes, and satisfaction compared with nonoperative treatment and led to higher rates of unexpected additional surgery and complications at 2-year follow-up. Unlike several adult studies showing superiority of operative treatment, this study demonstrated equivalent functional outcomes and lower complications with nonoperative treatment.

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