Intermediate-Term Outcomes Following Operative and Nonoperative Management of Midshaft Clavicle Fractures in Children and Adolescents

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Background: Although multiple prospective comparative studies exist for adults with midshaft clavicle fractures, few comparative studies exist in older children and adolescents. This study compares intermediate-term functional, pain, radiographic, and complication outcomes in children and adolescents with midshaft clavicle fractures treated operatively or nonoperatively.

Methods: Children and adolescents who were 10 to 18 years of age with midshaft clavicle fractures treated from 2006 to 2017 were identified through electronic picture archiving and communication system (PACS) radiographic and chart review. Closed injuries with a minimum of 1 year from the time of the injury were included. Patients completed patient-reported outcome measures and a focused questionnaire. The primary outcome was the abbreviated Disabilities of the Arm, Shoulder and Hand Questionnaire (QuickDASH) score; the secondary outcomes included the University of California Los Angeles (UCLA) Activity Scale, Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference (PI) and PROMIS Physical Function (PF) Upper Extremity (UE), Hospital for Special Surgery Pediatric Functional Activity Brief Scale (HSS Pedi-FABS), Numeric Rating Scale (NRS) for Pain, and rates of implant removal, nonunion, and refracture. Univariate comparisons between the operatively treated group and the nonoperatively treated group were performed.

Results: In this study, 302 patients were identified; of these, 79 patients (43 operatively treated and 36 nonoperatively treated) or their parent or legal guardian consented and the patients completed the study protocol. The mean age (and standard deviation) at the time of the injury was 16.0 ± 1.7 years for the operatively treated group and 13.5 ± 1.8 years for the nonoperatively treated group (p < 0.001). The median follow-up was 3.8 years. The patient-reported outcome scores were similar (p > 0.05 for all comparisons) between the operatively treated group and the nonoperatively treated group, even for patients at or near skeletal maturity and those with shortening of ≥15 mm or ≥100% translation. There were no nonunions. The refracture rate was 5% (2 of 43) for the operatively treated group and 3% (1 of 36) for the nonoperatively treated group (p = 1.00). There were 19% (8 of 43) who underwent implant removal. Responders were similar to nonresponders, other than female patients (p < 0.001) and surgically treated patients (p = 0.049) being more likely to respond.

Conclusions: In the subset of this cohort who responded and completed the study, both operatively and nonoperatively treated patients had excellent functional and pain outcomes, similar refracture rates, and no nonunions. Even in widely displaced and translated fractures, and in those at or near skeletal maturity, outcomes were similar. Operative management should potentially be reserved for special circumstances. A prospective comparative study of older adolescents (female patients who are 14 to 18 years of age and male patients who are 16 to 20 years of age) with displaced midshaft clavicle fractures is warranted.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

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The incidence of clavicle fractures in children is 13 to 19 fractures per 10,000 children, with 90% of clavicle fractures occurring in the midshaft. Traditionally, even displaced midshaft clavicle fractures in children and adolescents were not treated operatively because of documented excellent remodeling potential of the clavicle. Although surgical treatment gained popularity for displaced fractures in adults after improved functional outcomes and lower nonunion rates were reported in a randomized trial, few comparative studies exist in older children and adolescents, resulting in widespread controversy in the management of midshaft clavicle fractures in this population.

A survey of the Pediatric Orthopaedic Society of North America (POSNA) members demonstrated greater support for operative fixation in older adolescents and in severe fracture patterns. Adult literature was the greatest factor influencing treatment preference. Over 90% of POSNA members were in favor of nonoperative treatment for nondisplaced midshaft clavicle fractures, but there was notable disagreement about the need for operative fixation of segmental fractures in adolescents.

Recent meta-analyses identified a nonunion rate in patients <19 years of age of <1% to 2% for nonoperative management and <1% to 3% for operative management. Gao et al. reported faster union, earlier return to sports, a higher Constant score, higher rates of complication, and a high rate of secondary surgical procedures with operative management. In contrast, Nawar et al. reported no difference in time to union, return to activity, or complications between operative and nonoperative management. Both meta-analyses concluded that excellent outcomes followed both operative and nonoperative management. The original studies contributing to these meta-analyses were limited by notably small series or lack of sufficient patient-reported outcomes to fully compare functional and pain outcomes between groups.

The primary aim of this study was to determine if intermediate-term functional outcomes were improved with operative treatment compared with nonoperative treatment, measured by the abbreviated Disabilities of the Arm, Shoulder and Hand Questionnaire (QuickDASH) score. The secondary aims included comparison of union, implant removal, and refracture rates, as well as additional functional outcomes measured by the University of California Los Angeles (UCLA) Activity Scale, Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function (PF) Upper Extremity (UE), and Hospital for Special Surgery Pediatric Functional Activity Brief Scale (HSS Pedi-FABS) scores, and pain measured by the PROMIS Pain Interference (PI) score and by the Numeric Rating Scale (NRS) for Pain score. It was hypothesized that scores would be similar for patient-reported outcome measures (PROMs) between operative and nonoperative groups.

**Materials and Methods**

Patients who were 10 to 18 years of age at the time of a closed midshaft clavicle fracture treated between 2006 and 2017 with a minimum 1-year follow-up were identified through billing records and a picture archiving and communication system (PACS) radiographic search. Patients were treated at the Hospital for Special Surgery (HSS) and/or New York Presbyterian (NYP)-Weill Cornell Medical Center. Through chart reviews, demographic, radiographic, and treatment data were extracted, and patients were identified as having been treated operatively with plate fixation or having been treated nonoperatively with a sling. Fracture classification, translation, and shortening were measured by 2 senior orthopaedic surgery residents and were confirmed by a board-certified pediatric orthopaedic surgeon. Fracture shortening was measured from cortex to cortex. Study introduction was by mail and email. This was followed by a telephone contact to discuss study details and obtain oral informed consent. A minimum of 5 attempts were made to contact patients before considering them lost to follow-up.

Consent was obtained from the patients or their parent or legal guardian as appropriate. PROMs, including QuickDASH, UCLA Activity Scale, PROMIS PI and PROMIS PF UE scores, HSS Pedi-FABS, and NRS for Pain, were administered by an email link to the Outcomes Based Electronic Research Database (OBERD) website, whereby forms could be completed electronically. A brief questionnaire given by telephone surveyed complications relating to their management, including the requirement for an additional surgical procedure or treatment for nonunion, re-fracture, or a symptomatic implant.

The primary outcome was the QuickDASH score, and secondary outcomes included the UCLA Activity Scale, PROMIS PI, PROMIS PF UE physical function, HSS Pedi-FABS, NRS Pain scores, and nonunion, implant removal, and refracture rates. The QuickDASH is scaled from 0 to 100 points, with a higher score indicating greater disability. The normative value for the QuickDASH in adults who were 20 to 29 years of age has been reported at 5 for men and women. The UCLA Activity Scale ranges from 1 to 10, with a higher score reflecting greater sports participation. The HSS Pedi-FABS is an 8-item construct that evaluates the frequency of activity (“less than 1 time per month” to “more than 4 times per week”), with normative data having revealed a mean score (and standard deviation) of 15.4 ± 8.5 points and the maximum is 30 points. PROMIS CATs were used to minimize question fatigue. The PROMIS PI assesses the impact of pain on daily living over the past 7 days. The measure is on a scale of 0 to 100 points (normative mean, 50 ± 10 points), with higher scores indicating greater pain interference. The PROMIS PF UE evaluates activities requiring the use of an upper extremity (shoulder, arm, or hand). The PROMIS PF UE is also on a scale of 0 to 100 points (normative mean, 50 ± 10 points), with higher scores indicating better function. The NRS for Pain records pain ratings corresponding to a patient’s best (lowest) pain and worst pain level over the past 24 hours, scored from 0 (no pain) to 10 (worst pain imaginable).
bone diameter), age at the time of the injury, and age at the time of the telephone follow-up. The Mann-Whitney U test was used to compare time from the injury to follow-up and PROM scores (QuickDASH, NRS for Pain, HSS Pedi-FABS, UCLA, PROMIS PI, PROMIS PF UE). Univariate comparisons between the operatively treated group and the nonoperatively treated group were performed using a t test for normally distributed continuous variables, Mann-Whitney U test for non-normally distributed continuous variables, and Fisher exact test for categorical variables. Demographic characteristics and limited outcomes of nonresponders were compared with study participants. Female patients were more likely to participate than male patients (35% female participants compared with 16% female nonresponders; p < 0.001), as were those treated surgically (54% of participants were treated operatively compared with 41% of nonresponders treated operatively; p = 0.049).

The majority of patients were male and left-sided fractures were more common (Table I). The mean age at the time of the injury was 14.9 ± 2.1 years. Patients in the operative group were older than in the nonoperative group (mean age, 16.0 compared with 13.5 years; p < 0.001). The median time to follow-up for all patients was 3.8 years (range, 1.0 to 10.1 years). The mean age at the time of follow-up was 19.3 ± 3.4 years: 20.7 ± 3.3 years for the operatively treated group and 17.6 ± 2.7 years for the nonoperatively treated group. Forty-one (95%) of 43 operatively treated patients were treated by an adult orthopaedic surgeon, and 30 (83%) of 36 nonoperatively treated patients were treated by a pediatric orthopaedic surgeon.

### Results

#### Patient Demographic Characteristics

In this study, 302 patients met inclusion criteria, we obtained consent from 120 patients (40%) or their parents or guardians, and 79 patients (26%) completed PROMs and questionnaires. Of the 302 patients, 9% (28 patients) declined participation and 51% (154 patients) were lost to follow-up. Based on chart and radiographic review alone for the nonresponders, the nonresponders were of similar age, and refracture and implant removal rates were similar compared with study participants. Female patients were more likely to participate than male patients (35% female participants compared with 16% female nonresponders; p < 0.001), as were those treated surgically (54% of participants were treated operatively compared with 41% of nonresponders treated operatively; p = 0.049).

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### Radiographic Comparison

The complete radiographic data for 63 patients are presented in Table II.

#### Union, Refracture, and Implant Removal

There were no nonunions in either group. There were 1 ipsilateral refracture in the nonoperatively treated group (3%) and 2 ipsilateral refractures in the operatively treated group (5%) (p = 1.00). Eight patients (19%) treated operatively underwent removal of the implant during the study period.

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Patient-Reported Outcomes

PROM scores were similar comparing patients who were treated operatively and those who were treated nonoperatively (Fig. 1). Patients with ≥100% translation were more likely to be treated operatively (p = 0.005), yet patients with shortening of ≥15 mm or translation of ≥100% demonstrated PROM scores that were similar to those below this threshold (p > 0.05 for all comparisons) (Figs. 2 and 3). Operative treatment was used for 81% (26 of 32) of older adolescents (female patients ≥14 years of age and male patients ≥16 years of age at the time of the injury), yet PROM scores were similar (p > 0.05 for all comparisons) between operatively and nonoperatively treated older adolescents (Fig. 4).

Discussion

The goal of this study was to determine, at the intermediate-term follow-up, whether functional, pain, union, implant removal, and refracture outcomes were improved in children and adolescents with midshaft clavicle fractures treated operatively compared with nonoperatively. Scores were similar between groups; at the intermediate-term follow-up, patients in both groups had no pain and were functioning normally with no nonunions and similar refracture rates. The mean age for patients treated operatively was 2.5 years older than for patients treated nonoperatively. Patients treated operatively were more likely to have translation of ≥100%. In a subanalysis of patients with greater shortening and translation and in older patients at or near skeletal maturity, scores remained similar. Of the operatively treated patients, 19% underwent subsequent implant removal. The majority of patients treated nonoperatively were treated by pediatric orthopaedic surgeons, and the majority of patients treated operatively were treated by adult orthopaedic (sports, trauma, and upper extremity) surgeons.

Two recent meta-analyses studied operative management compared with nonoperative management of midshaft clavicle fractures in children and adolescents. In their meta-analysis, Gao et al. included 12 studies and concluded that operative management yields faster return to activity, superior Constant scores, and equal QuickDASH scores. Although Constant scores were significantly higher in operatively treated patients, all patients demonstrated favorable scores compared with the general, uninjured population. In their meta-analysis of 7 studies, Nawar et al. reported no difference in time to union, return to activity, or complications between operative and nonoperative management, concluding that there is no significant difference between operative and nonoperative management in the skeletally immature population. The lack of nonunions in this cohort is consistent with the low rate reported in these meta-analyses (nonunion rates of <1% to 2% for nonoperative management and <1% to 3% for operative management). The refracture rates of 5% in the operatively treated group and 3% in the nonoperatively treated group are in keeping with previously reported rates of 0% to 8.7%. Our implant removal rate of 19% is in keeping with the previously reported rate of 15%. The findings of the current study concur with both meta-analyses’
conclusions with regard to no difference in QuickDASH scores. Of note, meta-analyses can only be as good as the pooled studies that make them, and in these meta-analyses, many of the original studies were limited by the lack of a comparison group, small series\textsuperscript{1,9-21}, or, in larger cohorts, limited PROMs that, in turn, limited the comparison of functional outcomes\textsuperscript{13}.

Range of motion, strength, and endurance have been investigated following operative and nonoperative management. In a pilot (underpowered) study of 8 operatively treated and 8 nonoperatively treated displaced clavicle fractures with >15-mm shortening, Parry et al. noted similar patient satisfaction and PROMs (QuickDASH and Constant scores). There was no difference in range of motion, strength, or endurance between operatively and nonoperatively treated patients, although operatively treated patients had 3% decreased abduction endurance compared with the uninjured side. That study was limited by the small sample size\textsuperscript{15}. In their study, Schulz et al. reported on 16 nonoperatively treated pediatric fractures with a mean displacement of 11.8 mm (range, 5 to 21 mm)\textsuperscript{21}; strength deficits were observed. They compared the operative side with the nonoperative side; there was no control group. Importantly, the nonoperative side was the dominant side for 81% (13 of 16) of patients, and the dominant side is known to be stronger without exception in male patients and female patients\textsuperscript{35}. External rotation maximal strength was reduced by 8.4% (p = 0.04) and abduction endurance diminished by 12% (p = 0.04) compared with the uninjured side\textsuperscript{21}. The strength differential between dominant and nondominant arms is estimated at 3% to 10%\textsuperscript{36-42}. It is not possible to discern whether these identified strength differences are due to weakness after healing in a malunited state or confounding due to hand dominance. QuickDASH scores were similar to normative values\textsuperscript{21}. That study was limited by the small sample size of 16 patients, the lack of a comparison group, and the lack of control for hand dominance.

In a study of 16 children and adolescents with malunion following an initial fracture with displacement of ≥2 cm, Bae et al. noted no clinically important pain, loss of strength, loss of motion, or difference in patient satisfaction and aesthetic appearance\textsuperscript{43}. They concluded that motion and strength concerns in displaced nonsegmental fractures should not dictate the need for surgical fixation.

In adults, the COTS published the first randomized trial of operative compared with nonoperative management of displaced midshaft clavicle fractures. The time to radiographic union was shorter for operative treatment (16 weeks) compared with nonoperative treatment (28 weeks). The nonunion rates were 3% (2 of 62 patients) for operative treatment and 14% (7 of 49 patients) for nonoperative treatment. Satisfaction was superior in the operatively treated group at 1 year (84% compared with 53% satisfied) (p < 0.05). Constant and QuickDASH scores were superior across all time points in the operative group (p ≤ 0.05 for all comparisons)\textsuperscript{5}. Importantly, this study included only a few adolescents, all of whom were likely at or near skeletal

\[\text{Median PROMs for patients with translation of ≥100%}.\]
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maturity, which differs from the population of the present study. Since 2007, many additional high-quality studies have been performed in adults. A recent meta-analysis pooling results showed that operative treatment of midshaft clavicle fractures results in a nonunion rate of 1.4% compared with 10.5% for nonoperative treatment (p < 0.01). The malunion rates were 6.4% for operatively managed fractures and 13.6% for non-operatively managed fractures⁴. Constant and DASH scores favored operative treatment (p < 0.01). A faster return to work or daily activities was also seen for operative treatment⁴. Findings from the original COTS trial⁵ have been replicated over time, yet, with their focus on adults, the results still have limited relevance to guiding treatment for children and adolescents.

The results of this study should be interpreted in the context of its limitations. First, this was a retrospective study, and, although inclusion criteria were relatively tight, the operatively and nonoperatively treated groups were not the same at baseline, with the operatively treated group, on average, 2.5 years older, with a greater proportion of ≥100% translation (78% operative compared with 47% nonoperative; p = 0.005). However, in a subanalysis of patients with ≥100% translation and in patients at or near skeletal maturity, outcomes remained similar.

Second, there were no defined criteria for surgical treatment in this study; treatment was by surgeon preference. Patients <21 years of age presenting to the NYU/Weill Cornell Medical Center emergency department are typically treated by the pediatric orthopaedic surgeon on call, although skeletally mature patients in this age range may alternatively be treated by the on-call adult orthopaedic trauma surgeon on a case-by-case basis. Depending on patient and surgeon preference, some patients are discharged home from the emergency department in a sling and follow-up is arranged on an outpatient basis with their surgeon of choice, who then determines management. Some families of adolescents will seek treatment from a pediatric orthopaedic surgeon, and others will seek treatment from an adult sports, upper-extremity, or trauma surgeon. Forty-one (95%) of 43 operatively treated patients were treated by adult sports, trauma, and upper-extremity orthopaedic surgeons, and 30 (83%) of 36 nonoperatively treated patients were treated by pediatric orthopaedic surgeons. It is possible that adult sports, trauma, and upper-extremity surgeons, accustomed to treating many of their adult patients with clavicle fractures with a surgical procedure, may favor treating pediatric and adolescent patients in this same manner.

Third, this study did not investigate the effect of other factors such as fixation method, although all patients were treated with a single precontoured plate or the double-plating technique popular at our institutions. Similarly, postoperatively protocols were not evaluated, but are known to be fairly consistent within the institutions.

Fourth, only 26% (79 of 302) of potentially eligible patients responded, provided consent themselves or through their parents or guardians, and completed the study. A thorough attempt was made to include all patients, with 5 contact attempts made to each family before considering them lost to follow-up. Tracking down children and adolescents years after the injury is fraught with challenges; families move, children leave home, and telephone numbers and last names change. Nonresponse sampling error is possible; patients who responded may not have been representative of the entire cohort. Although subsequent refracture and implant removal appeared similar between responders and nonresponders, it is possible that the implant was removed or a refracture occurred following their last contact at our hospitals. Many characteristics were similar, but we did note that a higher proportion of participating patients were female and were managed operatively when compared with the nonresponders.

Fifth, function and activity were self-reported, and physical examination data were not collected at the time of the telephone follow-up. Sixth, the PROMs used were not validated for the age of every participant (for instance, the HSS Pedi-FABS is validated for 10 to 18 years, and some patients at the time of follow-up were 22 years of age), although they have been used previously in similar, slightly out-of-range age groups⁶. Seventh, the limited sample size was likely not sufficient to draw definitive conclusions from the analyses of the secondary outcomes, but the results presented here should provide preliminary data for powering future studies for these outcomes. Finally, the minimally clinical important difference (MCID), substantial clinical benefit, and patient acceptable symptomatic state (PASS) are unknown for many patient-reported outcome scores after pediatric orthopaedic procedures⁷⁻⁹, and the value of 10 points for the QuickDASH score used for sample-size calculation was based on adult literature⁸.

In this subset of the cohort who responded to questionnaires and PROMs, the outcomes of midshaft clavicle fractures in children and adolescents were similar at the intermediate-term follow-up when treated operatively compared with nonoperatively, even for notably shortened and translated fractures and patients at or near skeletal maturity. Outcomes were excellent regardless of treatment method. There was no measurable benefit to operative management in primarily older adolescents compared with nonoperative management in slightly younger patients. Nonoperative management should be considered as first-line treatment for most pediatric displaced clavicle fractures, and operative management should potentially be reserved for atypical cases such as floating shoulder, multitrauma, open fractures, nonunions, and symptomatic malunions, given similar pain and functional outcomes, increased cost of operative fixation, and potential need for a secondary surgical procedure or plate removal. A definitive, prospective comparative study focusing on the most controversial age groups (14 to 18 years of age in female patients and 16 to 20 years of age in male patients) is warranted.

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