

Acute Operative Stabilization Versus Nonoperative Management of Clavicle Fractures

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Abstract

We conducted a prospective, randomized study to determine if patients with midshaft clavicle fractures would benefit from immediate operative stabilization with a modified Hagie pin in comparison with a matched group treated with nonoperative therapy.

At a level II trauma center, patients with closed midshaft clavicle fractures were prospectively randomized to receive either operative or nonoperative treatment. Fifty-seven (29 operative, 28 nonoperative) patients were enrolled in the study. Operative patients underwent open reduction and internal fixation of the clavicle using a modified Hagie pin; nonoperative patients were treated with a sling for comfort. All patients were followed at regular intervals for 1 year. They were evaluated for radiographic healing and complications and were scored with the Single Assessment Numeric Evaluation and L'Insalata instruments.

Injury severities and radiographs were not statistically significantly different between the 2 groups. Functional scores in the operative group were slightly higher at 3 weeks, and the nonoperative group had slightly higher scores at 6 months and 1 year. The only statistically significant difference between the groups was at 3 weeks. Percentage follow-up at 1 year was 93% for the operative group and 82% for the nonoperative group. One patient in each group developed a nonunion, and 1 patient in each group had a refracture. Complications were higher in the operative group, and most were related to pin prominence at the posterior shoulder.

Results of this study suggest that, though patients with midshaft clavicle fractures had higher functional scores at short-term follow-up after internal fixation, functional scores were similar at 6 months and 1 year. In addition, internal fixation with a modified Hagie pin was associated with a higher complication rate.

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Closed midshaft clavicle fractures are usually successfully treated nonoperatively. However, nonoperative treatment is not without complications.¹⁻⁸ Concerns with nonoperative treatment include nonunion, malunion, altered shoulder mechanics, cosmetic deformity, and upper extremity weakness.^{3-5,7-11} Because of these concerns, there has been a trend toward operative treatment of displaced midshaft clavicle fractures.^{8,12-16} Cited advantages of operative fixation include decreased rate of nonunion, quicker return to activities, and improved functional results from restoration of the clavicular anatomy.^{10,14}

We postulated that active patients who sustain closed midshaft clavicle fractures would benefit from operative stabilization with a modified Hagie pin in comparison with a matched group treated with nonoperative therapy.

MATERIALS AND METHODS

Our scientific review and human use committees approved our research protocol for this study at our institution. Between February 2001 and June 2003, consecutive patients with acute midclavicular fractures were prospectively randomized to 1 of 2 treatment groups. One group underwent nonoperative treatment, and the other underwent operative treatment.

Patients who were included in the study were between ages 17 and 40 and had isolated acute, displaced, or angulated, closed fractures of the middle third of the clavicle. Exclusion criteria included open fractures, neurologic compromise, and fractures of the medial or lateral third of the clavicle.

Clavicle fracture patients who met the inclusion criteria were invited to participate in the study. Seven patients declined to participate. For each participant, appropriate consent was obtained by our clinical nurse after discussion with the attending surgeon involved in the case. Fifty-seven patients were enrolled in the study.

Patients were randomized to treatment groups with use of sealed envelopes placed in a random order. Neither the treating surgeon nor the patient knew the group assignment until after the patient consented to participate in the study and the envelope was opened. Two attending surgeons performed all the operations and used the same operative technique.

On entering the study, patients were asked to complete a shoulder survey that included the Single Assessment Numeric Evaluation (SANE)¹⁷ and L'Insalata¹⁸ shoulder scores. We used these self-administered shoulder ques-

Table I. Descriptive Data

	Nonoperative	Operative
n	28	29
Mean age, y	25 (range, 17-41)	28 (range, 19-40)
Sex		
Male	25 (89%)	27 (93%)
Female	3 (11%)	2 (7%)
Injury side (left/right)	12/16	17/12
Dominant arm injured	12 (43%)	13 (45%)
Comminuted fracture	17 (61%)	15 (52%)
>2 cm displacement/ shortening	14 (50%)	13 (45%)

tionnaires because of their relative simplicity, validity, reliability, and ability to be administered without additional ancillary staff. Both instruments provide a numerical score with 100 representing the highest level of function. Patients were then reexamined at 3 weeks, 6 weeks, 3 months, 6 months, and 1 year after injury. At each visit, patients were asked to complete the shoulder surveys. All complications were recorded.

Standard anteroposterior and 45° cephalic tilt radiographs were obtained at each visit and were evaluated for characterization of the initial fracture, including presence of comminution (≥ 1 fracture fragment) and degree of shortening and displacement. Two examiners used standard rulers and goniometers for the measurements, and their results were averaged and recorded as the final result. Subsequent radiographs were used to assess healing, defined as bony callus across the fracture site; the final radiograph was used to determine the position of fractured fragments. The position at final healing was defined as *anatomical* (no angulation or shortening), *near anatomical* (< 5 mm of displacement), or *nonanatomical* (10° of angulation).

Treatment for the nonoperative group consisted of a sling for comfort, shoulder motion as tolerated, and activity restrictions until healing occurred. Treatment for the operative group included undergoing open reduction and internal fixation (ORIF) using a surgical technique similar to that described by Boehme and colleagues.¹⁹ The fracture site was exposed through a small incision along Langer lines. The intramedullary canal of the medial fragment was then drilled with 1 of the 3 available drill bits in the set that most appropriately fit the patient's canal diameter. The intramedullary canal of the lateral fragment was drilled with the same drill bit. The fine-threaded end of the modified Hagie pin was drilled retrograde through the lateral fragment and out the posterolateral aspect of the clavicle. The fracture was reduced and the pin advanced anterograde across the fracture site and into the medial fragment. The Hagie nut was then applied to maintain compression, and the pin was cut beneath the skin using an end-cutting pin cutter (Figures 1, 2).

In both groups, gentle range-of-motion exercises and use of the extremity for activities of daily living were allowed as tolerated by comfort. Once the fracture healed, the patient was referred to physical therapy to ensure that

Table II. Follow-Up

Period	Nonoperative (%)	Operative (%)
3 weeks	57	86
6 weeks	61	86
3 months	36	66
6 months	68	93
1 year	82	93

full range of motion was obtained, to begin formal strength training, and to advance to full, unrestricted activities.

Once there was evidence of fracture callus healing at the fracture site, the Hagie pins were removed in the clinic under local anesthesia at a mean of 10.9 weeks (range, 6-20 weeks). Four pins were removed early because of infection.

SANE and L'Insalata shoulder survey scores were compared between the groups. Statistical analysis was performed with the SPSS for Windows software package (version 9.0), and data were recorded in a Microsoft Excel spreadsheet. A group \times time analysis of SANE and L'Insalata scores was performed with repeated-measures analysis of variance. Preoperative and postoperative radiographs were compared, and angulation and displacement differences were measured with an independent *t* test. The level for all statistical tests was $P = .05$. Incidence and type of complications were recorded for each treatment group.

RESULTS

Fifty-seven (28 nonoperative, 29 operative) patients enrolled in the study. The groups' demographic data were similar (Table I). Of the 29 patients who underwent ORIF with a modified Hagie pin, 19 were treated within 1 week of injury, and the other 10 were treated within 2 weeks.

Mechanisms of injury were motorcycle or motor vehicle accident (18 patients, 32%), contact-sports injury (15 patients, 26%), bicycle accident (12 patients, 21%), and a fall (12 patients, 21%).

Mean initial fracture angulation, shortening, and displacement were 12.7° (SD, 15°), 12.0 mm (SD, 9.5 mm), and 98% for the nonoperative group and 7.7° (SD, 8°), 13.4 mm (SD, 11.2 mm), and 99% for the operative group. The differences were not statistically significant ($P > .992$). Comminution and displacement percentages are listed in Table I. Follow-up percentages for each time interval are listed in Table II.

Mean SANE and L'Insalata functional scores and SDs are listed in Table III. Post hoc analysis with the Tukey honestly significant difference (HSD) test revealed that both groups had a significant increase in scores from injury to week 6 and from week 6 to month 6 ($P < .015$). Operative patients also had a significant increase in scores from injury to week 3, and their scores at week 3 were significantly higher than those of the nonoperative patients ($P < .015$).

Post hoc analysis with the Tukey HSD test revealed that both groups had a significant increase in SANE scores from injury to week 3, from week 3 to week 6, and from week 6 to month 6 ($P < .044$). At week 3, SANE scores were

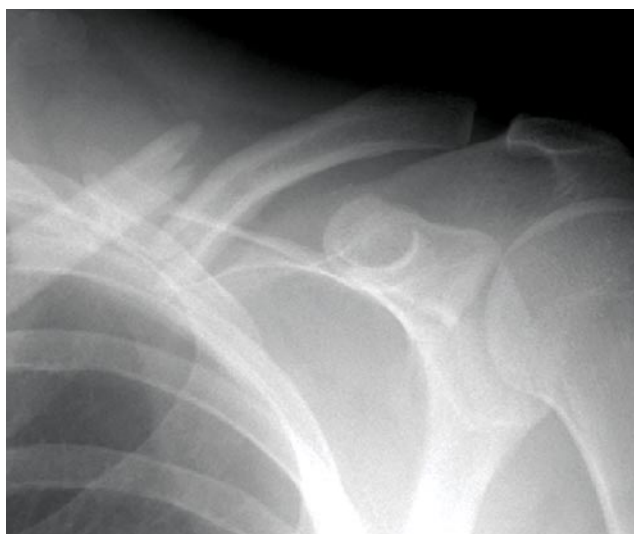


Figure 1. Preoperative radiograph.



Figure 2. Postoperative radiograph.

significantly higher for operative patients than for nonoperative patients ($P < .044$).

Because shortening of more than 2 cm has been cited as an indication for operative fixation and can result in shoulder dysfunction, we stratified the results for this group of patients.^{5,7,20} Patients who had initial fracture shortening of more than 2 cm and who underwent operative fixation had a significant increase in functional scores at 3 months in comparison with patients who had initial fracture shortening of more than 2 cm and who did not undergo operative fixation (Table IV), but functional scores were not significantly different between the 2 groups at later follow-ups.

Radiographic analysis at 1 year revealed increased incidence of anatomical to near anatomical reduction in the operative group (25/29 patients, 86%) versus the nonoperative group (3/28 patients, 11%). Patients who were treated nonoperatively usually showed minimal to no change in alignment with healing. Patients who were treated operatively usually had anatomical to near anatomical reduction after surgery, but some loss in reduction quality (10%-50% displacement, 10°-15° increased angulation) was noted in 4 patients after early pin removal. Table V compares the combined functional scores for patients with and without completely anatomical reduction for the treatment groups.

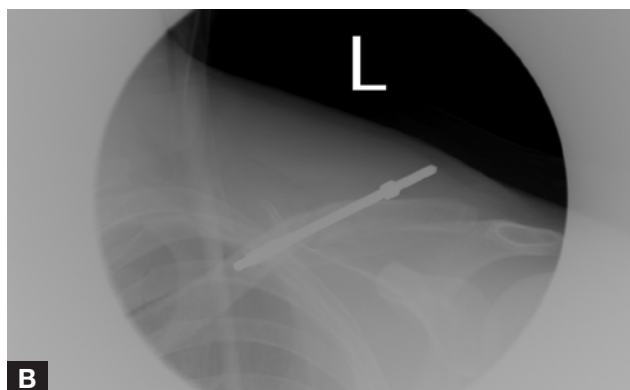
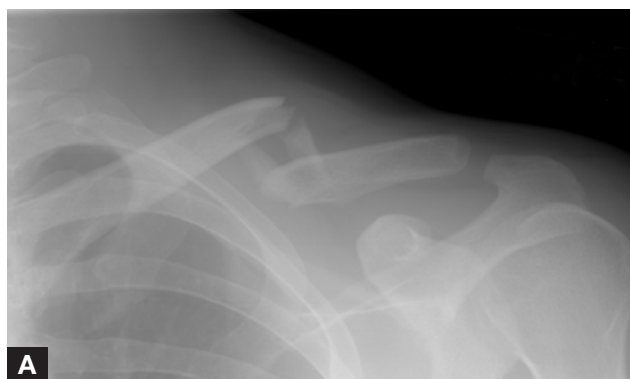


Figure 3. Nonunion: (A) injury radiograph, (B) intraoperative image, (C) 5 months after injury.

The nonunion rate was 3.5% overall and essentially the same in each treatment group; 1 patient in each group developed a nonunion (Figure 3). Neither preoperative displacement nor comminution was associated with development of delayed union or nonunion.

The nonoperative group had 2 complications (8%), a nonunion treated with intramedullary Hagie pin and bone graft at 6 months and a refracture that occurred at 7 months and healed with nonoperative treatment. The operative group had an increased complication rate (41%, 12/29 patients). Many of these complications were minor and related to prominence of the lateral aspect of the pin. Nine (31%) of the 29 patients in the operative group complained of prominent pins, and 6 of these 9 patients developed superficial pin-tract infections, 3 of which required early removal of the intramedullary pin, but 2 patients developed osteomyelitis, which required débridement and intravenous antibiotics. One patient had a second operation after developing an asymptomatic nonunion that was reinjured

Table III. Functional Scores

Period	Scoring	Mean (SD)	
		Nonoperative	Operative
Injury	SANE	16.1 (6.6)	10.3 (6.7)
	L'Insalata	33.9 (17.1)	31.7 (18.9)
3 weeks	SANE	36.4 (19.0)	49.8 (21.3)
	L'Insalata	40.8 (10.8)	48.8 (14.3)
6 weeks	SANE	56.1 (16.5)	65.9 (17.2)
	L'Insalata	51.6 (16.7)	61.3 (13.7)
3 months	SANE	70.7 (15.3)	78.5 (19.3)
	L'Insalata	66.4 (16.2)	73.5 (14.3)
6 months	SANE	85.8 (8.7)	87.1 (13.1)
	L'Insalata	85.3 (9.1)	87.5 (11.2)
1 year	SANE	97 (3.6)	93.5 (4.2)
	L'Insalata	97.9 (2.4)	95.5 (7.3)

Abbreviation: SANE, Single Assessment Numeric Evaluation.

and became symptomatic after a motor vehicle accident. This was successfully treated with open reduction and plate fixation. One patient had a partial, transient radial nerve palsy secondary to an interscalene block. One had a delayed union that united after the pin was left in place for 20 weeks. One intramedullary pin fracture occurred after the patient fell 8 weeks after surgery. The lateral portion of the pin was removed, and the fracture ultimately healed. One patient had a refracture 4 weeks after pin removal; this fracture healed with nonoperative treatment.

DISCUSSION

The goal of our study was to determine if operative fixation of midshaft clavicle fractures would result in a decreased nonunion rate and higher functional shoulder scores in comparison with nonoperative treatment of such fractures. We found similar nonunion rates and functional scores for these groups, with the exception of higher scores at 3 weeks in the operative group, and a higher rate of complications in the operative group.

Our results, both functional scores and complications, are similar to those reported by Grassi and colleagues,¹³ who used 2.5-mm threaded intramedullary pin fixation, and by Strauss and colleagues,²¹ who also used Hagie pin fixation.

In contrast, other authors have reported better results and fewer complications both with intramedullary pin fixation using a Rockwood pin compared with both nonoperative treatment and plating¹⁰ as well as plate fixation compared with nonoperative treatment.²²

Our nonunion rate of 3.5% is on the low side of published rates, most of which are around 4% to 6% (around 15% for displaced fractures). We did not find comminution or displacement to be associated with increased risk for nonunion. Our numbers are substantially smaller than those in the observational cohort studies from which these data are obtained, and our patient population (primarily young, healthy, male) differed from theirs.^{9,11,15}

Operative fixation also substantially improved the chance of having an anatomical reduction on radiographs. Theoretically, and as some studies suggest, a more anatomical reduction would better restore the normal clavicular function.^{5,9,20} We did not observe this in our study, with the shoulder scores of patients with anatomical healing not differing statistically from the scores of patients with nonanatomical healing. However, a weakness of our study was its not including objective shoulder function parameters of strength and range of motion. These parameters may have revealed differences in shoulder strength and velocity between the groups. However, as already mentioned, the groups' subjec-

Table IV. Displacement/Shortening and Mean of Combined Functional Scores (Single Assessment Numeric Evaluation, L'Insalata)

	Nonoperative		Operative	
	<2 cm	>2 cm	<2 cm	>2 cm
n	14	14	16	13
3 weeks	35	45	50	49
6 weeks	63	63	63	62
3 months	76	67	77	76
6 months	92	89	88	83
1 year	97	98	94	94

Table V. Anatomical Reduction and Mean of Combined Functional Scores (Single Assessment Numeric Evaluation, L'Insalata)

	Nonoperative		Operative	
	Nonanatomical	Anatomical	Nonanatomical	Anatomical
n	25	3	10	19
6 months	91	92	89	85
1 year	97	97	96	91

tive scores did not differ. Most of our patients are motivated to return to duty and regain their strength, and they have ready access to physical therapists, who can guide and optimize their recovery. Reports of poor functional results after nonoperative treatment have not addressed whether some of these defects in terms of muscle strength and endurance may be reversed with appropriate rehabilitation.

There may be a subpopulation of clavicle fracture patients who may benefit from operative fixation, and the optimal surgical indications have not been established. Unfortunately, another weakness of our study was its inclusion of minimally displaced or angulated, noncommittuted clavicle fractures, many of which, based on current recommendations, would have been managed nonoperatively. Inclusion of these cases likely biased our results to nonoperative treatment. Although we subdivided clavicle fractures on the basis of comminution and displacement and found no significant difference in functional scores, our numbers for these groups were relatively small and probably lacked sufficient statistical power.

Our results suggest that operative fixation can yield excellent functional scores, yet it did not offer an advantage over nonoperative treatment and was associated with a higher complication rate.

CONCLUSIONS

Results of this prospective, randomized study indicate that patients with acute midshaft clavicle fractures do not functionally benefit from internal fixation with a modified Hagie pin, and operative fixation was associated with a higher complication rate. Given our results, we do not recommend routine, acute operative fixation with a Hagie pin for the patient with a closed midshaft clavicle fracture.

AUTHORS' DISCLOSURE STATEMENT

The authors report no actual or potential conflict of interest in relation to this article.

The views expressed in this article are those of the authors and do not represent the policy or position of the US Government, the US Department of Defense, or the US Department of the Army.

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