A commentary by Brian K. Lee, MD, and John M. Itamura, MD, is linked to the online version of this article at jbjs.org.

Treatment of Displaced Midshaft Clavicle Fractures: Figure-of-Eight Harness Versus Anterior Plate Osteosynthesis

A Randomized Controlled Trial

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Background: Most midshaft clavicle fractures affect the economically active population, which is negatively impacted by transient limb impairment during the treatment. There is still debate about the advantages and disadvantages of surgical treatment for these fractures.

Methods: In this prospective randomized controlled trial, 117 patients were allocated to 1 of 2 groups: nonsurgical treatment with a figure-of-eight harness or surgical treatment with anteroinferior plate osteosynthesis. The primary outcome was upper-limb limitation measured with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire at 6 months. Other outcomes included pain, radiographic findings, satisfaction with the cosmetic result, complications, and time to return to previous work and activities. Participants were assessed at 6 weeks, 6 months, and 1 year after the intervention.

Results: No difference between the 2 groups was detected in the DASH score at any time point ($p = 0.398$, 0.403, and 0.877 at 6 weeks, 6 months, and 1 year, respectively), pain levels measured with a visual analogue scale (VAS), time to return to previous activities, or dissatisfaction with the cosmetic result. Seven patients (14.9%) developed nonunion after nonsurgical treatment, a nonunion rate that was significantly higher than that in the surgical group, in which all fractures had healed ($p = 0.004$). The patients in the nonsurgical group had radiographic evidence of greater clavicle shortening ($p < 0.001$) and more of the patients in that group answered "yes" when asked if their clavicle felt short ($p < 0.001$) and if they felt bone prominence ($p < 0.001$). More patients answered "yes" when asked if they felt paresthesia in the surgical group (7; 13.7%) than in the nonsurgical group (1; 2.1%) ($p = 0.036$).

Conclusions: This study did not demonstrate a difference in limb function between patients who underwent surgical treatment and those nonsurgically treated for a dislocated midshaft clavicle fracture. Meanwhile, surgical treatment decreased the likelihood of nonunion.

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

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Most midshaft clavicle fractures occur in the economically active population (people in their twenties, thirties, and forties), and these fractures may have a substantial negative functional impact[1-4].

Both surgical and nonsurgical treatment can have unfavorable outcomes such as transient or permanent limb impairment, the need for immobilization, the need for a secondary procedure for implant removal, or symptomatic nonunion or malunion[5-9]. These

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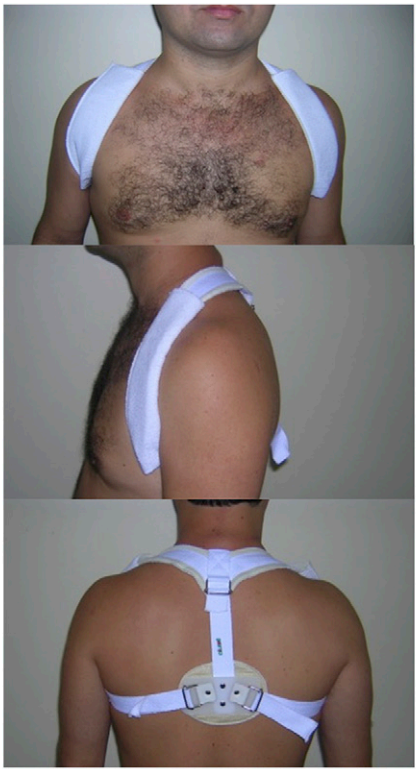

Fig. 1
Figure-of-eight harness for nonsurgical treatment.

outcomes have been assessed in a growing number of clinical trials and systematic reviews comparing different methods of treatment with the aim of providing better evidence to support shared decision-making with patients about how best to treat this injury[9-17].

The present study was designed to compare the effectiveness of 2 specific nonoperative and operative methods for treatment of displaced midshaft clavicle fractures. The figure-of-eight harness was chosen as the nonoperative method because it provides high rates of fracture-healing and, in contrast to a sling, encourages use of the limb during treatment[18-20]. Anterior plate osteosynthesis was selected as the surgical option as there may be less of a need for implant removal because of its theoretically more comfortable positioning[21]. Our hypothesis was that patients who undergo surgical treatment with open reduction and internal fixation would have superior upper-limb functional results with similar complication rates compared with those who undergo nonsurgical treatment with a figure-of-eight harness.

Materials and Methods

This multicenter randomized controlled trial (RCT) was developed in an upper limb surgery center of the Department of Orthopedics and Traumatology at Universidade Federal de São Paulo in São Paulo, Brazil, and at the Vila Velha Evangelico Hospital in Espirito Santo, Brazil, both of which are regional referral centers for trauma and pathological conditions of the shoulder. The protocol was registered in Current Controlled Trials (International Standard Randomized Controlled Trial Number [ISRCTN] 66495030).

We recruited adult patients with a midshaft clavicle fracture who had signed the informed consent form. Inclusion criteria were (1) <15 days between the fracture and trial enrollment and (2) a displaced fracture with total translation and no contact between the main fragments seen on at least 1 radiograph.

Exclusion criteria were (1) pathological fracture, (2) open fracture, (3) associated ipsilateral limb injury, (4) associated neurological or vascular injury, (5) bilateral fracture, and (6) multiple injuries.

Interventions were performed by 6 orthopaedic surgeons (3 from each center), all of whom had at least 2 years of experience in treating shoulder conditions and were familiar with both treatment methods.

Allocation and Randomization

Patients who met the inclusion and exclusion criteria were informed about the study and its objectives. Then, after reading and signing the written consent form and undergoing the pre-anesthesia evaluation, a participant was assigned a number in sequential order. The researcher then attached to this patient's medical record an opaque sealed envelope from a set numbered sequentially from 1 to 120 that contained the treatment assignment (surgical or nonsurgical). The sequence of interventions contained in these envelopes had been generated randomly with a computer program by an individual not directly related to the study. After verifying the inclusion and exclusion criteria, the person performing the intervention contacted the randomization and allocation center at the Hand and Upper Limb Surgery Clinic at Universidade Federal de São Paulo and then opened the envelope to reveal the method to be performed.

Intervention

In both centers, initial evaluation consisted of clinical examination as well as anteroposterior and oblique clavicle radiographs with 30° of cephalic inclination (Zanca views)[22] and bilateral anteroposterior clavicle radiographs.

Nonsurgical treatment was performed using a figure-of-eight harness (Salvapé) (Fig. 1). Patients allocated to this group were educated about managing the tension of the brace and skin care and were instructed to use the ipsilateral arm for normal activities as much as possible.

The intervention in the surgical group took place at both institutions' surgical centers and was done with general anesthesia with an ipsilateral interscalene nerve block. The patient was placed in the beach-chair position and, after administration of prophylactic antibiotics, skin preparation, and draping, an oblique incision of approximately 10 cm was made over the clavicle, followed by dissection by planes and identification, isolation, and protection of supraclavicular nerves. The fracture was reduced, and the clavicle was fixed with a 3.5-mm reconstruction plate placed on the anteroinferior surface of the bone. For proper stabilization, the fixation involved at least 6 cortices in the medial fragment and another 6 in the lateral fragment (Fig. 2). Immobilization with a sling was maintained for 7 to 10 days, until the skin sutures were removed. Active range-of-motion exercises were then initiated.

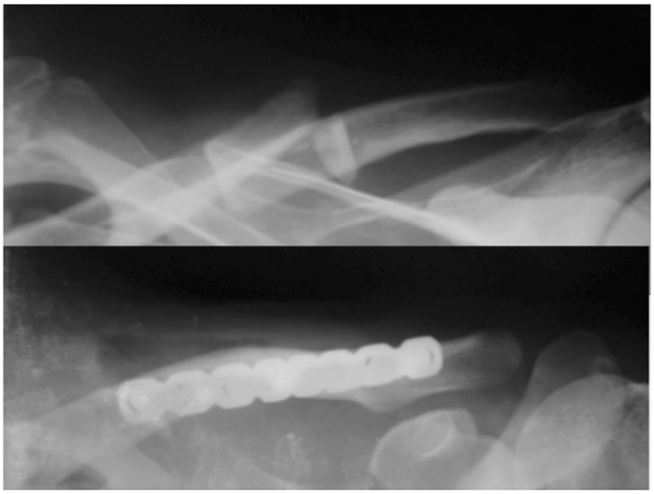

Fig. 2
Postoperative radiographs.

To ensure that the procedures and outcome evaluations were similar in the 2 centers, all orthopaedic surgeons reviewed and agreed to each step of the procedure (surgery and treatment with the harness) before patient recruitment. All staff from both centers who would administer the questionnaires and obtain the scores were trained how to carry out these measurements.

Patients scheduled weekly appointments until the sixth week after the procedure in order to be followed closely for possible complications. Radiographs were also obtained in the second week. Functional outcomes were measured and radiographs were made at 6 weeks, 6 months, and 1 year. An extra time-point for pain measurement was added at 3 months. If the fracture had not healed by the sixth week, radiographs were obtained every 15 days until consolidation was achieved or nonunion was diagnosed.

Outcomes

The primary outcome was upper-limb function at 6 months, measured with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire translated into Brazilian Portuguese[23], which has been validated.

Secondary outcomes included functional and radiographic findings as well as complications. The functional secondary outcomes were pain assessed with a visual analogue scale (VAS)[24], time to return to work or previous activities, and patient satisfaction with the cosmetic result (yes or no). The radiographic findings were consolidation of the fracture, which was considered to be obliteration of 3 cortices at the fracture site, and bone shortening after consolidation. Bone shortening was determined on an anteroposterior chest radiograph by outlining the sternal and acromial edges of each of the 2 clavicles, drawing a line connecting the centers of these 2 structures, and calculating the

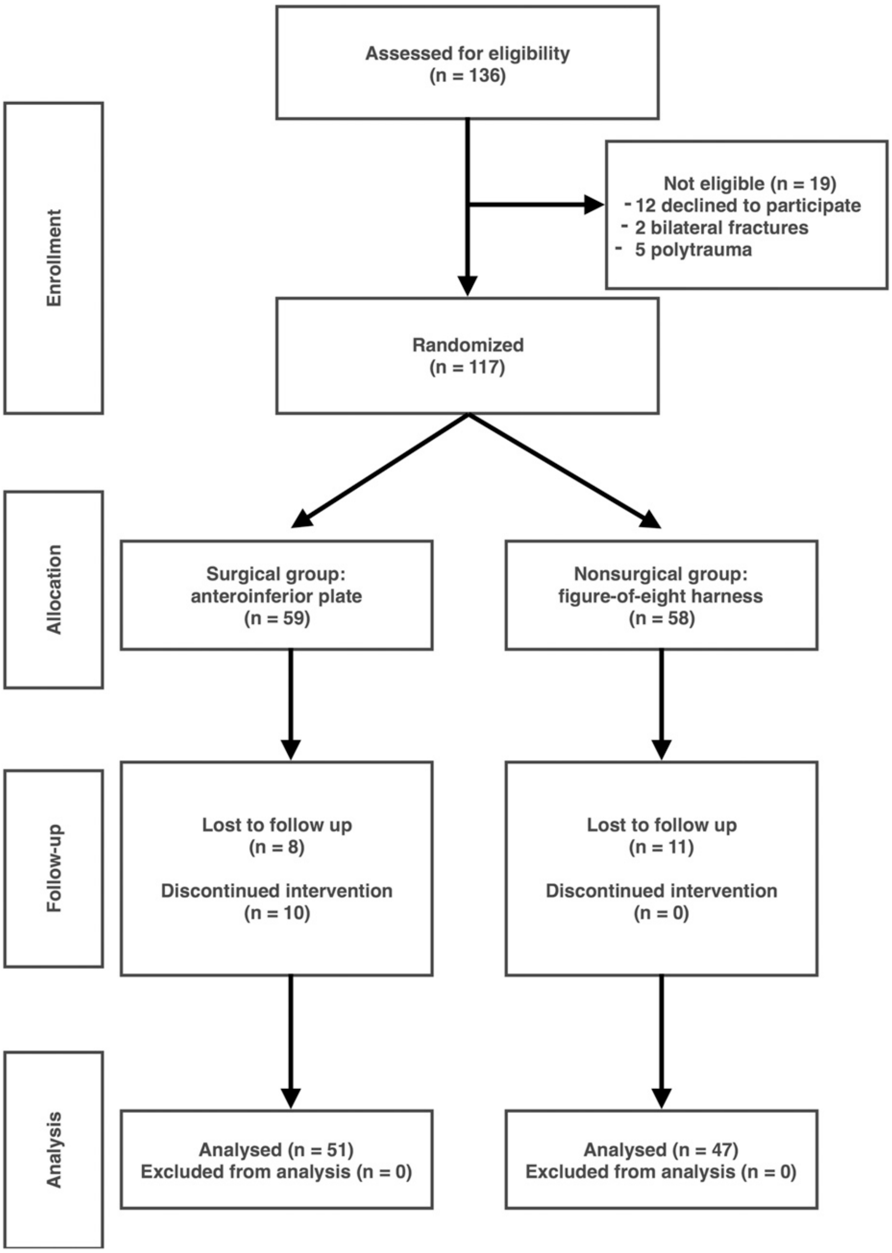

Fig. 3

Flowchart of inclusion in study of midshaft clavicle fractures.

difference in length between the normal and affected sides[6]. Complications, assessed as a dichotomous variable (yes or no), were recorded with their date of occurrence and method of treatment. Initial complications, considered until the sixth week, included infection, skin lesions, and neurological symptoms (paresthesia). The long-term complications were fracture nonunion, defined as a lack of radiographic healing after 6 months of treatment (surgical or nonsurgical); shoulder droop; shoulder malpositioning; and bone prominence. A change in the initially assigned treatment due to complications or fracture nonunion after 6 months was categorized as a severe complication. Patients who developed such complications were clinically followed and the results were included in their originally allocated group, according to the intention-to-treat principle.

Sample Size

Sample size was calculated prior to study enrollment on the basis of a 95% confidence interval (CI), a power of 90%, a standard deviation (SD) of 15% for the DASH score, and an absolute difference of 10 points in the DASH score between the surgical and nonsurgical groups. This revealed that 47 patients were needed for each group and, to account for participants being lost to follow-up, a total of 120 patients with a displaced midshaft fracture had to be recruited.

Blinding and Similarity of Rehabilitation

The outcome assessors were not directly involved in the study. To blind these assessors, all patients wore a figure-of-eight harness and a bandage on the ipsilateral clavicle and were instructed not to reveal the treatment that they had undergone. The rehabilitation program, which was strictly the same for the 2 groups, consisted of active motion of the elbows, wrists, and hands on the first day, passive motion of the shoulder after the seventh day, and then active motion of the shoulder as the patients felt comfortable and experienced less pain.

Statistical Analysis

When we compared epidemiological data, we used the chi-square test for all dichotomous variables except for the affected side, for which the Fisher exact test was used. Analysis of variance (ANOVA) was used to compare results that were continuous variables, and a test of equality of 2 proportions was applied for qualitative results. In all analyses, a p value of <0.05 was considered significant.

Results

In the period of the study, 136 patients with a clavicle fracture were evaluated, and 19 were considered ineligible (Fig. 3). Of the 117 eligible patients, 58 were allocated to the nonsurgical group and 59, to the surgical group. Nineteen patients (11 in the nonsurgical group and 8 in the surgical group) were lost to follow-up—2 because they died from other causes and 17 because they did not return for evaluations. Thus, 47 patients in the nonsurgical group and 51 in the surgical group were included in the final analysis.

The nonsurgical group had a higher mean age than the surgical group (34.6 and 30.5 years, respectively; p = 0.046). There were no differences between the groups with regard to sex, affected side, mechanism of trauma, hand dominance, fracture configuration (OTA/AO classification)[25], or time from trauma to treatment. A motorcycle accident was the most common cause of the injuries (Table I).

TABLE I Baseline Characteristics of Surgical and Nonsurgical Groups

	Surgical Group (N = 59)	Nonsurgical Group (N = 58)	P Value
Mean age ± SD *(yr)*	30.5 ± 9.6	34.6 ± 12.6	0.046*
Sex *(no. [%])*			0.177
Female	6 (10.2)	11 (19.0)	
Male	53 (89.8)	47 (81.0)	
Mean time to evaluation ± SD *(days)*	6.2 ± 3.3	6.7 ± 3.7	0.443
Side affected *(no. [%])*			0.649
Right	25 (42.4)	27 (46.6)	
Left	34 (57.6)	31 (53.4)	
Dominant hand *(no. [%])*			0.662
Right	56 (94.9)	56 (96.6)	
Left	3 (5.1)	2 (3.4)	
Mechanism of trauma *(no. [%])*			
Motorcycle accident	35 (59.3)	32 (55.2)	0.650
Bicycle accident	6 (10.2)	7 (12.1)	0.774
Fall from standing height	8 (13.6)	9 (15.5)	0.764
Other	10 (16.9)	10 (17.2)	0.967
OTA/AO fracture type *(no. [%])*			
B1	21 (35.6)	20 (34.5)	0.900
B2	31 (52.5)	34 (58.6)	0.508
B3	7 (11.9)	4 (6.9)	0.357

*A significant difference.

TABLE II DASH and VAS Pain Scores for Surgical and Nonsurgical Groups

	Mean ± SD		
	Surgical Group	Nonsurgical Group	P Value
DASH			
6 weeks	22.7 ± 22.4	26.3 ± 22.4	0.398
6 months	5.0 ± 11.5	7.0 ± 11.6	0.403
1 year	3.3 ± 10.4	3.0 ± 9.4	0.877
VAS			
6 weeks	2.23 ± 1.99	2.69 ± 2.53	0.289
3 months	1.53 ± 2.01	1.71 ± 2.16	0.656
6 months	0.78 ± 1.45	0.92 ± 1.51	0.633
1 year	0.46 ± 1.18	0.38 ± 1.04	0.711

No difference in the primary outcome—upper-limb function measured with the DASH score—or in pain measured with the VAS was detected between the groups at any of the assessment time points (Table II).

When radiographs were analyzed, we found the mean amount of bone shortening due to malunion to be greater in the nonsurgical group (0.93 cm) than in the surgical group (0.48 cm) ($p < 0.001$). The mean time to return to work or previous activities was 112 days in the surgical group and 127 days in the nonsurgical group, which was not a significant difference ($p = 0.385$) (Table III).

All of the fractures healed in the surgical group, whereas 7 patients developed fracture nonunion after nonsurgical treatment ($p = 0.004$). Two of these patients underwent surgical treatment of the fracture nonunion, whereas 5 allowed the fracture to remain united as they were asymptomatic. Paresthesia was found in 7 patients in the surgical group and in 1 in the nonsurgical group ($p = 0.036$). No difference was found between the groups with regard to dissatisfaction with the cosmetic result (11 patients in the surgical group and 7 in the nonsurgical group; $p = 0.390$) or shoulder droop (14 versus 17; $p = 0.373$). More patients in the nonsurgical group than in the surgical group answered "yes" when asked if they had shoulder malpositioning, shortening, and bone prominence ($p = 0.020$, $p < 0.001$, and $p < 0.001$, respectively) (Table IV).

No restriction in the range of shoulder movement was found in either group at the final assessment.

Two cases of superficial infection were found in the surgical group; both were treated with oral antibiotic therapy and fully resolved. Another patient in the surgical group developed deformity with bending of the reconstruction plate, but fracture-healing was still achieved.

TABLE III Radiographic Clavicle Shortening and Time to Return to Work/Activities for Surgical and Nonsurgical Groups

	Mean ± SD		
	Surgical Group	Nonsurgical Group	P Value
Shortening *(cm)*	0.48 ± 0.45	0.93 ± 0.66	<0.001*
Time to return to work/activities *(days)*	111.7 ± 62.9	126.6 ± 104.4	0.385

*A significant difference.

TABLE IV Complications for Surgical and Nonsurgical Groups

	No. (%)		
Complications	Surgical Group (N = 51)	Nonsurgical Group (N = 47)	P Value
Nonunion	0 (0.0)	7 (14.9)	0.004*
Paresthesia	7 (13.7)	1 (2.1)	0.036*
Dissatisfaction with cosmetic result	11 (21.6)	7 (14.9)	0.390
Shoulder droop	14 (27.5)	17 (36.2)	0.373
Shortening	8 (15.7)	27 (57.4)	<0.001*
Shoulder malpositioning	1 (2.0)	7 (14.9)	0.020*
Bone prominence	3 (5.9)	33 (70.2)	<0.001*

*A significant difference.

Discussion

Recently, there has been an increased tendency to treat clavicle fractures with surgery[26]. We believe that this is the first study in which surgery with an anteroinferior plate was compared with a figure-of-eight harness in an RCT. The choice of a plate in this position was based on previous reports that high percentages of superiorly positioned plates are removed because of discomfort due to prominence of the implant[8,9,27,28].

In contrast to our initial hypothesis, we could not identify a difference between the groups with regard to upper-limb function measured with the DASH questionnaire, even at the initial assessments. Furthermore, we did not detect a minimum clinically relevant difference or minimal detectable change (10.2 and 10.5, respectively[29]) in the mean DASH scores. Some studies have demonstrated differences in DASH scores in favor of surgical treatment[9,12]. However, our findings are in agreement with another RCT[13], which did not detect a clinical difference between the results of surgical and nonsurgical treatments. The variations in results among the studies may be due to differences in the populations and treatment approaches. Pain and range of motion were similar in the 2 groups in our trial.

Nonsurgical treatment resulted in more residual clavicle shortening than surgery, which was expected as surgical procedures are directed at achieving the most anatomical reduction possible. Nevertheless, no difference in functional result was found between the groups. The relationship between shortening and functional results has been controversial, with 1 study denoting no functional deficit with shortening[30] and another even suggesting that initial shortening is an indication for surgical treatment[5]. The time to return to work or previous activities was greater in our nonsurgical group but not significantly so.

The surgical group had a lower total complication rate than the nonsurgical group. This finding should be analyzed with caution because the same patient may present with >1 complication, leading to an overestimation of the results. For example, a patient with bone shortening due to malunion may have a higher chance of being dissatisfied with the cosmetic result and of having bone prominence and shoulder asymmetry.

Two nonunions in the nonsurgical group were treated with surgical fixation after 6 months, with 1 of them requiring iliac crest graft. Five other patients with nonunion in this group chose not to undergo surgery as they were asymptomatic. The nonunion rate in the nonoperative group was 14.9%, which is similar to the rate in another study[5].

Three patients (5.9%) in the surgical group had the plate and screws removed after 1 year. This rate is lower than that in a study with a superior plate positioning (18%)[9] and in 1 in which nails were used (89%)[12]. Of the 3 cases of plate removal, 2 were due to prominence of the plate and dissatisfaction with the cosmetic result and 1 was due to bending of the plate with normal fracture-healing.

Paresthesia was found in both groups and was more prevalent in the surgical group, despite the attempt to isolate supraclavicular nerve branches. Similar rates were found in other studies[9]. No additional procedures were needed to deal with this complication. In the nonsurgical group, the paresthesia was transient, occurring only while the patient wore the harness, which has been reported in other studies[31]. It is worth pointing out that this device was applied to provide comfort for the patient, not to regain bone length. Usually, exaggerated tension must be applied to obtain the full length of the clavicle, creating discomfort and increasing the risk of paresthesia.

The surgical group had a higher prevalence of dissatisfaction with the cosmetic result, which was always related to the appearance of the surgical incision. Dissatisfaction following nonsurgical treatment was due to bone prominence or shortening caused by malunion. The high rates of dissatisfaction in this study may be related to the geographic location of this RCT, where a tropical climate leads most people to wear clothes that leave the shoulders uncovered.

This RCT has limitations, including the assessment of only 1 functional outcome. Also, we believe that the results may deteriorate with longer follow-up, especially in cases with shortening and nonunion. In addition, we did not perform stratification or block randomization for fracture types with a higher risk of worse results. Finally, there was no cost-effectiveness analysis in our trial.

Future clinical trials might include different surgical fixation methods and different nonsurgical treatments, longer follow-up, cost-effectiveness analysis, and subgroup analysis to seek characteristics that can lead to better or worse results after treatment of displaced clavicle fractures.

In conclusion, this study did not demonstrate a difference in shoulder function between surgical and nonsurgical treatment of dislocated midshaft clavicle fractures. However, surgery did decrease the likelihood of nonunion, which should be taken into account when conducting shared decision-making with patients who sustain a midshaft clavicle fracture. ■

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