Fracture Site Mobility at 6 Weeks After Humeral Shaft Fracture Predicts Nonunion Without Surgery

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Objectives: To assess the presence of fracture site gross motion on physical examination to predict humeral shaft fracture progression to nonunion in patients managed nonoperatively.

Design: Retrospective cohort study.

Setting: Single trauma level 1 institutional center.

Patients: Eighty-four consecutive patients undergoing nonoperative treatment of a diaphyseal humeral shaft fracture were identified. The average age of the population was 48.3 years, and 50% of the cohort was men.

Intervention: Clinical examination for fracture stability was routinely performed on patients by the treating physicians and documented it in the medical record. Patients were followed until union or surgery for persistent fracture mobility.

Main Outcome Measurements: Stability was graded if there was motion at the site (1: motion of any kind and 0: moved as a unit).

Results: Seventy-three patients (87%) healed their fracture within our study cohort by 6 months postfracture. Of the remaining 11 patients, after discussion with their treating physicians about the option of surgical intervention, 8 chose to undergo open reduction internal fixation at an average of 8 months, 1 proceeded nonsurgical interventions, and 2 were lost of follow-up. If the humeral shaft fracture site was mobile at 6 weeks follow-up visit, it identified future fracture nonunion with 82% sensitivity and 99% specificity (only 1 patient with motion at 6 weeks proceeded to fracture union).

Conclusion: With a high negative predictive value, clinical examination of fracture motion at 6 weeks should be assessed in every patient to determine which patients should obtain closer follow-up for the risk of nonunion progression. Knowledge of gross fracture motion can be used in the shared decision-making model in counseling about early surgical options.

Key Words: diaphyseal humeral fractures, fracture healing, nonunion, shared decision making

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

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INTRODUCTION

Humeral shaft fractures account for 1%–3% of all fractures, with an incidence of 14.5 per 100,000 individuals.[1–3] Since its first description in 1977 by Sarmiento and colleagues, functional bracing, which uses the surrounding soft tissue to provide hydrostatic compressive forces, has been consistently used for the treatment for most of these fracture patterns. By avoiding unnecessary immobilization of the shoulder and elbow joints, physiologically controlled micromovement at the fracture site creates an ideal environment for blood flow, mineral deposition, and therefore osteogenesis.[4,5] Clinically, the literature has consistently demonstrated that nonoperative functional treatment of humeral shaft fractures progress to union in most patients.[6,7]

Functional bracing is not without its disadvantages. Pain and instability of the fracture limits the arm, shoulder, and elbow for at least 4 weeks. Close follow-up with proper brace management and serial x-rays is also required to monitor fracture alignment and healing. Finally, nonunion remains a significant concern, with approximately 10% of patients requiring surgery to obtain fracture stabilization.[5,6,8] Not only do nonunions prolong the morbidity associated with the injury, but it has also been shown that this population has a lower probability of returning to full functional recovery, even after corrective surgery and resulting bony union.[9]

Gross motion at the fracture site is a clear sign of an ununited bone. Although this finding can be difficult to elicit in the setting of pain and significant arm edema, whether it can predict healing outcomes has never been evaluated. Therefore, the purpose of this study was to assess if the presence of fracture site mobility at various time points (the lack of humerus moving as 1 unit) predicted humeral shaft fracture progression to radiographic nonunion in patients managed nonoperatively using a functional brace.

PATIENTS AND METHODS

By querying medical records for ICD-9 codes pertaining to humeral shaft fracture (OTA/AO 12) from 2007 to 2015

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(812.20 and 812.21), 416 patients' consecutive patients treated in our emergency department or outpatient clinics were retrospectively identified. Only patients initially managed nonoperatively with functional bracing for humeral diaphyseal shaft fractures were included in this study. Radiographs were reviewed from the picture archiving and communication system to determine that diagnosis was consistent with the record. These radiographs were reviewed for evidence of healing and maintenance of alignment. Exclusion criteria included any patient who was younger than 18 years, patients who had ipsilateral skeletal injuries, and patients who had less than 3-month follow-up. If a functional brace was not used, the patients were excluded from the study. All patients were treated by a fellowship-trained traumatologist at our institution. Eighty-four consecutive patients who met inclusion criteria were identified (Fig. 1).

Patient demographics and injury characteristics were documented in the medical record on presentation. During initial evaluation in the emergency department, all patients' upper extremity was stabilized in either a plaster coaptation splint or above elbow cast until their first outpatient appointment approximately 1 week after their injury. At that time, physicians thoroughly discussed the risk and benefits of surgical versus nonoperative treatment, tailoring toward the patients' preferences and need. If nonoperative treatment was elected, the patient's splint removed and a prefabricated "clam shell" plastic humerus functional brace with Velcro straps (Biomet Warsaw In, Fig. 2) was applied to the fractured humerus and each patient was educated on proper adjustment and tightening of the brace to be performed on a daily basis. The application of a clam shell plastic fracture brace secured with Velcro straps with or without deltoid extension was similar in placement on the humerus and at the discretion of the treating surgeon or availability of the brace. Fractures were classified descriptively (oblique, transverse, and spiral), by OTA/AO classification (ie, A–C), and location of fracture (proximal, middle, and distal third of the humeral diaphysis). Although there was no standard protocol for follow-up at our institution, patients were typically seen 1 week after the application of the brace, followed by an average of at least 2 more visits by or around the 6-week point and another follow-up visit at 3 months. Patients continued with follow-up visits until fracture union was obtained. Radiographs, including 2 views of the humeral shaft, were taken at all visits to examine for evidence of healing. Radiographic healing was defined as the point in which callus bridged the former fracture site. In this study, nonunion was defined as lack of radiographic healing progression over 3 consecutive sets of radiographs along with patients reported symptoms of pain/disability or lack of cortical bridging at 6 months. We used the Weber–Cech classification and dichotomously categorized nonunions as hypertrophic or atrophic. The category of oligotrophic, defined as either from unorganized osteogenesis, from absence of biological response, or from one where vascularity was intact but callus did not form, has historically been made based on radionuclide scanning.[10–12] Because we did not obtain bone scans in any case, we could not differentiate between oligo and atrophic types. These diagnoses were confirmed intraoperatively in those who underwent repair.

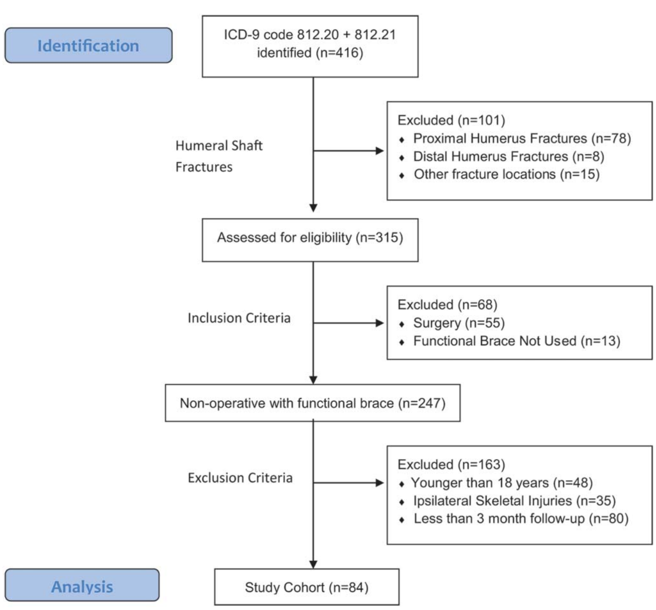

FIGURE 1. Patient population selection. **Editor's Note:** A color image accompanies the online version of this article.

FIGURE 2. A 65-year-old female with a displaced OTA/AO 12A humerus fracture treated in a functional brace. **Editor's Note:** A color image accompanies the online version of this article.

Physical examination at each visit included removal of the brace, inspection of the underlying skin and examination for fracture site mobility. One hand was placed on the humerus proximal to the fracture to stabilize and the other hand then applied anterior and posterior as well as varus and valgus forces to elicit motion at the fracture site. The injured arm was described to have fracture stability if no motion was elicited at the humerus fracture site. In the record, this was described as "no fracture site mobility" or "the humerus moved as a unit." Range of motion testing at the shoulder and elbow was also evaluated at later follow-ups.

Timing for surgical intervention was not dictated by the presence of gross motion at 6 weeks. Rather, a thoughtful discussion between the orthopaedic care provider and patients occurred to carefully consider the patient preferences and needs when deciding the best individual treatment course.

Univariate analysis was performed using χ^2 test and Student's *t* tests when appropriate. Mann–Whitney *U* test was used when comparing nonparametric variables. Multivariate logistic regression analysis was performed with the independent variables that had significant relationships at $P < 0.05$ on univariate analysis (age, obesity, fracture orientation, and gross motion at 6 weeks). Receiver operating curves (ROCs) were also created to determine optimal sensitivities and specificities of testing for fracture stability at different time points. Follow-up time point were defined as visits that occurred were within 1 week of the selected time point, with rounding up if a date was found exactly in the middle (ie, 3 weeks after injury was defined as the 4-week time point). All statistical analysis was conducted using SPSS Version 20 (Chicago, IL) with statistical significance level set at $P < 0.05$.

SOURCE OF FUNDING

There was no funding source involved in this investigation.

RESULTS

Eighty-four patients with 84 closed, isolated, low-energy humeral shaft fractures who followed up at 328 postfracture visits were identified. The cohort was followed for a mean 7.25 ± 7 months. Demographic information for the cohort is displayed in Table 1. The mean age of the study population was 48 ± 20 years, and 50% were male. Most of these patients sustained a fracture after a low-energy fall (65%). Six patients (7%) presented with radial nerve palsy, and all completely recovered at an average of 10 weeks. The patients were most likely to sustain an OTA/AO fracture A (61%), and the fractures were most likely to be localized in the middle third of the humeral shaft (Table 1).

Eleven (13%) of these patients failed to heal their humeral shaft by a mean 4.25 ± 1.5 months (range 3–6 months), 4 of which were atrophic and 7 hypertrophic nonunions (Table 2). Eight of the 11 nonunion patients had sufficient symptoms and eventually chose to undergo nonunion repair surgery, at an average 8 months after initial injury. All 8 were treated using compression plating with autogenous bone grafting, and all went on to fracture union without any additional surgical procedure. All these patients obtained good functional results with forward elevation of the injured extremity over 120 degrees by their last follow-up appointment. Of the 3 remaining ununited patients not treated surgically, 2 were lost to follow-up (possibly seeking intervention elsewhere in our large urban community), whereas the remaining 1 obtained good functional shoulder and elbow range of motion but continued pain with further nonsurgical intervention of their own choice.

TABLE 1. Background for All Patients Included (n = 84)

	n (%)
Patient characteristics	
Age, y	48.3 ± 20
Men	42 (50)
Low-energy fall	55 (65)
Radial nerve palsy	6 (7)
Fracture characteristics	
Fracture type	
12A	51 (61)
12B	18 (21)
12C	15 (18)
Fracture location	
Proximal	22 (26)
Middle	42 (50)
Distal	17 (21)
Fracture orientation	
Spiral	30 (36)
Oblique	28 (33)
Transverse	24 (29)

Examination for fracture site stability was documented in all the patients at varying time points: 41 patients at 2 weeks after injury, 52 at 4 weeks, 84 at 6 weeks, and 84 at 12 weeks. ROCs were created to define which time points provided the best sensitivities and specificities in determining patients who would achieve fracture union. The areas under the curve were 0.639, 0.888, 0.902, and 0.636 at 2, 4, 6, and 12 weeks, respectively (Fig. 3). The physical examination test for humeral shaft fracture site mobility at 6 weeks follow-up identified fracture healing with 82% sensitivity, with 9/11 nonunions correctly identified. Testing at the 6-week mark also had 99% specificity. Positive predictive value and negative predictive value were 90% and 97%, respectively.

Radiographic appearance of callus formation, when used in combination with the clinical motion assessment test, provided enhanced diagnostic accuracy. In our study population, when patients had both callus formation and no motion at 6 weeks (n = 60), all the patients proceeded to union (sensitivity 83.6%, specificity 100%, and positive predictive value 100%). Nineteen patients had no callus formation at the 6-week mark. Although 13 of these fractures had no gross motion, 2 of them still proceeded onto nonunion. When patients had both an absence of callus formation and motion at 6 weeks (n = 7), all proceeded to nonunion (sensitivity 63.6%, specificity 100%, and positive predictive value 100%).

TABLE 2. Failures of Treatment

Patient ID	Age	Sex	Gross motion at 6 wk	Treatment	Timing of surgery
1	67.27	Male	Yes	Surgery: ORIF with iliac crest bone grafting	52
2	31.38	Male	No	Surgery: ORIF with iliac crest bone grafting (outside facility)	36
3	43.10	Male	Yes	Surgery: ORIF with iliac crest bone grafting	14
4	76.66	Male	Yes	Function was improving so did not want surgery	
5	66.92	Female	Yes	Surgery: ORIF with iliac crest bone grafting	52
6	92.19	Female	Yes	Surgery: ORIF with Iliac Crest Bone Grafting	16
7	65.56	Female	No	Surgery: ORIF with iliac crest bone grafting	13
8	55.78	Female	Yes	Surgery: ORIF with iliac crest bone grafting	12
9	62.49	Female	Yes	Bone stimulator and lost to follow-up	
10	72.96	Female	Yes	Surgery: ORIF with iliac crest bone grafting	52
11	44.99	Female	Yes	Bone stimulator and lost to follow-up	

ORIF, open reduction internal fixation.

Results of the univariate analysis that compared the healed versus nonunion cohorts are shown in **Supplemental Digital Content 1** (see **Table**, http://links.lww.com/JOT/A58). Nonunion patients were significantly older than the rest of the study population. Although there were no significant differences in fracture classification between the 2 groups, nonunion patients tended to have more oblique fractures that were in the middle third of the humeral shaft. Pearson χ^2 test demonstrated a statistically significant association between gross motion at 6 weeks and nonunion formation ($P < 0.001$). Obesity based on body mass index was the only other variable significantly associated with development of fracture nonunion in univariate analysis. A multivariable logistic regression was performed to ascertain the effects of age, obesity, fracture location, and gross motion at 6 weeks on the likelihood patients have increased risk of nonunion formation (see **Table**, **Supplemental Digital Content 2**, http://links.lww.com/JOT/A59). Gross motion at 6 weeks remained the only independent predictor of nonunion formation (odds ratio = 242.92, 95% confidence interval, 11.49–5135.672).

DISCUSSION

Humeral shaft fractures continue to raise dilemmas as the current literature has failed to provide prospective randomized trials demonstrating a failsafe treatment algorithm for the population as a whole. No strict guidelines for these injuries exist. Therefore, to obtain optimal results for each individual patient, care providers need to emphasize a share decision-making model, where providers engage in thoughtful discussion with meticulous consideration of patient's preferences. Fortunately, physicians have many tools to offer patients to help regain their functional status after a humeral shaft fracture. Surgery, despite its inherit risks, remains a viable option for many patients. Not only does it provide patients with similar rates of progression to bony union and functional recovery but also can offer a more predictable treatment course with fewer early physical restrictions. For patients who would prefer to avoid surgery, nonoperative treatment with the use of a functional brace continues to remain a popular modality as healing rates remain above 90%. This method is still not without its disadvantages, including a painful and limited early injury course that can be unpredictable in nature. It is through this study that we hope to enhance our knowledge on the nonoperative recovery course, so that we can predict early which patients might fail nonoperative treatment, thereby salvaging several months of morbidity. We believe that through clinical assessment at 6 weeks for clinical healing, we can provide another tool to the physician's arsenal that can be used in the shared decision-making model.

In this retrospective review of 84 patients treated nonoperatively with a functional brace, 73 humeri (87%) healed without operative intervention, notably lower than found in the current literature. A recent review that analyzed 15 clinical studies found an average union rate of 94.5%.[5] Our patient population healed by an average of 18 weeks, which is slightly longer than comparative studies. This may be attributed to our patient population's age, which was on average 10 years older than other case series.[4,6,7] In this study, 8 patients who developed a fracture nonunion underwent surgical intervention at an average of 8 months. There is no current consensus in the orthopaedic community on the proper timing for the intervention of nonunion surgery. In a recent review, patients whose fractures do not heal by 3 months and have no interval healing on consecutive radiographs taken 6–8 weeks apart should have a high index of suspicion for nonunion and therefore should consider surgical treatment.[13] Other reports in the literature recommend intervention for nonunion anywhere from 7 to 9 months after initial injury.[9,14,15] There are reports, although rare, that recommend operation after only 6 weeks if there is no clinical or radiographic signs of consolidation. These authors reported a nonunion rate at 22.6%, highest noted in the current literature.[16]

Our data demonstrated that only fracture site gross motion at 6 weeks after initial injury was an independent predictor of nonunion formation, with a convincing odds ratio (242.92, 95% confidence interval, 11.49–5135.672). Although gross motion at the fracture site is agreed to be

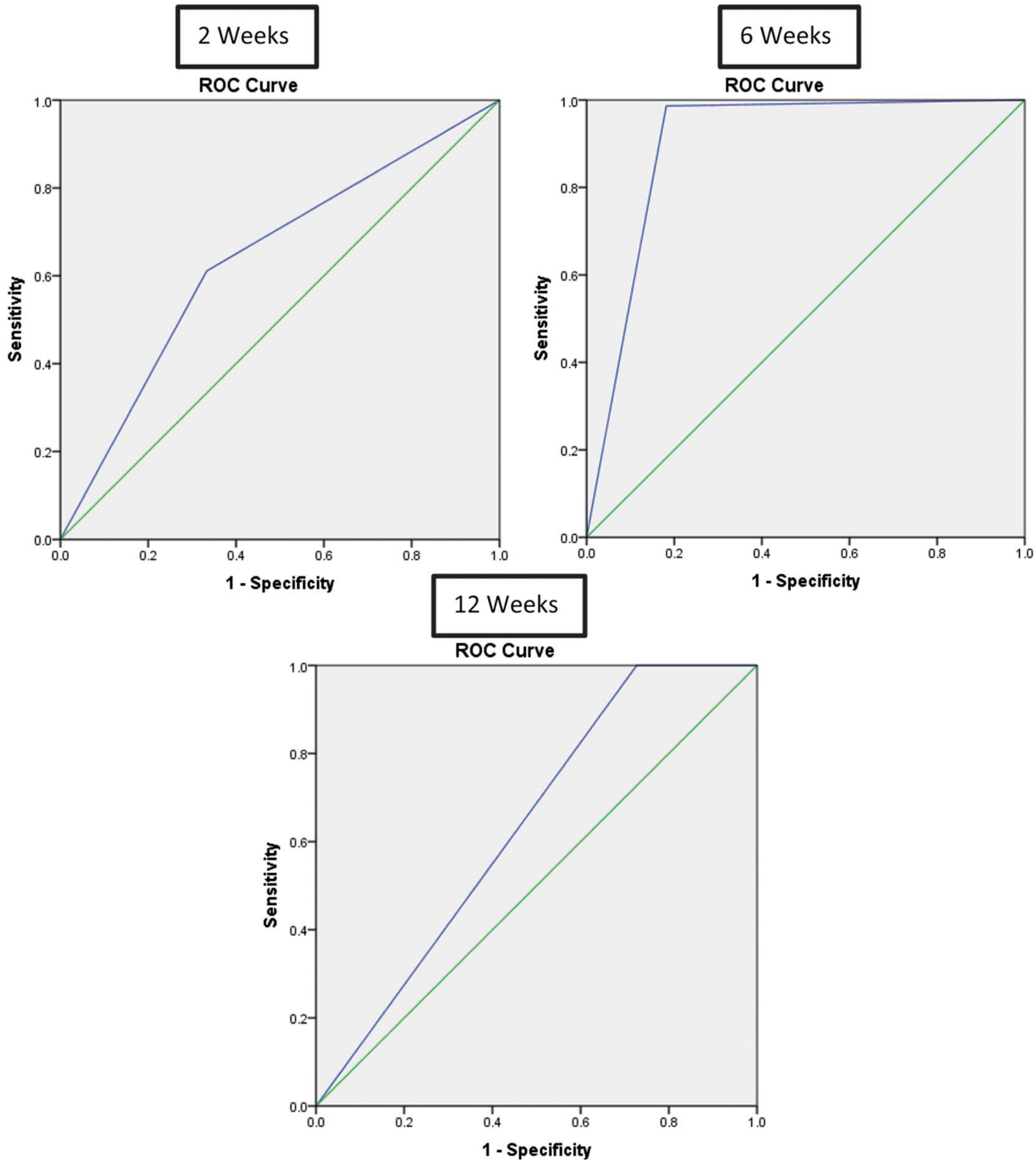

FIGURE 3. ROCs examining when gross motion is predictive of nonunion formation. **Editor's Note:** A color image accompanies the online version of this article.

a sign of a nonhealing fracture, no current work has examined if mobility at a particular time point could predict future fracture nonunion. In this report, receiver operator curves were used to determine which time points would provide the best sensitivity and specificity while testing for fracture stability on physical examination. Although 4 and 6 weeks had similar areas under the curves, 6 weeks was used in both the univariate and multivariate analyzes in that it provides surgeons an extra 2 weeks to educate the patient on healing progression. The multivariate analysis confirms that no other variable cofounded fracture stability at 6 week as an association with future fracture union. We therefore recommend that fracture instability at 6 weeks, with a high negative predictive value, should be assessed in patients to predict which patients will most likely result in fracture nonunion. Those with gross motion at this time point, especially without any callus formation seen on x-ray, should be educated and evaluated for early surgical intervention to speed time to healing.

Both obesity and older age were found to be associated with nonunion formation in the univariate analysis, which is consistent with the literature. Obesity is hypothesized to contribute to nonunion formation when mechanical impingement results in failure achieve acceptable alignment. It is believed that the patient's bulky torso, pendulous breasts, and arm circumference can impede the brace's ability to maintain proper immobilization and lead to angular deformities.[17,18] In a study by Foulk and Szabo[19] examining humeral shaft fractures, they found that obesity significantly correlated with nonunion formation ($P = 0.025$). However, because of a small study population of 15 nonunions of 23 patients, they were not able to show that obesity was independently predictive. Age has also been reported in previous works to contribute to fracture nonunion.[11,20] In a report by Kyro et al[21] examining tibial shaft fractures, advanced age was associated with increased incidence of nonunions, yet was deemed insignificant through their logistic regression model. Similarly, age and obesity were not predictive within our multiple regressions, suggesting that although these factors contribute to nonunion formation, they were most likely cofounded by other more predictive factors.

There are several limitations in this study. Retrospective in nature, this study relies on accurate record keeping from a hospital electronic medical record. Thus, data points that were not consistently gathered, such as brace compliance rates, were not analyzed. Although compliance may have affected ultimate healing, this was not the objective of this study. We also recognize that our lost to follow-up rate was higher than hoped; however, it is not unreasonable considering that many go on to heal rapidly. A standardized protocol was also not established between the treating physicians involved in this study accounting for varied physical examination findings. Therefore, follow-up scheduling and assessments were not homogenous. We also cannot confirm the uniformity in which the physical examinations were performed, just the documentation of fracture site motion. Still, although a precise description of the forces applied during fracture site mobility testing is lacking, we still believe that the assessment for gross motion was reliable between the evaluators as each was a fellowship-trained fracture surgeon with 4–20 years of practice experience. We assume that they can discern between stability and movement, just as there is in any described physical examination test. Finally, this study is limited by a small sample size, making it difficult to establish associations with nonunion formation.

In conclusion, examination for fracture site gross motion is a very simple clinical finding familiar to all trained orthopaedic providers. Its presence should be tested for at 6 weeks in all patients being treated nonoperatively for a humeral shaft fracture. This simple physical examination maneuver provides excellent sensitivity and specificity in identifying patients who will go on to fracture nonunion. In addition, when patients had both an absence of callus formation and motion at 6 weeks (n = 7), all proceeded to nonunion (sensitivity 63.6%, specificity 100%, and positive predictive value 100%). Gross motion can also identify those who are at early risk for nonunion formation and provide time for education in the shared decision-making model and prompt intervention to reduce morbidity associated with this significant complication. This information can also be used to reassure anxious patients who may be concerned about lack of radiographic evidence of union. We therefore recommend that a simple clinical evaluation of humerus fracture site mobility be implemented by physicians treating these injuries 6 weeks after fracture when the decision for nonoperative treatment has been initiated.

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