A commentary by David S. Ruch, MD, is linked to the online version of this article at jbjs.org.

Minimally Invasive Osteosynthesis with a Bridge Plate Versus a Functional Brace for Humeral Shaft Fractures

A Randomized Controlled Trial

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Background: Nonoperative treatment has historically been considered the standard for fractures of the shaft of the humerus. Minimally invasive bridge-plate osteosynthesis for isolated humeral shaft fractures has been proven to be a safe technique, with good and reproducible results. This study was designed to compare clinical and radiographic outcomes between patients who had been treated with bridge plate osteosynthesis and those who had been managed nonoperatively with a functional brace.

Methods: A prospective randomized trial was designed and included 110 patients allocated to 1 of 2 groups: surgery with a bridge plate or nonoperative treatment with a functional brace. The primary outcome was the Disabilities of the Arm, Shoulder and Hand (DASH) score at 6 months. The score on the Short Form-36 (SF-36) life-quality questionnaire, complications of treatment, Constant-Murley score for the shoulder, pain level, and radiographic results were assessed as secondary outcomes. Participants were assessed at 2 weeks; 1, 2, and 6 months; and 1 year after the interventions.

Results: The mean DASH score of the bridge plate group was statistically superior to that of the functional brace group (mean scores, 10.9 and 16.9, respectively; $p = 0.046$) only at 6 months. The bridge plate group also had a significantly more favorable nonunion rate (0% versus 15%) and less mean residual angular displacement seen on the anteroposterior radiograph (2.0° versus 10.5°) (both $p < 0.05$). No difference between the groups was detected with regard to the SF-36 score, pain level, Constant-Murley score, or angular displacement seen on the lateral radiograph.

Conclusions: This trial demonstrates that, compared with functional bracing, surgical treatment with a bridge plate has a statistically significant advantage, of uncertain clinical benefit, with respect to self-reported outcome (DASH score) at 6 months, nonunion rate, and residual deformity in the coronal plane as seen on radiographs.

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

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Historically, nonoperative treatment with a functional brace has been the most popular choice of orthopaedic surgeons for acute, isolated, closed humeral shaft fractures[1]. However, this method can lead to unsatisfactory results, including malunion, nonunion, and limb impairment[2,3]. It also may present more difficulties for obese patients and those with large breasts[4].

Surgical treatment for humeral shaft fractures is usually recommended for patients with associated neurovascular

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injury, an open fracture, associated elbow and forearm fractures, and polytrauma[5-7], but Level-I evidence regarding the treatment of isolated closed humeral shaft fractures is lacking[8].

Recently, a minimally invasive surgical technique with 2 small anterior approaches and use of a bridge plate—based on the relative stabilization concept—was described for these fractures[9]. This new method has been shown to be a safe technique, with good results reported in cohort studies[10-12].

This randomized controlled trial was designed to compare the effectiveness of bridge plate surgery with that of nonoperative treatment (functional bracing) for displaced humeral shaft fractures in adults. The outcomes that we considered included upper-limb functional limitation, pain, quality of life, shoulder function, complications, and radiographic outcomes.

Materials and Methods

This randomized controlled trial was approved by our Institutional Research Ethical Committee, and its protocol was registered in ISRCTN (number 24835397). The protocol of this clinical trial with details of its methodology was published previously[13].

From May 2012 to February 2015, consecutive patients with a displaced humeral shaft fracture were included in the study. All subjects were recruited, treated, and assessed in a specialized, referenced upper-limb surgery center of the Department of Orthopedics and Traumatology at the Universidade Federal de São Paulo.

Inclusion Criteria

Inclusion criteria were (1) an age of 18 years or older, (2) an isolated closed displaced fracture of the humeral shaft located in an area limited to 4 cm distal to the surgical neck and 4 cm proximal to the upper border of the olecranon fossa, (3) fewer than 21 days between the trauma and study enrollment, (4) no pathological fracture, (5) no associated neurovascular injury, (6) no contraindications to general anesthesia, (7) no previous impairment of the shoulder or elbow joint, (8) no cognitive impairment, and (9) the patient's agreement to participate and sign the written informed consent form.

Sample Size

A sample size of 50 patients in each group was previously calculated on the basis of a significance level of 0.05, a power of 90%, a standard deviation (SD) of 15 for the Disabilities of the Arm, Shoulder and Hand (DASH) score, and a minimal clinically important difference in the DASH score of 10 points between the groups[14]. Anticipating a loss to follow-up, we planned to recruit a total of 110 patients.

Randomization and Allocation

A randomization sequence was generated by computer software (http://www.randomizer.org). A list from 1 to 110 was created, with each number indicating 1 of the 2 methods of treatment: nonoperative treatment with a functional brace or surgical treatment with a bridge plate. The numbers were placed in 110 individual opaque sealed envelopes. The randomization was unrestricted.

Allocation was performed after the protocol was explained and both of the procedures were described to the potential participants. After they agreed to take part in the study and signed the informed consent form, an independent person opened the envelope to assign the intervention.

Nonoperative Treatment with Functional Brace

Patients were initially managed with closed reduction and immobilization with a coaptation U-splint[15] from the axilla to the elbow, ending at the shoulder. After 2 weeks, the splint was replaced by a functional brace[1] (Fig. 1) that allowed movement of the shoulder and elbow. The brace was worn until there was clinical and radiographic evidence of fracture consolidation.

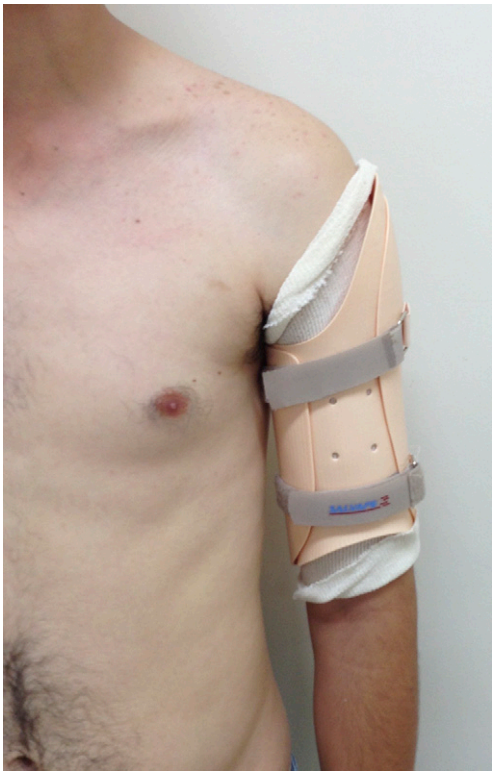

Fig. 1

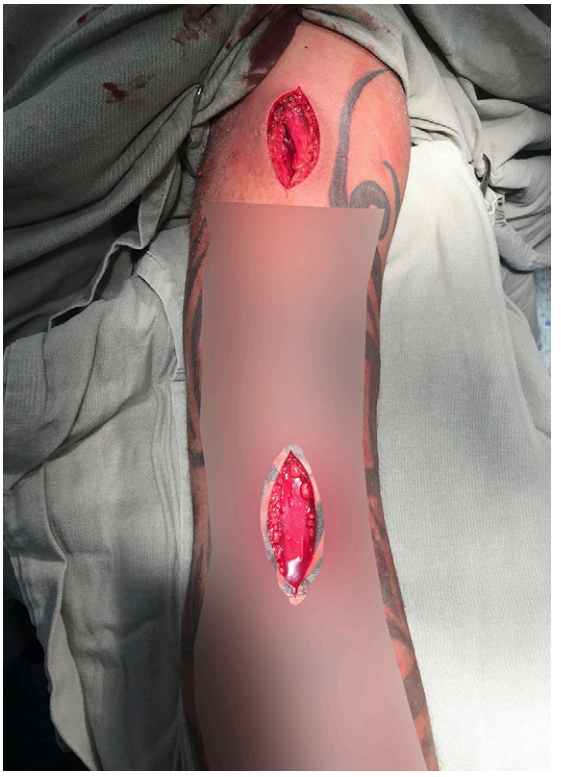

Fig. 2

Fig. 1 Functional brace. **Fig. 2** Surgical incisions for minimally invasive bridge plate osteosynthesis.

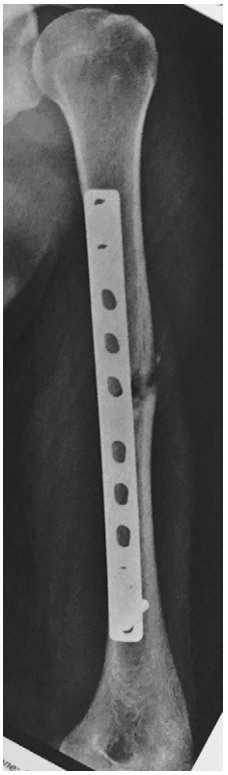

Fig. 3-A

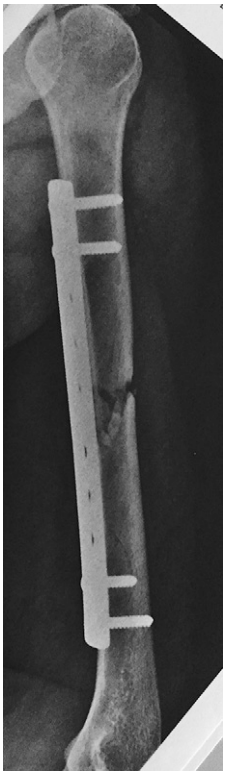

Fig. 3-B

Figs. 3-A and 3-B Postoperative radiographs.

Surgical Treatment with Bridge Plate

From the time of the initial recruitment to the surgical procedure, the upper limb was immobilized with a coaptation splint. Four previously assigned surgeons, who were experienced with the surgical technique of anterior-access bridge plate osteosynthesis, performed the surgical procedures. After the administration of the anesthetic and prophylactic antibiotics, the patient was placed in the horizontal dorsal decubitus position and 2 incisions were made in the arm; surgical access was obtained according to the originally described technique[9] (Fig. 2). The radial nerve did not have to be dissected once it was protected by the lateral part of brachialis muscle. Also, retractors for humeral exposure were not used in order to avoid damage to the radial nerve. Reduction was achieved with application of traction in the distal fragment and rotation control was obtained in the medial and lateral condyles, using fluoroscopy. Then a narrow 4.5-mm dynamic compression plate (DCP) was used with 2 screws inserted into each main fragment and, if the surgeon thought that these did not achieve good enough stability, a third screw to guarantee secure plate-to-bone fixation. After osteosynthesis, final radiographs were obtained (Figs. 3-A and 3-B) and the wounds were sutured and bandaged. The upper limb was immobilized with a sling until the first evaluation.

Rehabilitation

The rehabilitation program was similar for the 2 groups. Free movement (active and passive motion) of the elbow and pendulum exercises for the shoulder were allowed as soon as the patient felt comfortable. Internal and external shoulder rotation was permitted 6 weeks after the intervention.

Outcome Assessment

Health-care professionals who were not directly involved in the study performed radiographic and functional evaluations and administered questionnaires. The assessors were blinded to the treatment assignment whenever possible. Before the outcome assessments, the participants were instructed to not reveal the treatment that they had undergone, and an identical opaque gown was used to cover the injured arm in both groups[16].

Study Outcomes

The primary outcome was the mean score on a translated and validated native-language version of the DASH questionnaire (without its 2 optional modules) completed at 6 months to assess upper-limb disability[17,18]. The mean DASH scores were also compared between the groups at 2 weeks; 1, 2, and 6 months; and 1 year.

The secondary outcomes in this study included the Short Form-36 (SF-36) questionnaire[19,20], Constant-Murley shoulder score[21], pain measured on a visual analogue scale (VAS)[22,23], radiographic results, and treatment complications.

TABLE I Baseline Characteristics of the Functional Brace and Bridge Plate Groups

	Functional Brace Group (N = 52)	Bridge Plate Group (N = 58)	P Value
Age* *(yr)*	40.3 ± 17.2	37.3 ± 14.7	0.331
Sex *(no. [%])*			0.158
Male	38 (73%)	35 (60%)	
Female	14 (27%)	23 (40%)	
OTA/AO fracture type† *(no. [%])*			0.320
A	28 (55%)	38 (68%)	
B	17 (33%)	15 (27%)	
C	6 (12%)	3 (5%)	
Fracture location† *(no. [%])*			0.340
Proximal	6 (12%)	6 (11%)	
Middle	38 (75%)	36 (64%)	
Distal	7 (14%)	14 (25%)	
Loss to follow-up after 1 yr *(no. [%])*	8 (15%)	8 (14%)	0.813

*The values are given as the mean and standard deviation. †N = 51 in the functional brace group because 1 patient was lost to follow-up (including radiographic examination) between the intervention and outcome assessments. N = 56 in the bridge plate group because 2 patients were lost to follow-up between the intervention and outcome assessments.

The SF-36 quality-of-life questionnaire assesses 8 health concepts (physical functioning, bodily pain, limitations due to health problems, limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions) and 36 items in total. SF-36 data were obtained at 1, 2, and 6 months and at 1 year in the present study.

Functional evaluation of the shoulder was performed using the Constant-Murley score, which includes pain, daily living activities, range of motion, and strength, generating a score from 0 to 100. This score was determined at the same time as the DASH score.

To obtain the VAS pain score, patients were instructed to mark an "X" on a 10-cm line, the left end of which meant "no pain" and the right end of which indicated "pain as bad as it could be." The measured distance between the "X" marked by the patient and the left end of the line was the translation in numbers of the pain reported by the patient. The pain score was also determined at the same time as the DASH score.

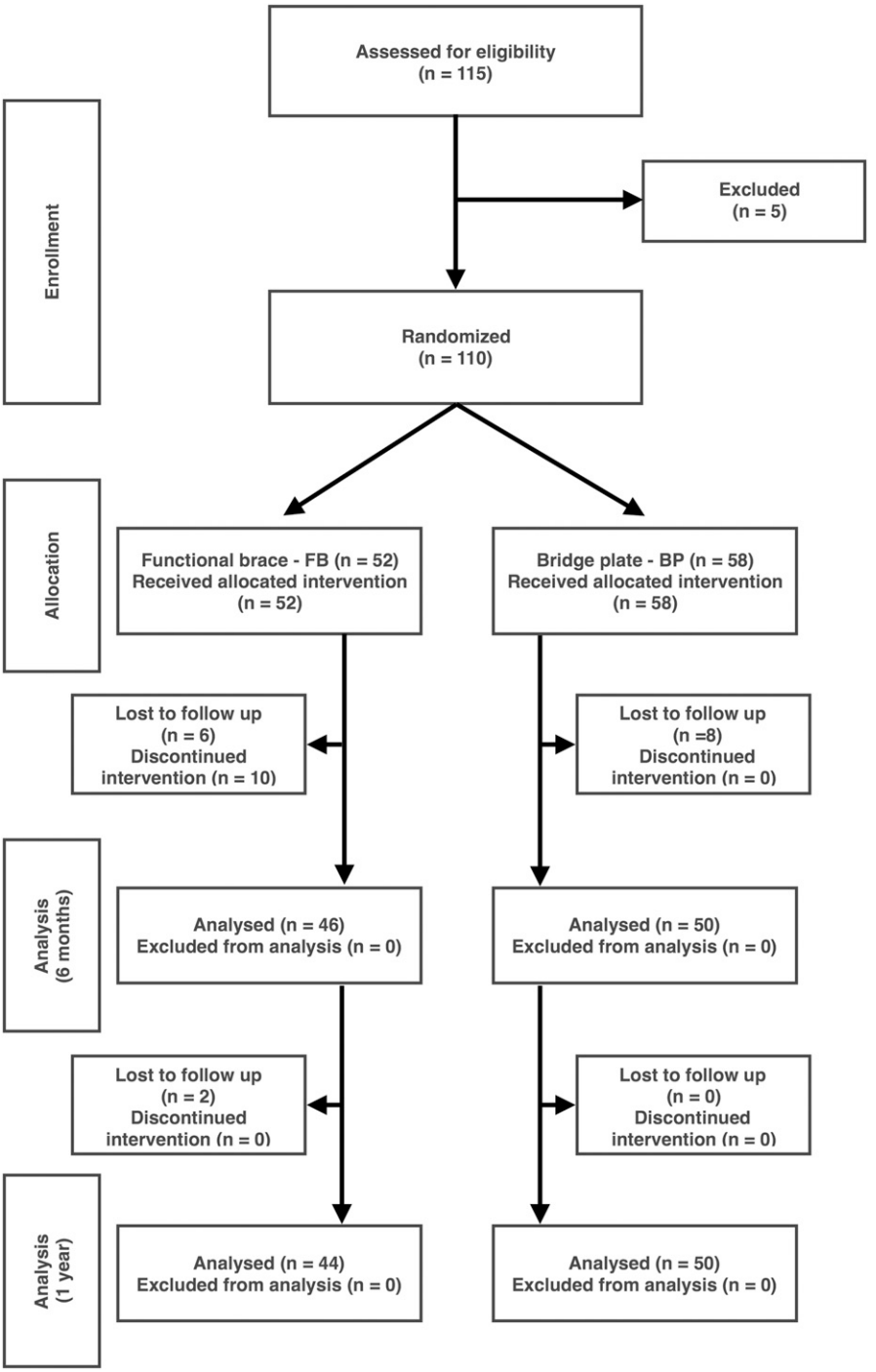

Fig. 4

Flowchart of inclusion of patients with humeral shaft fracture in the study.

Radiographs of the arm in 2 planes (anteroposterior and lateral views) were made to verify the consolidation of, and angles between, the principal fragments of the fracture. Fracture-healing was determined when bone continuity in 3 cortices was detected between the main fragments of the fracture in both planes assessed. The angle between the fragments was measured, in degrees, on both views. These data were obtained at 2 weeks; 1, 2, and 6 months, and 1 year.

Complications due to both interventions were closely monitored and treated as soon as they were detected. They were categorized as severe or minor.

The need to stop, or perform surgical intervention following, functional brace treatment; the need for surgical revision; or clinically important morbidity was considered to be a severe complication and a failure of treatment.

Nonunion was defined as the absence of clinical and radiographic progression of osseous fracture-healing for 3 consecutive months or the absence of healing by 6 months[24].

Complications that represented less interference with the final result of treatment were considered to be minor and represented secondary outcomes. In the functional brace group, these included skin lesions due to prolonged contact with the brace and transient neurological injury (neurapraxia). In the bridge plate group, they included superficial infection that did not require a new surgical procedure, transient neurological injury (neurapraxia), and hypertrophic scarring.

Patients for whom the treatment failed and required additional interventions continued to be monitored, and their results were included in the group to which they had been originally randomized, according to the intention-to-treat principle.

Statistical Methodology

The Student t test was performed to compare the functional brace and bridge plate groups using the mean difference, at all time points at which the outcomes were assessed. The Pearson chi-square test was used to compare categorical variables between the 2 groups.

A significance level of 5% (alpha = 0.05) was used for all statistical tests of the primary outcome (the DASH score at 6 months), so that a p value of <0.05 was considered significant. For secondary outcomes, an alpha value of 0.02 was considered significant, as described in the published protocol[13]. SPSS software version 17, Minitab 16, and Excel Office 2010 were used for the statistical analyses.

Results

Of the 115 patients initially enrolled, 5 were not included in the randomization. Of these 5 patients, 2 presented with a fracture that extended to the proximal end of the humerus, 1 had a fracture that extended to the distal end, 1 had cerebral palsy, and 1 had advanced dementia.

Of the 110 patients included, 52 were allocated to the functional brace group and 58, to the bridge plate group. The average age was 40.3 years in the functional brace group and 37.3 years in the bridge plate group, with no significant difference between the groups. The groups were considered homogeneous, since there was also no statistically significant difference in sex, fracture type (according to the OTA/AO classification)[25], or location of the fracture (proximal, middle or distal third of the shaft). After 12 months, 8 patients (15%) in the functional brace group and 8 (14%) in the bridge plate group were lost to follow-up, with no significant difference between the groups in terms of loss to follow-up (Table I and Fig. 4).

All of the 58 patients allocated to the bridge plate group underwent the surgical procedure with the proposed technique (minimally invasive bridge plate osteosynthesis). The mean time from the injury to the procedure was 12.4 days (range, 8 to 17 days). All 52 patients allocated to the functional brace group were initially treated for approximately 2 weeks with the splint, which was then replaced by the functional brace. The mean

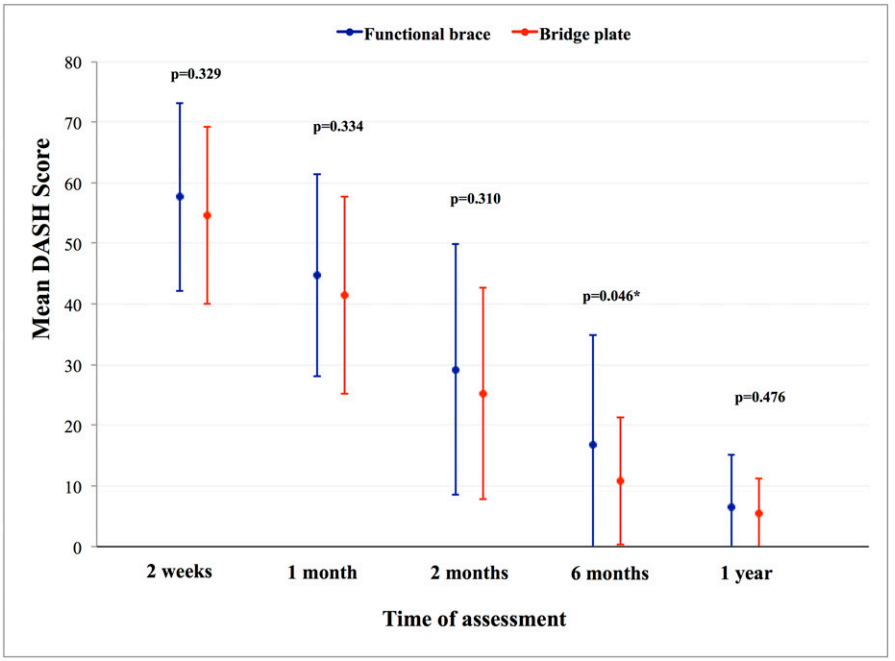

Fig. 5

The mean DASH scores (and SD) were 57.6 ± 15.5, 44.7 ± 16.6, 29.2 ± 20.7, 16.9 ± 18.0, and 6.5 ± 8.6 points at 2 weeks, 1 month, 2 months, 6 months, and 1 year following functional bracing and 54.6 ± 14.6, 41.4 ± 16.3, 25.2 ± 17.4, 10.9 ± 10.5, and 5.5 ± 5.8 points at the respective follow-up periods after treatment with a bridge plate. *Statistically significant.

time from the injury to brace application was 15.2 days (range, 12 to 17 days).

Clinical/Functional Outcomes

The bridge plate group had a significantly more favorable 6-month DASH score (mean, 10.9 compared with 16.9 in the functional brace group; p = 0.046) (Fig. 5).

There was no significant difference between the 2 groups with respect to any of the domains of the SF-36 questionnaire, at any of the measured times. There was a marginal difference in physical functioning at 1 month (mean, 67.6 in the functional brace group and 76.0 in the bridge plate group; p = 0.025) (Table II). There was no difference between the groups with regard to the Constant-Murley score or VAS pain score (Fig. 6).

Severe complications indicating failure of treatment were reported in 10 patients (23%) in the functional brace group and none in the bridge plate group. Of the 10 failures, 7 were due to nonunion, 1 to clinically symptomatic malunion, and 2 to an inability to tolerate the brace. The patients who developed fracture nonunion underwent surgical application of a plate and screws through a posterior approach—with an absolute-stability technique—to promote healing, which was achieved in all cases. The patient who developed fracture malunion had progressive angulation of the fracture fragments resulting in gross deformity of the limb (28° of angular displacement on the last radiographs). Osteotomy was performed, followed by fixation with a plate and screws. The patients who did not tolerate the functional brace underwent surgical treatment with a bridge plate, with good results. No additional surgery was needed in any patient in the bridge plate group (Table III).

Seven patients had a complication that required no additional intervention in the bridge plate group. One patient (2%) had a superficial infection that resolved after treatment with oral antibiotics; 2 patients (4%) had a postoperative transient radial neurapraxia, both of whom had full spontaneous sensory and motor recovery after approximately 5 months; and 4 patients (8%) developed hypertrophic scarring in the wound, with only cosmetic impact. Five patients in the functional brace group developed contact dermatitis from use of the brace, with no functional impact (Table III).

TABLE II SF-36 Scores of Functional Brace and Bridge Plate Groups

	1 Month		2 Months		6 Months		1 Year	
SF-36 Domain	Mean ± SD	P Value	Mean ± SD	P Value	Mean ± SD	P Value	Mean ± SD	P Value
Physical functioning		0.025		0.078		0.122		0.392
Functional brace	67.6 ± 19.1		81.1 ± 14.9		87.8 ± 14.4		94.2 ± 10.5	
Bridge plate	76.0 ± 17.1		86.1 ± 12.6		91.8 ± 10.4		95.7 ± 6.1	
Role limitation (physical)		0.294		0.381		0.259		0.409
Functional brace	3.8 ± 11.7		38.0 ± 31.1		72.3 ± 33.4		90.3 ± 20.3	
Bridge plate	6.5 ± 13.2		43.7 ± 31.8		79.5 ± 28.9		93.5 ± 16.6	
Mental health		0.236		0.143		0.889		0.288
Functional brace	85.6 ± 22.9		95.0 ± 12.0		95.7 ± 13.4		97.2 ± 9.1	
Bridge plate	90.7 ± 19.1		98.0 ± 7.9		96.0 ± 10.9		98.8 ± 5.8	
Energy/fatigue (vitality)		0.723		0.398		0.701		0.362
Functional brace	86.1 ± 9.8		86.8 ± 10.3		89.8 ± 7.5		91.5 ± 7.6	
Bridge plate	85.4 ± 9.2		88.4 ± 7.5		90.4 ± 8.1		92.9 ± 7.4	
Role limitation (emotional)		0.310		0.165		0.261		0.271
Functional brace	85.8 ± 12.5		88.0 ± 11.5		91.0 ± 8.6		94.0 ± 7.8	
Bridge plate	88.3 ± 11.4		91.0 ± 9.9		92.9 ± 7.7		95.7 ± 6.5	
Social functioning		0.107		0.657		0.562		0.111
Functional brace	74.1 ± 20.7		83.3 ± 18.8		91.2 ± 16.7		96.3 ± 9.0	
Bridge plate	80.3 ± 16.5		84.8 ± 13.9		92.8 ± 9.6		93.5 ± 7.4	
Bodily pain		0.754		0.058		0.926		0.644
Functional brace	69.8 ± 17.2		83.9 ± 14.3		86.6 ± 15.3		92.7 ± 11.0	
Bridge plate	70.8 ± 13.7		78.3 ± 14.4		86.3 ± 14.8		91.6 ± 11.5	
General health perception		0.991		0.706		0.230		0.427
Functional brace	85.5 ± 10.0		88.3 ± 9.1		90.2 ± 7.5		91.3 ± 7.6	
Bridge plate	85.5 ± 9.1		87.6 ± 9.0		92.0 ± 6.9		92.4 ± 6.4	

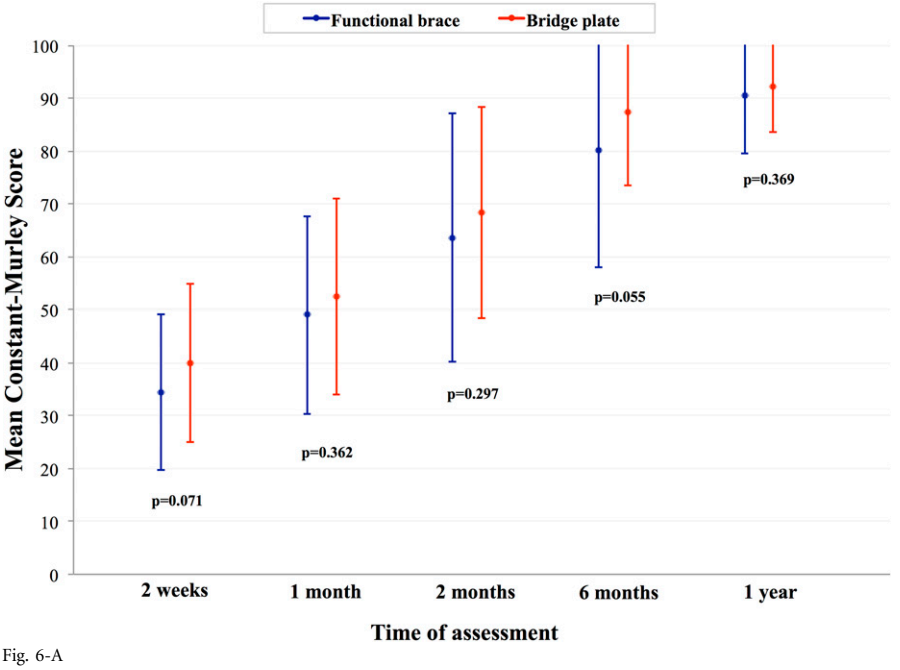

Fig. 6-A

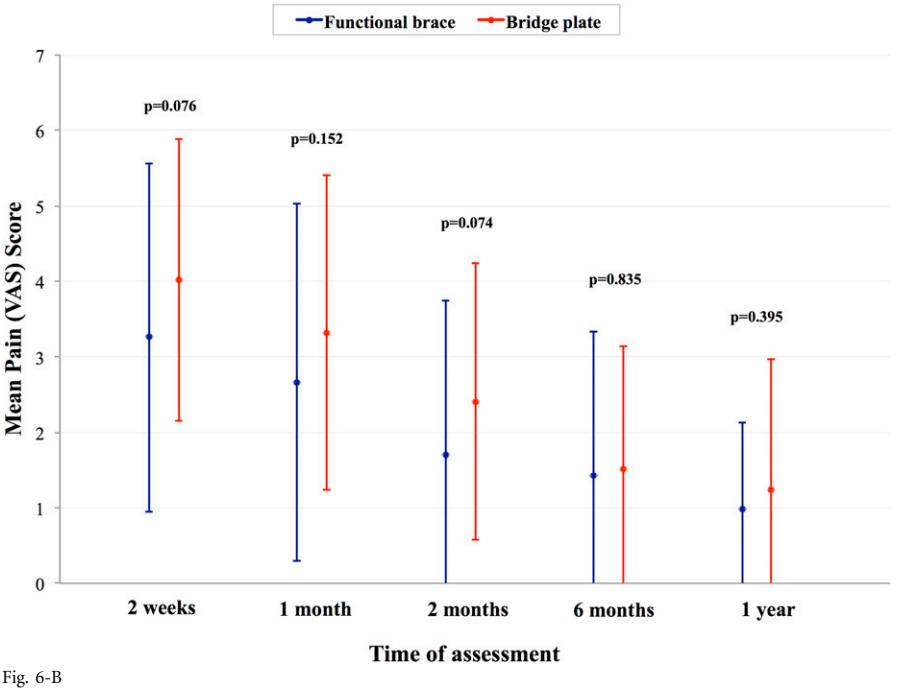

Fig. 6-B

Fig. 6-A The mean Constant-Murley scores (and SD) were 34.4 ± 14.6, 49.0 ± 18.7, 63.7 ± 23.4, 80.0 ± 22.1, and 90.4 ± 10.8 points at 2 weeks, 1 month, 2 months, 6 months, and 1 year following functional bracing and 39.9 ± 14.9, 52.5 ± 18.5, 68.3 ± 20.0, 87.3 ± 13.8, and 92.2 ± 8.6 points at the respective follow-up periods after treatment with a bridge plate. **Fig. 6-B** The mean VAS pain scores were 3.3 ± 2.3, 2.7 ± 2.4, 1.7 ± 2.0, 1.4 ± 1.9, and 1.0 ± 1.2 points at 2 weeks, 1 month, 2 months, 6 months, and 1 year following functional bracing and 4.0 ± 1.9, 3.3 ± 2.1, 2.4 ± 1.8, 1.5 ± 1.6, and 1.2 ± 1.7 points at the respective follow-up periods after treatment with a bridge plate.

Radiographic Analysis

The functional brace group had significantly greater final angular displacement of the main fracture fragments on the anteroposterior radiographs (10.5°) compared with the bridge plate group (2.0°). There was no significant difference between the groups with regard to the final angular displacement on the lateral views (Table III).

TABLE III Complications and Radiographic Outcomes of Functional Brace and Bridge Plate Groups

	Functional Brace Group (N = 46*)	Bridge Plate Group (N = 50)	P Value
Severe complications *(no. [%])*			
Nonunion	7 (15%)	0 (0%)	0.004†
Symptomatic malunion	1 (2%)	0 (0%)	0.295
Intolerance of treatment	2 (4%)	0 (0%)	0.136
Minor complications *(no. [%])*			
Superficial infection	0 (0%)	1 (2%)	0.335
Transient radial neurapraxia	0 (0%)	2 (4%)	0.170
Hypertrophic scar	0 (0%)	4 (8%)	0.050
Contact dermatitis	5 (11%)	0 (0%)	0.017†
Radiographic outcome (angular displacement)‡ *(°)*			
Anteroposterior view	10.5 ± 8.9	2.0 ± 4.7	<0.001†
Lateral view	1.4 ± 9.1	0.2 ± 0.7	0.350

*These data were collected at 6 months, when 46 patients were available for follow-up. Two other patients were lost to follow-up at 1 year. †A significant difference. ‡The values are given as the mean and standard deviation.

TABLE IV Comparison of No-Failure and Failure Subgroups in Functional Brace Group (N = 46*)

	No Failure	Failure	P Value
Age† *(yr)*	38.5 ± 17.7	41.8 ± 12.7	0.582
Sex *(no. [%])*			0.089
Female	10 (28%)	0 (0%)	
Male	26 (72%)	10 (100%)	
OTA/AO fracture type *(no. [%])*			0.760
A	19 (53%)	6 (60%)	
B	12 (33%)	4 (40%)	
C	5 (14%)	0 (0%)	
Fracture site *(no. [%])*			0.097
Proximal	7 (19%)	0	
Middle	23 (64%)	10 (100%)	
Distal	6 (17%)	0	

*These data were collected at 6 months, when 46 patients were available for follow-up. No more failures of treatment were reported after 6 months. †The values are given as the mean and standard deviation.

Analysis of Subgroups

The 10 patients in the functional brace group who had treatment failure did not differ, with regard to sex, age, fracture site, or OTA/AO classification, from the patients without failure in that group (Table IV).

Discussion

Previous randomized controlled trials comparing 2 surgical methods—intramedullary nailing and use of a compression plate—for humeral shaft fractures showed good results with both techniques[26,27]. The present study provides Level-I evidence concerning treatment of humeral shaft fractures and is the first comparing surgical treatment with nonoperative management for these fractures. A previous, thorough plan was executed in order to minimize bias. Non-pharmacological randomized controlled trials present difficulties in blinding assessors and participants[28]. In this trial, blinded assessment of the self-reported questionnaires (DASH, SF-36, and pain VAS) was possible whereas blinded radiographic evaluation was not. Blinded assessment of complications and the Constant-Murley score was attempted by instructing participants not to reveal their allocation to the assessor and to wear an opaque gown covering their affected arm.

Functional clinical outcomes measured with the DASH and quality of life measured with the SF-36 have increasingly been used in the literature on various orthopaedic conditions—as primary outcomes in most of these studies[29].

The bridge plate group in this trial had a statistically more favorable mean DASH score at 6 months. However, the difference in the mean scores between the groups was 6.0 points, which was less than the minimal clinically important difference of 10 points reported in previous studies[14,30].

Only 4.2% of clinical trials assess quality of life as an outcome, and fewer include interpretation of SF-36 scores[31,32]. Because these outcomes were previously defined as secondary for our study, a p value of <0.02 was considered significant. A p value of 0.025 was found for the difference, favoring the bridge plate group, in the physical functioning domain at 1 month, which can be interpreted as only a trend.

Other studies have shown fracture consolidation rates of 77% to 100% with functional bracing[33-35], and the rate of 85% (7 nonunions) in the functional brace group in our randomized controlled trial is similar. We found a higher rate of complications

related to nonoperative brace treatment than after surgical treatment with the bridge plate.

The nonunions in this study may have influenced other outcomes. It was possible to explore this issue as the intention-to-treat principle was applied to our randomized controlled trial. Less favorable DASH scores at 6 months in the functional brace group can be related to limb impairment of patients who developed nonunion and were still recovering from corrective surgery for this complication.

There was no association between clinical failure and the age or sex of the patient or the type (OTA/AO classification) or location of the fracture. Interestingly, none of the 7 patients who developed nonunion and neither of the 2 who did not tolerate the use of the brace were obese or had larger breasts.

The strengths of this study include the fact that it was a randomized controlled trial, with adequate methods of randomization and allocation; absence of industry conflicts of interest as it received governmental funding; previous publication of the protocol[13]; <20% loss to follow-up; and blinded assessment with self-administered outcomes tools. Limitations of this study include its lower external validity, since it was conducted in a single center; however, 2 ongoing registered randomized clinical trials comparing surgical and nonsurgical treatment of humeral shaft fractures are in progress[36,37]. We hope that publication of these trials will make it possible to synthesize data from all of the studies, providing more robust evidence regarding the treatment of humeral shaft fractures.

The present study demonstrated a statistically significant advantage of surgical treatment over functional bracing in terms of the self-reported DASH outcome at 6 months as well as a lower nonunion rate and less residual deformity in the coronal plane seen on radiographs after the surgery. Only the nonunion rate is likely of clinical relevance. ■

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