Functional and clinical outcomes after plate osteosynthesis versus intramedullary nailing of a humeral shaft fracture: the results of the HUMMER multicenter, prospective cohort study

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Functional and Clinical Outcomes After Plate Osteosynthesis Versus Intramedullary Nailing of a Humeral Shaft Fracture

The Results of the HUMMER Multicenter, Prospective Cohort Study

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Background: Plate osteosynthesis (referred to throughout as plating) and intramedullary nailing (referred to throughout as nailing) are the most common operative strategies for humeral shaft fractures. However, it is undecided which treatment is more effective. This study aimed to compare functional and clinical outcomes of these treatment strategies. We hypothesized that plating would result in an earlier recovery of shoulder function and fewer complications.

Methods: From October 23, 2012, to October 3, 2018, adults with a humeral shaft fracture, OTA/AO type 12A or 12B, were enrolled in a multicenter, prospective cohort study. Patients were treated with plating or nailing. Outcome measures included the Disabilities of the Arm, Shoulder and Hand (DASH) score, Constant-Murley score, ranges of motion of the shoulder and elbow, radiographic healing, and complications until 1 year. Repeated-measure analysis was done with correction for age, sex, and fracture type.

Results: Of the 245 included patients, 76 were treated with plating and 169 were treated with nailing. Patients in the plating group were younger, with a median age of 43 years compared with 57 years for the nailing group ($p < 0.001$). The mean DASH score after plating improved faster over time, but did not differ significantly from the score after nailing at 12 months (11.7 points [95% confidence interval (CI), 7.6 to 15.7 points]) for plating and 11.2 points [95% CI, 8.3 to 14.0 points] for nailing). The Constant-Murley score and shoulder abduction, flexion, external rotation, and internal rotation displayed a significant treatment effect ($p_{treatment} \leq 0.001$), in favor of plating. The plating group had 2 implant-related complications, whereas the nailing group had 24, including 13 nail protrusions and 8 screw protrusions. Plating resulted in more postoperative temporary radial nerve palsy (8 patients [10.5%] compared with 1 patient [0.6%]; $p < 0.001$) and a trend toward fewer nonunions (3 patients [5.7%] compared with 16 patients [11.9%]; $p = 0.285$) than nailing.

Conclusions: Plating of a humeral shaft fracture in adults results in faster recovery, especially of shoulder function. Plating was associated with more temporary nerve palsies, but fewer implant-related complications and surgical re-interventions, than nailing. Despite heterogeneity in implants and surgical approach, plating seems to be the preferred treatment option for these fractures.

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

The best operative treatment for humeral shaft fractures remains subject to debate. The treatment options are intramedullary nailing (referred to throughout as nailing) and plate osteosynthesis (referred to throughout as plating), each with their advantages and disadvantages. Nailing is less invasive and may require less surgical time, but may be

*A list of the HUMMER Investigators is included in a note at the end of the article.

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associated with rotator cuff symptoms. Plating allows anatomic reduction and fracture compression, but the more extensive surgical approach has a potential risk of radial nerve injury. Three meta-analyses reported ranges of pooled rates for both superficial and deep infections (1.6% to 2.3% after nailing compared with 1.7% to 7.7% after plating), secondary nerve palsy (2.5% to 6.4% after nailing compared with 2.9% to 6.9% after plating), and nonunion (3.6% to 9.2% after nailing compared with 1.1% to 8.6% after plating)[1-3].

Although some studies showed no significant effect of treatment on functional shoulder scores[4-6], both Li et al.[7] and Yuan et al.[8] showed higher Constant-Murley scores after plating than after nailing.

Because of heterogeneity in methodology, patient population, fracture type, and outcome measures across previous studies, it is undecided which treatment is more effective. Plating allows for anatomic reduction and fracture compression and avoids complications involving the rotator cuff, so we hypothesized that plating would result in earlier functional recovery and a lower complication risk compared with nailing. The aims of this study were to examine the effect of plating compared with that of nailing on functional recovery and complications in adults with a humeral shaft fracture.

Materials and Methods

Setting and Participants

This study used data from the operative treatment group of the HUMMER (HUMeral Shaft Fractures: Measuring Recovery after Operative versus Non-operative Treatment) study[9]. Twenty-eight hospitals that participated in this multicenter, parallel-group cohort study provided patients for the operatively treated group. The decision about surgical treatment was left to the discretion of the treating surgeon. All patients who were ≥18 years of age, had a humeral shaft fracture (OTA/AO type 12A or 12B, confirmed by radiography), and underwent a surgical procedure <14 days after hospital presentation were included after they provided written informed consent[10]. Patients with pre-trauma disability or additional trauma to the arm that could affect the outcome or with expected problems with maintaining follow-up were excluded. A full list of eligibility criteria is available in the published study protocol[11]. The local Medical Research Ethics Committee at each site exempted the study (no. MEC-2012-396).

Treatment Allocation and Masking

The decision about which implant to use was left to the discretion of the treating surgeon. Participants and investigators were not blinded to the treatment. To reduce bias, follow-up measurements were standardized. Two assessors (I.B. and D.D.H.) independently evaluated the radiographs. Consensus was reached after discussion.

Intervention

Treatment was provided on the basis of local protocols, and the surgical procedure was performed by certified, experienced, orthopaedic trauma surgeons. There were no study-specific requirements with regard to fracture reduction (open or closed), plating (open or minimally invasive), nailing (antegrade or retrograde), type and brand of the devices, and other elements of the surgical procedure, among others. With no evidence favoring a specific approach, the physical therapy and rehabilitation programs were also not standardized. Critical elements of treatment were recorded.

Assessments and Follow-up

The follow-up visits took place at 2 weeks (range, 7 to 21 days), 6 weeks (range, 4 to 8 weeks), 3 months (range, 11 to 15 weeks), 6 months (range, 6 to 7 months), and 12 months (range, 12 to 14 months) after the surgical procedure[11]. At each visit, clinical data were collected from the patients' medical files. Also, shoulder and elbow ranges of motion were measured using a goniometer, and patients were asked to complete questionnaires on the level of pain, functional recovery, activity resumption, and health-related quality of life. The Constant-Murley score was determined at 6 weeks and subsequent visits. Anteroposterior and lateral radiographs of the humerus were made at presentation, after the operation, and at each study visit.

The Disabilities of the Arm, Shoulder and Hand (DASH) score served as the primary outcome measure[12,13]. The secondary outcome measures were the Constant-Murley score[14], level of pain (on a visual analog scale [VAS]), analgesic drugs used, shoulder and elbow ranges of motion, time to resumption of work, resumption of activities of daily living (on a numeric rating scale [NRS]), health-related quality of life (Short Form-36 [SF-36] and EuroQol-5 Dimensions-3 Levels [EQ-5D-3L])[15-17], the occurrence of complications and associated secondary interventions, and radiographic healing[11]. Nonunion was defined as a failure to heal at 6 months postoperatively with no progress toward healing seen on radiographs[18]. The patient-reported outcome measures have been proven to be reliable, valid, and responsive in the studied population and were available in Dutch[19,20]. The outcome measures are detailed in the published study protocol[11].

Patient characteristics, injury-related details, and the number of physical therapy sessions were recorded[11].

Statistical Analysis

The HUMMER study was powered for detecting a 6-point difference in DASH score between the operatively treated group and the nonoperatively treated group, for which 95 patients per group were sufficient[11]. In order to allow for subgroup analysis and more advanced statistical modeling, a total of 400 patients were targeted. This analysis used only the operatively treated group.

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 25 (IBM). All statistical tests were 2-sided, and analysis was by intention to treat. The HUMMER study is registered at the Netherlands Trial Register (NTR3617). Missing data were not imputed. Categorical data were analyzed using the chi-square test. Continuous data, which were all non-normally distributed according to the Shapiro-Wilk test, were analyzed using the Mann-Whitney U test. Significance was set at $p < 0.05$.

Continuous outcomes that were repeatedly measured over time were compared between treatment groups using linear mixed-effects regression models[9]. These multilevel models included fixed effects for the treatment group, age, sex, and fracture type and random effects for the intercepts of the model and time coefficient of individual patients. Explorative analyses showed that fracture location on the dominant side, smoking, radial nerve palsy at the time of the injury, and hospital were nonsignificant in all models; therefore, these covariates were not included in the final models. Finally, time was included as a factor because the outcome measures did not change linearly over time. The interaction between time and treatment group was included in the model in order to test for differences between the groups that varied over time. The estimated marginal mean with the 95% confidence interval (CI) at each follow-up time was computed for each treatment group. The means were compared post hoc using a Bonferroni correction for multiple testing. The absence of overlap of the 95% CIs around the marginal means was regarded as significant at $p < 0.05$.

Source of Funding
This study was supported by a grant from the Osteosynthesis and Trauma Care Foundation (number 2013-DHEL), which had no role in the conduct of the study.

Results

Patient and Injury Characteristics

Between October 23, 2012, and October 3, 2018, 245 patients of the HUMMER study underwent a surgical procedure: 76 patients (31.0%) underwent plating, and 169 patients (69.0%) underwent nailing (Fig. 1). Twelve patients were lost to follow-up due to mortality (n = 3) or withdrawal of consent.

The plating group had a younger median age at 43 years (P_{25} to P_{75}, 25 to 61 years) than the nailing group at 57 years (P_{25} to P_{75}, 40 to 68 years) ($p < 0.001$); the plating group also had a lower median body mass index (BMI) at 24.8 kg/m^2 (P_{25} to P_{75}, 22.5 to 28.3 kg/m^2) than the nailing group at 26.3 kg/m^2 (P_{25} to P_{75}, 23.9 to 30.1 kg/m^2) ($p = 0.024$) (Table I). Radial

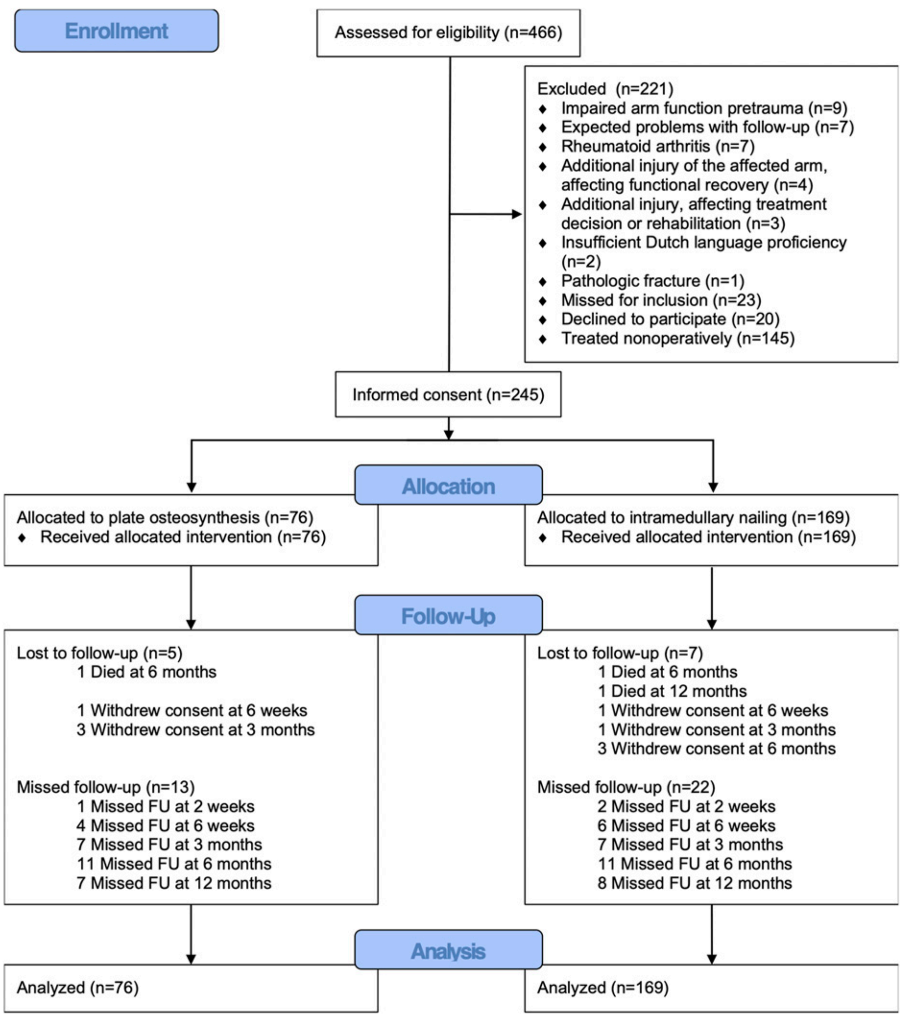

Fig. 1
Flowchart for the study. FU = follow-up.

TABLE I Patient, Injury, Treatment, and Admission Details of Study Participants by Treatment Group*

	All (N = 245)		Plating Group (N = 76)		Nailing Group (N = 169)		
	Patients with Available Data	Value†	Patients with Available Data	Value†	Patients with Available Data	Value†	P Value‡
Patient characteristics							
Female sex	245	133 (54.3%)	76	38 (50.0%)	169	95 (56.2%)	0.407
Age *(yr)*	245	53 (35, 66)	76	43 (25, 61)	169	57 (40, 68)	**<0.001**
BMI *(kg/m²)*	244	26.1 (23.4, 29.9)	76	24.8 (22.5, 28.3)	168	26.3 (23.9, 30.1)	**0.024**
Smoking	245	55 (22.4%)	76	17 (22.4%)	169	38 (22.5%)	1.000
ASA class 3 or 4	245	13 (5.3%)	76	1 (1.3%)	169	12 (7.1%)	0.070
Comorbidities							
Any	245	115 (46.9%)	76	28 (36.8%)	169	87 (51.5%)	**0.038**
Diabetes	245	18 (7.3%)	76	4 (5.3%)	169	14 (8.3%)	0.597
Arthritis and/or arthrosis	245	15 (6.1%)	76	3 (3.9%)	169	12 (7.1%)	0.404
Osteoporosis or osteopenia	245	1 (0.4%)	76	0 (0.0%)	169	1 (0.6%)	1.000
Medication use	245	127 (51.8%)	76	32 (42.1%)	169	95 (56.2%)	0.053
No. of medications	128	2 (1, 4)	32	2 (1, 4)	96	3 (1, 5)	0.166
Injury characteristics							
Dominant side involved	245	116 (47.3%)	76	34 (44.7%)	169	82 (48.5%)	0.678
Fracture classification	245		76		169		0.334
A1		57 (23.3%)		20 (26.3%)		37 (21.9%)	
A2		43 (17.6%)		13 (17.1%)		30 (17.8%)	
A3		71 (29.0%)		16 (21.1%)		55 (32.5%)	
B1		51 (20.8%)		19 (25.0%)		32 (18.9%)	
B2		10 (4.1%)		2 (2.6%)		8 (4.7%)	
B3		13 (5.3%)		6 (7.9%)		7 (4.1%)	
Radial nerve palsy at presentation	245	13 (5.3%)	76	10 (13.2%)	169	3 (1.8%)	**0.001**
Additional injuries	245	26 (10.6%)	76	5 (6.6%)	169	21 (12.4%)	0.188
Ipsilateral arm	245	6 (2.4%)	76	1 (1.3%)	169	5 (3.0%)	0.669
Contralateral arm	245	4 (1.6%)	76	1 (1.3%)	169	3 (1.8%)	1.000
Admission and follow-up characteristics							
Surgical delay *(day)*	245	6 (2, 9)	76	6 (2, 9)	169	5 (2, 9)	0.499
Duration of surgery *(min)*	245	81 (65, 112)	76	113 (84, 134)	169	81 (57, 89)	**<0.001**
Hospital length of stay *(day)*	245	2 (2, 4)	76	3 (2, 4)	169	2 (2, 4)	0.054
Discharge disposition							
Home	245	235 (95.9%)	76	76 (100.0%)	169	159 (94.1%)	0.196
Care hotel		6 (2.4%)		0 (0.0%)		6 (3.6%)	
Elderly care facility		1 (0.4%)		0 (0.0%)		1 (0.6%)	
Rehabilitation center		3 (1.2%)		0 (0.0%)		3 (1.8%)	
Other care facility admission	245	8 (3.3%)	76	0 (0.0%)	169	8 (4.7%)	0.061
Nursing home length of stay *(day)*	1	30 (30, 30)	0	NA	1	30 (30, 30)	NA
Care hotel length of stay *(day)*	4	8 (5, 25)	0	NA	4	8 (5, 25)	NA
Elderly care facility length of stay *(day)*	1	21 (21, 21)	0	NA	1	21 (21, 21)	NA
Rehabilitation center length of stay *(days)*	3	25 (24, 25)	0	NA	3	25 (24, 25)	NA
Physical therapy							
No. of sessions	217	25 (13, 48)	64	25 (8, 39)	153	26 (14, 51)	0.086

*ASA = American Society of Anesthesiologists, and NA = not applicable. †The values are given as the number of patients, with the percentage in parentheses, or as the median, with the P_{25} to P_{75} in parentheses. ‡Bold represents significance.

nerve palsy at presentation was more common after plating (10 patients [13.2%]) than after nailing (3 patients [1.8%]) ($p = 0.001$).

Treatment Details and Hospital Admission

A total of 121 surgeons operated on ≥1 patients: plating was performed by 47 surgeons and nailing was performed by 94 surgeons. All patients in the plating group were treated with a locking plate. The majority of patients in the nailing group (158 [93.5%]) were treated with an antegrade nail. Of the nails, 36 were an Expert Humeral Nail (DePuy Synthes); 44, a MultiLoc Humeral Nail (DePuy Synthes); 88, a T2 Humeral Nailing System (Stryker); and 1, a Titanic Elastic Nail (DePuy Synthes). The median duration of the surgical procedure was significantly longer ($p < 0.001$) after plating (113 minutes [P_{25} to P_{75}, 84 to 134 minutes]) than after nailing (81 minutes [P_{25} to P_{75}, 57 to 89 minutes]) (Table I). The other admission and follow-up characteristics, including the number of physical therapy sessions, were similar in both groups.

Patient-Reported Functional Outcome, Pain, and Activity Resumption

The DASH score, Constant-Murley score, pain level, and ability to perform daily activities all improved over time in both treatment groups (Fig. 2, Table II; see also Appendix Supplemental Table S1). Table II provides the results of the multilevel model (i.e., the significance of treatment effects and estimated marginal means at 3 months, which was the time that a difference between the treatment groups was expected). Appendix Supplemental Table S1 shows the crude, unadjusted, values (median, P_{25} to P_{75}, and univariate p value) and the adjusted values (i.e., estimated marginal means with 95% CIs) by follow-up time. The mean DASH score diminished from 48.9 points at 2 weeks to 11.7 points (95% CI, 7.6 to 15.7 points) at 12 months in the plating group and from 48.3 points at 2 weeks to 11.2 points (95% CI, 8.3 to 14.0 points) at 12 months in the nailing group (Fig. 2-A). Although treatment overall had no significant effect on the DASH score ($p = 0.479$), patients in the nailing group showed a faster functional recovery ($p = 0.008$) (Table II).

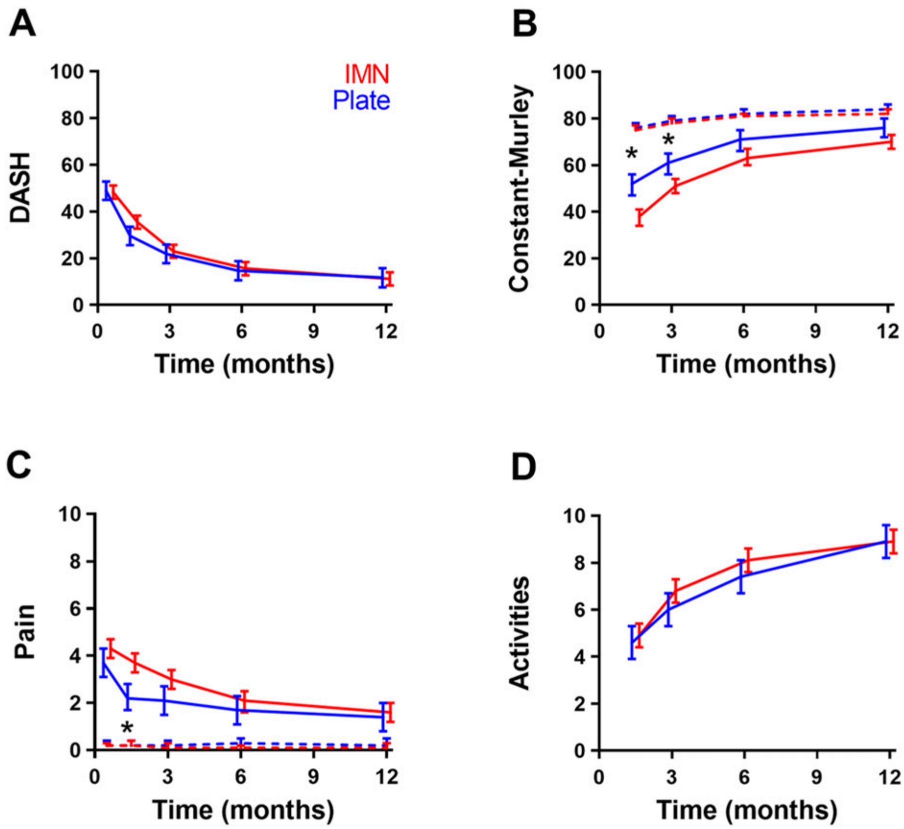

Fig. 2

Figs. 2-A through 2-D Changes in functional outcome scores, pain, and activity resumption over time by treatment group. Higher scores represent more disability (DASH), better function (Constant-Murley), more pain (VAS), and a higher level of activity resumption (NRS). Data are shown as the estimated marginal mean with the corresponding 95% CI (shown as error bars), adjusted for age, sex, and fracture type, as calculated in the multivariable analysis. Blue lines represent the plating group; red lines represent the intramedullary nailing (IMN) group. Dashed lines represent the values of the contralateral side. *P < 0.05 (Bonferroni test). **Fig. 2-A** The DASH overall score. **Fig. 2-B** The Constant-Murley score of the affected arm. **Fig. 2-C** Pain (VAS) on the affected side. **Fig. 2-D** The extent to which patients resumed their activities at the pretrauma level (NRS) over time.

TABLE II Treatment Effect Over Time and Outcome at the 3-Month Follow-up by Treatment Group*

	Effect†‡				Outcomes at the 3-Month Follow-up§	
	Treatment		Interaction			
	F Value	P Value	F Value	P Value	Plating Group (N = 76)	Nailing Group (N = 169)
Patient-reported outcome measures						
DASH score	0.50	0.479	3.45	**0.008**	21.9 (17.9 to 25.9)	23.0 (20.2 to 25.8)
Constant-Murley score#	20.43	**<0.001**	4.88	**0.002**	61 (56 to 65)**	51 (48 to 54)**
VAS pain score#	7.53	**0.007**	4.09	**0.003**	2.1 (1.5 to 2.7)	3.0 (2.6 to 3.4)
Activity resumption	1.97	0.162	1.86	0.135	6.0 (5.3 to 6.7)	6.8 (6.3 to 7.3)
Health-related quality of life						
SF-36 PCS	2.61	0.108	1.04	0.386	45 (43 to 47)	42 (41 to 44)
SF-36 MCS	6.13	**0.014**	0.87	0.482	53 (51 to 56)	55 (53 to 57)
EQ-5D US	1.97	0.162	2.17	0.071	0.79 (0.74 to 0.84)	0.76 (0.73 to 0.79)
VAS pain	0.06	0.802	2.00	0.092	76 (72 to 80)	76 (73 to 78)
Shoulder range of motion# *(deg)*						
Abduction	35.66	**<0.001**	7.89	**<0.001**	122 (114 to 131)**	97 (91 to 103)**
Flexion	34.06	**<0.001**	7.68	**<0.001**	125 (117 to 134)**	104 (98 to 110)**
External rotation	16.36	**<0.001**	8.18	**<0.001**	63 (58 to 69)	56 (52 to 59)
Internal rotation	11.25	**0.001**	0.32	0.865	63 (58 to 68)	56 (53 to 60)
Elbow range of motion# *(deg)*						
Flexion-extension arc	0.32	0.572	1.05	0.380	131 (125 to 136)	133 (129 to 137)
Pronation-supination arc	0.14	0.712	1.73	0.141	165 (160 to 170)	166 (163 to 170)

*MCS = Mental Component Summary, PCS = Physical Component Summary, and US = Utility Score. †Changes in the recovery pattern were assessed in the multilevel model. ‡Results are shown as the F-value for treatment and for the interaction term in the model (treatment × follow-up time) and their corresponding p value; significant p values are shown in bold. §Data of the outcomes at 3 months are shown as the estimated marginal mean, with the 95% CI in parentheses, after the 3-month follow-up adjusted for age, sex, and fracture type. #For the involved side. **The 95% CIs of the 2 treatment groups did not overlap (p < 0.05, per the Bonferroni test).

Similar to the DASH score, the Constant-Murley score showed a significant treatment effect in favor of the plating group ($p_{treatment} < 0.001$ and $p_{interaction} = 0.002$) (Fig. 2-B, Table II; see also Appendix Supplemental Table S1). Scores for the affected side increased from 52 points at 6 weeks to 76 points at 12 months in the plating group and from 38 points at 6 weeks to 70 points at 12 months in the nailing group. Significantly higher scores for the involved side were noted in the plating group at 6 weeks (52 compared with 38 points; $p < 0.001$) and 3 months (61 compared with 51 points; $p < 0.001$).

The plating group reported less pain ($p_{treatment} = 0.007$ and $p_{interaction} = 0.003$) (Fig. 2-C, Table II). The effect was most prominent at 6 weeks (2.2 after plating compared with 3.7 after nailing).

Treatment had no significant effect on activity resumption ($p_{treatment} = 0.162$ and $p_{interaction} = 0.135$) (Fig. 2-D, Table II). The resumption of work and sports activities was unaffected by treatment (see Appendix Supplemental Table S2). Treatment also had no significant effect on the health-related quality of life, except for the SF-36 Mental Component Summary (MCS) ($p_{treatment} = 0.014$ and $p_{interaction} = 0.482$) (Fig. 3, Table II; see also Appendix Supplemental Table S1).

Shoulder and Elbow Ranges of Motion

Changes in range of motion are shown in Figure 4, Table II, and Appendix Supplemental Table S1. Shoulder range of motion showed a significant treatment effect in favor of plating ($p_{treatment} < 0.001$) (Figs. 4-A through 4-D). Abduction, flexion, and external rotation also showed a significant interaction with time ($p < 0.001$). Treatment had no significant effect on elbow range of motion (Figs. 4-E and 4-F).

Complications and Secondary Surgical Interventions

Complications (in 58 patients [23.7%]) did not differ significantly ($p = 0.417$) between the plating group (19.7%) and the nailing group (25.4%) (Table III). Complications were unrelated to the type of intramedullary nail. In 30 patients, the complication required secondary surgical intervention, primarily in the nailing group (28 patients, compared with 2 in the plating group; $p < 0.001$). One deep infection occurred in the nailing group. After irrigation and debridement, the intramedullary nail was removed. Two patients in the plating group had implant-related

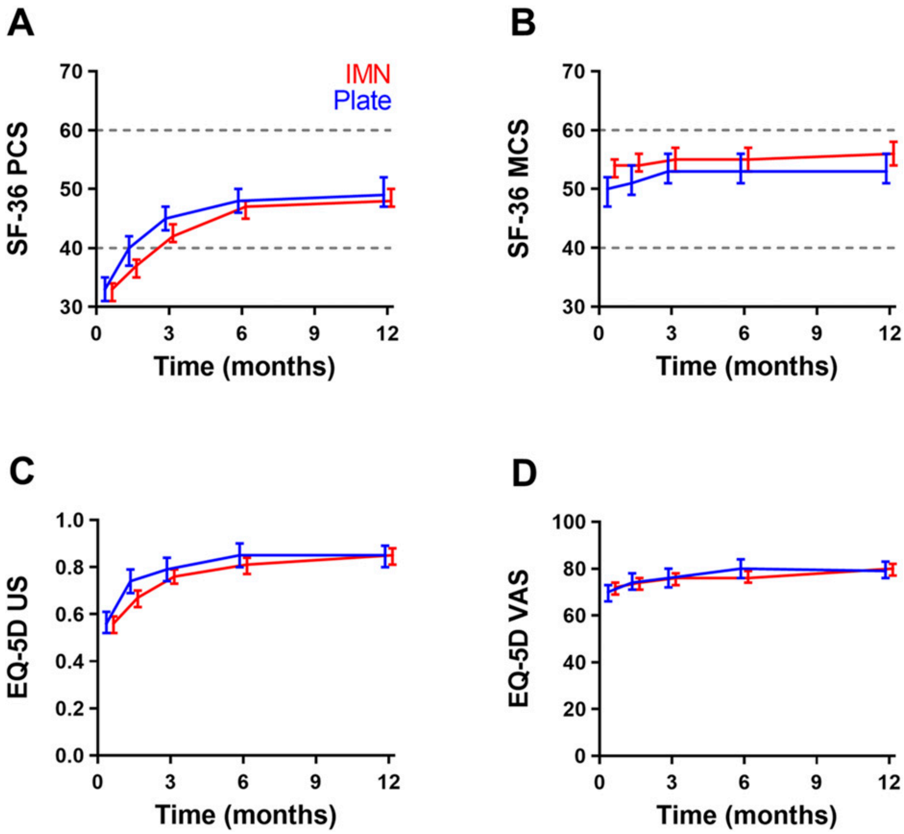

Fig. 3

Figs. 3-A through 3-D Changes in health-related quality of life over time by treatment group. Higher scores represent better quality of life. Data are shown as the estimated marginal mean with the corresponding 95% CI (shown as error bars), adjusted for age, sex, and fracture type, as calculated in the multivariable analysis. Blue lines represent the plating group; red lines represent the intramedullary nailing (IMN) group. **Fig. 3-A** SF-36 Physical Component Summary (PCS); the dashed lines represent the mean and the standard deviation (50 ± 10) that were used for normalizing the data. **Fig. 3-B** SF-36 Mental Component Summary (MCS); the dashed lines represent the mean and the standard deviation (50 ± 10) that were used for normalizing the data. **Fig. 3-C** EQ-5D utility score (EQ-US). **Fig. 3-D** EQ-VAS over time.

complications. One patient had screw cutout that did not require treatment. In the second patient, the plate was not long enough to span the fracture plane and was replaced. The vast majority of implant-related complications occurred in the nailing group. These were mostly nail protrusion (n = 13) or screw protrusion (n = 8), but screw cutout (n = 1), an inadequate implant type (n = 1), and chronic pain (n = 1) also occurred. In 16 patients in the nailing group, the nail was removed, and, in 2 other patients, the implant was replaced. Postoperative radial nerve palsy without preoperative symptoms was more prevalent after plating (8 patients [10.5%]) than after nailing (1 patient [0.6%]) ($p < 0.001$); it fully recovered in 83.3% of patients after plating and 100% of patients after nailing ($p = 1.000$). Nonunion rates did not differ between the plating group (3 patients [5.7%]) and the nailing group (16 patients [11.9%]) ($p = 0.285$). Revision surgery due to nonunion was performed in 1 patient in the plating group and 9 patients in the nailing group.

Discussion

This study showed faster functional recovery, as measured by the DASH score, after plating, but the plating and nailing groups had similar DASH scores at 12 months. The plating group showed superior Constant-Murley scores and shoulder range of motion after plating until 6 months after trauma. Significantly more surgical reinterventions were needed in the nailing group, which also showed more implant-related complications.

A previous randomized controlled trial showed superior Constant-Murley scores for minimally invasive plate osteosynthesis (MIPO) at 95.3 points compared with intramedullary nailing at 89.0 points at 12 months[7]. The difference at 12 months in the current study is within the same range. Superior scores for plating after 2 years were reported in a large cohort study of >400 participants: 90.3 points compared with 82.1 points[8]. In other studies, with a follow-up of 1 to 2 years, the University of California Los Angeles (UCLA) shoulder score and the American Shoulder and Elbow Surgeons (ASES) score did not differ between plating and nailing[4-6]. This lack of significance may be due to the sample size of <25 per group.

Similar to the Constant-Murley score, shoulder abduction, flexion, and external rotation improved faster after plating than after nailing. This may be the consequence of introducing an intramedullary nail through the supraspinatus tendon. Three

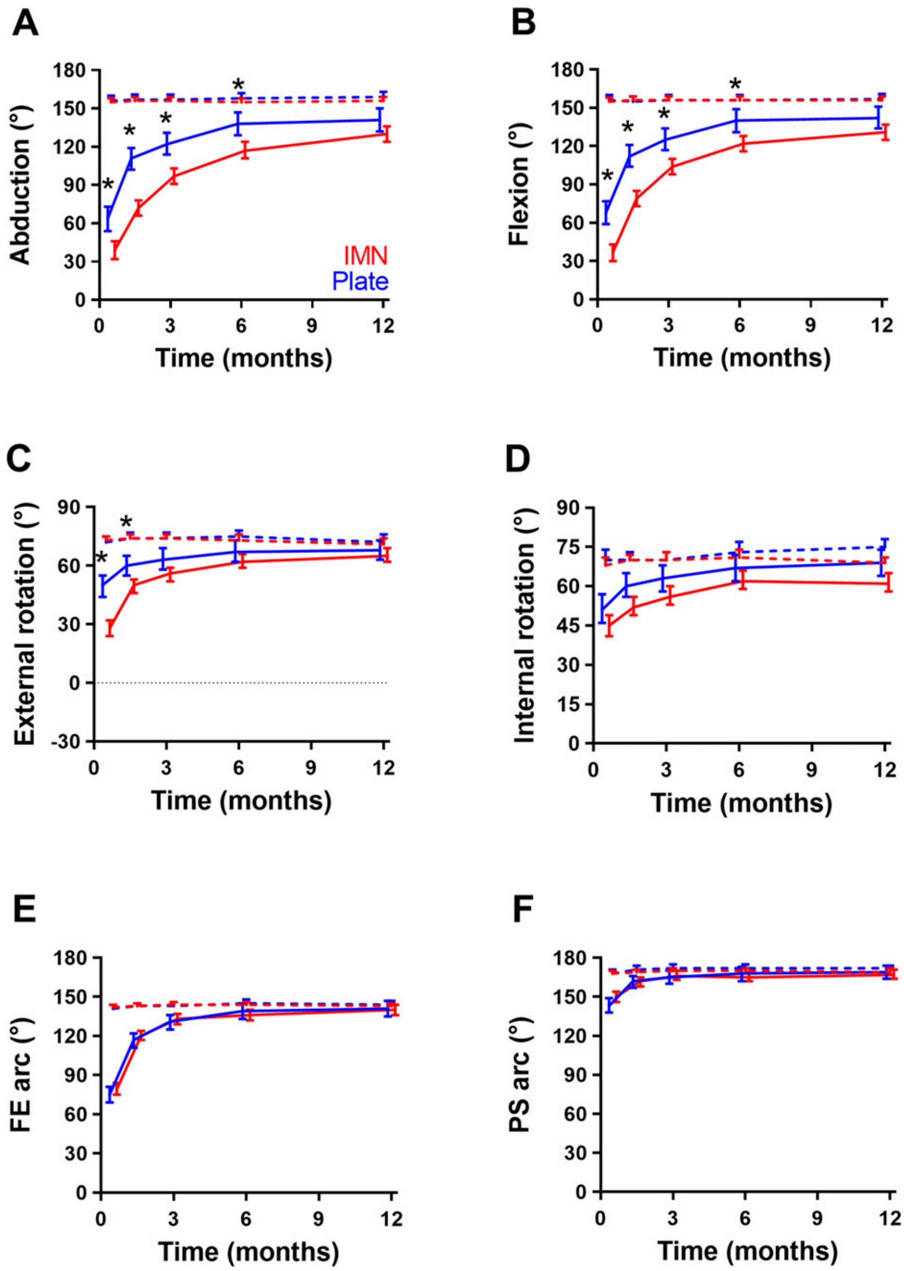

Fig. 4

Figs. 4-A through 4-F Changes in ranges of motion of the shoulder and elbow over time by treatment group. Higher scores represent better range of motion. Data are shown as the estimated marginal mean with the corresponding 95% CI (shown as error bars), adjusted for age, sex, and fracture type, as calculated in the multivariable analysis. Blue lines represent the plating group; red lines represent the intramedullary nailing (IMN) group. Dashed lines represent the values of the contralateral side. *P < 0.05 (Bonferroni test). FE = flexion-extension, and PS = pronation-supination. The graphs show abduction (**Fig. 4-A**), flexion (**Fig. 4-B**), external rotation (**Fig. 4-C**), and internal rotation of the shoulder (**Fig. 4-D**), and flexion-extension arc (**Fig. 4-E**) and pronation-supination arc of the elbow over time (**Fig. 4-F**).

recent meta-analyses[1-3] mentioned only 1 study that showed superior shoulder abduction after MIPO[21].

The current study showed a 6.4-fold greater reintervention rate and a 5.5-fold greater implant-related complication rate in the nailing group. The risk of a technical error seems higher after nailing. The main indication for revision surgery in this group was nail protrusion, which may explain the inferior shoulder function (i.e., Constant-Murley score and shoulder range of motion) in this group. The literature has been inconclusive, with 1 meta-analysis showing a significantly higher revision rate after nailing (odds ratio [OR], 0.29; p = 0.02) and 2 reporting no significant difference (risk ratio [RR], 0.40, and OR, 1.21; p > 0.05)[1-3].

TABLE III Complications and Secondary Interventions by Treatment Group*

	All (N = 245)		Plating Group (N = 76)		Nailing Group (N = 169)		
	Patients with Available Data	Value†	Patients with Available Data	Value†	Patients with Available Data	Value†	P Value‡
Any complication	245	58 (23.7%)	76	15 (19.7%)	169	43 (25.4%)	0.417
Any surgical reintervention	245	30 (12.2%)	76	2 (2.6%)	169	28 (16.6%)	**0.001**
Cuff pathology	245	3 (1.2%)	76	0 (0.0%)	169	3 (1.8%)	0.554
Superficial infection	245	5 (2.0%)	76	3 (3.9%)	169	2 (1.2%)	0.175
Deep infection	245	1 (0.4%)	76	0 (0.0%)	169	1 (0.6%)	1.000
Drainage and implant removal		1		NA		1	NA
Implant-related complication	245	26 (10.6%)	76	2 (2.6%)	169	24 (14.2%)	**0.006**
Screw cutout		2		1		1	
Inadequate implant type		1		0		1	
Nail protrusion		13		0		13	
Screw protrusion		8		0		8	
Inadequate implant size		1		1		0	
Chronic pain		1		0		1	
Surgical reintervention for implant-related complication							
Implant exchange		3		1		2	
Implant removal		16		0		16	
Postoperative radial nerve palsy	245	9 (3.7%)	76	8 (10.5%)	169	1 (0.6%)	**<0.001**
Full recovery	21	18 (85.7%)	18	15 (83.3%)	3	3 (100.0%)	1.000
Nonunion	188	19 (10.1%)	53	3 (5.7%)	135	16 (11.9%)	0.285
Revision osteosynthesis		10		1		9	

*NA = not applicable. †The values are given as the number of patients, with or without the percentage in parentheses. ‡Chi-square test for categorical variables or Mann-Whitney U test for continuous variables. Bold p values are significant.

Only 6 (2.4%) of 245 patients developed a postoperative infection, with no meaningful difference between the treatment groups. Previous meta-analyses, all with <5% infection rates, showed either no effect of treatment or a higher infection rate after nailing or plating than in our data[1,22].

The current study showed no significant difference in nonunion rates between plating (5.7%) and nailing (11.9%), although the study may have been underpowered for this outcome. This was in line with 2 recent meta-analyses[1,3], in which rates for plating were reported to be 3.0% and 5.6% and rates for nailing were reported to be 4.3% and 6.9%. The nonunion rate of 9.0% after nailing reported by van de Wall et al.[2] was in line with our study. However, the low nonunion rate in the plating group in their meta-analysis (1.2%) resulted in a significantly lower risk of nonunion in the MIPO group than in the nailing group (OR, 0.18; $p = 0.002$)[2].

Secondary radial nerve palsy was observed more commonly after plating (10.5%) than after nailing (0.6%) ($p < 0.001$). The lower risk of palsy after nailing than after plating was in line with a meta-analysis of 26 studies (2.5% compared with 6.9%; OR, 0.44; $p < 0.001$)[1]. Other recent meta-analyses showed no effect of osteosynthesis (MIPO compared with nailing and MIPO or open reduction plate osteosynthesis [ORPO] compared with nailing) on secondary radial nerve palsy[2,3]. Nerve function recovered spontaneously during follow-up in all but 3 patients in the plating group, leading to a 1-year risk of nerve palsy of 3.9% in this group.

Strength and Limitations

A strength of this prospective, multicenter study is the large sample size. The study was designed to achieve the best possible outcome for either treatment group by allowing surgeons to treat individual patients according to the operative procedure with which they had extensive experience. Moreover, the treatment heterogeneity across participating hospitals that resulted from not standardizing perioperative care or rehabilitation will have increased the generalizability of the results. However, lack of standardization may have caused an unknown bias in the results. Nevertheless, given the number of sites and therefore the differences in implants and surgical approaches used, it is unlikely that a specific technique has either caused or masked a significant difference between the treatment groups. This is also supported by the fact that 85% of the participating surgeons used only 1 type of implant.

A limitation inherent to observational studies was that some imbalance in baseline data across the treatment groups was noted. However, we were able to correct for this in the linear mixed-effects models. Furthermore, despite our efforts, some bias due to missed follow-up visits could not be ruled out. The rates of loss to follow-up were 7% after plating and 4.1% after nailing, which are low and unlikely to represent an important differential.

Conclusions

The plating of a humeral shaft fracture in adults results in faster functional recovery, especially of shoulder function. Plating was associated with more temporary nerve palsies, but fewer implant-related complications and surgical reinterventions, than nailing. Despite heterogeneity in implants and surgical approach, plating seems to be the preferred treatment option for these fractures.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H555). ■

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