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Evaluation of the treatment efficacy of titanium elastic nail in addition to external fixator in humeral diaphyseal fractures: Comparison of three treatment methods

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Abstract

Aim: This study aimed to compare the clinical and radiological outcomes of combined titanium elastic nailing and external fixator application (TEN+EFA) with EFA and plate osteosynthesis in patients with humerus diaphysis fractures.

Materials and Methods: Data of the patients who underwent surgical treatment for a humerus diaphysis fracture were retrospectively reviewed. The patients were divided into three groups based on the surgical technique. Group 1 consisted of the patients who underwent plate osteosynthesis, Group 2 included those who underwent EFA, and Group 3 included those who went through TEN+EFA.

Results: Eighty patients were included. The number of patients in the study groups was 32, 25, and 23 in Group 1, 2, 3, respectively. The duration of surgery was statistically significantly shorter in Groups 2 and 3 than in Group 1 (p=0.02). Nonunion was diagnosed in 3 patients (9.3%) and in 1 patient (4%) in Groups 1 and 2, respectively. The presence of nonunion was not statistically significant. (p=0.28) Malunion was encountered in 2 patients (4%) in Group 2, while no patients experienced malunion in Groups 1 and 3. The presence of malunion was not statistically significant. (p=0.10).

Conclusion: The EFA+TEN is a practical, safe and fast procedure providing a minimally invasive surgical treatment option for patients with humerus diaphysis fractures.

Introduction

Humerus body fracture is a common problem in orthopedic clinical practice, accounting for 3% of all adult fractures [1]. Conservative treatment approaches yielded promising results in humerus body fractures, while surgery is the primary option in cases where conservative treatment fails [2]. Surgery is also preferred in patients with multiple traumatic injuries, pathological fractures, or those who require a stable or an ideal reduction. The available surgical options are plate osteosynthesis, intramedullary nailing, and external fixator applications [3]. Several studies reported to date investigated the surgical decision process; however, there is an ongoing debate regarding the optimum treatment approach since all surgical methods have their unique biomechanical advantages and disadvantages [4-6]. The open reduction and internal fixation method has been widely accepted as the standard approach, although this method has some disadvantages, including the requirement of extensive surgical exposure and the risk of radial nerve injury [7]. The application of external fixators is preferred primarily for open fracture management and damage control surgeries [8]. This technique has advantages such as providing a definitive treatment and being a relatively less invasive method with a lower risk of neurovascular damage and a shorter duration of surgery [9]. Although some authors suggested using titanium elastic nails for the treatment of humeral diaphyseal fractures, to the best of our knowledge, there are no reports in the literature concerning simultaneous use of external fixators and titanium elastic nails in these patients [10,11].

This study aimed to compare combined titanium elastic nailing and external fixator application (i.e., TEN+EFA) with the other surgical methods plate osteosynthesis and EFA regarding clinical and radiological outcomes in adult patients with humerus diaphysis fractures in adults.

Materials and Methods

Patients who underwent surgery due to isolated humeral body fractures in our center between 2016 and 2020 consti-

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Figure 1. Distribution of patients evaluated within the scope of the study and excluded from the study.

tuted the target population of this study. It was approved by the Ethical Review Committee of our institution (Ethical form number: 2021/52). The study was conducted in compliance with the Helsinki declaration. Electronic folders of these patients were retrospectively reviewed. Patients aged 18 years or older and were followed by our team for at least 12 months postoperatively were included. All study participants underwent one of the following procedures: Plate fixation, unilateral EFA, or TEN+EFA. Patients with incomplete follow-up data, open fractures, pathological fractures, or additional injuries and those on immunosuppressive medications were excluded from the study. (Figure 1). After application of the inclusion and exclusion criteria, the entire cohort was divided into three groups based on the surgical procedure performed: Patients who underwent plate osteosynthesis were included in Group 1, patients who went through unilateral EFA procedure were included in Group 2, and those who underwent combined unilateral EFA and TEN were included in Group 3. Data including age, gender, mechanism of injury, type of fracture according to the AO classification, history of cigarette smoking, duration of follow-up, duration of union, development of malunion or nonunion, and requirement of a revision procedure and emergence of surgical site infection during postoperative follow-up were retrieved from patient folders. Union status was evaluated via radiographs obtained at months 1, 3, 6, 9, and 12, and union was defined as the presence of callus formation in three cortices. Functional results were evaluated using the American Shoulder and Elbow Surgeons (ASES) scoring system and the Short Form Questionnaire (SF-36) [12]. The ASES scoring system was reported by the American Shoulder and Elbow Surgeons Research Committee for evaluating daily life activities and pain assessment. The SF-36 is a scoring system used for evaluating the patient's quality of life before surgery and the psychological effects of the treatment [13].

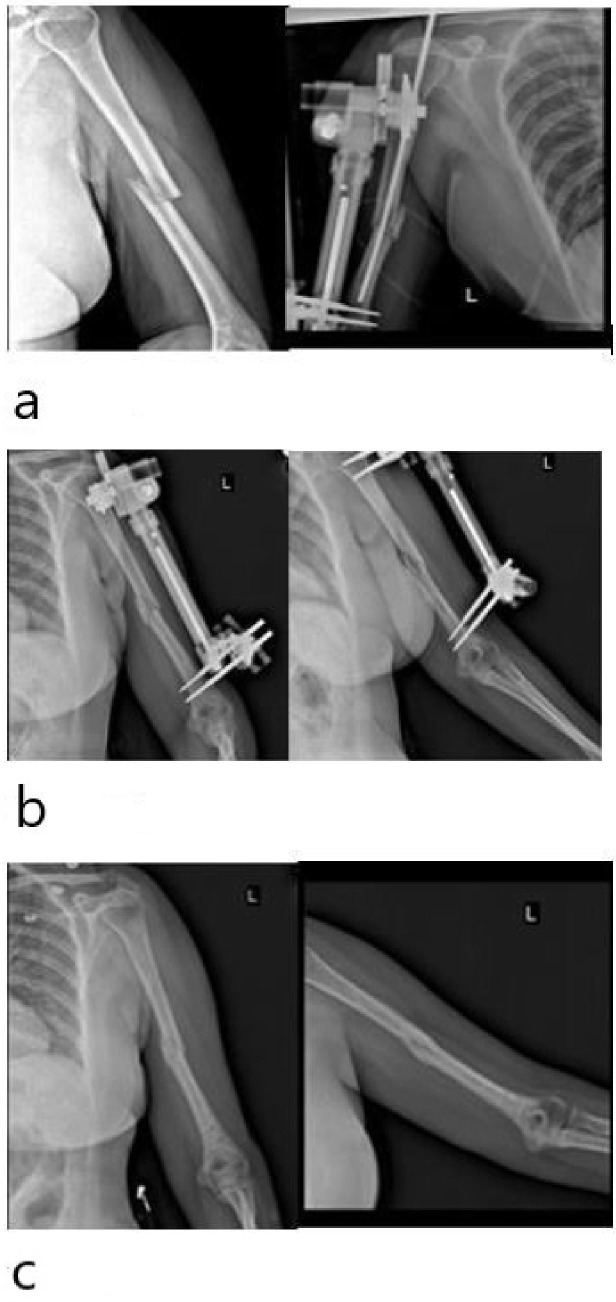

Figure 2. EF/TEN application after humeral diaphyseal fracture of a 33- year-old-male patient and the final state of the fracture after TEN and then EF removal.

Surgical technique

The surgical procedures were performed under peripheral block anesthesia in the supine position while the shoulder and elbow of the affected extremity were positioned at 45º abduction and 90º flexion, respectively. The standard antibiotic prophylaxis was given with preoperative 1 gr intravenous cefazolin. An additional 1 g intravenous cefazolin was administered at the end of postoperative day 1. The surgical methods were selected as per the preference of the surgeon. The choice of surgical technique was made randomly and there is no special criterion. The humerus was exposed anterolaterally during the plate osteosynthesis procedure, and a 4.5mm LC-DCP plate was used. Fixation was provided by four screws inserted to the proximal and distal ends of the fracture. In the patients who underwent EFA, four Schanz screws (4.5mm) were inserted to the distal and proximal ends of the fracture using a unilateral external fixator system. The placement of Shanz screws is in the lateral trace and a total of 4 Schanz screws were placed proximal and distally. Schanz screws were placed distal to the course of the radial nerve. The optimal entry point for TEN was determined after providing exposure to the anterolateral part of the proximal humerus in patients who underwent TEN+EFA (Figure 2). The intramedullary nailing procedure was performed using 3.5 mm titanium elastic nails; the radial nerve was identified and protected during this procedure. The protruding proximal nail end was exposed outside the skin. The distal end of the elastic nail was carefully advanced manually towards the olecranon's proximal margin. After completing the TEN procedures, the EFA procedure was performed by placing four 4.5 mm Schanz screws to the proximal and distal parts of the fracture. A shoulder and arm strap was applied following surgery, and the patients were prescribed range of motion (ROM) exercises for the elbow and wrist on the second postoperative day. The routine removal of the titanium elastic nail was performed on the eighth postoperative day.

Statistical analysis

The descriptive data were expressed as mean±standard deviation and median (minimum-maximum) while the nominal variables as numbers (n) and percentages (%). The statistical significance of the differences between nominal variables of the three groups was tested using a Chi-square test. In addition, the Kruskal-Wallis test was used for analyzing the differences between continuous variables. The p value was considered significant when it was lower than 0.05. The Statistical Package for Social Sciences (SPSS v22.0, IBM Corp., Armonk, NY, US) software was used for all statistical analyses.

Results

After the application of the inclusion and exclusion criteria, 80 patients were included in this study. There were 32, 25, and 23 patients in Group 1, 2, and 3, respectively (Table 1). Among 80 patients, 43 (53.75%) were male, while 37 (46.25%) were female. The mean age of the entire cohort was 43.52 years (18–74). The humeral fracture was on the right side in 50 (62.5%) patients and on the left side in 30 (37.5%). While 51 (63.75%) patients had type A fractures, 16 (20%) had type B, and 13 (16.25%) had type C fractures as per the AO classification. The fractures were sustained in traffic accidents in 51 (63.75%) cases and during falls in 29 (36.25%) patients. Among all patients, 24 (30%) were non-smokers, while 56 (70%) were smokers. The mean duration of postoperative follow-up was 14.94 (12–18) months.

Table 1. Distribution of demographic data within the groups.

		Group 1	Group 2	Group 3
	Number	32	25	23
	Age (year)	44.15(22-71)	43.30(18-70)	42.91(19-74)
Gender	Male	15(46.87%)	15(60%)	13(56.53%)
	Female	17(53.13%)	10(40%)	10 (43.47%)
Side	Right	19 (59.37%)	17 (68%)	14 (60.86%)
	Left	13 (40.63%)	8 (32%)	9 (39.14%)
Ao Classification	A	21 (65.62%)	16 (64%)	14 (60.9%)
	B	6 (18.75%)	5 (20%)	5 (21.7%)
	C	5 (15.63%)	4 (16%)	4 (17.4%)
Cause of Fracture	Fall	12 (37.5%)	9 (36%)	8 (34.78%)
	Traffic Accident	20 (62.5%)	16 (64%)	15 (65.22%)
Cigarette Smoking	Present	10 (31%)	7 (28%)	7 (30%)
	None	22 (69%)	18 (72%)	16 (70%)
	Duration of Follow-Up (month)	17.81(12-18)	13.32(12-16)	12.73(12-15)

The duration of surgery was significantly longer in Group 1 than in Group 2 and 3 (p=0.02). Although the time until fracture union was shorter in Group 2 and 3 than in Group 1, the difference was not statistically significant (p=0.45).

Nonunion was detected in 3 patients in Group 1 (9.3%) and 1 in Group 2 (4%). No patients were diagnosed with nonunion in Group 3. The presence of nonunion was not statistically significant. (p=0.28) Malunion was detected in 2 (4%) patients in Group 2, while no patients experienced malunion in Group 1 or 3. The presence of malunion was not statistically significant. (p=0.10) Implant failure developed in 1 (3%) patient in Group 1. Superficial infections developed in 3 patients in Group 2 (7.5%) and Group 3 (13%). Postoperative radial nerve injury developed in 2 (6.4%) patients in Group 1. Mean ASES ss calculated at postoperative month 12 were 47.43 (41–49), 48.24 (47–49), and 48.30 (47–49) in Groups 1, 2, and 3, respectively (p=0.52). Mean SF-36 scores calculated at postoperative month 3 were 66.59 (42–77), 75.32 (43-78), and 75.65 (71–77) in Groups 1, 2, and 3, respectively. These scores were significantly higher in Group 2 and 3 than in Group 1. (p=0.02) However, no significant difference was found between the SF-36 scores of the groups calculated at postoperative months 6 and 12 (p=0.09, p=0.13) (Table 2).

Discussion

In this study, we compared three surgical approaches (i.e., unilateral EFA+TEN, plate osteosynthesis, and unilateral EFA) in treating humerus diaphysis fractures regarding radiological and functional outcomes. Our analysis revealed that the EFA+TEN was a safer and more practical approach than the others.

In our cohort, the most frequent causes of humerus diaphysis fractures were traffic accidents (63.75%) and falls (36.25%). Similarly, traffic accidents were the primary cause of humerus shaft fractures in the study of Tsai et al. with a rate of 63.2% [14]. On the other hand, it is known that the causative factors can vary according to socio-economic and environmental factors [15]. Furthermore, in our study, gender distribution was in favor of males (53.75 vs. 46.25%). Although this finding is consistent with some reports, some studies reported contradictory results [16,17].

In the literature, there is no consensus on the optimum treatment approach to humerus diaphysis fractures [18]. Open reduction is one of the possible treatment options which can be performed either as an open reduction with internal fixation or an open reduction with external fixation [19]. It is known that this procedure can provide favorable outcomes with the early promotion of functional

Table 2. Complications and Scores in the Groups ASES Score: American Shoulder and Elbow Surgeons scoring system, SF-36: Short Form Questionnaire.

	Variables	Group 1	Group 2	Group 3	P values
	Duration of operation (minute)	61(53-69)	41(35-45)	46(40-52)	0.02
	Time yo union (month)	4.5(4-10)	4.3(3-9)	4.20(3-9)	0.45
Complications	Nonunion	3 (9.3%)	1 (4%)	0	0.28
	Malunion	0	2 (8%)	0	0.10
	Radial Injury	2 (6.2%)	0	0	0.21
	Infection	0	3 (12%)	3 (13%)	0.12
	Implant Failure	1 (3.1%)	0	0	0.24
Scoring	Preoperative SF-36	95.62(92-100)	95.76(94-98)	95.78(92-100)	
	Postoperative 3	66.59(42-77)	75.32(43-78)	75.65(71-77)	0.02
	Postoperative 6	86.81(62-97)	85.28(65-92)	87.17(80-94)	0.09
	Postoperative 12	88.46(70-94)	91.08(84-96)	91.91(85-98)	0.13
	ASES Score	47.43(41-49)	48.24(47-49)	48.30(47-49)	0.52

movement capacity. Plate fixation is considered as another surgical treatment option in patients with humerus shaft fractures [20]. Although some recently published systematic reviews favored plate fixation, Zhao et al., who reported a meta-analysis including 16 randomized controlled studies, suggested that this procedure had disadvantages such as risks of infection, radial nerve injury, and delayed union [21]. Our analysis revealed that mean surgical duration was 61, 41, and 46 minutes for the patients who underwent plate osteosynthesis, EFA, and TEN+EFA, respectively. Comparison of the surgical times elucidated that the plate osteosynthesis procedure lasted significantly longer than the others. Bisaccia et al. reported that mean surgical times were 69 and 47 minutes in cases treated with plate osteosynthesis and EFA, respectively [22]. On the other hand, Fan et al. reported that the duration of surgery could be as long as 90 minutes in patients who underwent plate osteosynthesis [23]. In our study, although the combination of EFA with TEN increased the duration of surgery, the difference was not statistically significant. Thus, we suggest that TEN+EFA is a convenient, rapid, and practical procedure especially compared with plate osteosynthesis.

In our study, the mean time until union was shorter in the EFA and EFA/TEN groups than in the plate osteosynthesis group, although the difference was not statistically significant. Scaglione et al. reported a mean time until union of 12 weeks in 85 humerus shaft fracture cases treated by EFA [6]. On the other hand, Costa et al. noted that this duration was 13 weeks in patients treated by EFA [9]. Westrik et al. worked on 227 patients, 135 of whom underwent plate osteosynthesis [24]. These authors stated that type-A fractures healed in 13 weeks while type-B and type-C fractures healed in 14 and 18 weeks, respectively. These findings suggest that EFA and plate osteosynthesis have similar results concerning the time until union.

Studies reported to date did not reach a consensus regarding the optimal surgical treatment method for humerus diaphysis fractures [6,9,18,25,26]. Plate osteosynthesis allows for the direct examination of the fracture configuration, provides a large surgical exposure, and enables anatomical reduction [25]. On the other hand, it has some disadvantages related to the opening of the fracture line, drainage of the fracture hematoma, alteration of fracture biology, extensive scarring, in addition to the risk of radial nerve paralysis [18]. In our study, 3 (9.3%) of the patients who underwent plate osteosynthesis experienced nonunion while 2 (6.2%) developed radial nerve paresis and 1 (3.1%) experienced implant failure. Lode et al. reported a meta-analysis including 12 studies conducted with patients treated by plate osteosynthesis [26]. These authors noted a nonunion rate of 0–19%, a radial nerve paralysis rate of 2–16%, an infection rate of 2–8%, and a malunion rate of 0–16%. In our study, 1 (4%) patient experienced nonunion, 2 (8%) developed malunion, while 3 (12%) had superficial infections. Costa et al. reported that the rates of superficial infection, reduction loss, and nonunion were 11.9%, 2.8%, and 0.9% in patients who underwent EFA for the treatment of humerus diaphysis fractures [9].

On the other hand, Scaglione et al. reported 1.2% nonunion and 7.2% reduction loss in patients who underwent EFA [6]. In our study, no nonunion, malunion, or radial nerve paralysis cases were encountered in the group treated with TEN+EFA. The EFA procedure is primarily performed in patients with multiple traumas, radius comminuted intraarticular fracture, mainly for managing open fractures [27,28]. Although this procedure has advantages such as being less invasive and causing no alterations in fracture physiology, some authors reported that it might lead to reduction loss, mainly if performed as a single procedure [29]. However, the TEN+EFA is a safe and fast procedure that facilitates fracture stabilization and maintains fracture reduction over time. Therefore, we suggest that the TEN+EFA technique is a reasonable surgical treatment option for humeral diaphyseal fractures. In our study, the SF-36 scores were significantly higher at postoperative month 3 in patients who underwent EFA and EFA/TEN than those who underwent plate osteosynthesis. However, the SF-36 scores were similar between three patient groups at months 6 and 12. Similarly, another study comparing the patients who underwent plate osteosynthesis and those who went through the EFA procedure revealed that ASES and SF-36 scores calculated at the postoperative 12th month were not significantly different [22]. One of the main concerns of the patients in the plate osteosynthesis group was visible scarring, while the visibility of the implant through the skin was reported as the primary concern by the patients in the EFA and TEN+EFA groups. We also observed that patients expected that their implants would be removed once the union was achieved.

This study has some limitations which need to be considered while evaluating its findings. It is a retrospective study with relatively small sample size. However, to the best of our knowledge, it is the first study in the literature assessing the use of TEN+EFA for treating humerus diaphysis fractures, with findings suggesting that TEN+EFA is a reasonable surgical treatment method with encouraging outcomes in patients with humerus diaphysis fractures.

Conclusion

Despite the weaknesses mentioned above, we conclude that several surgical methods can be implemented to treat humerus diaphysis fractures. Among these methods, plate osteosynthesis can be associated with risks, including radial nerve paresis and scarring, while EFA bears a risk of reduction loss. However, TEN+EFA is relatively less invasive and is associated with a lower risk of neurovascular injury and reduction loss. These conclusions need to be confirmed by randomized, multi-center studies including more extensive patient series.

Ethics approval

Ethical approval for this study was obtained from Gaziantep University Clinical Research Ethics Committee (Decision no: 2021/52).

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