Outcome of elastic stable intramedullary nailing of displaced midshaft clavicular fracture: does the presence of fracture comminution differ?

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Background
The mainstay of the treatment of the fractures of the clavicle has been nonoperative, even with substantial displacement. Elastic stable intramedullary nailing of displaced midshaft clavicular fracture is a relatively new method for stabilization of these fractures, having a significantly lower rate of complications and earlier return of function. However, there is no general consensus about its indications, especially in comminuted fractures.

Materials and methods
A prospective study of 46 patients with displaced midshaft clavicular fractures was conducted to evaluate the efficacy and safety of fixation of such fractures using titanium elastic intramedullary nail and to assess the effect of the presence of fracture comminution on the final outcome. Patients were divided into two groups. Group I comprised 21 patients with noncomminuted fractures, whereas group II comprised 25 patients with comminuted fractures. The primary outcome measure was the Constant shoulder score, and the secondary outcome measures included the following: the disability of the arm, shoulder and hand (DASH) score, the union rate, the duration of union, the patients' satisfaction as regards the cosmetic results, and the prevalence of complications related to surgery.

Results
All patients were available for follow-up after a minimum of 1 year postoperatively. Osseous union was achieved in all patients in both groups, except in one patient in group II. The median Constant and DASH scores showed progressive postoperative improvement in both groups throughout the follow-up period. At 6 weeks postoperatively, the median Constant and the DASH scores in the noncomminuted group (group I) were significantly better than that in group II ($P<0.001$ and 0.005, respectively). However, there were no significant differences thereafter. At 1 year postoperatively, 18/21 (86%) patients in group I and 20/25 (80%) patients in group II were satisfied as regards the cosmetic result of the procedure ($P=0.71$).

Conclusion
This study has shown that elastic stable intramedullary nailing of displaced midshaft clavicular fractures gives good cosmetic and functional results with minimal morbidity and complications. Medial prominence of the elastic nail was the most common complication. The presence of fracture comminution was associated with a delayed functional recovery; however, it did not affect the final functional outcome or the cosmetic result.

Keywords:
clavicle, elastic, fixation, intramedullary, nailing

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Introduction

Fracture of the clavicle accounts for about 4% of all fractures and 35% of shoulder girdle injuries. Around 80% of fractures of the clavicle involve the midshaft and over half of these fractures are displaced [1,2]. Traditionally, clavicular fractures have been treated nonoperatively, even with substantial displacement. Malunion of the clavicle in the form of shortening in the medial-lateral dimension and inferior displacement of the distal fragment is expected in most cases. This may result in mechanical, neurologic, and cosmetic problems leading to persistent pain and weakness, poor functional outcome, and less patient satisfaction [1,3–10].

Operative treatment of displaced midshaft clavicular fractures provide a significantly lower rate of

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complications and an earlier return of function compared with nonoperative treatment [3,4,6,7,9,10].

However, no gold standard method of operative fixation of such fractures is known [11]. Elastic stable intramedullary nailing (ESIN) of displaced midshaft clavicular fracture was first described by Jubel *et al.* [12,13]. Although the technique is minimally invasive and yields better cosmetic results compared with plate fixation, there is no general agreement on its indications, especially in comminuted fractures [12–19].

The aim of this study was to evaluate the efficacy and safety of ESIN in the treatment of displaced midshaft clavicular fracture and to assess the effect of the presence of fracture comminution on the outcome. The primary outcome measure was the Constant shoulder score [20], and the secondary outcome measures included the following: the disability of the arm, shoulder and hand (DASH) score [21,22], the union rate, the duration of union, patients' satisfaction as regards the cosmetic results, and the prevalence of complications related to surgery.

Materials and methods

Forty-six consecutive patients with displaced midshaft fracture of the clavicle were enrolled in a prospective case series between November 2003 and December 2011. Fractures were classified according to the AO classification for diaphyseal fractures of the clavicle [23]. The study was approved by the local ethical committee performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000. All patients gave their informed consent.

Exclusion criteria

We excluded cases of bilateral fracture of the clavicle, polytrauma patients, cases of open fractures, head injury, pathological fractures, old factures (duration more than 1 month), nonunion, or concomitant neurovascular injury, patients younger than 16 years, those with medical contraindications to general anesthesia, those with segmental fractures (B3), and those with pre-existing ipsilateral shoulder pathology.

Patients were divided into two groups. Group I comprised 21 patients with no fracture comminution (B1), whereas group II comprised 25 patients with comminuted fractures (B2). The background information, patient demographics, duration of operation, and mode of injury of the two groups are presented in Table 1. Patients were scheduled for surgery, as soon as it was comfortable (usually within few days after trauma).

Table 1 The baseline characteristics of both groups included in the current study

	Group I (21 patients)	Group II (25 patients)	*P*-value
Age (years)	36±11	39±9	0.35
Sex (female/male)	12/9	19/6	0.22
Side (right/left)	9/12	14/11	0.55
Side (dominant/ nondominant)	11/10	15/10	0.76
Duration to operation (days)	4.1±2.6	5.5±2.8	0.1
Mode of injury			
RTA	19	13	0.69
Work related	4	4	
Sport related	1	2	
Others	1	2	

Data are expressed as mean±SD or number of participants. RTA, road traffic accidents.

Preoperatively, patients were educated on the expected outcome of the operation and an informed consent form was signed by all patients.

Operative technique

Surgical technique was the same for both groups. Surgeries were performed on a standard radiolucent operating table under fluoroscopic guidance. Patients were placed in the supine position with a small bag underneath the shoulder blade, the head slightly tilted to the opposite side, and the involved upper extremity freely draped.

A skin incision of 1–1.5 cm was made about 1 cm lateral to the sternoclavicular joint. The anterior cortex was obliquely drilled with a 2.7 mm drill, and then the hole was widened using a sharp pointed awl, taking care not to accidentally perforate the posterior cortex. A titanium elastic intramedullary nail (TEN) of adequate diameter (between 2 and 3.5 mm) was inserted in the medullary canal of the clavicle using a universal chuck and T-handle. The nail was advanced with oscillating movements until it reached the fracture site. Closed reduction was attempted under fluoroscopic control and maintained with percutaneously applied pointed reduction clamps. Open reduction was performed through an accessory 2–4 cm incision, for cases in which closed reduction maneuvers were unsuccessful. After complete introduction of the TEN in the lateral fragment, the protruding end of the nail was cutoff at as short as possible. Bone grafting was not performed and suction drainage was not used in any case. Following wound irrigation, a two-layer soft-tissue closure was performed.

Postoperative management

Both groups were managed similarly postoperatively. Compression dressing was applied and the dressing

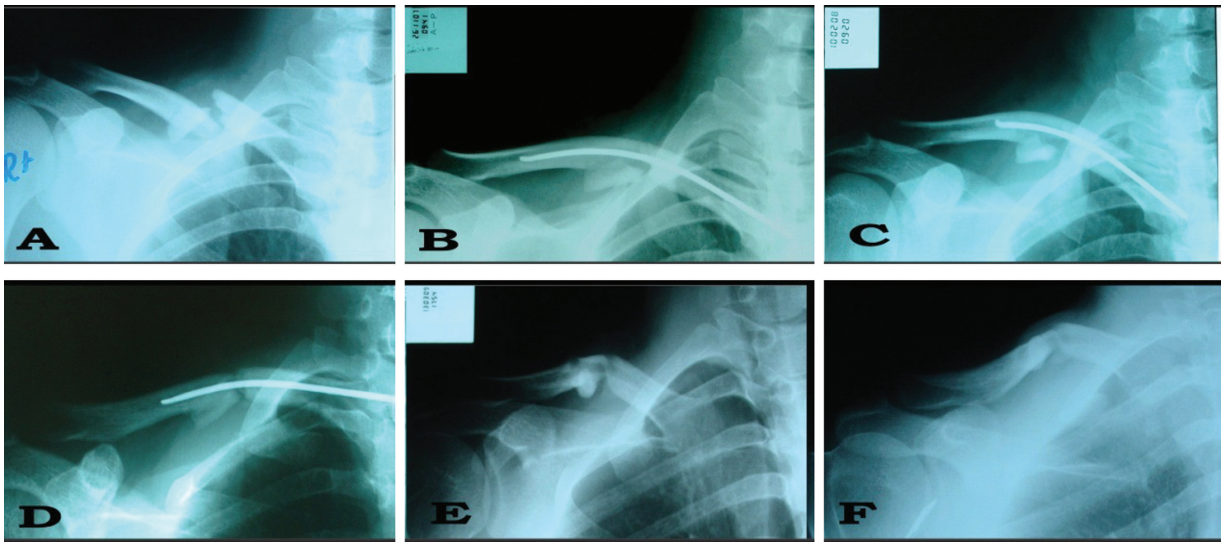
was changed on the second postoperative day. The arm was placed in a broad arm sling for 2 weeks. Patients attended for clinical and radiographical review every 2 weeks for 3 months and then every 1 month for 1 year followed by every 6–12 months thereafter (Figs 1 and 2). Patients started active and passive range of motion exercises as soon as they were comfortable and as tolerated. When clinical and radiographic signs of starting union were achieved, strengthening exercises of the deltoid and trapezius were begun. Radiographic union was defined as the presence of complete adequate bone bridging trabeculae between the proximal and distal fragments on radiograph.

Postoperative assessment

Clinical outcomes were evaluated at 6 weeks, 3 months, 6 months, 1 year, and at the final follow-up using the scoring system of Constant and Murley [20] (primary outcome) and the DASH scoring system [21,22].

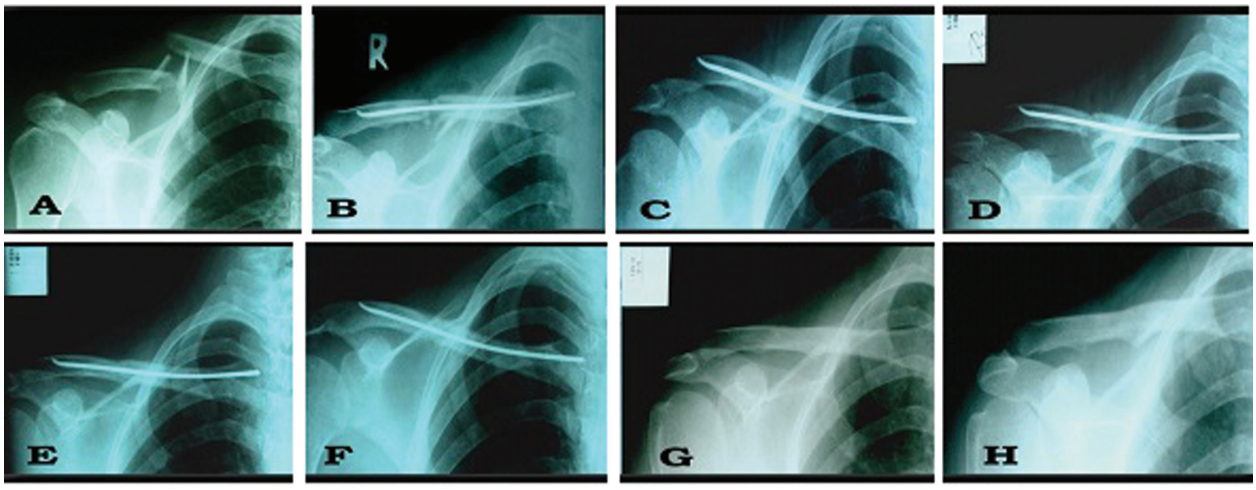
The Constant score [20] consists of four variables that were used to assess the function of the shoulder: pain (15 points) and activities of daily living (20 points),

Figure 1



(A) Preoperative x-ray of a male patient 29 years old, (B) postoperative radiograph, (C) after two months the nail was medially migrated and was trimmed, (d) 6th month follow up radiograph showed no signs of union, (E and F) Radiograph at 15th month postoperatively.

Figure 2



(A) Preoperative x-ray of a female patient 34 years old, (B) postoperative radiograph, (C, D) postoperative radiograph at the first and second month, (E and F) Third and Forth months follow up radiograph, showed fracture union (G and H) Radiograph one year after nail removal.

range of motion (40 points), and strength (25 points). Pain was scored from 0 (no pain) to 15 (worst pain the patient might experience), depending on the location marked by the patients on the visual analog scale. Strength was measured with the arm in 90° of elevation in the plane of the scapula, elbow straight, and forearm pronated. A spring balance was attached distal on the forearm and a downward force was applied. The patient was asked to maintain this resisted elevation for 5 s. Measurement was repeated three times and the average result was noted. If patient was unable to achieve 90° of elevation in the scapula plane or the maneuver was painful, the patient got 0 points.

The DASH outcome measure [21,22] is a 30-item self-report questionnaire. Each function was rated from 0 to 5 according to the degree of difficulty of performing it in an ascending manner. At least 27 questions were filled to calculate the final score.

All complications and the need for second operation were recorded. Nonunion was defined as the lack of radiographic healing with clinical evidence of pain and motion at the fracture site at 1 year. At the last follow-up visit, the final evaluation was conducted.

Statistical analysis

PASW (Predictive Analytics SoftWare, Chicago, Illions, USA) was used for statistical analysis and PASS 11 (NCSS, LLC, Kaysville, UT, USA) was used for sample size calculation. Descriptive analysis was conducted to explore the characteristics of the participants at baseline. The median and the 25th and the 75th interquartile percentiles of Constant and DASH scores were calculated. The mean and the SD of age, duration of operation, and the percentages of the sex, dominance, and side distribution were calculated.

Assuming a SD of 15%, the required sample size after setting the power to 80% to detect a mean Constant score difference (primary outcome) of 10 (10%) points between groups as statistically significant at the 5% level is 34. Each group should have at least 17 participants. Allowing a drop of 20%, each group included 21 participants at least. The primary analysis was intention-to-treat and involved all patients.

Continuous variables were tested for normality. For comparing the two groups, variables were analyzed using two-tailed unpaired *t*-tests or the Mann–Whitney *U*-test as appropriate. The Fisher exact test was used for categorical data, and the χ^2-test for mode of injury. The difference was considered statistically significant if *P*-value was less than 0.05.

To compare the different Constant and Dash scores across the different time periods, Friedman's analyses were carried out. Post-hoc tests were used to compare the scores between a given time period and the one that preceded it. As post-hoc tests were used several times, the significance level was divided by the number of planned comparisons and each two-sample test was accordingly performed at the reduced level. The Kruskal–Wallis test was used to compare the different scores between the two groups at the different time periods.

Results

The average patients' age at the time of operation was 36±11 years for group I versus 39±9 years for group II. No statistically significant difference was found between the two groups, as regards patient demographics, baseline characteristics, and duration to operation, as shown in Table 1.

The mean operating time was 37±13 min in group I versus 42±11 min in group II. The TEN could be advanced into the lateral fragment under fluoroscopy in 12/21 (57%) of the cases in group I versus 13/25 (52%) cases in group II with no statistically significant difference between the two groups (*P*=0.77). Advancement of the TEN had to be performed with open reduction through an additional incision at the fracture site in the rest of cases.

All patients were available to follow-up after a minimum of 1 year postoperatively. The mean follow-up period was 49±24 and 53±22 months for the two groups, respectively. The results of all patients were collected and statistically analyzed (Table 2). Osseous union was achieved in all patients in both groups except in one patient in group II (Fig. 1). The mean duration for osseous union was 11.6±2 weeks in group I versus 12.8±2.2 weeks in group II (*P*=0.07). The hardware was removed after 19±6 weeks in group I versus 22±5 weeks in group II. We did not encounter any cases of refracture after nail removal.

At final follow-up, the median Constant score was 92 points in both groups, whereas the median DASH score was 10 points in group I and 8.3 points in group II. The median Constant and DASH scores showed progressive postoperative improvement in both groups throughout the follow-up period. No significant difference between the two groups was recorded, except at 6 weeks postoperatively when the median Constant and the DASH scores in group I were

Table 2 Clinical and functional results of both groups included in the current study

	Group I (21 patients)	Group II (25 patients)	*P*-value
Mean operative time (min)[a]	37±13	42±11	0.14
Successful closed reduction[a]	12/21	13/25	0.77
Mean duration of union (weeks)[a]	11.6±2	12.8±2.2	0.08
Removal of hardware (weeks)[a]	19±6	22±5	0.12
Follow-up period (months)[a]	49±24	53±22	0.55
Constant score			
6 weeks	59.0 (56.5–64.0)	49.0 (47.0–56.0)	**<0.001**
3 months	75.0 (73.5–82.0)*	73.0 (67.5–80.0)*	0.15
6 months	85.0 (82.0–91.5)*	82.0 (78.5–90.0)*	0.14
12 months	91.0 (86.0–94.0)*	90.0 (85.5–93.0)*	0.42
Final	92.0 (88.0–94.0)*	92.0 (86.0–96.0)*	0.62
P value[b]	<0.01	<0.01	
DASH score			
6 weeks	31.7 (29.25–34.6)	37.5 (34.6–47.9)	0.005
3 months	21.7 (17.9–24.2)*	23.3 (19.6–28.3)*	0.30
6 months	15.8 (13.75–17.5)*	15 (14.2–18.7)*	0.95
12 months	11.7 (9.6–12.5)*	12.5 (10.0–13.3)*	0.26
Final	10.0(7.1–11.7)*	8.3 (5.8–11.7)*	0.52
P value[b]	<0.01	<0.01	
Complications			
Nonunion	0	1	0.71[c]
Malunion			
Shortening	0	2	
Angulation >20°	1	2	
Total	1	4	
Skin complications	3	3	
Perforation of lateral cortex	1	4	
Medial prominence of the nail	6	9	
Vascular injury	0	0	
Nerve injury	0	0	
Deep infection	0	0	
Lung injury	0	0	
Implant failure	0	0	

Data are expressed as median (25th–75th percentile) or mean±SD. [a]The Student *t*-test or the Fisher exact test was used as appropriate. [b]The Friedman test with post-hoc analysis was used. [c]The χ^2-test (Monte–Carlo method) was used. *Significantly different from the preceding time period. The bold value is significant *P* value <0.01.

significantly better than that in group II ($P<0.001$ and 0.005, respectively). At 1 year postoperatively, 18/21 (86%) patients in group I and 20/25 (80%) patients in group II were satisfied with the cosmetic results of the procedure. This difference between the two groups was found to be statistically nonsignificant ($P=0.71$).

Complications

Skin irritation due to nail prominence medially was recorded in 6/21 patients in group I and 9/25 patients in group II. Iatrogenic perforation of the lateral cortex was recorded in 1/21 patient in group I and 4/25 patients in group II. Local skin problems including hypertrophic scar or keloid, minor wound dehiscence, and superficial infection were recorded in three patients in each group; all were treated with local care and healed uneventfully.

No statistically significant difference was found between the two groups, as regards complications (Table 2). Angulation more than 20° was recorded in 1/21 patient in group I and 2/25 patients in group II. Secondary shortening more than 1 cm compared with the other side was observed in 2/25 patients in group II only. No clinical shoulder asymmetry was observed in both groups.

One patient in group II (Fig. 1) presented with postoperative medial migration of the TEN with medial prominence and impending skin perforation managed with nail trimming. However, there were no signs of union for 6 months; the nail had to be removed after 11 months due to skin irritation. The patient declined revision fixation with plate, screws, and grafting.

Deep-seated infection, neurovascular injury, lung injury, nail breakage, and numbness at the skin incision were not observed in the current series. No

incidence of refracture occurred after an average of 4 years of follow-up in both groups.

Discussion

The indications and the methods of surgical fixation of displaced fracture clavicle continue to be controversial with a growing trend for surgical fixation of completely displaced fractures in the last few years. [1,3–11,24].

ESIN is a relatively new and technically more demanding technique, especially when closed fracture reduction can be achieved, which gives the advantage of maintaining an intact fracture hematoma and could speed up fracture healing. Even if open fracture reduction is performed, surgical incisions are in general smaller in comparison with plate fixation, resulting in improved cosmetic results and lower infection rates [9].

The results of the current study support the results of previous clinical trials [12–19], suggesting that intramedullary fixation using TEN is an effective and reliable method for the management of midclavicular fractures with or without fracture comminution. It gives good cosmetic and functional results with minimal morbidity and complications.

Patient-reported outcomes remain paramount in determining the success or failure of treatment following orthopedic injury and to guide the decision-making process. Various scoring systems have been proposed for functional assessment of shoulder joint. None of these systems has found worldwide acceptance, and none of them focuses specifically on the clavicle. In the current study, we chose the Constant scoring system [20] and the DASH scoring system [21,22], being simple, practical, easy to apply, and they target the effect of the procedure on the overall daily function. Moreover, being universally accepted scoring systems, this helped to standardize the results in comparison with those of other studies reported in the literature. Both scoring systems showed progressive postoperative improvement in both groups throughout the follow-up period. At final follow-up, the median DASH score was 10 points in group I and 8.3 points in group II, compared with a published normative value for the general population of 10.1 points [25], and the median Constant score was 92 points in both groups, compared with a published normative value for the general population of 92 points [26].

We believe that the advantages of TEN can be attributed the fact that they are being flexible and small enough to enable its passage through the S-shaped clavicle, and it is also strong enough to stabilize the fragment ends. Its curved tip facilitates nail passage within the medullary cavity. It blocks itself in the bone, thus improving fixation stability by providing 3 points for support within the medullary canal to effectively control rotation, angulation, and shortening [14,15]. The unique anatomy of the clavicle may allow the surgeon to extend the indications of using the TEN to mildly and moderately comminuted fractures. Compared with plating, intramedullary fixation offers several advantages [12–19,24], it acts as an internal splint at the fracture site. It has significantly shorter operation time, smaller wound incision, minimal scaring, less pain level, less analgesic use, less symptomatic hardware, less stress shielding, and the ability to remove the implant under local anesthesia with minimal dissection. Moreover, it provides biological fixation while preserving soft tissue and the periosteal blood supply. The healing process involves external bridging callus through intramembranous bone formation. In the current study, all patients, except one patient, achieved adequate osseous union after a mean duration of 11.5±1.8 weeks in group I and 12.8±2.2 weeks in group II.

However, the procedure is technically demanding and requires a lot of surgical expertise [15–17,27,28]. Prominence of the tip of the nail leading to skin irritation over the entry portal, which requires nail trimming and/or removal, was the most common complication in the current study.

Moreover, the sigmoid shape of the clavicle implies a lot of technical difficulties during the insertion of the TEN. Moreover, the clavicle does not have a true medullary canal and the cortices are thin and relatively indistinct [29]. The TEN is inserted at the sternal end of the clavicle, where the sagittal diameter is at its maximum to minimize the risk for cortical perforation. Iatrogenic perforation of the cortex occurred in 5/46 patients in the current study. Moreover, as a result of the narrow medullary canal, closed reduction maneuvers were not always successful and insertion of the TEN in the lateral fragment had to be performed through an additional incision at the fracture site in 21/46 patients. Inability to statically lock those implants risks collapse and shortening, especially if there is comminution. Plate fixation was found to provide a stronger construct for early rehabilitation protocols [30]; however, the downward force of the arm challenges the holding power of the screws in the often osteopenic lateral fragment, especially with the presence of inferior comminution [31]. In the current study, patients started active and passive range of motion exercises immediately postoperatively as tolerated.

Fracture malunion was observed in 5/46 patients (mostly in comminuted fractures) that did not appear to affect the total functional outcome.The results of the current study show that the presence of fracture comminution was associated with a higher incidence of delayed functional recovery and fracture malunion in the form of shortening and angulation. This is attributed to inadequate cortical contact of the nail in the midshaft. We did not compare the results of the cases that developed malunion with the other cases because of the small number of the former. Correction of the potential shortening of the clavicle may be important for good cosmetic outcome. However, the relationship between clavicular shortening and shoulder function is not well established, although shortening decreases the shoulder elevation moments of the upper extremity muscles, mainly during abduction [18,32,33]. In the current study, no statistically significant difference was recorded at 1 year and at the final follow-up (at an average of 4 years) between the two groups as regards the median Constant and the DASH scores or the number of patients satisfied with the cosmetic result of the procedure.

There were two limitations to the current study: first, the rate of return to the same level of prefracture athletic activity, which was reported in the literature as one of the indicators of the success of the procedure [12]. This parameter was not measured because most of our middle-aged patients were not willing to join sport activities. The second limitation was the duration elapsed before return to work, which was not measured in this study because 67% of the patients enrolled in the current study were women and most of them were housewives.

Conclusion

This study has shown that intramedullary fixation using TEN is an effective and reliable method for the management of midclavicular fractures with or without the presence of fracture comminution. It gives good cosmetic and functional results with minimal morbidity and complications. Medial prominence of the TEN that required nail trimming and/or removal was the most common complication. The presence of fracture comminution was associated with a higher incidence of fracture malunion in the form of shortening and angulation (although not statistically significant), and delayed functional recovery. However, it did not affect the final functional outcome or the cosmetic result.

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Conflicts of interest
There are no conflicts of interest.

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