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ORIGINAL ARTICLE

S-shaped titanium endomedullary nail reduces telescoping of comminuted midshaft clavicular fractures

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Abstract

Background The surgical treatment of displaced midshaft clavicular fractures (DMCF) is clinically relevant and a much discussed topic. The axial stability of DMCF after intramedullary nailing (IMN) is still a matter of debate.

Objective Our objective was to present a modification of IMN of DMCF with S-shaped titanium endomedullary nail (TEN) and determine fracture telescoping from day one after surgery to the time of fracture healing.

Method In a prospective analytic cohort study over a 6-year period (2012–2017) at a Level II trauma care centre, a total of 128 patients with DMCF were included and classified according to the AO/OTA classification system. Group I was AO/OTA type 15.2A/15.2B ($N=68$) and group II was AO/OTA type 15.2C ($N=60$). After a modified open stabilization technique of each DMCF with IMN (S-shaped TEN), the dynamics of radiological assessed telescoping until union and rate of surgical adverse events were measured. Significance was assumed for $p<0.05$.

Results One day after surgery, fractured clavicles were lengthened slightly in both groups compared to the unfractured clavicules (group I: 1.2%; group II: 0.9%). After osseus consolidation, the fractured clavicules were significantly shortened in both groups (group I: −2.9%; group II: −3.6%). Measurement of the clavicular shortening at one day postsurgically and at consolidation revealed a mean telescoping of −3.99% in group I and of −4.6% in group II. The difference between the two groups was not significant ($P=0.522$). The overall rate of major surgical adverse events was 2.3%.

Conclusion The proposed operative technique of IMN (stabilization of the DMCF with a long, S-shaped, tight-fitting TEN) provides enough axial stability to prevent significant telescoping of the comminuted fractures. The rate of nonunion is low and the overall rate of major adverse events is similar to the reported events after plate fixation in the literature.

Keywords Displaced midshaft clavicular fracture · Intramedullary nailing · Telescoping · Comminuted clavicular fracture

Introduction

After conservative management, displaced midshaft clavicular fractures (DMCF) have a risk of symptomatic malunion of 15.1% [1]. Surgical treatment may result in decreased treatment failure [2]. Therefore, the past decade has shown a paradigm shift towards operative treatment, in which plate fixation (PF) became the standard fixation method [3, 4]. Wound infection/breakdown, nonunion, implant failure, poor cosmesis, and local skin numbness after PF point to an instrumentation-related problem. To prevent plate irritation and limit soft tissue stripping, intramedullary nailing (IMN) has been used [5]. Lateral perforation of the intramedullary device and axial instability are considered to be major problems of IMN [6, 7]. Smekal et al. [7] recommended the use of an elastic stable IMN for all simple displaced midshaft fractures, wedge clavicular fractures, and comminuted fractures with moderate posttraumatic shortening. In comminuted DMCF with severe posttraumatic shortening, they found telescoping to be the main complication and recommended PF to ensure optimal stability, clavicular length, and endosteal blood supply [7].

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Our hypothesis is that a long, S-shaped, tight-fitting TEN in the S-shaped clavicle increases axial stability and decreases shortening of the clavicle in comminuted fractures. Therefore, we modified the operative technique of the IMN described by Murray [8] and Schwarz and Leixnering [9] who advance the TEN not too far towards the lateral end of the clavicle, but only as far as to bridge the fracture. We splinted the lateral fragment of the clavicle as far as possible with a TEN that was bended according to the 3 D anatomical clavicle shape.

The primary object of this study was the comparison of fracture telescoping after IMN in comminuted, severely shortened clavicular fractures (AO/OTA type 15.2C) with the fracture telescoping of two and three part fractures (AO/OTA type 15.2A/15.2B) that stops until the lateral main fragment gets into contact with the medial main fragment. The second object was the observation of major surgical adverse events (nonunion and wound infection) until bone union.

Materials and methods

Patient recruitment and study design

Between January 2012 and December 2017, all patients of a level II trauma centre with unilateral DMCF with a displacement greater than the diameter of the clavicle shaft and IMN stabilization underwent prospective trial registration. Inclusion criteria for this study were patients with a closed DMCF, a minimum age of 16 years on admission, and radiological follow-up at day one postsurgically and after fracture consolidation. We excluded patients with multiple injuries, open and pathological fractures, clavicular fractures that were associated with neurovascular injury, and fractures of severely ill patients. Data extraction included patient age at the time of fracture, sex, dominant side and body mass index (BMI).

Fracture classification and group assignment

Fractures were classified according to the AO/OTA classification system [10]. Two-part midshaft fractures were coded as 15.2A, wedge fractures as 15.2B and comminuted fractures as 15.2C. Patients with 15.2A and 15.2B fractures were assigned to group I. In these fractures, telescoping after IMN seems to be impossible, because the lateral main fragment contacts the medial main fragment. Patients with 15.2C fractures were allocated to group II, because after intramedullary stabilization there is no primary contact of the lateral and medial main fragments and therefore telescoping occurs [7].

Operative technique and postoperative care

In contrast to the well-known techniques with strive for closed reduction and therefore often only short splinting of the lateral fragment to bridge the fracture we inserted a long, S-shaped, tight-fitting TEN in the S-shaped clavicle as far as possible. In detail: All patients received a single dose of 1.5 g of cefuroxime at induction of general anaesthesia. Surgical fracture treatment was performed or guided by one of the senior study authors. Patients were positioned on a radiolucent table in beach-chair position. After disinfection, a 1 cm incision was made over the sternal end of the clavicle. After soft tissue dissection, the ventral cortex of the medial clavicle was opened with an awl. A 2- to 3-mm titanium endomedullary nail (TEN, Synthes, Umkirch, Germany), depending on the size of the medullary cavity (TEN diameters − group I: 60×2.0 mm, 8×2.5 mm; group II: 50×2.0 mm, 9×2.5 mm, 1×3.0 mm), was fixed in an universal T-handle chuck and inserted into the medullary canal of the medial clavicular fragment using rotating movements under radiographic control. The fracture site was minimally opened with an incision according to Langer's lines. The overlying deltoid and pectoralis major attachments were sharply divided in line with the clavicle, leaving thick flaps for later closure. A 1.8-mm Kirschner wire (K-wire) was bended to copy the three-dimensional curvature of the lateral fragment of the clavicle (Fig. 1a). This fragment was grasped with a Weber clamp (Fig. 1b). To preform the TEN glide path, which had been placed in the medial fragment of the clavicle, the bended 1.8-mm K-wire was advanced into the medullary canal of the lateral fragment as long as possible without perforating the cortex (Fig. 1c). After removal of the 1.8-mm K-wire, the TEN was advanced over the lateral edge of the medial fragment side and the curvature of the 1.8-mm K-wire was replicated by the TEN (Fig. 2a). After pulling back the bent TEN into the medial clavicular fragment, the two main fracture fragments could be reduced, and the still bent TEN could be inserted into the preformed cavity of the lateral fragment. As the medullary canal of the lateral fragment was underreamed, blows of equal force were used as the TEN was placed under radiological control. The proper length of the clavicle was determined and corrected. In multi-fragmentary DMCF, large fragments affecting the stability of length maintenance were fixed anatomically with resorbable string cerclage (Vicryl™ 6, Ethicon®, Johnson & Johnson Medical GmbH, Norderstedt, Germany) into the bony defect without disturbing the soft tissue of the fragments (Fig. 2b), adapting the clavicle to the correct length. After radiological control and medial epicortical shortening of the TEN, the deltoid and trapezius aponeuroses were sutured to the periosteum

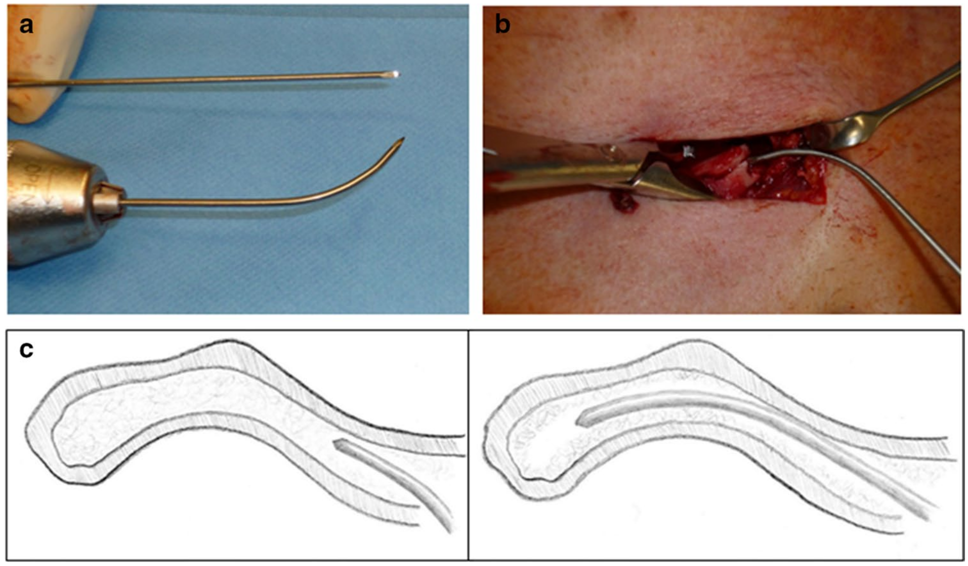

Fig. 1 Operation technique—preparation of the lateral main fragment. **a** 1.8 mm Kirschner's wire after customization for lateral main fragment curvature. **b** Insertion of the Kirschner wire into the lateral main fragment. **c** Reaming the lateral medullary cavity with the Kirschner wire

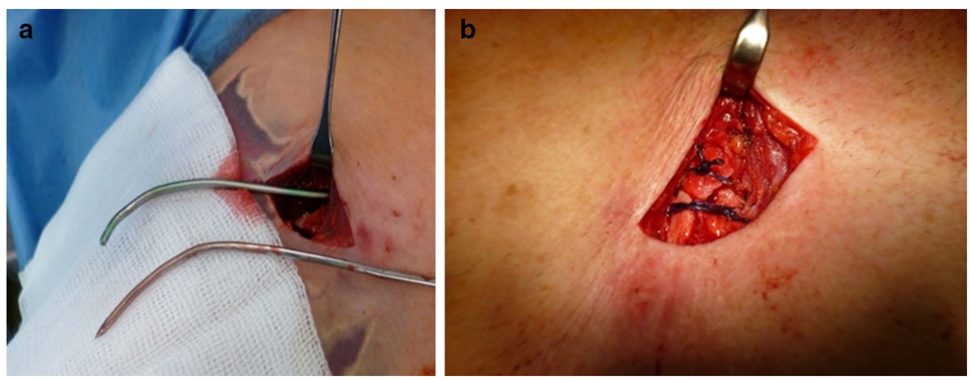

Fig. 2 Operation technique—positioning of the TEN. **a** Curvature of the TEN driven in the lateral main fragment using the Kirschner wire as a template. **b** Minor fragments are modelled into the fracture gap and fixed using a resorbable cerclage

(Vicryl™ 2–0; Ethicon®, Johnson & Johnson Medical GmbH, Norderstedt, Germany). Skin closure was performed using Ethilon™ 3–0 sutures (Ethicon®, Johnson & Johnson Medical GmbH, Norderstedt, Germany).

From day one after surgery, all patients were permitted functional and pain-adapted movement of the shoulder with a maximum of 90° for abduction and flexion. After six weeks, all limitations were suspended.

The TEN was removed in 125 patients after an average of 17.4 weeks (SD 10.303) in a short general anaesthesia when fracture union was confirmed clinically and radiographically. Fracture consolidation was presumed if callus bridged the fracture gap. In case of TEN irritation over the sternal end, the TEN was shortened under local anaesthesia or was preterminally explanted. TEN irritation was defined as a patient-reported sensation of pressure, pain, and skin irritation around the area where the TEN was inserted. If symptomatic delayed union or nonunion after a minimum of three months were assumed (pain at the fracture site combined with absence of bridging callus), we performed computer tomography (CT) of the shoulder region. In case of nonunion, the fracture zone was revised with decortication, adding autolog spongiosa and stabilizing the clavicle with a low-contact locking plate.

Postoperative radiological measurements

Panoramic radiographs of the shoulder girdle showing both clavicles on a single x-ray film (standing patient, hanging arms close to the body and midline at the thoracic spinous processes) and axial shoulder radiographs at 90° abduction (Fig. 3) were taken one day after stabilization and at 1, 6, and 12 weeks postoperatively. Diagnosis was performed using PACS software (Carestream, Rochester, NY, USA) and diagnostic flat screens (EIZO, Hakusan, Ishikawa, Japan).

As it can be assumed that the length of the splinted lateral clavicular fragment has an influence on the stability of fracture fixation, we related the length of the lateral clavicular fragment to the length of the splinted lateral clavicular fragment. The TEN movement in the lateral clavicular fragment was documented until consolidation of the fracture.

The length of the lateral clavicular fragment was determined by the distance between a line perpendicular to the centre of the medial fracture edge (Fig. 4, black cross) and the acromial end of the bone (Fig. 4, white cross). The length of the splinted part of the lateral fragment was determined by the distance between a line perpendicular to the centre of the medial fracture edge (Fig. 4, black cross) and the lateral end of the TEN. The length of the lateral clavicular fragment was considered to have a relative length of 100%. The splinted lengths were expressed as proportional differences to the length of the lateral clavicular fragment in percentage.

To determine postoperative telescoping, clavicular lengths of the fractured side (FS) and of the unfractured side (US) of each patient were measured on day 1 after surgery and after fracture consolidation. For both clavicles, the length between the centres of the sternal and the acromial end of the bone was measured (Fig. 5). Lengths were subtracted from each other and expressed as proportional length differences (PLD) in percentage. The unfractured side (US) served as a control and was considered to have a relative length of 100%. The PLD was measured using the validated technique by Smekal et al.: PLD (in %) = (FS − US)/US × 100 [11].

In addition, we calculated the alteration of PLD between the first day after the stabilization and after fracture consolidation (i.e., telescoping).

Statistics

Statistical analyses were conducted using Excel 2010 (Microsoft, USA) and XLSTATs Version 2016.02.27955 (Addinsoft, Witzenhausen, Germany). Descriptive statistics included mean values and standard deviation (SD). Comparisons were performed with Student's t-tests for normally distributed data and Mann–Whitney U-tests for non-normally distributed data. Significance level was set to $p < 0.05$. For the determination of the probability of making a type II error, power analysis was used to calculate the minimum sample size required [12]. A minimum sample size of $N = 58$ for each group I was calculated.

All postoperative radiological measurements were performed by a single consultant (R.L.) after blinded tests for intra- (R.L.) and inter-observer (R.L. and A.H.) reliability

Fig. 3 **a** Posttraumatic panoramic x-ray of the shoulder girdle and **b** axial shoulder radiograph with 90° abduction of the arm showing a comminuted DMCF (AO/OTA type 15.2C)

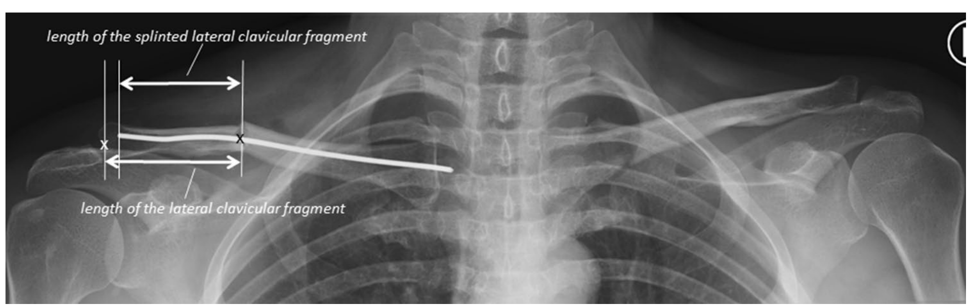

Fig. 4 Proportional splinting of the lateral fragment. Length of the splinted lateral clavicle fragment/length of the lateral clavicle fragment × 100 (= 90.3%)

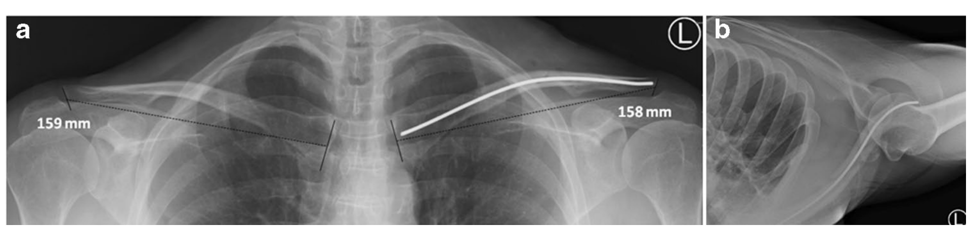

Fig. 5 **a** Panoramic x-ray of the shoulder girdle and **b** axial shoulder radiograph with 90° abduction of the arm on day one after IMN in DMCF (AO/OTA type 15.2B) with a PLD of − 0.63% of the anatomically reconstructed clavicle stabilized with an S-shaped TEN

using intra-class correlation (ICC) according to Büttner and Büttner [13].

Results

Of the 166 patients presented with DMCF, who underwent fixation with IMN, a total of 128 patients met the inclusion criteria (excluded patients: 10× aged under 16 years on admission; 4× with multiple injuries; 1× with open fracture; 2× with missing correct radiological follow-up; 1× died after 6 months because of cancer; 11× were lost for follow-up, e.g. moved away; 9× refused participation of the study). Group I had 68 patients (15.2A: 32; 15.2B: 36), while group II had 60 patients (15.2C). Demographic data are shown in Table 1. Significant differences between group I and group II were found in age, BMI, and dominant sides. Three patients denied removing the implant.

In Table 2, the position of the TEN in the lateral fragment and the telescoping of the fractured clavicle compared to the unfractured clavicle (PLD) until union are shown. The difference of the proportional splinting of the lateral fragments between day one after surgery and after healing was not significant in both groups ($p > 0.05$). This justifies the assumption that the S-shaped TENs are fixed in the lateral fragment of the clavicle tightly.

One day after surgery the fractured clavicles were slightly longer in both groups in comparison to the unfractured clavicles (PLD group I: 1.2%, PLD group II: 0.9%). This could be an intraoperative overcorrection of the clavicular lengths in both groups. During fracture healing, we observed telescoping of the fractured clavicles in both groups. The length difference was significant in each group ($p < 0.0001$).

Table 1 Demographic data of the patients ($N = 128$)

Parameter	Group I ($N = 68$)	Group II ($N = 60$)	*p*
Mean age (years) ± SD	34.77 (SD 15.099)	43.2 (SD 15.041)	0.002*
Gender distribution (female/male)	11/57	6/54	0.308
Dominant side	20 patients	34 patients	0.002*
Ø BMI (kg/m^2)	24.48 (SD 3.115)	25,93 (SD 3.912)	0.022*

SD standard deviation, *Ø* average, *BMI* Body Mass Index

*Statistical significance

Table 2 Proportional splinting of the lateral fragment (length of the splinted part of the lateral fragment/length of the lateral clavicular fragment) and proportional length difference (PLD) of the fractured and unfractured clavicles

Parameter	Day one after surgery	After fracture healing	*p*
Group I ($N = 68$)			
Ø length of the splinted part of the lateral fragment/length of the lateral clavicular fragment (%)	85.4 (SD 13.948)	80.3 (SD 18.249)	0.081
Ø PLD (%)	1.2 (SD 4.223)	−2.9 (SD 4.754)	< 0.0001*
Group II ($N = 60$)			
Ø length of the splinted part of the lateral fragment/length of the lateral clavicular fragment (%)	87.3 (SD 8.344)	85.7 (SD 14.331)	0.455
Ø PLD (%)	0.9 (SD 5.454)	−3.6 (SD 5.288)	< 0.0001*

Ø average, PLD (%) = (FS − US)/US × 100 [11], *PLD* proportional length difference, *FS* fractured side, *US* unfractured side, *SD* standard deviation

*Statistical significance

Table 3 Dynamics of the telescoping and surgical adverse events in group I (AO/OTA type 15.2A and AO/OTA type 15.2B, $N = 68$) and group II (AO/OTA type 15.2C, $N = 60$)

Parameter	Group I ($N = 68$)	Group II ($N = 60$)	*P*
Ø telescoping until union (%)	−3.99 (SD 4.771)	−4.6 (SD 5.231)	0.522
Nonunion (%)	1 (1.47)	2 (3.33)	0.491
Skin irritation (%)	2 (2.94)	4 (6.67)	0.324
Wound infection	0	0	1

SD standard deviation, *Ø* average

*Statistical significance

Table 3 shows the telescoping of the fractured clavicles in group I and group II. In group I, the mean difference of PLD from day one after surgery until consolidation was − 3.99% (representing a shortening), while in group II it reached − 4.6%. The difference of telescoping in both groups was not significant ($p > 0.05$). Intra- (R.L.) and inter-observer (A.H.) reliability were calculated with ICC = 0.97 and 0.85, respectively, for both examiners.

Adverse surgical events

In six patients, we observed skin irritation, but no skin penetration, over the sternal end of the clavicle. One patient underwent minor operative revision under local anaesthesia with a normal course of fracture healing. Preterm TEN removal (after week 5 and 6) was necessary in the other five patients. After TEN removal, no dislocation of the fracture fragments occurred. In five of six patients with skin irritation, the fractures healed, while one patient showed a symptomatic delayed union after three months.

Two other patients developed symptomatic nonunion without preterm TEN removal. Overall, we observed three major surgical adverse events (2.3%). After stabilization with low-contact locking plates, all three clavicles healed uneventfully. There were no other adverse events (Table 3).

Discussion

No differences exist in terms of re-interventions in general and, more specifically, regarding function, between PF and IMN for DMCF [14–16]. When focusing on major re-interventions, such as those due to refracture and infection, an advantage for the IMN treatment was found [14–16]. In comminuted fractures, telescoping and medial nail protrusion are considered to be the main problems of IMN. Smekal et al. [7] showed that in comminuted fractures, the mean improvement of posttraumatic shortening was only 1.3% after fracture union. IMN in comminuted fractures with severe posttraumatic shortening was considered not to provide enough stability, clavicular length, and endosteal blood supply. Therefore, PF is recommended for comminuted fractures.

However, the exact stiffness threshold for inducing healing of DMCF is currently unknown [17]. The threshold seems to be low, because conservative treatment of DMCF has a success rate of 76% [18] and IMN is successful in the treatment of simple clavicular fractures, even if the TEN was not advanced too far towards the lateral end of the clavicle [6]. In comminuted fractures, however, a short splinting of the lateral fragment and the absence of cortical alignment influence the fixation stability directly [17].

Bakota et al. [19] presented a modified K-wire intramedullary technique for fixation of comminuted, multi-fragment DMCF type Robinson 2B.2. They observed a high rate of nonunion and discussed a rotational instability.

Our hypothesis was that a long, S-shaped, tight-fitting TEN in the S-shaped clavicle improves the axial stability to prevent telescoping and increases rotational stability to decrease the nonunion rate.

The determination of clavicular length is not a trivial problem. CT allows reconstruction of the clavicle in three dimensions and measures its true length [11]. Spatial digitalization that localizes three-dimensional coordinates of predefined bony landmarks with an electromagnetic tracking device is another method to calculate the true length accurately and reliably [20]. Due to radiation exposure and complexity, the two methods are considered to be unsuitable for daily use. Therefore, clavicular length is measured on two-dimensional radiographs. Plain radiographs, however, are prone to error because the clavicle is seldom located parallel to the x-ray film, and the distance to the x-ray film becomes a critical factor due to the amplification effect [11, 20]. Additionally, there was only a weak-to-no-inter-observer and minimal intra-observer agreement on the amount of shortening on unilateral anterior–posterior and 30° cephalic views [21]. And, assuming clavicular symmetry, the comparison of the length of the fractured and unfractured clavicle seems to be unreliable. Significant differences in clavicle length exist depending on dominant side or sex [22]. For standardization, we took panoramic radiographs of both clavicles and expressed the clavicular shortening as PLD between the FS and US with the uninjured side serving as a control for clavicular length (100%). This method of measurement has shown to have a high agreement with measurements on CT as well as a high repeatability [7]. To improve the reliability in our study, two examiners measured the clavicular length independently and the inter- and intra-observer agreement was calculated with ICC = 0.97 and 0.85, respectively, reflecting a sufficient standardization of the panoramic radiographs in our study.

On day one after surgery, we found a near-complete lateral fragment splinting in both groups, and that the tight fit prevented TEN dislocation in the lateral fragment until union (Table 2).

In comparison to the unfractured clavicles, we observed a slight overcorrection of the mean length of the fractured clavicles on the first post-surgical day in both groups (Table 2). This might be explained by the fact that we under-reamed the lateral fragment and inserted the TEN forcefully to achieve a tight fit in the lateral fragment. However, after osseus consolidation, we found a significant fracture shortening in both groups (Table 2). Given that after IMN of AO/OTA type 15.2A and type 15.2B fractures the lateral main fragment contacts with the medial main fragment, shortening of the injured clavicle seems to be impossible. A telescoping in this group corrects the excess length of the clavicles. The fact that we could not find statistical differences in the dynamics of the telescoping between the two groups (Tab. 3) supports our assumption that our modification of the operative technique prevents significant telescoping in comminuted fractures.

This is in accordance to the findings of Bakota et al. [19]. Using a modified K-wire intramedullary technique for fixation of multi-fragmentary DMCF, they found no significant differences in clavicular shortening in two-part or multi-fragmentary fractures. However, they observed a 2.4-time greater clinical incidence of nonunion in the displaced multi-fragmentary fractures (7.41%) compared to the two-part fractures (3.13%). They discussed rotational instability and hypothesized that excessive micromotion of the fragments leads to hypertrophic nonunion. The fact that we observed a higher rate of skin irritation in group II (Table 3) might be explained by an increased TEN motion in these less stable fractures.

In our study, nonunion was found in 1 patient in group I (1.47%) and in 2 patients in group II (3.33%). The clinical nonunion ratio in displaced multi-fragmentary fractures and two-part fractures is that of Bakota et al. [19]. However, our proposed operative technique of IMN decreased the overall rate of nonunion in comparison to the study of Bakota et al. [19]. This might be explained by the observations of Drosdowech et al. [23]. Comparing four different techniques of fixation for DMCF (IMN, dynamic compression plate, locking compression plate, and reconstruction plate) they described that IMN provided the least amount of torque stiffness among all the implants tested and that IMN had lower stiffness to bending loads than the reconstruction plate. They assumed that this might be the result of the S-shape of the clavicle in the transverse plane, which provides a moment arm and thus converts a pure bending load into a combination of bending and torque. This would allow the clavicle to spin about the axis of the intramedullary device and manifest as a lower bending stiffness.

We assume that the S-shaped TEN inserted in the S-shaped clavicle reduced the extra moment arm, decreased the axial spin, and therefore decreased the rate of nonunion.

The difference in effectiveness between IMN and PF for the treatment of DMCF is still a matter of controversy, and the optimal operative procedure remains unknown. An increasing number of randomized clinical trials and meta-analyses [15] have reported no differences in long-term treatment effectiveness between IMN and PF, while other studies concluded that IMN is superior to PF.

However, most studies excluded comminuted fractures from IMN treatment, so the conclusions reached in these studies are often limited to non-comminuted DMCF. If comminuted fractures had been included, overall outcomes might have changed [14]. In addition, IMN in DMCF is still associated with significantly lower costs compared to other fixation methods, despite the need for implant removal when compared with PF [24].

Limitations

This study presents some limitations. This is an analytic cohort study of a prospective trial registration from a single trauma centre. Therefore, we were unable to fully exclude selection bias. For example, patients with comminuted fracture types (group II) were significantly older and more obese. Furthermore, no own control group with patients treated with PF was present. A confirmation of our results and randomized controlled trials are needed.

Conclusion

In conclusion, our study shows that the proposed operative technique of IMN provides enough axial stability so that significant telescoping of the comminuted fractures compared to simple fractures does not occur. In addition, we could show that the rate of nonunion is low and the overall rate of major adverse events is similar to the reported events after PF in the literature [2]. If other groups confirm our results, it should be possible to randomize patients with DMCF that receive PF or IMN independently of fracture classification. Selection bias could be minimized and the true outcomes regarding major intervention rates after PF or IMN could be seen. These findings could benefit patients suffering comminuted DMCF with severe posttraumatic shortening.

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Authors contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Ronny Langenhan, Stefanie Bushuven and Niklas Reimers. The first draft of the manuscript was written by Ronny Langenhan and Axel Probst and all authors commented on previous versions of the manuscript. The statistical work was done by Stefanie Bushuven. All authors read and approved the final manuscript.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval This article does not contain any studies with animals performed by any of the authors. The study was approved by the responsible ethics committee (Landesärztekammer BW, F-2017-051) and is in accordance with the Helsinki Declaration in 1964.

Informed consent Informed consent was obtained from all individual human participants included in the study. Data were processed under German national terms and regulations.

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