



Intramedullary nailing of displaced midshaft clavicle fractures using a TEN with end cap: issues encountered

Martijn HULSMANS, Mark VAN HEIJL, Roderick HOUWERT, Egbert Jan VERLEISDONK, Herman Frima

From the Diakonessenhuis, Nederland

The purpose of this study was to describe our experience with a possible solution for implant-related irritation after intramedullary nailing of displaced midshaft clavicle fractures: the end cap.

Ten patients with a displaced midshaft clavicle fracture were treated with intramedullary nailing and an end cap in 2013. Patients were followed in the outpatient clinic until fracture union. In 2015 patients were contacted again. Prospectively collected data included shoulder function and complications.

The median follow-up time was 28.5 months (between 27 and 30 months). No patients were lost to follow-up. QuickDASH scores were 18.2, 9.1 and 2.3 after 6 weeks, 3 month and latest follow-up respectively. Nine patients (90%) had some type of implant-related complication. In three of these patients implant removal was required before union. One implant failure occurred which required major revision surgery using plate fixation.

In conclusion, because in 70% of the patients the implant-related irritation was directly caused by the end cap, we believe end caps should not be used after intramedullary nailing for displaced midshaft clavicle fractures.

Key words : Intramedullary ; nailing ; TEN ; end cap ; complication ; clavicle.

INTRODUCTION

Intramedullary (IM) nailing has gained recognition as one of the preferred treatment

modalities for displaced midshaft clavicle fractures (DMCF) (1,7,17,18). Excellent results are reported in terms of consolidation and functional outcome after intramedullary fixation (3,8,15).

Complication rates after IM fixation for DMCF are reported to be up to 63% (7,14,15,17). Most of these complications are implant related and technique-specific, like medial protrusion and irritation (1,3,13).

A possible solution that was recently proposed for implant-related irritation was the application of an end cap at the medial end of the titanium elastic nail (TEN) (4). It may also prevent soft tissue irritation from the sharp end of a TEN.

The present study describes our experience with IM nailing for DMCF and the use of end caps.

MATERIALS AND METHODS

Between June 2013 and September 2013, 10 patients with an isolated DMCF were recruited for

- Martijn H.J. Hulsmans¹.
- Mark van Heijl¹.
- Roderick M. Houwert¹.
- Egbert Jan M.M. Verleisdonk¹.
- Herman Frima².

¹Diakonessenhuis, Nederland.

²Kantonsspital Graubunden, Chur, Switzerland.

Correspondence : Egbert Jan M. M. Verleisdonk, Diakonessenhuis, Nederland

E-mail : ejverleisdonk@gmail.com

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this study. Patients who had undergone previous surgery to the shoulder or patients with an open fracture, a pathological fracture, a fracture sustained more than one month previous to the first visit or pre-existing neurovascular disorders were excluded. All patients were treated with intramedullary fixation using a TEN in combination with an end cap. All patients provided informed consent and volunteered to participate in the study. Approval was granted by the VCMO (United Commissions of Human Related Research).

Operative procedure intramedullary nailing

The operations were performed or supervised by one orthopedic trauma surgeon who has substantial experience (> 50 procedures) with IM nailing using a TEN for DMCF. In addition, the surgical technique of TEN and end cap had been used extensively in treating other types of fractures, e.g. in pediatric long-bone fractures.

Patients were positioned in a supine position. A small incision at the medial end of the clavicle was made, the anterior cortex was opened with a pointed reamer, and the TEN (Titanium Elastic Nail, DePuy Synthes, Amersfoort, the Netherlands) was inserted. If closed reduction was not successful, a minimal incision at the fracture site was used to perform open reduction. The nail was inserted as far as possible in the lateral part of the clavicle without penetrating the lateral cortex. Any distraction over the fracture was relieved by lateral manual compression to the shoulder. After satisfactory fluoroscopic control, the nail was cut at the introduction point approximately 5mm outside of the cortex. The corresponding end cap (green for 3-4mm TEN, pink for 1.5-2.5 mm TEN) was inserted over the external portion of the nail and threaded into the cortical bone. Fascia and skin were then closed in layers.

Data collection

Prospectively collected data included patient characteristics, shoulder function and complications. Shoulder function was assessed at 6 weeks, 3 months and at least 27 months after surgery using the short version of the Disabilities of the Arm, Shoulder, and Hand (QuickDASH) questionnaire, a reliable patient-oriented outcome measure for

assessing upper-extremity disability. A higher score represents greater disability and a lower score indicates a good functioning extremity (range 100-0) (2,5). Verbally conducted QuickDASH scores replicate clinically relevant scores of the written QuickDASH and have good test-retest performance (10). Complications included infection, implant-related problems (medial or lateral soft tissue irritation or failure), nonunion, and refracture after implant removal.

The definition of infection was redness, swelling and/or purulent discharge from the wound that could be treated with antibiotics. Irritation at the entry site or at the dorsolateral side of the shoulder due to a palpable implant as reported by the patient during the follow-up period was considered implant-related irritation. Implant failure was defined as implant breakage or the implant not bridging the fracture anymore. An unsuccessfully healed clavicle by radiographic 6 months after surgery with clinical evidence of pain was defined a non-union. Re-interventions needed to treat these complications and performed before routine removal was indicated were considered and registered as complications of treatment. Removal of the implant before fracture union was considered early implant removal. Revision surgery, in which IM fixation was revised with plate fixation, was considered a major revision.

Post-operative treatment and follow-up

Postoperatively, patients were instructed to start immediately with active, pain-dependent mobilization. Our standard clinical protocol dictates removal of the TEN 3 months postoperatively in all patients treated with IM nailing for DMCF, or after the fracture has healed adequately when delayed union is suspected. Patients were followed in the outpatient clinic until union was achieved. Patients were contacted again in December 2015 to obtain additional information regarding shoulder function, complications and interventions needed to treat these complications.

Statistics

Data were presented as mean \pm standard deviation (SD) or median \pm interquartile range (IQR) for

continuous variables and as absolute numbers (percentage) for categorical variables. Statistical analysis was performed with SPSS, version 20.0 (IBM Corp., Armonk, NY) for Windows.

RESULTS

Mean age was 39.7 years (20 to 65) and all patients were men (Table I). No patients were lost to follow-up. The median follow-up time of all 10 patients was 28.5 months (IQR: 27.0-30.0). After 6 weeks, 3 months and latest follow-up, the median QuickDASH scores were 18.2, 9.1 and 2.3, respectively. Nine out of ten patients (90%) had some type of complication (Table II).

In one patient, the TEN migrated laterally from the medial fragment, resulting in inadequate fracture bridging. The x-ray taken after 2 weeks is shown in Fig. 1. Revision surgery using plate fixation was performed to treat this patient. In one other patient, postoperative shortening of the clavicle caused the nail to migrate laterally. After 5 weeks, tenting of the skin at the lateral aspect of the clavicle was observed, prompting implant removal under local anesthesia. The end cap was removed medially. Union was achieved after 4 months without any additional procedures.

Table I. — Baseline characteristics

Variables	Intramedullary nailing (N = 10)
	Mean (SD)
Age (yr)	39.7 ± 16.4
Sex	Number (%)
Male	10 (100)
Fracture side	
Right	9 (90)
Left	1 (10)
Fracture classification ^a	
Simple (AO/OTA type B1)	4 (40)
Wedge (AO/OTA type B2)	3 (30)
Complex (AO/OTA type B3)	3 (30)

SD = Standard deviation

^aFractures classified according to the AO/OTA classification.¹⁶

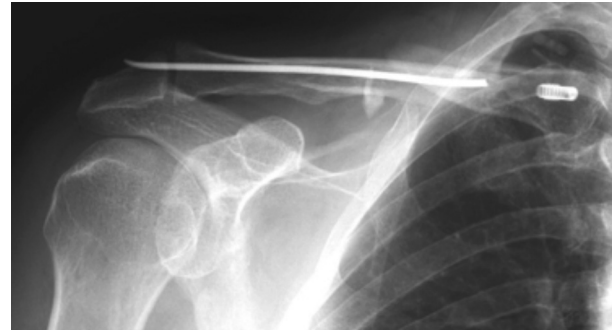


Fig. 1. — Standing AP view of the right clavicle with lateral migration of the TEN. Lateral migration of the TEN not adequately bridging the fracture anymore with the end cap still threaded into the cortical bone on the medial side of the clavicle

Implant removal under general anesthesia due to irritation of the end cap on the medial side was performed in one patient. In two other patients, the end cap migrated out of the clavicle with concurrent medial migration of the nail, resulting in irritation at the medial entry site. An x-ray after 6 weeks taken in one of these two patients is shown in Fig. 2. In only one of these two patients, implant removal under local anesthesia was required 3 months after surgery due to the irritation when fracture union was not yet achieved. In five patients, the end cap was irritating beneath the skin, but early implant removal was not necessary. One asymptomatic patient requested implant removal after 24 months, which was performed under general anesthesia. No infections or refractures after implant removal were observed, union was achieved in all patients and they all regained full range of motion.

DISCUSSION



Fig. 2. — Standing AP view of the right clavicle with medial migration of the TEN. The end cap was pulled out of the clavicle and medial migration of the pin was observed

Table II. — Postoperative follow-up

		Intramedullary Nailing (N = 10)
		Median (IQR)
Follow up, months		28.5 (27.0-30.0)
Shoulder function		
QuickDASH at 6 weeks		18.2 (14.2-22.2)
QuickDASH at 3.0 months		9.1 (5.7-12.5)
QuickDASH at latest follow-up		2.3 (0-4.6)
Complications	Treatment	Number (%)
Superficial infection	Antibiotics	0
Implant-related irritation, medial side	Incidence	7 (70)
	Observation ^a	5 (50)
	Implant removal, local anesthesia	1 (10)
	Implant removal, general anesthesia	1 (10)
Implant-related irritation, lateral side	Incidence	1 (10)
	Observation	0
	Implant removal, local anesthesia	1 (10)
	Implant removal, general anesthesia	0
Implant failure	Major revision ^b	1 (10)
Nonunion	Major revision	0
Refracture after implant removal	Major revision	0
Implant removed, without irritation (by patient request)	Local anesthesia	4 (40)
	General anesthesia	2 (20)

IQR interquartile range

^aPatients suffered from moderate irritation under the skin at the medial side, where the end cap was located, but no immediate implant removal was necessary. In 4 of these patients subsequently the pin and end cap were removed under local anesthesia and in 1 patient under general anesthesia when union was achieved.

^bPin was removed and plate fixation was performed.

Although IM nailing with an end cap resulted in union and good functional outcome in all patients, a vast majority of the patients (90%) developed some type of complication. In three patients (30%), implant removal was required before union due to severe lateral or medial irritation or migration of the end cap. One implant failure (10%) was observed, which required major revision surgery using plate fixation.

Although previous studies already reported high irritation rates after treatment with TEN and an end cap, we encountered an even higher implant-specific complication rate (3,4). In the present series

of 10 patients, the incidence of post-operative complications was 90% and all implant-related.

One explanation for the high rate of complications in the present study could be the presence of comminuted fractures. Intra- or postoperative shortening of the clavicle is more often seen in these fractures and may cause the nail to migrate medially (9,16). Smekal et al. already concluded that implant-related irritation after IM nailing without end cap for DMCF was more frequently reported in patients with comminuted fractures due to migration of the pin (13). With the end cap blocking the medial side, the TEN may migrate and

protrude laterally as a result of fracture shortening while the end cap remains at the entry site where it is threaded into the cortical bone. Migration of the TEN may continue until the lateral main fracture fragment is supported by the medial main fragment (13). However, lateral protrusion of the TEN might not solely be caused by the use of the end cap. It is possible that the lateral cortex is iatrogenically perforated with the TEN itself during the surgical procedure. Because the lateral end of the TEN is than not fixated anymore it easily migrates through the lateral cortex. Since we report on two patients in which lateral migration of the TEN was seen, we may only conclude that in seven (70%) patients the implant-related irritation was directly caused by the end cap.

The one patient without irritation had a simple (AO/OTA type B1) fracture (12). Moreover, in the other three patients who had “simple” fractures, no migration was seen and the irritation was only caused by the bulkiness of the end cap beneath the skin. Problems with migration of the TEN (lateral protrusion or medial dislocation of the end cap) were observed in patients with more comminuted fractures (AO/OTA type B2 – B3) (12). Therefore, we believe fracture classification and the risk of clavicle shortening should be considered before deciding which implant is most suitable for treatment. Careful selection of simple (AO/OTA B1) fractures might be effective in reducing implant-related problems after elastic stable intramedullary nailing.

Another explanation for the high implant-related irritation rate could be the post-operative policy of immediately active, pain-dependent mobilization. Biomechanical studies showed that abduction up to 80° results in a peak compressive force of 34N (6). These compressive forces should be avoided in patients with oblique or comminuted fractures to prevent secondary fracture shortening. Furthermore, at 110° of forward flexion, posterior rotation or the clavicle along the longitudinal axis is reported up to 31° (11). Care should be taken, therefore, not to abduct or flex the arm over 80° for the first weeks after fixating clavicle fractures with an IM device.

A third possible explanation for the high irritation could be the fact that this was our first experience

with IM nailing and the use of end caps in patients with clavicle fractures. Nevertheless, due to our extensive experience with IM fixation using a TEN with an end cap in pediatric fractures, we believe inadequate technique to be an unlikely explanation for the relatively high rate of complications.

The severity of the irritation was not quantified which could be considered another limitation of this study. Irritation of the end cap itself might be of a different type compared to irritation caused by the sharp end of a nail. Unfortunately, no validated questionnaire is currently available to investigate the severity of implant-related irritation. However, the high functional outcome scores after 3 months in the present study suggest that severity of irritation might be low or at least bearable in most patients.

In conclusion, high rates of implant-related irritation are still seen after intramedullary nailing of displaced midshaft clavicle fractures using a TEN in combination with an end cap. Since in 70% of the patients the irritation was directly caused by the end cap, we believe no end caps should be used after elastic stable intramedullary nailing for displaced midshaft clavicle fractures.

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