The Association of Metal Frame Construct of ESIN and radiographic bone healing of pediatric forearm fractures

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ABSTRACT

Introduction

The gold-standard surgical procedure of both-bone forearm shaft fracture repair is elastic stable intramedullary nailing (ESIN). Disadvantages effects of ESIN have suggested to be a consequence of inappropriate surgical techniques, while recommendations are not always followed. The purpose of the study was to analyze the effect of inadequate metal frame construct on impaired fracture healing, refracture and changing alignment.

Materials and Methods

It is a population-based study including all consecutive patients, aged less than 16 years, who had been treated for forearm shaft fracture by ESIN during the ten-year period 2009–2018. Altogether 71 patients were included. Non-union, delayed union, and re-fracture during the following 12 months were taken as the main outcome, while inferior metal frame construct of ESIN and the surgical technique characteristics were taken the explanatory factors. Radiographic loss of reduction was a secondary outcome and a change $>5^\circ$ in alignment at any postoperative follow-up exam was recognized.

Results

Two out of 71 fractures (3%) failed to unite, and ossifying operation was needed. Five cases (7%) showed delayed bone healing, but they ossified in five months without any intervention. These seven patients (10%) had been treated more often with larger nails ($>0.7 \times \text{MCD}$) ($p=0.027$) and by open reduction ($p=0.02$), compared with thinner nails and closed reduction, respectively. Two (3%) patients had a second fracture; however, they happened 2 years after the initial injury. Other surgery or fracture related factors didn't associate with impaired ossifying.

Regarding the secondary outcome, altogether 24 (35%) of the analyzed 67 patients showed $>5^\circ$ change in alignment during the postoperative follow-up but only one patient had clinically significant instability that required re-reduction. The alignment changed more usually in distal-third fractures, compared with middle or proximal third fractures ($p=0.019$).

Conclusions

ESIN resulted in good radiographic bone healing in the vast majority (90%) of the patients and completely perfect metal frame construct was not required.

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Introduction

Of all forearm fractures, both-bone shaft fractures are most often treated operatively [1,2] and the incidence of their surgery is still increasing [3,4]. Elastic stable intramedullary nailing (ESIN) is the gold-standard procedure [3,5–8] indicated in cases of complicated, unstable, or irreducible fractures [9–11]. Theoretically, ESIN works as internal splint aligning the bone fragments [12]. It is fundamentally based on the tension metal frame achieved by pre-bending the nails [7,8,13–15] when the apex of their bow is placed at the fracture level [7]. This technique is minimally invasive, and periosteal stripping is minimized. Even if minimal open reduction is needed [16,17

], functional outcomes of ESIN have been satisfactory [5,6,9]. The elasticity of the nails allows micro-motion between the fragments, promoting rapid callus formation [18].

However, high elasticity of ESIN is not exclusively an advantage in bone union. Particularly, too-thin nails may not provide enough support [13], while too-thick implants are rigid and may hinder bone bridging and normal lateral curving of the radius [7]. The recommended ratio of ESIN nail diameter compared to intramedullary canal diameter (ND/MCD ratio) varies between 0.6 and 0.8 for pediatric long bones in general [8,9,13,15,19], while thinner nails ($\text{ND/MCD} < 0.4$) have been suggested for the forearm [13]. However, the evidence of optimal nail thickness in forearm shaft fractures is sparse [15]. Moreover, there are just a few reports about the impact of correct versus inferior metal frame construct, regarding nail pre-bending, configuration of the nails with opposite concavities, the location of the maximal radius curve, and interosseous tension [7,9,20].

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The purpose of this study was to critically analyze the radiographic bone healing of forearm shaft fractures, treated with ESIN, and technical characteristics of the achieved metal frame construct in the light of current recommendations of surgical technique. Another purpose was to study, which characteristics of the metal frame or fracture related disadvantages factors may be associated with nonunion, delayed union, refracture or changing alignment postoperatively.

Materials and methods

Study design

This population-based study included all consecutive patients, aged less than 16 years, who had been treated for a forearm shaft fracture using ESIN in the geographical research area of Oulu University Hospital between 2009 and 2018. There are no other pediatric 24-hour trauma departments in the study area, with approximately 87,000 children-in-risk annually; the enrollment was taken to be inclusive. However, some individual cases may have been treated at other trauma units, e.g. during their vacation abroad. All primary and follow-up radiographs were reviewed to confirm the inclusion. The fractures were classified based on AO-classification [21].

Patients

Altogether 112 patients with forearm shaft fractures were primarily reviewed, but 41 of them were excluded: 35 (31%) had been treated using other osteosynthesis such as Kirschner wires intramedullary and four patients (3.6%) were non-operatively treated. Two patients had an isolated ulna fracture and thus excluded. Non-shaft fractures, fractures with a concomitant dislocation, and fractures in patients with bone dysplasia or an underlying syndrome were also excluded but there were none among the primary enrollment.

The mean age of the patients (N=71) was 9.7 years (range 2–15, SD 2.6); It (age) was 9.5 years (range 2–15, SD 2.9) in boys and 10.1 years (range 6–15, SD 2.3) in girls (P=0.228). Half of the patients (N=35, 49%) were boys. A slight majority (N=39, 54%) was classified as type 22-D/5.1, while N=15 (21%) were type 22-D/5.2, and N=11 (65%) presented type 22-D/4.1. The most common single cause of injury was trampoline jumping (36%). Failed non-operative treatment preceded ESIN in N=12 (17%) of the cases. There were two patients with repeated fractures in the same forearm, both of which happened two years after the initial injury. The first fractures of these patients were included in the study and the latter were not taken as re-fractures in this research.

Outcome variables

Non-union, delayed union, and re-fracture during the next 12 months postoperatively were the main outcomes. Bone healing of the fracture was evaluated based on the validated Lane-Sandhu score: poor callus formation, visible fracture line, or absent cortical healing during three-month and six-month follow-up visits were considered delayed union and nonunion, respectively [1,22]. Insufficient stability of osteosynthesis was chosen as secondary outcome. A change > 5° in alignment in either in the radius or ulna at any time during the post-operative out-of-hospital follow-up was taken abnormal [7]. Both anteroposterior (AP) and lateral plain films of all follow-up visits were reviewed. Further, higher change in alignment was recognized and classified in three groups: 5°–10°, 10°–15° and 15°–20°. The axis of the forearm long bones could not be appropriate measured of four pa-

tients, whose plain films were not large enough or otherwise insufficient.

Explanatory variables

Technical deviations in surgical procedure and the metal frame construct, as compared with the recommendations, were noted as the potential explanatory factors of inferior outcomes. More than 10 mm of residual redisplacement was taken as an unsatisfactory result. Anatomic medial angulation (lateral bowing) of a normal radius was taken to be 5°–15° [23]. The opposite direction and curve of the nails were taken to refer to opposing concavities of the nails at the fracture site, yielding the correct tension for the IOM (**Fig. 1**) [24,25]. The lacking metal frame was taken as an explanatory factor.

The recommended length of interosseous space was taken to be at least 10%, compared with the length of the radius, demonstrating the satisfactory tension of the IOM. Thickness and the number of the implants and their symmetry in size were analyzed. The impact of nail thickness was investigated using two threshold values for the ND/MCD ratio: < 40% vs. 40% and < 70% vs. 70%. Length of the nail introduced over the fracture site was measured, and less than 40 mm was not recommended. Furthermore, some fracture related factors, such as the distal fracture site compared to proximal and mid-shaft, was considered as potential risk factor for impaired bone healing and worsening alignment. In determining the segments of the shaft, the total length of the radius was measured from the bicipital tuberosity to the distal physis or if absent to the radioulnar joint. The complete list of the explanatory factors used in this study is shown in the (**Table 1.**)

Fig. 1. The figure is illustrating the technical characteristics of ESIN metal frame that were analyzed in the radiographs; a) the length of the interosseous space between the radius and ulna, b) the nail tips forming the opposite concavities, c) the maximum curve placed at the fracture site, d) the length of the nail left outside the cortex, e) the thickness of the nail and the medullary canal.

Table 1

The table presents A) the quality of the metal frame construct after elastic stable intramedullary nailing of treating pediatric forearm shaft fractures, and B) patient and fracture related potential risk-factors of inferior fracture healing.

A Metal frame construct that was determined inappropriate	
Fracture reduction	>10 mm residual ad latum displacement
Configuration of the nails	Length of the IOM < 10% of total length of radius >1 mm of distance in the fracture line
Implant size and coherence	Opposite concavities of the nails at the fracture are not achieved
Tapping of the nails	Maximal curve of the nails is not placed at the fracture line ND/MCD < 40% or > 70% Different thickness of the implants
Reduction	Too short tapping of the nail (<40 mm) beyond the fracture line Too long tapping of the nail (reaching the rear growth plate) Limited cutting of a nail, resulting in that >10 mm of it is left on the bone surface
B Fracture and patient related risk-factors of impaired union	Open reduction needed
Fracture segment	Distal third vs. midshaft / proximal third
Fracture severity	Open fracture (regardless on the Gustilo grade)
	Comminuted fracture

Statistics

The study population and the results are described by using frequencies (N) and proportions (%). Standardized normal deviate (SND) was used to compare the difference proportions between two independent groups. Continuous variables were described as mean, range and standard deviation (SD). An independent sample *t*-test was used to find differences between the groups of continuous variables and logistic regression was used to analyze the potential risk factors of the main and secondary outcomes. Odds ratios (ORs) were reported with their 95% confidential intervals and *p*-values. Less than 5% was considered to be the level of statistical significance ($p < 0.05$). All tests were two-sided, and 95% confidence intervals were used. Statistical analyses were performed using SPSS version 24 software (IBM-SPSS Inc., USA) and StatsDirect Ltd. 2013 version 3.1 (Sale, Cheshire, England).

Ethical aspects

The research was initiated by the study group. The patients were not contacted for the study purpose and they cannot be identified. According to the official instructions by the Ethical Board of Northern Finland Hospital District (Oulu, Finland), Ethical Board evaluation was not performed for the registry-based study. However, institutional approval was achieved in advance, in accordance with the protocol.

Results

Outcome variables

The rate of nonunion, delayed union and refracture

Seven (9.9%) patents suffered from disturbed bone healing. Two (2.8%) out of 71 fractures failed to unite and reoperation was

Table 2

The differences of proportions of inappropriately achieved metal frame construct after elastic stable intramedullary nailing (ESIN) and fracture and patient related factors, as compared with the postoperative change of alignment. More than 5° of change in alignment in any radiographs during the follow-up visits was recognized.

A Metal frame construct that was determined inappropriate	>5° change in alignment (N=24)	No change in alignment (N=43)	Difference of proportions, their 95% of CI and P-value
>10 mm residual displacement	0	0	NA
Length of the IOM <10% of total length of radius	8 (33%)	4 (9.3%)	24% (4.6%-46%) P= 0.012
>10 mm of the implant left on the bone surface	13 (54%)	21 (49%)	5.3% (-19%- 29%) P=0.624
Opposite concavities not achieved	18 (75%)	30 (70%)	5.2% (18%-26%) P=0.591
Curve of the nails not placed at the fracture line	11 (46%)	14 (33%)	13% (-11%-37%) P=0.213
<40% of MCD	2 (8.3%)	1 (2.4%)	6.0% (-50%-24%) P=0.166
>70% of MCD	5 (21%)	11 (26%)	4.7% (-24%-18%) P=0.577
Different thickness of the implants	3 (13%)	6 (14%)	1.5% (-18%-19%) P>0.99
Tapping of the nails too long to growth plate	0	0	NA
Too short tapping of the nail (<40 mm) beyond the fracture line	2 (8%)	0	8.3% (-0.4%-26%) P=0.062
Limited cutting of a nail, resulting in that >10 mm of it is left on the bone surface	13 (54%)	21 (49%)	5.4% (-19%-29%) P=0.624
Open reduction needed	8 (33%)	18 (42%)	8.5% (-31%-16%) P=0.451
B Fracture and patient related risk-factors			
Distal third shaft fracture	9 (38%)	7 (16%)	21% (2% 44%) P=0.049
Open fracture	2 (8%)	7 (16%)	7.9% (-24%-12%) P=0.307
Comminuted fracture	4 (17%)	12 (28)	11% (-30%-11%) P=0.259

*P-value measured by the standardized normal deviate (SND)

CI: confidence interval.

Medullary Canal Diameter

needed. Five more cases with delayed (>3 months) bone healing were found but they all ossified upon six months without any intervention. Two (2.8%) patients suffered from a second fracture, which occurred over 2 years after the initial injury and were not counted. In one case the nails had been removed and the other occurred with the nails in situ.

The rate of changing alignment postoperatively

As the secondary outcome, we found that alignment changed > 5° in one of three of the patients (N=24, 36%) during the out-of-hospital follow-up, despite the ESIN.

Twelve patients had a slight (5° 10°) change. One case showed greater (10° 15°) change and one patient had a change >15°. The alignment was measured of 67 out of 71 patients (94%), who had proper follow-up radiographs. The mean change in the alignment of the radius was 2.5° (0° 15°, SD 2.6°) and 4.9° in the ulna (0° 22°, SD 4.6°) at the follow-up.

Explanatory factors

Inferior reduction and metal frame construct

Immediate postoperative displacement was mean 1.8 mm (range 0 9 mm, SD 1.9 mm) in the radius and 1.4 mm in the ulna (range 0

6 mm, SD 1.7 mm). The mean lateral angulation of the radius (radial bowing) was 7.6° (range 5° – 13° , SD 2.4°) and dorsal angulation of the ulna was 1.8° (range 1° – 2° , SD 0.4°). Postoperative alignment was not anatomic in 50 (71%) patients, while the normal lateral curve of the radius (5° – 15°) was not reached (**Table 1, Fig. 2**). Appropriately opposing concavities of the two nails were not achieved in 79% (N=56) of the cases. The maximal pre-bent curve of the nail was placed at the fracture site in half of the cases (radius N=44, 62%, and ulna N=40, 56%). Altogether, four (5.6%) patients had > 1.0 mm of gap in the fracture line, three of which were treated using thick (> 0.7 MCD) nails ($p=0.071$). The length of IOM was 10% of the total length of the radius in almost all (N=59, 83%) patients. The majority (N=66, 93%) of the fractures were stabilized with two implants and five (7%) with one nail, which was taken an inappropriate technique. All implants were of titanium alloy (*Styntes DePuy Ltd*, TEN or *Stryker Ltd*, T2Kids), except one stainless steel nail (*Stryker Ltd*, T2Kids). In the radius bones, the mean nail to medullary canal thickness was 0.61 (range 0.33–0.95, SD 0.14) and in the ulna 0.62 (range 0.40–0.93, SD 0.13). In most (N=61, 86%) cases the nails were equal in size. The implants were introduced over the fracture line mean 95 mm (49–169 mm, SD 31 mm) in the radius and 80 mm (27–170 mm, SD 27 mm) in the ulna. No implant was tapped deep enough to reach the physis. The closest distance to physis was 27 mm. The implants were cut/tapped inappropriate leaving >10 mm outside the cortex surface in 39 (55%) radius bones (mean 11 mm, 0–26 mm, SD 6.4 mm) and in 39 (55%) ulna (mean 7.4 mm, 0–30 mm, SD 5.7 mm). Open reduction for either one or both bones was performed in 56% (N=40) of the cases. Close to all fractures (N=66, 94%) were immobilized postoperatively by above-the-elbow

Fig. 2. The illustrative radiographs of a child, who suffered from a forearm shaft fracture and was treated with ESIN. The alignment was lost in the follow-up and the interosseal distance between the radius and ulna was narrowed. The nails were not orientated against each other, while their tips are not against each other (tip-to-tip), which is against the recommendation. Further, the implants are not equal in size, which is neither suggested. The radiographs were taken six months postoperatively, showing nonunion in the ulna.

splint, in mean for 4.1 (2–8) weeks. In two (2.8%) cases, the immobilization was longer than 42 days. 51 (72%) the fractures were in the midshaft, 15 (20%) were proximal and 5 (8%) were distal third fractures. 10 (14%) were open fractures and 17 fractures were comminuted (24%).

The association of the explanatory factors with nonunion and delayed union

Seven (9%) patients had disturbed (i.e., delayed or lacking) radiographic fracture ossifying, and they all had been treated with thicker nails (> 0.7x MCD) ($p=0.021$). One in four of the patients (25%) with thicker nail presented nonunion or delayed union, compared to the 3 (4.7%) among the patients with thinner nails (Difference 19.2%, 95% CI 17.4%–44.6%, $P=0.027$). There was a 5.4-fold risk (CI 95%; 1.1–27.6, $p=0.041$) for delayed bone healing in the case of thick nails (ND/MCD > 70%). Open reduction was associated with increased risk of ulna nonunion (OR 9.7; 1.1–89, $p=0.043$), but such a risk was not found for the radius (OR 0.2; 0.02–2.9, $p=0.271$). One in four of the patients (24%) with open reduction (ulna) suffered nonunion or delayed union compared to 2.3% among the patients with closed reduction (Diff. 20.0%, 95% CI 6.1%–39.0%, $P=0.02$). However, greater primary displacement (mean 7.7 mm, SD 4.8 mm) was found among the cases with open reduction, compared with 4.1 mm (SD 4.8 mm) with close reduction ($p=0.003$). Other potential explanatory factors of ESIN metal frame construct didn't associate with nonunion or delayed union. Further, there was no difference in the age of the patients (0–10 years vs. >10 years) in impaired vs. normal bone healing; three out of seven patients (42.9%) with disturbed healing were >10 years of age and four (57.1%) were younger ($P=0.973$) (Tables 3 and 4).

The association of the explanatory factors with changing alignment

Distal-third shaft fractures were associated with a 4-fold risk for > 5° changing alignment (OR 4.2; 1.1–14, $p=0.027$) compared to mid- and proximal third fractures. Two of three (66.7%) of distal third fractures changed alignment, compared to one in three (32.5%) among proximal or midshaft fractures (Diff. 34.5%, 95% CI 44.9%–57.8%, $P=0.019$). Other explanatory factors didn't associate with changing alignment. Three out of 8 (37.5%) patients with > 5° changing alignment were more than 10 years old, while 62.5% (N=5) of them were younger ($P=0.824$) (Tables 3 and 4).

Discussion

The purpose of this research was to analyze the bone healing of forearm shaft fractures, treated with ESIN, and technical characteristics of the achieved metal frame construct. We also aimed to analyze, which characteristics of the ESIN metal frame may be associated with impaired bone ossifying, re-fracture or changing alignment. These study purposes were based on the preconception that the surgical technique of ESIN is not always as good as recommended, which may explain the inferior outcomes [7]. As the main outcome, we found that nonunion and delayed union concerned seven (9.9%) cases. The ulna was involved in six cases and the radius in one. As another main outcome, we found that impaired fracture healing was more common in patients to whom thicker nails (> 70% of the medullary canal) were used. Furthermore, we found that all cases with impaired fracture healing were primarily treated by means of open reduction. Distal-third location of the fracture was associated with greater risk for changing alignment, compared with mid- or proximal shaft fractures.

The high rate of impaired fracture healing in this study (9.9%) is in accordance with the previous literature, as the vascular supply

Table 3

The differences of proportions of inappropriately achieved metal frame construct after elastic stable intramedullary nailing (ESIN) and fracture and patient related factors, as compared with impaired fracture ossifying. No bridging bone formation in 3 and 6 months were taken delayed union and nonunion, respectively.

Inappropriately achieved metal frame construct	Delayed union N = 7	Normal bone healing N = 64	P-value* (95% CI)
>10 mm residual displacement	0	0	NA
Length of the IOM <10% of total length of radius	0	12 (19%)	19% (-31%-17%) P=0.341
<40% of MCD	0	3 (4.7%)	4.7% (-13%-32%) P>0.99
>70% of MCD	4 (57%)	12 (19%)	38% (4%-68%) P=0.023
Different thickness of the implants	2 (29%)	10 (16%)	13% (-11%-50%) P=0.213
>10 mm left on the bone surface	5 (71%)	32 (50%)	21% (-21%-43%) P=0.289
Opposite concavities not achieved	6 (86%)	44 (69%)	17% (-46%-19%) P=0.425
Curve of the nails not placed at the fracture line	4 (57%)	23 (36%)	21% (-14%-51%) P=0.258
Tapping of the nails too long to growth plate	0	0	NA
Too short tapping of the nail (<40 mm) beyond the fracture line	1 (14%)	1 (1.6%)	13% (0.1%-50%) P=0.099
Limited cutting of a nail, resulting in that >10 mm of it is left on the bone surface	4 (57%)	32 (50%)	7.1% (-28%-38%) P>0.99
<28 days of postoperative casting	5 (71%)	47 (73%)	2.0% (-39%-26%) P>0.99
Open reduction needed	6 (86%)	34 (53%)	33% (9%-70%) P=0.048
B Fracture and patient related risk-factors			
Midshaft vs. proximal vs. distal third	3 (43%)	18 (28%)	15% (-16%-48%) P=0.26
Open fracture	2 (29%)	8 (13%)	16% (-07%-53%) P=0.150
Comminuted fracture	2 (29%)	15 (23%)	5% (-19%-42%) P=0.436

P-value measured by the standardized normal deviate (SND)

CI: confidence interval.

Medullary Canal Diameter

Table 4

The effect of inappropriately achieved metal frame construct of elastic stable intramedullary nailing (ESIN) on nonunion or delayed union and changing alignment. No bridging bone formation in 3 and 6 months were taken delayed union and nonunion, respectively. More than 5° of change in alignment in any radiographs during the follow-up visits was recognized.

A Metal frame construct that was determined inappropriate	Non-union/delayed union	Unstable osteosynthesis, change > 5°
	OR*(95% CI*)	P-value
>10 mm residual displacement	0	NA
Lateral curve of the radius <5° or >15° not reached	2.7 (0.6-13.4)	0.215
Length of the IOM <10% of total length of radius	0.0 (NA)	>0.99
<40% of MCD	0.0 (NA)	>0.99
>70% of MCD	5.4 (1.1 27.6)	0.041
Different thickness of the implants	2.2 (0.4 12.7)	0.395
Opposite concavities not achieved	1.6 (0.18 14.9)	0.662
Curve of the nails not placed at the fracture line	2.3 (0.48 11.2)	0.298
Tapping of the nails too long to growth plate	0	NA
Too short tapping of the nail (<40 mm) beyond the fracture line	12 (0.65 222)	0.095
Limited cutting of a nail, resulting in that >10 mm of it is left on the bone surface	2.1 (0.4 11.8)	0.394
<28 days of postoperative casting	0.4 (0.06 2.75)	0.362
Open reduction needed	9.7 (1.1 8.9)	0.043
B Fracture and patient related risk-factors		
Midshaft vs. proximal vs. distal third	2.4 (0.48 12.1)	0.285
Open fracture	2.9 (0.47 17.2)	0.254
Comminuted fracture	1.3 (0.22 7.14)	0.799

OR: odds ratio

analyzed by using binary logistic regression analysis

CI: confidence interval

Medullary Canal Diameter

70%) were not associated with nonunion, delayed union or changing alignment during the postoperative follow-up and thus seemed to be feasible in forearm shaft fracture. Very thin nails (<30% of MCD) have been shown to associate with delayed bone healing [13] but we were not able to confirm this, because such thin nails were not used in this population.

There is an agreement in the literature that the risk of impaired bone healing is increased by open fractures and open reduction, compared with close fractures and closed reduction, respectively [22,26,28]. In this study, all cases with lacking or delayed radi-

in the midshaft of ulna is poor and forearm shaft fractures are known to be vulnerable for complications; the previously reported non-union rate is 4–7% [13,26–27]. The association between impaired fracture healing and thicker nails (>70% of the medullary canal), which was one of our main findings, was also understandable. Such implants may distract the fracture and cause a gap in the fracture line when they are tapped beyond the fracture [28]. In the present study, four patients had > 1.0 mm of gap in the fracture line and three of them were treated using thick (> 0.7 MCD) nails. We conclude that too thick nails should be avoided, to prevent from diastasis at the fracture line. Actually, thinner nails with approximately 0.4-fold diameter compared to the intramedullary canal have been suggested in the literature [9,13]. In this study such thinner nails (ND/MCD 40%)

ographic bone healing were primarily treated by means of open reduction. Three of them had suffered from open fracture. Open reduction may disturb the periosteal blood supply, which interferes with callus formation and bone stabilization [26,29]. The finding warrants gentle approach when dissecting the tissues in the forearm area. Nevertheless, there were in total 40 patients in this population-based study, to whom open reduction was performed and not all but a minority ($N=7$, 18%) of them suffered from delayed or lacking union. Closer research of the effect of open reduction on impaired bone healing is thus needed. Furthermore, there is no doubt that fractures requiring open reduction are more severe *per se* [30], with deprived bone healing, while trauma energy has been great enough for larger soft tissue damage [31]. Also in this study initial displacement was slightly higher in the patients who were treated in means of open reduction. Surprisingly, we found that nail pre-bending, the site of the maximal bow, or inappropriate orientation, including even lacking concavity configuration of the nails, were all not associated with impaired bone healing.

Changing alignment of operatively fixed forearm fractures was taken as the secondary outcome in this study [32,33]. ESIN is literally elastic method and it is not intended to be a rigid osteosynthesis. Consequently, angular reduction changed in all operatively treated cases in this study population. Taking all eligible postoperative radiographs into account, and evaluating both AP and lateral projections, altogether 36% of the cases ($N=24$) showed increased malalignment $>5^\circ$. The 5° cut-point of worsening alignment was chosen to evaluate the satisfactory stability of the osteosynthesis method, but we are aware that the clinically important malalignment in these fractures is rather $>10^\circ$ than $>5^\circ$ [9,34,35]. Higher $>10^\circ$ of change in alignment was seen in two patients and only one patient was re-operated for malalignment. The implants were of two different sizes in that case (Fig. 2). Altogether four patients out of 24 (17%) with changing postoperative alignment had not been treated with equal-sized implants. This is absolutely not recommended [13]. Even though the equal-sized implants were not statistically significantly better in bone healing or keeping alignment in this study, we do not recommend using asymmetric nails [34]. Lascombes *et al.* have described that [9] appropriate configuration of two paired nails, one in the radius and one in the ulna, are crucial in creating metal frame and tension in the interosseous membrane (IOM). This, in particular, is the sophisticated theory of IOM tension that justifies the use of only single flexible nail in each forearm bone. A satisfactory stability is still achieved. Principally, the missing normal lateral curve in the radius is a problem, because the curve is crucial for forearm motions. Narrowing and scarring of the interosseous membrane (IOM) may also limit rotation movement [32,33]. The radius curve is restored about 1° per year by remodeling in immature bones [23]. However, the metallic implants *in situ* may hinder this spontaneous remodeling, and for that reason it is important that the radial lateral curve will be restored in the operation, by using pre-bended and medially curving nail in the radius.

We also found that distal-third location of the fracture was associated with greater risk for changing alignment, compared with mid- or proximal shaft fractures. This is in accordance with the current literature [34]: In particular, the distal metaphyseal-diaphyseal junction zone is vulnerable for radial malalignment and should not be treated by ESIN at all. External cast immobilization was an additional treatment in 94% of the study patients, according to the practice in the study institution. It remains unclear if the fractures would have been stable enough without postoperative casting, because the lack of prospective comparative aspect in this research. We understand that the current practice in many pediatric trauma units is to avoid us-

ing postoperative external immobilization, which has reported to be a good option [7]. However, there is no consensus about the postoperative immobilization. Immobilization is still the recommended practice in many handbooks of pediatric orthopaedics.

This study is a subject to some criticism. This was a retrospective study, lacking randomization of the patients to particular technical characteristics. However, the purpose was to analyze the effects of limited metal frame construct on bone healing. A randomized, comparative trial to perform inferior treatment that is against the current literature was excluded from the repertoire. The study was observational study that could be performed to analyze the limited fixation technique. In addition, all children patients who were operatively treated by using ESIN were included, despite the age of the patient at the time of trauma. This is a weakness, because both the fractures and the treatment options differ according to the age: younger children may tolerate higher residual angular deformity, due to greater potential of spontaneous remodeling, compared with older children [10,23]. Adolescents with mature skeleton would be treated by rigid fixation, similar to adult patients [11,23]. However, impaired bone healing and changing alignment didn't differ among the patient <10 years vs. >10 years of age. In addition, no systematically collected data regarding the functional outcomes or patient satisfaction were available of all patients [35]; nevertheless, the purpose of this study was to analyze the fracture nonunion, delayed union, refracture and changing alignment, which all are radiographic findings. That information was inclusively available of all in this study population and the findings are generalizable. According to institutional practice, the follow-up was short, therefore, bone remodeling that is time-consuming process could not be evaluated in this study [36,37]. Regarding the statistical analyses, there may have been confounding factors, while open fracture, open reduction and other potential risk factors may have mutual associations. However, additional multivariate analysis was performed, but the subgroups were small.

As strength, this was a population-based study, including all consecutive patients with operatively (ESIN) treated forearm shaft fractures in the geographically defined recruitment area. Radiographs of the primary injury were available of all cases, and fulfillment of the inclusion criteria was confirmed by reviewing all images. In particular, metaphyseal or meta-diaphyseal fractures, for which ESIN is not indicated, were excluded from the analysis. A satisfactory number of cases was achieved. They all presented diaphyseal both-bone fracture of the forearm and the findings are certain and thus generalizable. Radiographically impaired bone union (nonunion or delayed union) was considered the primary outcome, and it was clearly determined by using a validated scoring [37]. Malangulation $>5^\circ$ during the follow-up was taken as a sign of instability because full rigidity is not required for ESIN and slight angular deformity may not affect the range of motion or patient satisfaction [35,38]. However, prospective clinical research is needed in the future to evaluate the potential association of inferior quality of the metal frame build with clinical recovery, particularly on range of motions. Additional analyses in a larger population should be performed regarding the patients' age and the association between poor surgical technique and poor bone healing. A greater study cohort would also aid in analyzing the details of technical issues of ESIN on bone ossifying.

Conclusion

There were limitations in achieved metal frame construct of ESIN in the majority of the patients, treated for forearm shaft fractures. Open reduction, thicker nails and distal third location of forearm shaft fractures associated with impaired radiographic bone heal-

ing. However, bone union was still good in the majority. We conclude that the fundamental theory of tension metal frame may not be essential for adequate ossifying of forearm shaft fractures. In clinical point of view, ESIN is a procedure that shows good bone healing, even if the correct technical metal frame had not been achieved.

Declaration of Competing Interest

None.

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