Direct comparison of elastic stable intramedullary nailing and external fixation for managing diaphyseal femoral fractures in children: a retrospective analysis

Norbert Thomas , Ulrike Wittig , Thomas Boehm , Maximilian Burtscher , Harald Binder , Micha Komjati , Stephan Payr , Kambiz Sarahrudi , Thomas Manfred Tiefenboeck *

Posted Date: 28 September 2023

doi: 10.20944/preprints202309.1946.v1

Keywords: children; diaphyseal femur fractures; external fixation; ESIN; outcome

Article

Direct Comparison of Elastic Stable Intramedullary Nailing and External Fixation for Managing Diaphyseal Femoral Fractures in Children: A Retrospective Analysis

Norbert Thomas [#,+], Ulrike Wittig [#], Thomas Boehm [°], Maximilian Burtscher [#], Harald Binder [°], Micha Komjati [$], Stephan Payr [°], Kambiz Sarahrudi [#,°] and Thomas M. Tiefenboeck [°,*]

° Department of Orthopedics and Trauma Surgery, Division of Trauma Surgery, Medical University of Vienna, Vienna, Austria
Department of Trauma Surgery, Landesklinikum Wiener Neustadt, Lower Austria, Austria
+ Department of Orthopedics, Otto-Wagner-Hospital, Vienna, Austria
$ I. Department of Orthopedics, Sacred Heart Hospital of Jesus, Vienna, Austria
* Correspondence: Thomas M. Tiefenboeck, MD, Medical University Vienna, Department of Trauma Surgery, Waehringerguertel 18-20, 1090 Vienna, Tel: +43 1 40400 56190, Email; thomas.tiefenboeck@meduniwien.ac.at

Investigation performed at the Department of Trauma Surgery, Medical University of Vienna, Vienna General Hospital, Vienna, Austria and the Department of Trauma Surgery, LKH Wr. Neustadt, Lower Austria, Austria

Abstract: Intramedullary fixation with elastic stable intramedullary nailing and stabilization with an external fixator are standard methods for the treatment of diaphyseal femoral shaft fractures in children. A retrospective bi-centre cohort study was carried out, including all patients between the ages of 2 and 16 years with isolated traumatic diaphyseal femur fractures, treated either with intramedullary nailing or an external fixator. In total, 57 patients (17 female and 40 male) with a mean age of 6.5 ± 2.7 years (min. 2; max. 16 years) with a mean follow-up period of 6.1 ± 4.6 months (min. 2; max. 26 months), were included in this retrospective study. 33 patients were treated with elastic stable intramedullary nailing and 24 patients, and external fixation. In total, 18 patients (32%) experienced osteosynthesis-related complications: 8 patients (24%) in the elastic stable intramedullary nailing group and 10 (42%) in the external fixation group, leading to revision surgery in 10 patients (18%). At the latest follow-up, all fractures were radiologically healed with no evidence of malangulation or malrotation (defined as >20°) and full weight-bearing. There was a lower rate of complications in the ESIN group than in the external fixation group. Overall, we were unable to show a significant difference between the two methods.

Keywords: children; diaphyseal femur fractures; external fixation; ESIN; outcome

Introduction

Femoral shaft fractures in pediatric patients account for 1-2 % of all fractures. [1] These fractures have been managed both operatively and conservatively, whereby in patients aged 3 years or older they are mostly treated operatively.

Owing to the development of less invasive techniques in trauma and orthopedic surgery, there has been an increase in the operative treatment of these fractures. [2] Over the years, different surgical methods have been described for this fracture type; however, the technique that yields the best results is still under debate. [1] These methods include intramedullary nailing, plating, internal fixation and external fixation, with each technique having its own limitations. [3-9]

In the last few years, elastic stable intramedullary nails (ESIN) have become popular because of their less invasive application, good clinical and functional results, and low complication rates. [4,

 doi:10.20944/preprints202309.1946.v1

10-14] However, the external fixator is considered an appropriate treatment and is frequently performed in this fracture type as a little invasive technique. [5]

The choice of treatment depends on the fracture length stability. Length stable diaphyseal femur fractures in children older than 3 years should be treated with ESIN and length unstable fractures, and all displaced fractures in polytraumatized pediatric patients should be stabilized using external fixation. [15, 16]

In literature, hardly any studies directly compare ESIN with external fixation in the treatment of pediatric diaphyseal femur fractures. Therefore, the purpose of this study was to compare both treatment methods for this fracture type, focusing on the rate of complications and reoperations, as well as the clinical and radiological outcomes during the follow-up process.

We hypothesized that lower complication and revision surgery rates can be achieved by using intramedullary devices for the treatment of length stable femoral shaft fractures and by using external fixation for length unstable femoral shaft fractures in pediatric patients.

Methods

This retrospective cohort study was performed in two level I trauma centers. After approval by the institutional ethics committee, a retrospective analysis of the collected data of those blinded to the review was conducted (EK Nr:2036/2018, Borschkegasse 8b E06, 1080, Vienna, Austria).

All included patients were (1) aged between 2 and 16 years, (2) sustained a traumatic diaphyseal femur fracture, (3) treated with either ESIN or an external fixator, and (4) operated between January 2002 and December 2016 (15 years).

Patients were excluded if they (1) were under the age of 2 and over the age of 16, (2) had pathological fractures, (3) had polytrauma, (4) had undergone treatment other than ESIN or external fixation, and (5) underwent surgery prior to January 2002 or after December 2016. All included fractures were classified according to the AO classification of pediatric long bone fractures [17] and were divided into length stable and unstable fractures. The outcomes were assessed by trauma surgeons at every follow-up appointment. The standard follow-up protocol for these patients foresees weekly clinical follow-up after the surgical procedure until wound healing, with routine radiography in two planes. The external fixation group was routinely observed once weekly until the removal of the external fixator. At least one visit prior to removal of the implant was needed in all patients, where radiological bone healing was assessed. Radiological bone healing was defined by cortical healing with bridging callus in three of four cortices and was deemed absolutely necessary before implant removal. Complications that occurred intraoperatively (cortical perforation by a nail, instability of the osteosynthesis) and postoperatively (soft tissue irritation, malangulation or malrotation >20°, refractures) leading to revision surgery (shortening of the ESIN, axis correction, re-osteosynthesis, etc.) were documented.

Data Analysis

Descriptive data (mean, median, range, and proportions) are reported for the entire patient cohort. Statistical analysis focused on the occurrence of complications, reoperations, clinical and radiological outcome. Therapeutic- (surgery and function) and demographic variables (sex, age, and follow-up) were examined.

A normal distribution of data was assumed, which was tested using the Shapiro-Wilk test and Kolmogorov-Smirnov test. Homoscedasticity was evaluated using the Levene's test. To determine significant differences in normally distributed data, Student's t-test was performed. In case of non-normal distribution of metric data, the Mann-Whitney-Test was performed. Testing of nominal data was performed using the Chi-Squared-Test with Cochran–Mantel–Haenszel statistics. Statistical significance was set at $p < 0.05$. The problem of multiple testing was handled using the Bonferroni-Holm correction. All calculations were performed using Microsoft Excel® and SPSS® software (version 21.0, SPSS Inc., Chicago, IL, USA).

Results

 doi:10.20944/preprints202309.1946.v1

In total, 57 patients (33 ESIN and 24 external fixation) with a mean follow-up period of 6.1 ± 4.6 months were included. In the ESIN group, the mean patient age was 6.6 ± 2.7 years and the mean follow-up period was 6,6 ± 4,6 months, whereas in the external fixation group the mean age was 6.5 ± 2.8 years and the mean follow-up period was 5.4 ± 3.5 months. The ESIN group included 9 girls and 24 boys, compared to the external fixation group, which included 8 girls and 16 boys.

In 23 out of 57 (41%) patients, the leading injury pattern was a fall from a height <1m, in 7 out of 57 (12%) a fall between 1-3m and in 4 out of 57 (7%) a fall from a height >3m. In 15 of 57 patients (26%), a sports injury led to the fracture. In 5 of 57 patients (9%), blunt force trauma caused the fracture, and in 3 of 57 (5%), a road traffic accident was recorded.

The AO classification of fracture types with their corresponding treatments (ESIN or external fixation) are shown in Table 1.

Table 1. AO classified fracture types with their corresponding treatment (ESIN or external fixator).

Fracture Type according to AO classification of long bone pediatric fractures	**Length stability**	**ESIN**	**External fixator**
32-D/4.1	stable	8 (24%)	5 (21%)
32-D/5.1	unstable	18 (55%)	17 (71%)
32-D/4.2	stable	2 (6%)	0 (0%)
32-D/5.2	unstable	5 (15%)	2 (8%)
		33 (100%)	**24 (100%)**

Length stable fractures (∑=16) were treated twice as often with ESIN (11/16, 69%) than with external fixation (5/16, 31%). Unstable fractures (∑=41) were treated with ESIN (22/41, 54%) and external fixation (19/41, 46%) in almost equal proportions.

Patients treated with external fixation (4.0 ±1.9 weeks) returned significantly earlier to full weight-bearing than patients with ESIN (5.3 ±1.9 weeks) (p=0.045). Patients treated with ESIN showed a three-day shorter hospital stay after primary surgery compared to the external fixation group. Implant removal in the external fixation group was performed twice as early as that in the ESIN group. The time to primary surgery was only slightly shorter in the ESIN group compared to the external fixation group. (Table 2).

Table 2. Comparison of operative and clinical outcome parameters.

	ESIN (n=33)	**External fixator (n=24)**	**p-value**
Time of primary surgery (minutes)	47.2 ± 32.5 (39; 15 to 195)	57.3 ± 31.0 (48; 19 to 165)	-
Hospital stay after primary surgery (days)	5.5 ± 3.5 (5; 2 to 17)	8.8 ± 3.0 (8; 4 to 18)	-

Time until full weight bearing (weeks)	5.3 ± 1.9 (5; 1 to 8)	4.0 ± 1.9 (4; 1 to 9)	**0.045***
Time until implant removal (months)	4.7 ± 1.5 (4; 2 to 10)	2.3 ± 0.6 (2; 1 to 3)	-
Last follow-up (months)	6.6 ± 4.9 (5; 3 to 26)	5.4 ± 4.1 (4; 2 to 15)	-

n = number; * = significant; - = not tested.

Complications:

In total, 18 patients (32%) presented with 20 osteosynthesis-related complications, leading to revision surgery in 10 patients (18%). In the ESIN group, eight patients (24%) experienced nine osteosynthesis-related complications, and three (9%) required revision surgery. In contrast, after external fixation, 10 patients (42%) with 11 osteosynthesis-related complications were documented, leading to revision surgery in seven patients (29%).

In each group, one patient with a length unstable fracture experienced two independent osteosynthesis-related complications. Furthermore, after subdividing these results according to the length stability of the fracture, the following results were found: In the ESIN group with length stable fractures, 1 out of 11 patients (9%) had an osteosynthesis-related complication but no revision surgery (0/11). In the ESIN group with unstable fractures, 7 of 22 patients (32%) had osteosynthesis-related complications leading to revision surgery in 3 of 22 patients (14%). In the external fixation group with stable fractures, three of five patients (60%) showed an osteosynthesis-related complication leading to revision surgery in two of five patients (40%). The external fixation group with length unstable fractures had an osteosynthesis-related complication rate of seven out of 19 patients (37%), leading to revision surgery in five out of 19 patients (26%).

Three complications and two indications for revision surgery (two complications causing two revision operations after ESIN-treated length stable fractures, one complication after external fixation on a length unstable fracture) were unrelated to osteosynthesis and therefore excluded (complications: one traumatic re-fracture ~2 years after primary surgery, one superficial wound infection after suture removal, and one postoperative fever and anemia requiring a blood transfusion. Revision surgeries:1 re-osteosynthesis [due to a traumatic refracture] and 1 abscess incision and drainage [due to superficial wound infection]).

All other complications and indications for revision surgery were osteosynthesis-related, and are listed in Tables 3 and 4. Overall, five of the six soft tissue irritations, caused by distal migration of the ESIN implant, occurred in the group with length unstable fractures. Furthermore, all three cortical perforations of the ESINs occurred in the group with length unstable fractures. Both refractures after external fixation were observed in the group with length stable fractures. However, no non-union was observed in either group. Overall, there was no significant difference between the osteosynthesis-related complication rates and revision surgery rates of length-stable and unstable fractures treated with ESIN or external fixation (complication rates, p=0.312; revision surgery rates, p=0.259 using Mantel-Haenszel statistics). (Tables 3 and 4)

Table 3. Comparison of osteosynthesis-related complications between ESIN and external fixation and between length stable and unstable fractures.

Osteosynthesis-related complications	**ESIN**	**External fixation**
Number (n, %)	**8 (24%)**	**10 (42%)**

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 28 September 2023 doi:10.20944/preprints202309.1946.v1

Number depending on the length stability (n, %) [p= 0,312 (Mantel-Haenszel)]	length stable **1**/11=**9%**	length unstable **7**/ 22 = **32%**	length stable **3**/5 = **60%**	length unstable **7**/ 19 = **37%**
Listing: (Annotation: one patient in each group with a length unstable fracture experienced 2 independent complications)	• 6x soft tissue irritation • 3x corticalis perforation		• 4x axis deviation >10° • 3x fixation loosening • 2x refracture • 1x pin infection • 1x persisting pain	

Table 4. Comparison of osteosynthesis-related revision surgery between ESIN and external fixation and between length stable and length unstable fractures.

Osteosynthesis-related revision surgeries	**ESIN**		**External fixation**	
Number (n, %)	**3** (9%)		**7** (29%)	
Number depending on the length stability (n, %) [p= 0.259 (Mantel-Haenszel)]	length stable **0**/11=**0%**	length unstable **3**/ 22 = **14%**	length stable **2**/5 = **40%**	length unstable **5**/ 19 = **26%**
Listing:	• 3x ESIN shortening		• 5x fixation revision • 2x re-osteosynthesis (1x ESIN, 1x plating)	

Outcome:

At the latest follow-up, all patients had reached radiologically verifiable bony union without malalignment (antecurvation <20°, no recurvation, valgus, and varus deviation <10°) or malrotation, and full weight-bearing was possible. Moreover, all patients were satisfied with the achieved results.

Discussion

One of the most important findings of this study was that no statistically significant difference regarding overall osteosynthesis-related complications and revision surgery rates between the treatment with ESIN in contrast to external fixation for pediatric diaphyseal femoral fractures was found. However, lower amounts for both osteosynthesis-related complications and revision surgery rates could be shown in the ESIN group (complication rate 24%, revision surgery rate 9%) compared to the external fixation group (complication rate 42%, revision surgery rate 29%). The main complication of ESIN was soft tissue irritation (18%), which did not occur in the external fixation group. These findings have been highlighted in previous studies. However, some of these studies

 doi:10.20944/preprints202309.1946.v1

detected statistically significant differences between the ESIN and external fixation groups regarding complications and complication rates [8, 18, 19].

Moreover, concerning the ESIN subgroup, no statistically significant difference could be found between length stable and length unstable fractures regarding osteosynthesis-related complications and revision surgery rates, although lower amounts for both rates were revealed in the length stable group (complication rate 9%, revision surgery rate 0%) compared to the length unstable group (complication rate 32%, revision surgery rate 14%). Furthermore, the previously mentioned soft tissue pin irritation remains the main cause of complications, which is in line with recent literature [11, 16, 20-22]. This is caused by the impaction at the fracture site associated with the beginning of weight bearing, which can lead to pin migration through the entry points and, therefore, lead to soft tissue irritation. This so-called "telescoping-effect" occurs particularly in unstable fractures [23]. Additionally, good results have been reported for using ESIN in comminuted and difficult diaphyseal femoral fractures [24]. In the current study, patients with length unstable fractures treated with ESIN were restricted to weight-bearing for several weeks to prevent "telescoping."

Furthermore, in the external fixation subgroup, no statistically significant difference was observed between length stable and length unstable fractures regarding osteosynthesis-related complications and revision surgery rates, although lower amounts for both rates were observed in the length unstable group (complication rate 37%, revision surgery rate 26%) than in the length stable group (complication rate 60%, revision surgery rate 40%). The differences in complication rates are underlined by the results found in previous literature, although the frequently (23%) described delay in fracture consolidation in length stable fracture types could not be observed in the current study [25].

In summary, patients treated with an external fixator could start full weight-bearing significantly earlier than patients treated with ESIN. Patients treated with ESIN had a shorter time to hospital discharge. This observation can be explained by the lack of knowledge on how to take care of the external fixator.

In the current study, no patient showed malangulation or malrotation (defined as >20°) at the latest follow-up. This is underlined by the findings of Rollo et al. [5], who reported no significant differences regarding rotation, angulation, or growth at end of follow-up in their study comparing external fixators and ESIN.

In summary, different surgical implants associated with different limitations in treating pediatric diaphyseal femoral fractures were presented. The use of an external fixator may cause pin tract infections, loosening, limitation of range of motion, and cosmetic problems. Consequently, the ideal implant should be a simple internal fixation device that allows early weight-bearing without damaging the epiphysis until the fracture is healed [4-6, 13].

Two of the main factors affecting the choice of treatment for pediatric diaphyseal femoral fractures are patient age and weight. Furthermore, the time until union was significantly longer in patients treated with external fixators than in those treated with elastic nailing [3]. The current study showed no significant differences regarding age or time until union regardless of the method used.

This study has several limitations. First, it is limited by its retrospective design and the lack of long-term results that do not allow the observation of eventual growth discrepancies. Moreover, our results showed a trend towards a lower rate of complications in the ESIN group, although we were not able to record a significant difference between the two methods and therefore reach a definitive decision concerning the superiority of one method over the other. This is due to the low number of patients included in this study. Therefore, future multi-center studies with a larger patient cohort are needed to prove the superiority of one of the described methods over the other.

Conclusion

Both of the treatment options lead to excellent function and fracture restoration at latest follow up. At the latest follow-up, all fractures were radiologically healed with no evidence of malangulation or malrotation (defined as >20°) and full weight-bearing. The rate of complications was lower in the

ESIN group (24%) than in the external fixation group (42%). Overall, we were unable to show a significant difference between the two methods.

Funding: There was no funding regarding this manuscript.

Acknowledgments: Not applicable

Competing interests: The authors declare that they have no competing interests

Declarations: Ethics approval and consent to participate: Ethics approval was obtained prior to study start. The corresponding ethic review board of the Medical University of Vienna approved the study.

Consent for publication: All included patients in this study gave informed consent.

Availability of data and material: The datasets generated and/or analysed during the current study are not publicly available due to data privacy but are available from the corresponding author on reasonable request.

Disclosure:

According to the definition given by the International Committee of Medical Journal Editors (ICMJE), the authors listed above qualify for authorship based on making one or more of the substantial contributions to the intellectual content of: (i) Conception and design [TT, NT, TB, UW, MB, HB, MK, SP, KS]; and/or, (ii) Analysis and interpretation of data [TT, NT, TB, UW, MB, HB, KS]; and/or (iii) Participated in drafting of the manuscript [TT, NT, UW, MK, SP, KS]; and/or (iv) Critical revision of the manuscript for important intellectual content [TT, NT, TB, UW, MB, HB, MK, SP, KS]

Reference

1. Mohamed, A. and A.S. Rajeev, *Clinical outcomes and complications of titanium versus stainless steel elastic nail in management of paediatric femoral fractures-a systematic review.* Eur J Orthop Surg Traumatol, 2017. **27**(2): p. 157-167.
2. Hubbard, E.W. and A.I. Riccio, *Pediatric Orthopedic Trauma: An Evidence-Based Approach.* Orthop Clin North Am, 2018. **49**(2): p. 195-210.
3. Ramseier, L.E., et al., *Femoral fractures in adolescents: a comparison of four methods of fixation.* J Bone Joint Surg Am, 2010. **92**(5): p. 1122-9.
4. Busch, M.T., et al., *A Quartet of Elastic Stable Intramedullary Nails for More Challenging Pediatric Femur Fractures.* J Pediatr Orthop, 2019. **39**(1): p. e12-e17.
5. Rollo, G., et al., *TEN versus external fixator in the management of pediatric diaphyseal femoral fractures: evaluation of the outcomes.* Eur J Orthop Surg Traumatol, 2018. **28**(7): p. 1421-1428.
6. Andreacchio, A., et al., *Comparison between external fixation and elastic stable intramedullary nailing for the treatment of femoral shaft fractures in children younger than 8 years of age.* J Pediatr Orthop B, 2016. **25**(5): p. 471-7.
7. Moroz, L.A., et al., *Titanium elastic nailing of fractures of the femur in children. Predictors of complications and poor outcome.* J Bone Joint Surg Br, 2006. **88**(10): p. 1361-6.
8. Stans, A.A., R.T. Morrissy, and S.E. Renwick, *Femoral shaft fracture treatment in patients age 6 to 16 years.* J Pediatr Orthop, 1999. **19**(2): p. 222-8.
9. Roaten, J.D., et al., *Pediatric Femoral Shaft Fractures: A Multicenter Review of the AAOS Clinical Practice Guidelines Before and After 2009.* J Pediatr Orthop, 2019. **39**(8): p. 394-399.
10. Nielsen, E., et al., *The effects of body mass index on treatment of paediatric femur fractures managed with flexible intramedullary nails.* J Child Orthop, 2017. **11**(5): p. 393-397.
11. Khazzam, M., et al., *Use of flexible intramedullary nail fixation in treating femur fractures in children.* Am J Orthop (Belle Mead NJ), 2009. **38**(3): p. E49-55.
12. Kapil Mani, K.C., R.C. Dirgha Raj, and A. Parimal, *ediatric femoral shaft fractures treated by flexible intramedullary nailing.* Chin J Traumatol, 2015. **18**(5): p. 284-7.
13. Frei, B., et al., *Elastic stabile intramedullary nailing (ESIN) of diaphyseal femur fractures in children and adolescents: A strobe-compliant study.* Medicine (Baltimore), 2019. **98**(14): p. e15085.
14. Kawalkar, A. and C.M. Badole, *Percutaneous titanium elastic nail for femoral shaft fracture in patient between 5 and 15 years.* J Orthop, 2018. **15**(2): p. 695-700.
15. Laer L, K.R., Linhart WE, *Frakturen und Luxationen im Wachstumsalter*. 6 ed. 2013.
16. Sink, E.L., J. Gralla, and M. Repine, *Complications of pediatric femur fractures treated with titanium elastic nails: a comparison of fracture types.* J Pediatr Orthop, 2005. **25**(5): p. 577-80.

17. Slongo, T.F., L. Audige, and A.O.P.C. Group, *Fracture and dislocation classification compendium for children: the AO pediatric comprehensive classification of long bone fractures (PCCF).* J Orthop Trauma, 2007. **21**(10 Suppl): p. S135-60.
18. Guo, Y.C., et al., *A meta-analysis of flexible intramedullary nailing versus external fixation for pediatric femoral shaft fractures.* J Pediatr Orthop B, 2016. **25**(5): p. 466-70.
19. Chen, X., et al., *Treatment of pediatric femoral shaft fractures with elastic stable intramedullary nails versus external fixation: A meta-analysis.* Orthop Traumatol Surg Res, 2020. **106**(7): p. 1305-1311.
20. Siddiqui, A.A., et al., *Titanium Elastic Nails Are a Safe and Effective Treatment for Length Unstable Pediatric Femur Fractures.* J Pediatr Orthop, 2020. **40**(7): p. e560-e565.
21. Bhuyan, B.K. and S. Mohan Singh, *Titanium elastic nailing in pediatric femoral diaphyseal fractures in the age group of 5-16 years - A short term study.* J Clin Orthop Trauma, 2014. **5**(4): p. 203-10.
22. Lascombes, P., et al., *Early complications with flexible intramedullary nailing in childhood fracture: 100 cases managed with precurved tip and shaft nails.* Orthop Traumatol Surg Res, 2012. **98**(4): p. 369-75.
23. Jubel, A., et al., *[Pitfalls and complications of elastic stable intramedullary nailing (ESIN) of femoral fractures in infancy].* Unfallchirurg, 2004. **107**(9): p. 744-9.
24. Rathjen, K.E., A.I. Riccio, and D. De La Garza, *Stainless steel flexible intramedullary fixation of unstable femoral shaft fractures in children.* J Pediatr Orthop, 2007. **27**(4): p. 432-41.
25. Weinberg, A.M., et al., *[Experience with external fixation in treatment of shaft fractures in childhood].* Unfallchirurg, 1994. **97**(3): p. 107-13.