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Testing a new method of osteosynthesis of forearm fractures in children; a prospective randomized controlled longitudinal study

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Abstract

Purpose: Displaced children's forearms fractures are commonly treated surgically with Kirschner Wires or Elastic Stable Intramedullary Nails. The osteosynthesis system "Minimally Invasive Reduction and Osteosynthesis System" might be beneficial in the treatment of these fractures due to being minimally invasive while achieving fracture stability. In this exploratory prospective randomized controlled longitudinal study, we compared Minimally Invasive Reduction and Osteosynthesis System to Kirschner Wires and Elastic Stable Intramedullary Nails osteosynthesis.
Methods: Twenty children were included consecutively to treatment with either conventional surgery (5 Kirschner Wires/5 Elastic Stable Intramedullary Nails) or Minimally Invasive Reduction and Osteosynthesis System (10). Evaluation of radiographic alignment and clinically of range of motion, pain status, grip strength, level of physical activity and scar size were compared after 3 months and after 5 years.
Results: Surgical parameters of the duration of insertion- and removal-surgery, the need for postoperative casting and scar size were significantly better for Minimally Invasive Reduction and Osteosynthesis System. All osteosynthesis systems maintained radiographically fracture alignment at three months and 5 years follow-up. Clinical status regarding pain, grip strength difference, and return to recreational activities were not significantly different. The complication rates were nonsignificant, but MIROS had moderate severe complications of refractures, while mild complications occurred when operated on with Kirschner Wires/Elastic Stable Intramedullary Nails. Our study was sufficiently powered at 3 months, but the comparisons are suggestive at 5 years.
Conclusion: In conclusion, Minimally Invasive Reduction and Osteosynthesis System is not significantly different to other surgical methods in radiological outcomes for forearm fractures in children. Minimally Invasive Reduction and Osteosynthesis System has the clinical benefit of omitting casting after surgery, obtaining reduced scar size, and shorter insertion and removal time without general anesthesia. However, moderately severe complications occurred.
Level of evidence: Level II—a prospective comparative study

Keywords: Forearm fractures, children, minimally invasive reduction osteosynthesis system, external fixation, internal nailing

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Introduction

Forearm fractures account for almost 34%–40% of all fractures in children.[1-5] Traditionally, we treat the distal and metaphyseal fractures with Kirschner Wires (KW)[6,7] and diaphyseal shaft fractures with Elastic Stable Intramedullary Nails (ESIN).[8,9] Some of the forearm fractures, as the mixed metadiaphyseal fractures, are prone to complications,[10] since neither KW's nor ESIN's are technically suited for this fracture. These forearm fractures are often treated with KW/ESIN and postoperative casting[11,12] for 4–6 weeks when operated on to increase rotational stability. This can lead to inconvenient swelling and stiffness of the wrist and elbow joints.[13-15] The "Minimally Invasive Reduction and Osteosynthesis System" (MIROS) might be able to address this particular fracture. This system supposedly combines the benefits of external fixation and intramedullary nailing with the advantages of being minimally invasive and providing adequate fracture stability, thus omitting the need for postoperative casting. The latter is achieved by combining three flexible intramedullary pins with external fixation. This allows normal mobility of the wrist and elbow after surgery. To our knowledge, only a few studies have examined MIROS for fractures. This has been applied to specific types of tibial,[16] calcaneal,[17] and humeral[18] fractures, which are difficult to treat with currently available fracture osteosynthesis systems,[16-18] but the pediatric forearm fracture has not been investigated.

In this exploratory study, we wanted to compare MIROS to KW and ESIN in a consecutive sample of children with forearm fractures. Comparing the radiographic and clinical outcomes with those of traditional KW and ESIN in a prospective, randomized design, with the hypothesis of MIROS and KW/ESIN being equally sufficient for the treatment of pediatric forearm fractures.

Materials and methods

The patients included in our study were children with displaced, dislocated, and angulated forearm fractures, where surgical treatment was indicated. Children with forearm fractures older than 24 h were excluded. Our study was a prospective randomized study design with 3 months and 5 years follow-up (FU). Before study initiation, patients were randomized in a block of 10 to either conventional surgery with KW or ESIN (pooled) or MIROS, by drawing a sealed-envelopes by a non-involved person. Patients were included consecutively from the department of orthopedic surgery after informed consent from all children and parents before surgery. In the KW/ESIN group, patients with distal forearm fractures were treated with KW, and patients with diaphyseal and metadiaphyseal fractures were treated with ESIN. A perioperative evaluation of fracture stability after surgery by the operating surgeon determined if a plaster cast was needed. Removal of osteosynthesis material was performed after 1–2 months for MIROS and KW, and 6–12 months for ESIN. We conducted clinical evaluation after the removal of osteosynthesis material and/or at 3 months and 5 years. Radiological examinations of the forearm and wrist were performed before and after surgery, at the time of removal of osteosynthesis material, and the 3 months and 5 years FU. In general, we presupposed that the unfractured, contralateral arm was normal, thus examining the differences of both clinical and radiographic evaluation of the fractured forearm by comparing it to the unfractured side when appropriate. For example, the radiographic measurements were evaluated assuming that the non-fractured forearms or wrists (depending on fracture) were normal, thus examining the difference between the fractured and contralateral forearm after surgery of either KW/ESIN and MIROS. The clinical evaluation included a comparison of pain status (by the visual analogue scale from 1 to 10), bilateral wrist and forearm range of motion, handgrip strength, scar size, and return to prior recreational activity. Bilateral strength measurements were performed three times using the CITEC Newton-meter Type CT 3001. We compared the average strength difference between the two osteosynthesis methods. We also performed a perioperative evaluation of the duration of insertion-surgery and removal-surgery, adverse events, and complications. Complications were evaluated and graded based on the severity of the complication in accordance to Sink et al.[19] Refractures were graded as III or moderate complications, and cast and pin complications were graded II or mild complications (Table 5).

Surgical technique

Surgical procedures were conducted by one experienced orthopedic resident. Osteosynthesis with KW or ESIN was performed according to standard operating procedures. The MIROS technique is initiated by three entry points (distal radial side of radius, distal dorso-ulnar side of radius, and distal ulna) with perpendicular posterior skin

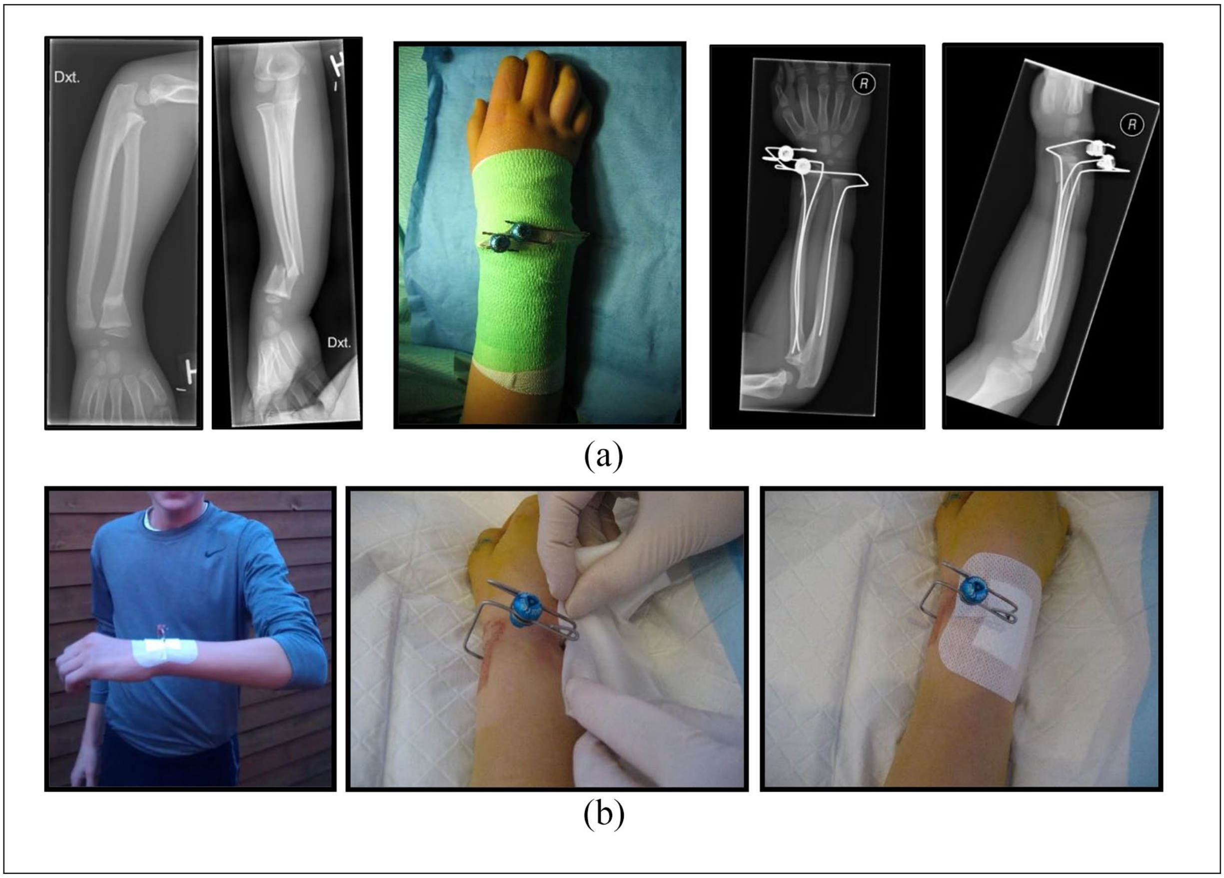

Figure 1. (a) Photos 1–5 show an example of one of our patients, before and after surgery, who had a diaphyseal shaft fracture treated with Minimally Invasive Reduction and Osteosynthesis System (MIROS) (notice: no plaster cast). (b) Photos 6–8 show an example of two of our patients, who had a metadiaphyseal fracture treated with MIROS (notice: no plaster cast). On the left, a 15-year-old boy who participated in the 800 m at the national athletics championships a week after surgery. On the right, two photographs showing the simple pin care using disposable chlorhexidine rags.

incisions of five millimeters. Subsequent blunt dissection was performed to secure soft tissues from inappropriate pinning. The semi-sharp tip of the MIROS-pin allowed cortical penetration into the medullary canal without needing a drill or an awl. The elastic pin was pre-bent and advanced by using a simple cannulated insertion tool. After three-point cortical contact, the elastic pins were bent perpendicular to the axis of the bone (straight out of the skin incision), where the external part of the pins was bent twice (angulation of 90°) and aligned parallel over the dorsal side of the wrist. The nails were connected by a clip, which applied tension in between the nails for additional fracture stability. The elastic pins of the MIROS engage the proximal fragment and radiological evaluation throughout the procedure was performed. The need for postoperative casting was assessed according to fracture stability perioperatively. When performing the ESIN procedure, open reposition with an additional skin incision at the site of the fracture was anticipated if the adequate fracture reduction was not obtained. In our surgical set-up using the MIROS procedure, we were prepared for open reposition, however, this was not needed in this study.

The aftercare for MIROS consisted of applying simple band-aids at the pin sites, and disposable chlorhexidine rags were used for postoperative pin care. Figure 1(a) and (b) illustrates the radiographic results of MIROS osteosynthesis of a forearm fracture, the clinical result without a plaster cast, and the principles of aftercare. The implant removal of MIROS entailed cutting off the clips, extracting the pins and finally closing the skin using steri-strips. This was performed in the outpatient clinic without full anesthesia.

Statistical analyses

Post hoc, we performed an estimation of sample size using Gpower©. The standard deviations were determined by double examinations of angulation by the single examinator. Our primary outcome was that MIROS and KW/ESIN achieved comparable radiological outcomes when treating pediatric forearm fractures. The chi-square cross-tabulation test (χ^2) 2 by 2 for determining if there was significant distribution of age, gender, hand dominance, the handedness of fracture sites, complications, dropouts, and the necessity of casting concerning surgical technique. This was also performed to investigate

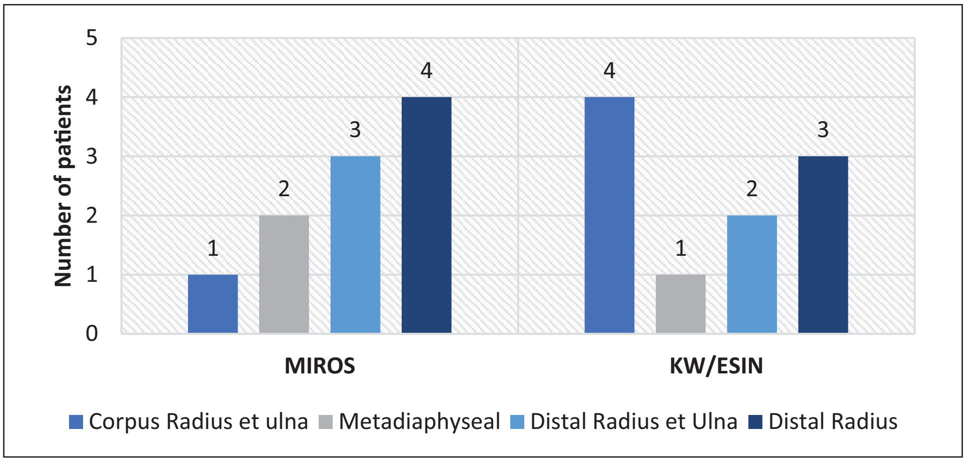

Figure 2. Distribution of the anatomical location of fractures treated with Minimally Invasive Reduction and Osteosynthesis System (MIROS) or Kirschner Wires/Elastic Stable Intramedullary Nails (pooled) (KW/ESIN).

a possible learning curve concerning MIROS. The distribution of anatomical locations of fractures was investigated by a 2 by 4 cross-tabulation test. *p* values for any violated assumptions were adjusted for. We performed the Mann–Whitney U-test (MWU) when comparing MIROS to KW/ESIN for the parameters duration of surgery, pain evaluation, level of recreational activity, as well as grip strength measurement, and range of motion. For analyzing the radiological data of angular deformities, differences between the fractured side after surgery and the contralateral side were compared. Double measurements were performed by the single evaluator of 10 radiographic parameters, and a two-way mixed model of ICC for absolute agreement for intra-rater reliability. Study variables were tested for normal distribution by the Kolmogorov–Smirnov test and Levene's Test for homogeneity. If normally distributed, we tested for significant differences with the independent t-test. If not normally distributed, we performed an MWU. We considered p values of ≤ 0.05 statistically significant. Appropriate Bonferroni corrections were then applied to our analyses when making multiple comparisons. All tests were performed using IBM SPSS Statistics, Version 25 (IBM, Richmond, VA, USA).

Results

Population

Twenty children were included in our study as a convenience sample and block-randomized (10 + 10) to either conventional surgery (5 KW/5 ESIN) or MIROS (10). The gender ratio for male:female was 4:1 with a mean age of 8.9 years (range: 4–15). The relationship between groups of osteosynthesis and distribution of gender (χ^2; p=0.582) or age (χ^2; p=0.475) was nonsignificant. Nineteen of the 20 children were righthanded, and 11 of the 20 fractures occurred in the dominant hand. The distribution of fractures in the dominant versus non-dominant side did not differ between the groups (χ^2; p=1.0).

The anatomical distribution of fracture sites were five corpora, three metadiaphyseal, five distal radius et ulna, and seven distal radius fractures (Figure 2). The distribution was not significantly different between MIROS and KW/ESIN (χ^2; p=0.591).

None of the children was lost or excluded at the 3 months clinical examination (mean 3.4 months). The radiographic evaluation was not performed for four children (χ^2; p=0.582) at 3 months FU. At 5 years FU (mean: 5.2 years.), we evaluated 13 participants clinically (χ^2; p=1.0) and 14 radiologically (χ^2; p=0.350). Seven children were lost to FU, whereas two were due to refracture in the MIROS group, thus excluded from the long-term FU. Figure 3 shows a flow chart of the timeline of dropouts, and the enrollment and FU process.

Radiological outcomes

We performed comparisons between MIROS and KW/ESIN for differences in angulations in the transverse and sagittal plane between the fractured and contralateral forearm or wrist. The angulations of both radius and ulnae were examined. The radiographical assessments revealed no statistical difference in any of neither radial/ulnar angulation nor dorsal/volar angulation at the 3 months and 5 years FU (Table 1). We applied a Bonferroni correction of four for the radius and ulnae (p:0.05/4=0.0125).

The ICC for intra-rater reliability for the various angle measurements ranged from 0.81 to 0.99. The estimated number of included patients was *nine* in each group for a sufficiently powered study, when using Gpower with a power (1–β) of 0.80, an α level of 0.05, and when looking at the difference in dorsal/volar angulation for the operated and contralateral side for the postoperative and 3 months FU. A sufficient number of subjects was achieved in the 3 months FU, but not in our 5 years FU; therefore, our evaluations at 5 years FU should be considered suggestive.

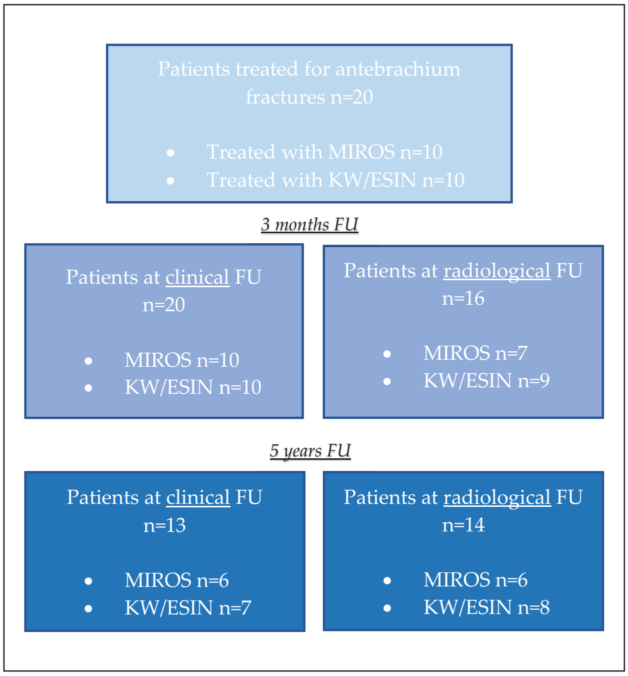

Figure 3. The inclusion process. Post hoc. power analysis indicated the need of nine patients in each group for a sufficiently powered study. The distribution of gender and age was nonsignificant between patients treated with Minimally Invasive Reduction and Osteosynthesis System (MIROS) and patients treated with Kirschner Wires/Elastic Stable Intramedullary Nails (pooled) (KW/ESIN). The demography of our population is representative of age and gender when compared to other studies. There was no significant difference in the number of patients lost to FU operated on with the surgical methods MIROS or KW/ESIN as well as in their gender and age.

Surgical parameters

The duration of insertion-surgery was not significantly different between MIROS and KW/ESIN (Table 5). We observed a statistically significant shorter duration of removal-surgery for MIROS with an average time of 5.7 min compared to 18.7 min of removal time for KW/ESIN (MWU; $p = 0.03$). Table 2 shows the average duration of surgical insertion-time and numbers of fractures operated with MIROS when divided into two groups for the first and latter five subjects. There was no significant difference in duration of insertion-surgery between the two groups (χ^2; $p = 1.00$).

Incision size/postoperative scar and postoperative casting

The average volume of the scar (as defined by length, width, and height) was 45.6 mm^3 for MIROS and 145 mm^3 for KW/ESIN at the 3 months FU (MWU; $p = 0.002$). At the 5 years FU, this was 47.67 mm^3 for MIROS and 153.1 mm^3 for KW/ESIN (MWU; $p = 0.013$). The postoperative scar was significantly smaller for patients treated with MIROS when compared to KW/ESIN (Table 4). No difference in mobility of the scars was observed since all were mobile. Casting after surgery was used significantly less when operated on with MIROS (χ^2; $p < 0.001$) (Table 5).

Pain status after surgery

The pain status was evaluated when at rest, in movement, and when palpated over the scar. Children treated with

Table 1. Average difference (diff.) in angulation at 3 months- and 5 years follow-up for Minimally Invasive Reduction and Osteosynthesis System (MIROS) and Kirschner Wires/Elastic Stable Intramedullary Nails (KW/ESIN) (pooled).

Angulation, 3 months follow-up	MIROS **Fractures in total: 7 radii* *Assoc. ipsilateral ulnae: 3*	KW/ESIN **Fractures in total: 9 radii* *Assoc. ipsilateral ulnae: 6*	p value
Radius dorsal/volar diff.	5.5°	3.44°	=0.283 (MWU)
Radius radial/ulnar diff.	3°	3.22°	=0.884 (t-test)
Ulnae dorsal/volar diff.	4.5°	4.75°	=0.869 (t-test)
Ulnae radial/ulnar diff.	2.5°	6°	=0.240 (MWU)
Angulation, 5 years follow-up	MIROS **Fractures in total: 5 radii* *Assoc. ipsilateral ulnae: 1*	KW/ESIN **Fractures in total: 8 radii* *Assoc. ipsilateral ulnae: 5*	p-value
Radius dorsal/volar diff.	1.8°	4°	=0.182 (t-test)
Radius radial/ulnar diff.	1.1°	3.75°	=0.067 (t-test)
Ulnae dorsal/volar diff.	0°	2.3°	=0.419 (t-test)
Ulnae radial/ulnar diff.	1°	2°	=0.736 (t-test)

MIROS: Minimally Invasive Reduction and Osteosynthesis System; KW/ESIN: Kirschner Wires/Elastic Stable Intramedullary Nails; MWU: Mann–Whitney U-test.
*Numbers of evaluated radius fractures and numbers of associated ipsilateral ulna fractures. The radiological follow-up was maintained, but might not be sufficiently powered.

Table 2. Insertion time and numbers of Minimally Invasive Reduction and Osteosynthesis System (MIROS) conducted.

Insertion time	Early in study	Late in study	Total
MIROS knife to skin time < 35 min	2	3	5
MIROS knife to skin time > 35 min	2	3	5
Total	4	6	10
Average knife to skin time	38.8 min	39.5 min	39.2 min

MIROS: Minimally Invasive Reduction and Osteosynthesis System.

Table 3. An overview of sports activities in each group; Minimally Invasive Reduction and Osteosynthesis System (MIROS) and Kirschner Wires/Elastic Stable Intramedullary Nails (pooled) (KW/ESIN).

Sports activities—Patients treated with MIROS	Sports activities—Patients treated with KW/ESIN
National championships of horse show jumping	Swimming
National championships of athletics	Football
Biking	Gymnastics
Handball	Karate at Olympic level
Football	Biking
Piano	Skateboard
Swimming	

MIROS: Minimally Invasive Reduction and Osteosynthesis System; KW/ESIN: Kirschner Wires/Elastic Stable Intramedullary Nails.

MIROS had less pain on average when evaluated by the VAS scale (Table 4). We applied a Bonferroni correction of three (p:0.05/3 = 0.0166). The differences in pain status were nonsignificant. For all types of surgery, analgesic medication was omitted at 3 months and 5 years FU.

Range of motion and strength measurement after surgery

We evaluated the difference in passive wrist motion of supination, pronation, dorsiflexion, volar flexion, radial, and ulna flexion between the fractured and contralateral wrist at 3 months and 5 years FU. We applied a Bonferroni correction of six (p: 0.05/6 = 0.0083). No statistically significant differences in the range of motion between MIROS and KW/ESIN were discovered (Table 4).

The difference in bilateral handgrip strength was 4% (MIROS) versus 11.11% (KW/ESIN) at 3 months FU, and 5.05% (MIROS) versus 10.65% (KW/ESIN) at 5 years FU. There were no statistical differences between groups at either 3 months FU (MWU; p = 0.271) or 5 years FU (MWU: p = 0.660) (Table 4).

Physical activities of daily living

Nineteen out of 20 of the children were sports active before their injury. An overview of the children's recreational activities is shown in Table 3. At 3 months FU, 9 out of 10 children treated with MIROS regained the same level of sports activity including participating in competitions. One child operated on with MIROS was not sports active before the injury but reported a return to activity as a piano-playing musician. All children treated with KW/ESIN resumed their previous level of sports activity. Five of these had reduced intensity of training and five avoided contact sports at 3 months FU. All children participated in their regular physical activities at school at 3 months. There were no statistical differences between the groups in the level of daily activities (MWU 3 months p = 0.582; 5 years p = 0.462) (Table 4).

Complications

The complications after surgery were divided into mild and moderate (Table 5). Two children experienced moderate complications due to refractures after MIROS. The difference in the number of moderate complications was nonsignificant (2 MIROS, χ^2; p = 0.474). One of the refractures occurred 4 months postoperatively due to a high-energy trauma when falling from a height of two meters. For the second refracture, the radiological evaluation at the 3 months FU raised that there was a risk of possible refracture at a later stage due to a distal radial cyst. This was located at the site of the previous fracture. Two years later a refracture occurred at the previous fracture site due to a fall on roller skates. Figure 4 shows the two patients with refractures at the time of initial fracture, treated with MIROS, at the 3 months FU and after the refracture occurred.

One of these children also experienced a mild complication due to the external part of MIROS causing an impression of the skin. The subject was recalled for re-bending of external wires under full anesthesia. A third child treated with MIROS experienced a postoperative superficial infection. This was also defined as a mild

Table 4. Clinical evaluations comparing Minimally Invasive Reduction and Osteosynthesis System (MIROS) and Kirschner Wires/Elastic Stable Intramedullary Nails (pooled) (KW/ESIN). Average scores of pain were measured at rest, in movement and when palpated over the scar.

Clinical evaluation at 3 months follow-up	MIROS	KW/ESIN	*p* value
Size of scar (mm^3)	45.6	145	=**0.002** (MWU)
Pain (difference*, VAS-score)	0.417	0.867	$>$0.05 (MWU)
Daily activities (problems = 1, none = 0)	0.1	0.3	=0.582 (MWU)
Grip strength (% difference*)	4%	11.11%	=0.271 (MWU)
Range of motion (% difference*)	5.3%	4.4%	$>$0.05 (MWU)
Clinical evaluation at 5 years follow-up	**MIROS**	**KW/ESIN**	***p* value**
Size of scar (mm^3)	47.67	153.1	=**0.013** (MWU)
Pain (difference*, VAS-score)	0.11	1.23	$>$0.05 (MWU)
Daily activities (problems = 1, none = 0)	0	0.29	=0.462 (MWU)
Grip strength (% difference*)	5.05%	10.65%	=0.660 (MWU)
Range of motion (% difference*)	1%	1.5%	$>$0.05 (MWU)

MIROS: Minimally Invasive Reduction and Osteosynthesis System; KW/ESIN: Kirschner Wires/Elastic Stable Intramedullary Nails; MWU: Mann–Whitney U-test.
Average scores of passive range of motion of supination, pronation, dorsiflexion, volar flexion, radial, and ulna flexion. *Difference between fractured and non-fractured sites. Results of 5 years follow-up are suggestive since the study was not sufficiently powered at this time.

Table 5. Evaluation results. Minimally Invasive Reduction and Osteosynthesis System (MIROS) and Kirschner Wires/Elastic Stable Intramedullary Nails (pooled) (KW/ESIN). Complications graded according to Sink et al.[19]

	MIROS	KW/ESIN	*p*-value
Insertion time (average, min)	39.2	54.3	=0.362 (MWU)
Removal time (average, min)	5.7	18.7	=**0.030** (MWU)
Mild complications due to cast or pin (none = 0, each complication = 1)	2	7	=0.070 (χ^2)
Moderate complications refracture (none = 0, refracture = 1)	2	0	=0.474 (χ^2)
Need of postoperative casting	0	10	**<0.001** (χ^2)

MIROS: Minimally Invasive Reduction and Osteosynthesis System; KW/ESIN: Kirschner Wires/Elastic Stable Intramedullary Nails; MWU: Mann–Whitney U-test.

complication. The superficial skin infection was attributed to poor parental compliance in daily pin care. The infection responded to oral antibiotics. For the KW/ESIN group, seven mild complications were observed due to problems with the postoperative casting or infection. The number of mild complications was nonsignificant (2 MIROS, 7 KW/ESIN, (χ^2; p = 0.070).

Six out of 10 children treated with KW/ESIN requested a change of plaster cast. This was due to itching, limitations of movement, and too tight-fitting of the cast. These were changed in the outpatient clinic without full anesthesia. One of these children also needed to get the KW removed before the planned removal due to an infection. When comparing these seven complications in KW/ESIN-group to the overall four complications in MIROS-group, we observed no statistical difference (χ^2; p = 0.370). We argue that a refracture is a worse complication than superficial infection, wire bending or cast complications,[19] however, this was still nonsignificant when comparing the number of refractures between the two groups (χ^2; p = 0.474)

Discussion

In this study, we compared clinical and radiographical evaluations of MIROS with the conventional osteosynthesis techniques KW and ESIN for forearm fractures in children. We found similar results in radiological outcomes after 3 months as well as at the 5 years FU. Children's fractures in the forearm and especially in the wrist have a high potential for bone remodeling.[20-22] We would expect that whichever osteosynthesis method was chosen, we would see a spontaneous remodeling and correction of even severe angulated fractures when the child has not reached skeletal maturity and still has at least 2 years of growth remaining.[22] In addition, the speed of the remodeling process and union rate are argued to be influenced by the initial angulation of fracture.[23] Only patients with indications of surgical treatment due to displaced, dislocated, and angulated fractures were included in our study. As expected, we found full remodeling and no difference in angulation, thus KW/ESIN and MIROS are equally good for achieving radiological good results. Several parameters of comparison of the

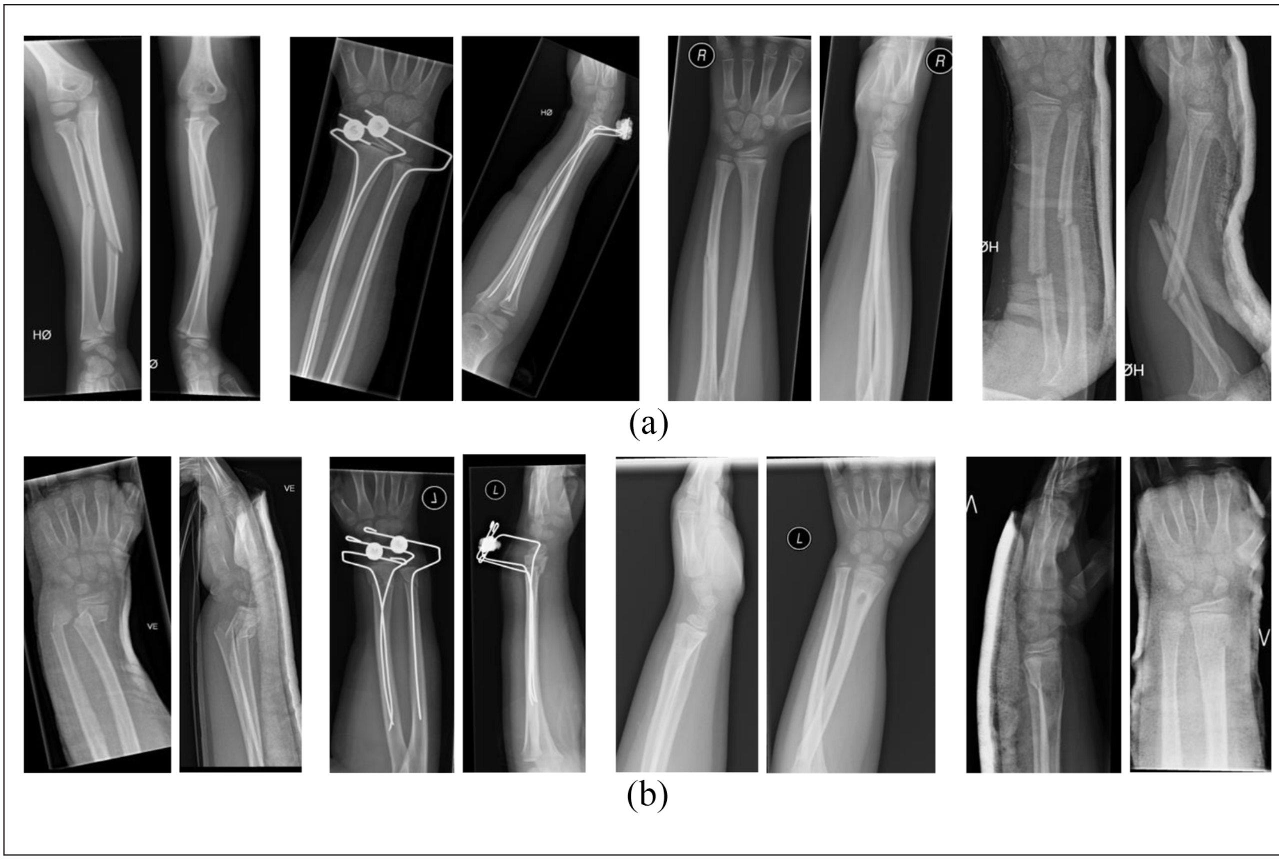

Figure 4. (a) Showing one of the patients operated with MIROS (Minimally Invasive Reduction Osteosynthesis System), who experienced a refracture 4 months postoperatively, due to a high energy trauma, when falling from a height of 2 m. Three months follow-up showing clinical healing of ulna and both clinical and radiological healing of radius. This patient also needed a re-bending of the external wire. Pictures from the left; the initial fracture, when operated with MIROS, 3 months follow-up and refracture 4 months postoperatively. (b) Showing the other patient treated with MIROS, who experienced a refrature 2 years postoperatively due to a fall on roller skates. Pictures from the left; the initial fracture, when operated with MIROS, 3 months follow-up, showing a radial cyst in left distal radius, and picture of the refracture 2 years postoperatively.

surgical procedure and the clinical evaluation after surgery were not significantly different at 3 months- and 5 years FU, when MIROS and KW/ESIN were compared. The benefits of MIROS were omitting the need for postoperative casting, significantly shorter removal time without the need for full anesthesia, and significantly smaller total scar size. However, there was a nonsignificant difference in the severity of complications. We observed two refractures when operated on with MIROS, thus raising concerns about inferior healing when using MIROS. One refracture occurred after a relevant high-energy trauma. The other refracture occurred two years later, at the previous fracture site due to a fall on roller skates. The initial fractures occurred in either the early stage of the study, one late, thus making it less likely to be due to surgeon experience. None of the refractures was reoperated with MIROS; one was treated conservatively and the other with ESIN. We argue that refractures are worse complications than the complications categorized as "mild."[19] Mild and moderate complication rates, as well as the overall complication rate, were nonsignificant between the osteosynthesis methods. Elsebaie et al.[16] found that the complication rate for MIROS was comparable to other surgical methods, and concluded closed reduction would improve chances of rapid recovery and less risk of infection. Concerning complications, Flynn et al.[24] emphasized the importance to observe for severe complications such as compartment syndrome when treated with ESIN. Moreover, performing an additional skin incision might be necessary at the site of the fracture.[24] In this study, neither compartment syndrome nor additional skin incision was observed.

Previous studies have examined MIROS in fractures with otherwise dubious surgical outcomes, due to either inadequate surgical methods or complicated postoperative care. These studies examined the three- or four-part humeral fractures in the elderly in poor general condition,[18] complex intra-articular calcaneal fractures in adults,[17] and comminuted tibial fractures in adults.[16] According to these studies, MIROS seems to be an adequate method for these selected fractures. A. Battaglia et al.[17] highlighted the benefits when using MIROS, namely early weight-bearing and subsequent positive bone healing, and also omitting the need for plaster cast resulting in less joint stiffness. Casting is also sometimes omitted after i.e. ESIN surgery, but in our study, this was needed after KW/ESIN surgery. In our study, plaster casts were unnecessary when using MIROS, but this seems inconsequential for joint stiffness for this group of pediatric subjects. Carbone et al.[18] reported that MIROS was the best alternative compared to other types of external fixations when open reduction was contraindicated. We concur with the findings of previous studies, that MIROS has easy and swift osteosynthesis removal. Due to an uncomplicated and swift removal-surgery without full anesthesia, this is suited for children.

Before study initiation, our single surgeon had performed only one osteosynthesis using MIROS but was experienced using KW/ESIN. The average time of insertion-surgery was faster when operating while being inexperienced with MIROS (39.2 min) than while being experienced with KW or ESIN (54.3 min). However, this difference was not significant. Decreased insertion-surgery time was not observed. This was expected to improve during a learning curve. This suggests that MIROS is an easy surgical method with a short learning curve. Elsebaie et al.[16] reported complications occurred in early cases during the learning curve. Our experience is that carefully choosing the proper placement of the entry points using the C arm and performing reposition using the cannulated insertion tool (the manipulator) is important for conducting adequate surgery using MIROS.

In this study, our subjects were chosen as a convenience sample and could be influenced by selection bias. The block randomization was chosen to make sure the two groups were equal in size. We are aware that since our study size is small, there is a risk of predicting the allocation process, during the process and thereby biasing the randomization. Blocks of ten have been acceptable according to previous studies.[25] We had similar demography in gender- and age distribution of the general fracture population.[20,22] This indicates that the demography of our population is representative concerning age and gender, thus minimizing the risk of selection bias. We were unable to blind our single evaluator when analyzing the results. Our single evaluator was not involved in the prior surgeries nor having economical or other disclosures relevant to MIROS. We utilized Bonferroni corrections in our statistical significance levels thus reducing the risk of type 1 error. As in previous studies examining MIROS,[16-18] our study has a small sample size of 20 participants, reducing study power. However, our post hoc power analysis indicated that nine patients in each group were adequate for a sufficiently powered study, indicating that three months FU should be interpreted with more confidence than the five years FU, which we consider as suggestive.

We added a control group for a strong scientific design, and to achieve an adequate sample size for each osteosynthesis method, the KW / ESIN patients were pooled in our comparisons with MIROS. This has influenced the outcome since the two methods and types of fractures treated with KW and ESIN are different. However, the distributions of gender, age, and anatomical fracture sites were nonsignificant between MIROS and KW/ESIN. Initial clinical evaluation after surgery was not performed but would have been interesting to determine if MIROS had an effect, especially on the postoperative pain status. Since pain treatment was discontinued and all subjects were without pain at 3 months, only a postoperative pain evaluation would have been relevant.

The intra-rater reliability for our single rater evaluated by ICC was high for all the radiographical evaluations (>0.80).[26] Future studies should include larger sample size, focusing on a specific type of fracture (anatomical location), and a comparison to only one method of osteosynthesis when exploring the efficacy of MIROS. This could be performed in a multicenter design to focus, that is, on the mixed metadiaphyseal fracture.

Our initial purpose of the present study was based on the clinical need for an adequate surgical method to address the metadiaphyseal forearm fractures in children,[10] thus investigating if MIROS was significantly different to the conventional osteosynthesis techniques. Since few of our subjects had a metadiaphyseal fracture, the conclusions of our study are based on all included forearm fractures. We are encouraged to use MIROS as a surgical method for forearm fractures in children. However, these fractures were also addressed well by KW or ESIN. Our study suggests that MIROS and KW/ESIN have similar radiological outcomes, however, we observed nonsignificant more severe complications of refractures when treated with MIROS.

Conclusion

In conclusion, we found a significant difference in surgery removal time and scar size favoring MIROS. We found a significantly less need for postoperative casting using MIROS but was inconsequential for joint stiffness. Moderate severe complications of refractures occurred, but this finding was nonsignificant. All surgically treated children achieved full function with no restrictions and return to their recreational activities within a short period.

Compliance with ethical standards

All authors declare that they have nothing to disclose. The study was investigator-driven and not funded. The MIROS system was provided by the company. All procedures performed in this study were in accordance with the ethical standards of the Helsinki declaration. Informed consent was obtained from all parents and children included in this study.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Author Lærke Gyllenborg, Christian Wong, and Ture Karbo declare that they have no personal conflict of interest. Author Ture Karbo states that the MIROS system was provided by the company. Study design and data acquisition were done by author Ture Karbo and author Christian Wong. Author Lærke Gyllenborg and Christian Wong were responsible for the analysis and interpretation of data.

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