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The use of flexible nails in the treatment of paediatric long bone fractures: Experience at a level one paediatric trauma centre, a cohort study

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ABSTRACT

Introduction: Fractures occur in children at an incidence only surpassed by women >85 years and account for 25 % of paediatric injuries. Over the last three decades, there has been a trend towards operative management of children's fractures including utilisation of flexible nails as popularised by the Nancy group in the 1980s. Between 5 and 11 % of paediatric forearm fractures are now fixed in this manner with complication rates of 12–42 %. This study shares the experience of a paediatric level one major trauma centre using this technique in managing long bone fractures in children.

Methods and materials: This retrospective cohort study comprises a sequential series of 109 cases (71 children) of upper and lower limb fractures in children (aged 16 years and below) who underwent fracture fixation using flexible intramedullary nails between 1st April 2015 and 31st March 2019. Radiological and clinical outcomes and complications were assessed.

Results: Ninety-three cases (10 in the lower limb, 83 in the upper limb) satisfied the inclusion criteria in 57 children with a mean age of 8.6 years. All cases were successfully reduced intra-operatively and 92 (98.9 %) achieved union. Taking into account all complications in the upper and lower limb, the overall complication rate is 30.1 % (28 cases) with the vast majority (13 cases, 46.4 %) occurring in the upper limb due to prominence of metalwork prompting early removal.

Conclusions: This study has shown flexible intramedullary nailing to perform well with good stabilisation of a wide variety of paediatric long bone fractures with restoration of bone alignment, satisfactory outcomes with good union rates and a return to normal function. The technique is also safe and in the upper limb can be performed as day-case surgery by a generalist orthopaedic surgeon. Although the overall complication rate is not insignificant, major complications are rare.

1. Introduction

Paediatric fractures have historically been managed non-operatively,[1–5] but this results in extended hospital length of stay, which can be more expensive than operative management,[1–5] and involves prolonged immobilisation. There has therefore been a trend towards operative management of paediatric fractures.[6,7] Flexible intramedullary nailing, also known as Elastic Stable Intramedullary Nailing (ESIN), has become widely accepted since it was popularised in Nancy (France) in the 1980s.[8] The technique uses malleable metal 'nails' inserted into the medullary canal of a long bone fracture, in an opposing configuration, such that they each maintain three points of contact.[3] This splints the bony cortices and continually braces against axial loading and angulation forces. However, when used in the femur, flexible nail constructs can be weaker against rotational forces.[9] End caps may provide further stability to flexible nails in axial loading of the femur and prevent nail end prominence.[10] Alternative methods of fixation such as plating can provide more stable constructs in the femur but come with disadvantages such as increased soft tissue stripping.[10,11]

Upper limb diaphyseal fractures are still predominantly managed non-operatively in children unless irreducible, unstable, open, or if conservative management fails.[3] However, to minimise prolonged immobility and hospital stay, diaphyseal lower limb fractures are typically managed surgically. The American Academy of Orthopaedic

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Surgeons (AAOS) recommends ESIN for diaphyseal femoral fractures sustained in children aged five to eleven while the National Institute of Health and Care Excellence (NICE) in the United Kingdom recommends a similar approach in children aged four to twelve years and who are under 50kg.[12,13]

ESIN is generally less invasive than plating with less disruption of the fracture site (the "zone of injury") and, in particular on metalwork removal, only a small incision at the site of nail insertion is required, affording better cosmesis overall.[7] It can also offer shorter surgical times than plating in both bone fractures of the upper limb.[14] ESIN has continued to evolve since its introduction with modifications such as end caps, pre-bent nails and improved operative techniques rendering it the gold standard of long bone shaft fracture management in children.[15] Overall, a recent review article comparing ESIN to plating and external fixation highlighted its very good risk/benefit ratio in the lower limb.[16] Specifically in the tibia, although external fixation is usually simple and operative times are short,[16] time to union is less favourable with seven weeks for ESIN compared to 18 weeks for external fixation.[10]

This study set out to explore surgical and radiographical outcomes following the use of ESIN for long bone fractures in children at a level one major trauma centre in London, England.

2. Methods

This was a retrospective observational cohort study of a consecutive series of children (aged 16 years and under) who underwent operative management of any long bone fracture with flexible nailing at a level one major trauma centre in central London, England, between 1st April 2015 and 31st March 2019. The Stryker T2 Kids Paediatric Flexible Nail was used and all children received the titanium version of the implant. The upper age range of 16 years was selected in reference to the Nancy group who popularised the ESIN in the 1980s.[2] We adhered to the UK NICE guidelines of utilising ESIN in lower limb fractures for children under 12 years of age and below 50 kg[13]; for the upper limb, no specific age or weight limit guidance exists and hence ESIN was utilised in any child under 16 years of age with open physes and hence remaining growth with remodelling potential.

The data was extracted from a prospectively collected database of all paediatric trauma patients. Electronic or paper operation notes were interrogated. Data collected included patient demographics, co-morbidities, injury mechanism, operating surgeon, surgery and implant specifics. Digital radiographs were analysed preoperatively to record the severity of fracture angulation, postoperatively at two weeks to assess the adequacy of fracture alignment and then at six weeks, three months and six months (or longer) until bone union had been achieved. Surgery was performed either by general orthopaedic surgeons or specialist paediatric orthopaedic surgeons of differing grades (i.e. trainee registrars or consultants). Any difficulties encountered during surgery, such as those requiring open fracture reduction, were recorded. All fractures were considered to be independent, thus a 'both bone forearm fracture' counted as two cases. Cases of children operated on for non-fracture pathology, operated on outside of our centre or those with insufficient follow up were reviewed but excluded from final analysis. Length unstable or complex fracture patterns (e.g. long spiral or multi-fragmentary fracture configurations) are typically not suitable for ESIN and we likewise adopted alternative fixation methods for such fracture patterns and they were thus not part of the study cohort.

The technical aspects of the procedure were carried out as per the recommendation of the Stryker T2 Kids Paediatric Flexible Nail system although the procedures were carried out by several trauma surgeons who may have subtle differences in techniques. The entry point for the ulna nail was the lateral border of the proximal ulna, distal to the physis; whilst the entry point for the radius was at the radial styloid, proximal to the physis. The nail size was calculated as 40 % of the medullary canal diameter (mean 2.0 mm in the upper limb and 3.0 mm in the lower limb in this study). Both nails in each limb segment were of identical diameter to ensure balanced forces and with the aim to attain maximum nail bend (and hence maximum brace and corrective forces) at the fracture site. Each pre-bent nail was inserted to its full desired length in the bone, its entry point in the bone marked with a marker pen and the nail then bent approximately 30° away from the bone to ease future removal. The nail was then partially retracted, cut approximately 1 cm distal to the marked point and re-impacted to its desired position taking care not to penetrate the opposite cortex or the physis. The skin was also palpated to ensure the nail end was not too prominent and any entrapped soft tissue released.

The post-surgery protocol was not fixed instead being dependent on the individual surgeon. All fracture types, except for the femur, were immobilised in a plaster cast for a minimum of three weeks to allow for wound healing and early callus formation. Patients were advised not to return to sporting activities for at least three months or until evidence of fracture union.

The primary outcome was post-operative fracture reduction. There were three secondary outcomes. Firstly, bone union, which was defined as callus that had bridged three of four cortices. Acceptable time to union was defined as less than 90 days in the upper limb, in agreement with Schmittenbecher,[17] and 120 days in the lower limb. Secondly, an acceptable clinical outcome was defined as no clinical deformity, no motion deficits and no restriction in activities. Thirdly, all complications were recorded.

Descriptive statistics were utilised for each of demographics, co-morbidities, clinical measurements and outcomes. Continuous variables were described using mean, standard deviation (SD), median, lower quartile (LQ), upper quartile (UQ), minimum (min) and maximum (max) values, where appropriate. Categorical variables were described using frequencies and percentages. Patients could be included more than once if they had more than one fracture: either concurrent fractures from one incident or two fractures (ie. re-fracture) that occurred at different times. Specifically for forearm fractures where two elastic nails were typically implanted (one in each of the forearm bones), patients were included twice with independent analyses carried out for the radius and ulna.

All analyses were undertaken using SPSS Version 26 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp).

The study received ethical approval from the NHS Health Research Authority and Health and Care Research Wales (HCRW) on 28th September 2018 (IRAS 251777).

3. Results

There were 109 consecutive cases in 71 children over the four-year study period. Of these, 16 cases (12 children) were excluded due to alternative indications for the use of the T2 Kids Flexible Nail (three cases in three children for decompression of bone cysts), index surgery performed outside of St George's Hospital (nine cases in seven children) or incomplete notes for the evaluation of the primary or secondary endpoints (four cases in two children).

Two children (four cases) sustained re-fractures of their forearm during the study period and hence were included twice as separate cases. As such there was a total of 57 children included in the study (93 cases), 34 were girls (55 cases, 59.6 %) and 23 were boys (38 cases, 40.4 %) with a mean age of 8.6 (range 2.1–16.0) years. The majority of cases involved the upper limb (83 cases in 47 children) with 10 lower limb fractures in 10 children. Paediatric orthopaedic specialists performed 53.8 % of the cases. One child had a condition which impacted on the study - neurofibromatosis type one (NF-1) - resulting in a non-union of a both bone forearm fracture but was not excluded from the study. Pseudarthrosis of the forearm is a very rare but known association of NF-1.[18]

3.1. Upper limb

Of the 83 upper limb fractures in 47 children, two were in the humerus, three in the radial neck, 42 in the radius, and 36 in the ulna. 16 (19.3 %) were open fractures, in 10 children [Table 1]. One child had an ipsilateral mid-shaft humerus and forearm fracture ("floating elbow" injury). The mechanisms of injury included fall from height (21 cases), fall from standing (28), sports-related (33) and one road traffic accident (RTA).

Thirty three of the 83 upper limb cases (39.8 %) required open reduction - 16 radial shaft, 16 ulna shaft and one radial neck. 82 (98.8 %) cases had a plaster cast backslab applied after surgery for a mean of 5.5 (range 3–12) weeks.

The primary outcome was post-operative fracture reduction which was achieved in all cases. The mean pre-operative alignment on the AP radiograph of 17.8°, improved to a mean of 5.2° post-operatively, a change of 12.6° (range −5°–96°). On the lateral radiograph, the mean pre-operative angulation of 25.0° improved to a mean of 3.8° post-operatively, representing a change of 21.2° (range −4°–96°) [Table 2].

The mean time to union was 89.3 (range 27–253) days; 35 % of cases (29 cases) had a delayed union, where union occurred after 90 days, and 1 % (one case) had a non-union of the radius. Clinically, 96.4 % of cases (80 cases in 45 children) achieved a satisfactory result. There were three unsatisfactory outcomes, two of which concerned metalwork failure in one child with a both bone forearm fracture - an error in surgical technique with malorientation of both nail tips and nails of insufficient size resulted in early re-displacement of both radius and ulna fractures requiring revision surgery. The remaining unsatisfactory clinical outcome was of a non-union due to an undiagnosed patient factor (NF-1, as previously described).

The complication rate in the upper limb is 31.3 % (26 cases in 19 children). This comprised the unsatisfactory outcomes above plus 13 cases (10 children) of early metalwork removal due to exposed or prominent metalwork, two cases (two children) of superficial infection with no cases of osteomyelitis, two cases (one child) of metalwork failure, four cases (two children) of re-fracture, one case of temporary anterior interosseous nerve palsy and one case of extensor pollicis longus entrapment requiring early metalwork removal [Table 2]. There were no cases of compartment syndrome or superficial radial nerve palsy, recognised complications of the ESIN technique.

61.7 % (29 children) had their surgery carried out as a day case in our ambulatory care centre with an overall median length of hospital stay of 1.0 day (range 0–4 days). There was no difference in the complication rates between the children who were discharged home on the same day as their surgery or those who had remained as in-patients. Specifically, there were no cases of compartment syndrome, a recognised complication of the ESIN technique. The operating surgeon was a paediatric orthopaedic specialist in 33 cases (40 %).

Table 1
Demographic data, location of injury and injury pattern of the patient cohort. All data expressed as cases or as otherwise stated.

	Upper Limb. n = 83 (%)	Lower Limb. n = 10 (%)
Age (years)		
Combined: 8.6 (2.1–16)		
Mean (range)	8.6 (2.1–16)	8.4 (4.3–11.8)
Location of Injury		
Humerus	2 (2.4 %)	–
Radial Neck	3 (3.6 %)	–
Radius	42 (50.6 %)	–
Ulna	36 (43.4 %)	–
Femur	–	7 (70 %)
Tibia	–	3 (30 %)
Injury type		
Closed	67 (80.7 %)	8 (80 %)
Open	16 (19.3 %)	2 (20 %)
Surgery type	5 no data	
Closed	45 (57.7 %)	5 (50 %)
Open	33 (42.3 %)	5 (50 %)

Table 2
Primary and secondary outcomes including delayed union. All data expressed as cases, or otherwise stated.

	Upper Limb (n = 83)	Lower Limb (n- = 10)
Primary outcome: Postop Alignment AP (degrees)		
Mean (SD)	5.1 (3.67)	4.0 (3.02)
Min: Max	0 : 22	0 : 10
Primary outcome: Postop Alignment Lat (degrees)		
Mean (SD)	3.8 (2.90)	5.6 (2.99)
Min: Max	0 : 19	2 : 10
Time to Union following Surgery (days)	(n = 81)	(n = 9)
Mean (SD)	89.3 (46.91)	112.8 (49.36)
Min: Max	27 : 253	38 : 180
Delayed Union	(n = 81)	(n = 9)
No	51 (63.8 %)	4 (44.4 %)
Yes	30 (37.0 %)	5 (55.6 %)
Delayed if		
Upper: Time to Union >90 days		
Lower: Time to Union >120 days		
Secondary Outcome: Clinical Outcome		
Satisfactory	80 (96.4 %)	9 (90 %)
Unsatisfactory	3 (3.6 %):	1 (10 %)
	- Non-union	- Metalwork failure
	- Metalwork failure	
Secondary Outcome: Complications		
Early metalwork removal due prominence/ irritation	12	0
Refracture	4	1
Superficial infection	2	0
Keloid	2	0
Metalwork failure	2	1
Non-union	1	0
Anterior interosseous nerve palsy	1	0
Extensor pollicis longus (EPL) entrapment requiring early metalwork removal	1	0

3.2. Lower limb

Lower limb fractures occurred in 10 cases in 10 children. Seven cases were due to a fall from height and three due to an RTA. Seven cases involved the femur and three the tibia. There were two open fractures, both involving the tibia. Open reduction was required in five cases (three tibiae, two femora) [Table 1].

In terms of the primary outcome, all fractures were successfully reduced post-operatively. Pre-operative radiological alignment on the AP radiograph had a mean of 11.4° improving to 4.0° post-operatively, representing a change of 7.4° (range 0°–15°). On the lateral radiograph, the pre-operative angulation of 16.0° improved to 5.6° post-operatively, representing a change of 9.4° (range −1°–18°). However, since 60 % of fractures were 100 % displaced ("off-ended") the pre-operative angulation was less marked [Table 2].

Union occurred at a mean of 112.8 (range 38–180) days, with six (55 %) cases having a delayed union and one case was excluded due to a complication (discussed below). Clinically, 90 % of cases were satisfactory. The one unsatisfactory outcome was of metalwork failure in a femur resulting in prominence of both nail ends 10 days postoperatively. This required early metalwork removal 56 days postoperatively, and produced a limb length discrepancy of 2 cm. The likely cause was a fracture "blow-out" during nail insertion as a butterfly fragment was evident in the intraoperative and postoperative films that was not noticed preoperatively, rendering an initially stable fracture pattern unstable. In addition, there was one case of a re-fracture of the tibia, five months post-index surgery: this was managed conservatively in a cast with full union eventually achieved.

Unlike with the upper limb, all children with lower limb surgery

required an in-patient stay mainly to practice safe mobilisation on crutches with the physiotherapist; the median length of stay was 3.0 days (range 1–8 days). There were no cases of compartment syndrome. 70 % of cases were performed by paediatric orthopaedic specialists.

4. Discussion

This study has demonstrated that ESIN performs well and does so in the hands both of paediatric and non-paediatric orthopaedic surgeons. It is however vital that the principles of the surgical technique are adhered to.[3,19] The technique has proven to adequately manage a wide range of long bone fractures and patterns, including the humeral shaft, both bone forearm, radial neck (via the Metaizeau technique), Monteggia fracture of the proximal ulna, tibial shaft and femoral shaft. 40.9 % of fractures in our cohort required an open reduction which is consistent with published literature[20] and likely represents the initial severity of fracture displacement not amenable to closed reduction and casting.

The technique was also successfully used to treat open fractures. Our cohort comprised 19.4 % open fractures (16 cases in the upper limb and 2 in the lower limb) with all cases undergoing formal debridement of the open fracture site and subsequent stabilisation with flexible nails. All fractures achieved union without infection (either superficial or osteomyelitis). It is recognised that open fractures (especially Gustilo and Anderson Grade I) in children do not necessitate such aggressive management as in adults and that implantation of internal metalwork has good outcomes.[21]

Of our 93 cases, 95.7 % (90 cases) radiographically achieved a satisfactory outcome which is consistent with published literature.[7,8,20–23] There were only four cases (in three children) of an unsatisfactory outcome, three of which were due to inadequate adherence to the surgical technique and one case due to an underlying (extremely rare) and pre-operatively undiagnosed patient factor of neurofibromatosis and subsequent pseudoarthrosis of the radius. The one unsatisfactory outcome in the lower limb group was the result of a "blow out" of the femoral shaft fracture during implantation of the nail rendering the fracture axially unstable. This is a recognised relative contraindication to the use of ESIN and adjunctive measures such as use of a postoperative cast or traction, end caps or an external fixation device could have been considered.[22,24] Otherwise, all satisfactory cases in the upper and lower limb achieved good overall radiological alignment with no recorded functional deficits or clinical deformity.

Our time to fracture union rates are higher than those published in most series in the upper limb (mean 89.3 days) and lower limb (mean 112.8 days).[2,5,7,8,20,23–25] This may be a result of fixed routine time points at which our cohort of patients are followed up (typically six weeks, three months then six months post-op and beyond until fracture union has been achieved). There is also no set definition for classifying a fracture as having delayed union or not. However, as previously mentioned, for the purposes of our study a time point of >90 days for the upper limb and >120 days for the lower limb was utilised.[17] This gave a high figure of 37.0 % and 55.6 % of delayed union for the upper and lower limbs respectively. Further analyses into contributory factors for the cause of the delay in fracture union may be warranted in a larger series of patients.

Taking into account all complications in the upper and lower limb, our overall complication rate was 30.1 % (28 cases) which is in line with that reported in the literature which ranges from 14 to 42 %.[7,14,20,23,25] The vast majority of complications in our cohort occurred in the upper limb (13 cases) due to prominence of the metalwork prompting early removal prior to full fracture consolidation (i.e. all four bone cortices bridged): the ulna nail end at the olecranon caused problems more frequently than the radial nail which is not unexpected considering the minimal soft tissue coverage in this area and the mobility of the elbow joint. This nonetheless raises the question of whether the metalwork should be more deeply buried to which this must be balanced against the failure to remove metalwork, as seen in some other studies.[20] Hyper-flexion of the elbow following skin closure may help better assess the extent of nail prominence at the time of index surgery. Our major complication rate was 4.3 % (four cases: three metalwork failure, one non-union). Of the three cases of metalwork failure, two (in one child) were in the upper limb due to a technical error (where the maximal bend of each nail was not orientated adequately) resulting in the loss of fracture bracing by the nails and one in the lower limb with collapse of the fracture soon after the index operation due to a failure to recognise a "blow out" of the fracture intra-operatively which rendered the fracture pattern axially unstable. This subsequently caused the nails to effectively back out and resulted in metalwork prominence which required early removal and a resultant leg length discrepancy. These cases can therefore be attributed to errors in surgical technique rather than to the implant itself. Awareness of pearls and pitfalls of the surgical technique would have allowed greater success in paediatric fracture management using ESIN.[3,19] There were no cases of implant breakage and there were no problems with removal of the metalwork.

There were five cases (in three children) of re-fractures, four (in two children) occurred in both bone forearm fractures with the remaining one in the tibia. With the two children with both bone mid-shaft forearm fractures, one occurred within two months of the original T2 Kids nails being removed following full fracture consolidation and in the other the re-fracture occurred five months following the original injury and with the flexible nails still in situ and full union achieved. Both cases of refractures of the forearm occurred at the same site as the previous fracture. The child with the re-fracture of the tibia had done so following minor trauma in an incompletely united bone. Re-fractures of the forearm are a recognised phenomenon, with a rate of 6–10 %, typically related to incomplete union.[3,19] There were rare complications of a transient anterior interosseous nerve (AIN) palsy and entrapment of the extensor pollicis longus (EPL) tendon by the radial nail in one case each. The latter is typically encountered when a Lister's tubercle entry point is utilised. However, in our case it was via a radial styloid entry point but the nail end was bent too sharply and orientated towards to the dorsal wrist prior to trimming, entrapping the tendon. There were no cases of compartment syndrome or superficial radial nerve palsy in our cohort, recognised complications of the ESIN technique.[7,20,23]

The mean age of this cohort (8.6 years) is representative of other upper and lower limb studies of flexible nailing in the paediatric population.[20,23,26] It is however notable that although the majority of paediatric fractures occur in males, the majority of this cohort was female (60 %).

This study's sample size was calculated by number of bones fractured, rather than by number of children, but compares with similar studies[14] with the majority (89 %) occurring in the upper limb, which is consistent with childhood fracture epidemiology. In the upper limb, the mean length of stay of <1.0 day is markedly less that seen in the literature[27] with 62 % of our cohort being safely operated upon in a day-case setting with no increased complication rates. This has both favourable financial and patient experience implications and further studies exploring this are warranted.

The limitations of this study include its retrospective nature and the difficulty in standardising clinical outcome data such as functional scores or patient-reported outcome scores. Furthermore, our study cohort is small in the humerus and lower limb and occurred in a paediatric population where most children are healthy: as such, attributing causation to complications or unsatisfactory outcomes is at best limited. This study can therefore only afford descriptive epidemiological data from a level one trauma centre in the UK. However, it is a pragmatic study, representative of daily clinical practice, with data collection and analysis remaining independent of the clinical team. Our data outcomes are in line with published series and is therefore likely representative of the usual paediatric population with results that can be extrapolated to other units (see Fig. 1).

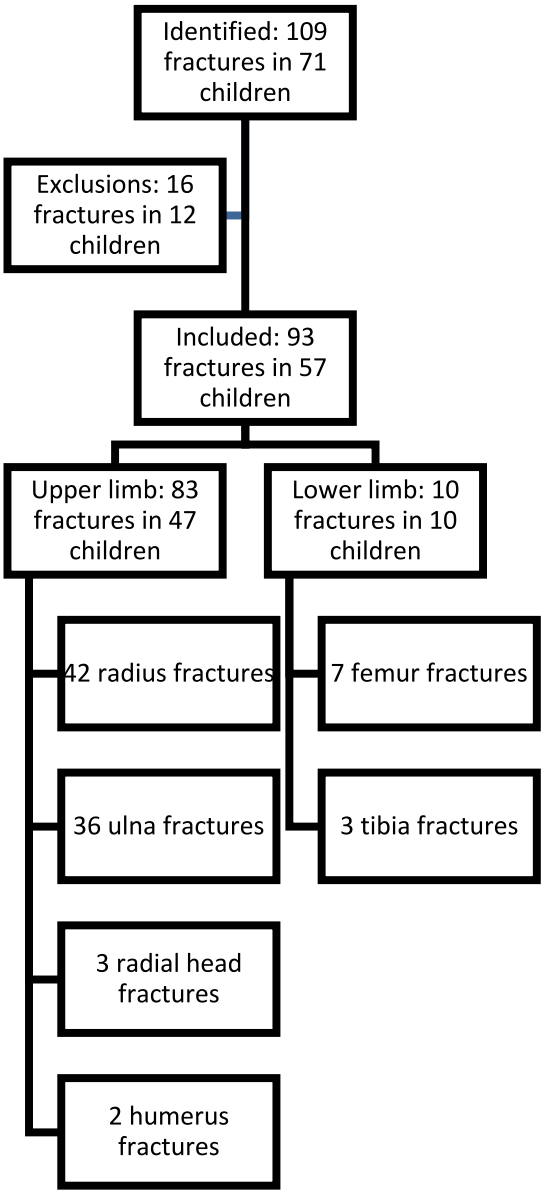

Fig. 1. Study flow diagram showing inclusion and exclusion cases.

5. Conclusion

Our study has shown flexible nails to be an excellent method for maintaining fracture reduction in paediatric long bone fractures when used in the appropriate setting and the surgical technique respected leading to restoration of bony alignment, good union rates and a return to normal function (Figs. 2, 3 and 4). As it is a minimally invasive procedure there is less disruption to the fracture site (the "zone of injury") and the surrounding soft tissues through a smaller incision than may be required for plating particularly with regards to subsequent plate removal. Our study has also demonstrated that ESIN can be safely used in open fractures with no increased complications, specifically of infection, and in the upper limb it can be safely performed on a day-case basis which has favourable patient experience and financial implications While the complication rate is not insignificant it is line with that reported in the literature and most of the complications observed were minor with the majority due to metalwork prominence prompting early removal with no untoward outcome as a result.[7,14,20,23,25]

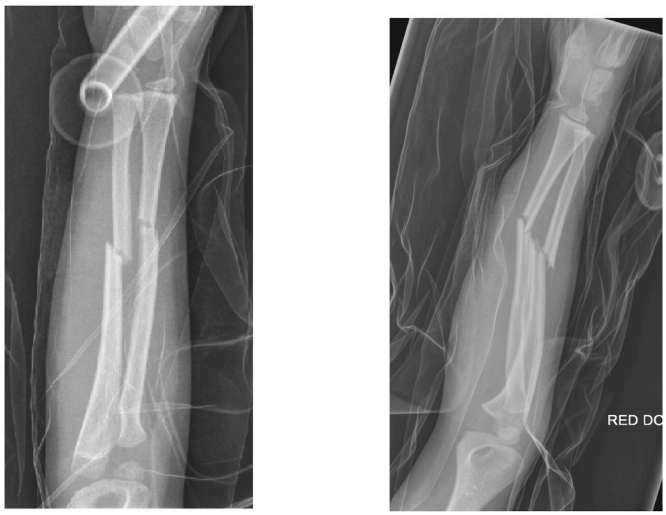

Fig. 2. Preoperative AP and Lateral right forearm radiographs of a 4-year-old boy following a fall off a climbing frame. Both forearm bones are fractured and displaced with an open wound in the volar forearm (Fig. 2–4 are all the same child).

Fig. 3. AP and Lateral radiographs of right forearm taken 1 week post-operatively following reduction and stabilisation with the T2 Kids Flexible Nailing System. Bone alignment has been successfully restored.

Author contributions

AH. Author of submitted article.
NJ. Author and data analysis.
AB. Data collection and analysis.
PS. Statistical analysis.
CH. Author and investigator.
AY. Author and chief investigator.

Provenance and peer review

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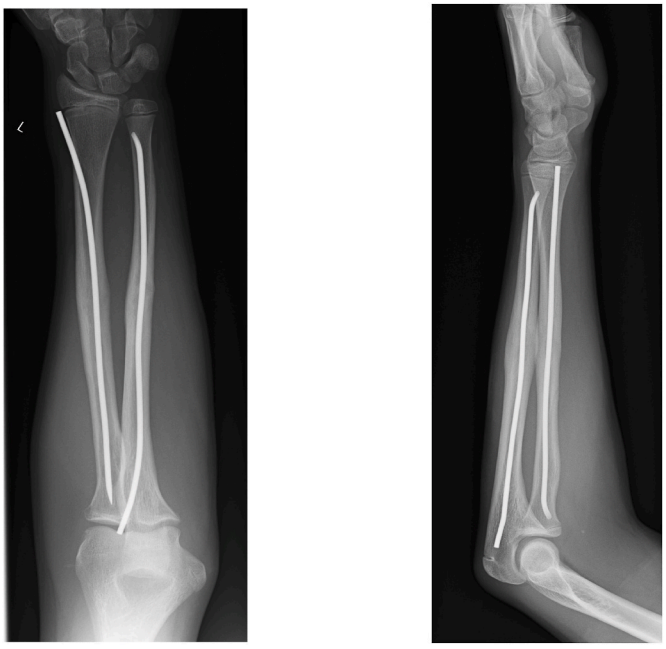

Fig. 4. AP and Lateral radiographs 5 months post-operatively showing complete radiologic bone union. This child is ready for the metalwork to be removed.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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