Title:

Flexible nails have a significantly increased risk of complications compared with plating techniques when treating diaphyseal femoral fractures in children aged 5-12: a systematic review.

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Abstract

Background

One third of paediatric femoral fractures occur between the ages of 5 and 12. The American Academy of Orthopaedic Surgeons (AAOS) provide evidence-based guidance for treating such fractures that occur in children under 5 and over 12 but not for this age cohort. We aimed to synthesise the available evidence comparing flexible nailing versus plating techniques for diaphyseal femoral fractures in children between the ages of 5 and 12.

Methodology

A systematic review was performed of interventional and observational studies using MEDLINE, EMBASE, Cochrane CENTRAL, Web of Science, WHO Global Index Medicus and LILACS. The search strategy combined keywords for: children, diaphyseal femoral fractures, plates and nails. Two independent reviewers screened, selected, assessed quality and extracted data from identified studies. The primary outcome was overall complication rates. Secondary outcomes assessed rates of individual complications, and operative variables (e.g. operative time, blood loss).

Results

Five studies fulfilled the eligibility criteria. No RCTs were identified. The studies included 308 femoral fractures in 306 patients: 174 fractures were treated with flexible nailing and 134 with plating. The post-operative complication rate was 27.0% (n=47) after flexible nails and 12.7% (n=17) after plating, relative risk 2.13 (95% CI 1.28, 3.53; p=0.0035). The relative risk of malunion was 3.59 (95% CI 1.05, 12.25; p=0.0409) with flexible nails and of prominent metalwork was 5.39 (95% CI 1.25, 23.31; p=0.0241) with flexible nails.

Conclusions

Data on this topic for this age group is limited despite accounting for one third of paediatric femoral fractures. This review identified a significantly increased relative risk of all complications, and in particular with respect to malunion and prominent metalwork when fractures in this cohort are

treated with flexible nails compared to plates. A multi-centre randomised trial to determine if either treatment is superior would be justified.

Level of evidence: II

Highlight 1

Evidence-based guidance for treating traumatic diaphyseal femoral fractures in children under 5 and over 12 is lacking.

Highlight 2

The relative risk for any complication was 2.13 (95% CI 1.28, 3.53; p=0.0035) when comparing flexible nails with plating techniques.

Highlight 3

The relative risk of malunion in this cohort was 3.59 (95% CI 1.05, 12.25; p=0.0409) for flexible nails when compared with plating techniques.

Highlight 4

The relative risk of prominent metalwork in this cohort was 5.39 (95% CI 1.25, 23.31; p=0.0241) for flexible nails when compared with plating techniques.

Highlight 5

Further high-quality prospective interventional data is required to determine if there is a true treatment effect and if either treatment is superior in terms of complication rates whilst mitigating for biases.

Introduction

Paediatric femoral fractures are the most the common long bone fracture in children, with one third of these occurring between ages 5 to 12[1-2]. These injuries are usually the result of road traffic accidents, recreation/sports and non-accidental injury. Different modalities exist for managing these fractures, often stratified according to the age of the patient[3].

The American Academy of Orthopaedic Surgeons (AAOS) provides guidance for the treatment of paediatric diaphyseal femoral fractures, this guidance was most recently updated in 2015[4]. These guidelines provide evidence for managing fractures in three sub-groups based upon age, but recommendations for the 5- to 12-year old group are lacking, merely stating that flexible nails are an option.

Options for stabilisation and fixation in this age group include flexible nailing, plating (open or submuscular), external fixation, or hybrid techniques[3]. Flexible nailing and plating are the most commonly used and both have case series data to support them[5-8], but there are few comparative studies. Complications of both treatments include malunion, non-union, infection, limb length discrepancy, implant failure, prominent metalwork and revision surgery[5,8-13].

A 2014 Cochrane review of the treatment of diaphyseal femoral fractures in children and adolescents identified no literature for this age group[14]. To date, there are no published RCTs on this topic. Nevertheless, a number of observational comparative studies have been published since the last AAOS guidelines were published, and these are included in this evidence synthesis.

Materials and Methods

We performed a systematic review using a pre-defined protocol as per the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) recommendations[15]. The protocol was registered with PROSPERO (international prospective register of systematic reviews) [registration number = CRD42019118328].

The following databases were searched from inception to 23rd January 2019: Medical Literature Analysis and Retrieval System Online (MEDLINE); Excerpta Medica Database (EMBASE); Cochrane Central Register of Controlled Trials (CENTRAL); Web of Science; WHO Global Index Medicus; and Literatura Latino Americana em Ciências da Saúde (LILACS). Grey literature sources such as OpenGrey were reviewed but did not yield any relevant results. Additional papers were sought by reviewing the reference lists of relevant articles.

The search included terms (and variants of) for the following keywords: “child” AND “diaphyseal femoral fracture” AND “plate” AND “nail”. The primary search strategy was constructed using MEDLINE and subsequently adapted to suit the other databases. Appendix 1 provides the search strategy used for MEDLINE.

The search results were imported into Covidence[16], an online bibliographic software platform, and any duplicates were removed. Two authors (RLD, LH) independently screened the remaining titles and abstracts against the following eligibility criteria.

Eligibility criteria:

Studies were assessed for eligibility against the following PICOS criteria:

Population: children aged between 5-12 years old with traumatic diaphyseal fractures of the femur, without underlying musculoskeletal conditions; (N.B. diaphyseal fractures were defined as OTA grade 32);

Intervention: studies in which the intervention/observation group undergo treatment with flexible/elastic nailing techniques;

Comparator: studies in which the comparator group undergo treatment with plating techniques;

Outcomes: the primary outcome measure was all (any) post-operative surgical complications. Secondary outcomes analysed individual complications (infection; limb length discrepancy; malunion; non-union; prominent metalwork; implant failure; unplanned revision surgery rates; other; mortality) and operative variables (operative time; estimated blood loss; fluoroscopy time; elective metalwork removal rates; surgical costs).

Study design: interventional and observational comparative studies were sought, with interventional studies being preferred. Included studies must have directly compared the above surgical techniques in their studies.

Exclusion criteria with respect to the population, intervention and comparator included: other forms of treatment (external fixation; traction; hip spica casting); hybrid fixation; pathological fractures; structural/metabolic bone disorders; animal studies; and cadaveric studies. Gustilo grade I open fractures were included as they are typically managed in a similar manner to closed fractures, but all other grades of open fracture were excluded.

Exclusion criteria with respect to the study design included: case reports/series; editorials and comments; guidelines and protocols; abstracts; demographic studies; narrative reviews; and non-English language literature. Studies where data could not be extracted for analysis were also excluded.

Full text articles were acquired for any titles and abstracts that were deemed eligible for the systematic review and were subsequently independently screened by the same two authors. Any disputes were settled through discussion.

Data extraction and analysis

A data extraction form was developed and piloted. Data extracted from full text articles included study details (author; objective; funding; country/setting), study design (type of study; selection of participants; duration of follow-up; sample size calculations; statistical analyses), population (inclusion and exclusion criteria; number of participants; participant characteristics), intervention, comparator, primary outcome (all post-operative complications), secondary outcomes (individual complications [infection; limb length discrepancy; malunion; non-union; prominent metalwork; implant failure; unplanned revision surgery rates; other; mortality] and surgical variables [operative time; estimated blood loss; fluoroscopy time; elective metalwork removal rates; surgical costs]).

Two researchers (RD, LH) independently extracted the data. Data sets were compared, and any disputes were settled through discussion. The same researchers then assessed the quality of the studies for risk of bias, and consensus was again reached through discussion.

The Cochrane Risk of Bias tool[17] was chosen to assess risk of bias in any included interventional studies, and the Cochrane Risk of Bias In Non-randomised Studies – of Interventions (ROBINS-I) tool[18] was selected to assess risk of bias in observational studies.

Statistical Analysis:

Primary outcome data was pooled and the relative risk between the intervention and the comparator was calculated. The same analysis was performed for individual complications and for surgical variables. Pooling of data was performed where possible and comparisons of proportions were calculated. Narrative discussion has been provided where statistical analysis was not possible.

Statistical analyses were performed using MedCalc for Windows, version 15.0 (MedCalc Software, Ostend, Belgium)[19]. Statistics were expressed with alpha values of 0.05 and 95% confidence intervals. Meta-analysis was not performed due to the heterogeneity amongst studies in inclusion criteria, fracture fixation methods, lengths of follow-up, reporting of time period of complication (incidence can vary over time[20]) and descriptions of matching.

Results

Study selection

The results of the search strategy are detailed in the PRISMA flow diagram in Figure 1. The database searches yielded 1,186 citations, which was reduced to 356 following the removal of duplicates. Two additional papers were identified from reference lists. Screening of titles and abstracts identified ten papers for inclusion. Five papers were included for the systematic review[20-24]. Five studies were excluded for the following reasons: two studies compared against alternative comparators[25-26], two studies assessed a different patient population[27-28], and one full text article was inaccessible[29]. All five studies that met the PICOS criteria for this review were observational studies, of which four were retrospective and one was prospective. All studies were of small size with the number of participants ranging from 54-67.

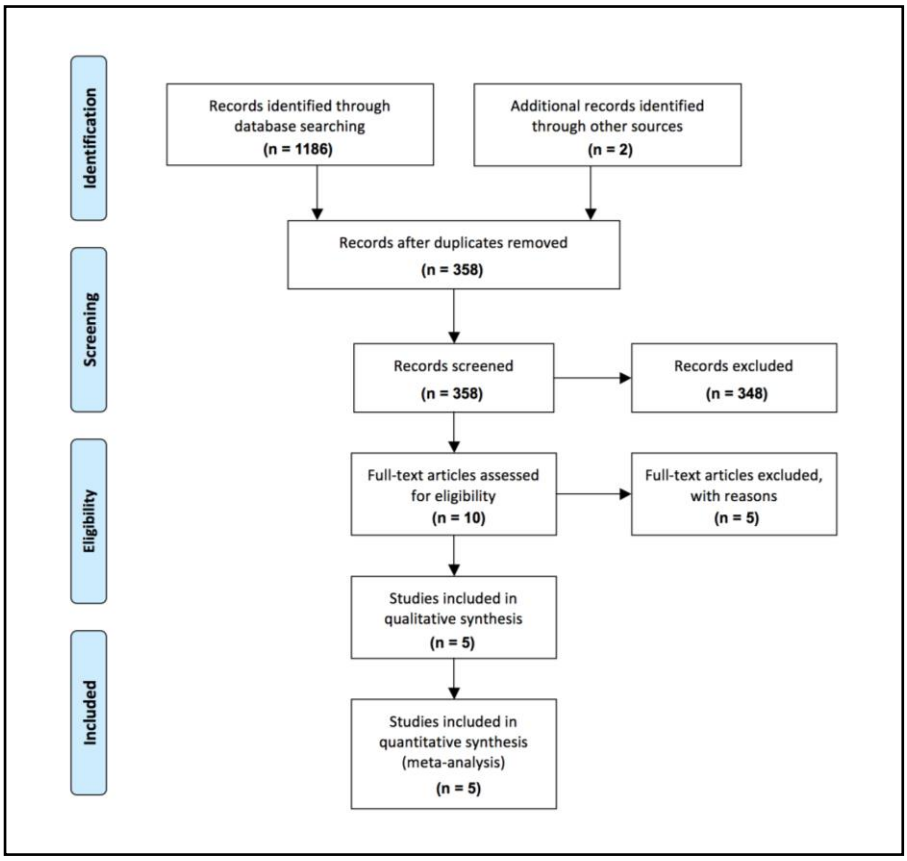

Figure 1: PRISMA flow diagram

Overview of quality assessment and risk of bias of included studies

Individual observational studies were assessed using the ROBINS-I tool. All five studies scored very high for risk of bias. Common themes included serious risk of bias with respect to confounding and selection bias. Notable issues that were identified were that most studies were retrospective, and one study did not report on all of the outcomes outlined in their methodology. There was also a lack of clarity regarding the extent of follow-up periods. A detailed analysis of the risk of bias for each study according to seven domains has been included in Appendix 2.

Cohort characteristics

The studies detailed 308 femoral fractures in 306 patients, of whom 219 were male and 87 were female, with a mean age of 8.4 years (range 5 - 12). 174 patients were treated with flexible nailing techniques and 134 patients were treated with plating techniques (a combination of open plating and sub-muscular plating techniques were used across the studies; some studies used both). Eight fractures were open (Gustilo grade I) and the remaining 300 fractures were closed. Only four out of five studies stated their follow-up durations, with a mean follow-up time of 20 months (range 3 - 83).

Summaries of each of the five individual studies can be found in Table 1.

Source & Study Design	Participants & Characteristics	Intervention & Comparator	Duration of Follow-Up	Primary Outcomes	Secondary Outcomes: Individual Complications			Secondary Outcomes: Operative Variables
Ahmed et al (2016) Pakistan Prospective observational study	**n=64** *Age*: mean = 8.81 (range 6 - 12) *Sex*: 51 male; 13 female *Weight*: not reported *Fracture types*: 45 mid-shaft; 11 proximal 1/3; 8 distal 1/3 *Severity*: 60 closed; 4 open (Gustilo 1)	**FN: n=32** **Plate: n=32** 2 flexible retrograde nails (2-4mm) vs. 4.5mm DCP with cortical/cancellous screws/both	6 months	**FN = 6** **Plate = 0**	**Complication**	**FN**	**Plate**	*Operative time (mins)*: FN: 29.91 +/- 4.61; Plate: 53.28 +/- 6.86 (p<0.05)
					Infection	1	0	
					Limb length discrepancy	0	0	
					Malunion	5	0	
					Non-union	0	0	
					Prominent metalwork	NR	NR	
					Implant failure	0	0	
					Revision surgery (unplanned)	NR	NR	
					Other	NR	NR	
					Mortality	NR	NR	
Allen et al (2018) USA Retrospective observational study	**n=63** (65 fractures) *Age*: mean = 8.7 +/- 2.0y *Sex*: 43 male; 20 female *Weight*: mean = 33.9 +/- 10.5kg *Fracture types*: length stable = 44; length unstable = 21 *Severity*: 61 closed; 4 open (Gustilo 1)	**FN: n=50** **Plate: n=32** FNs vs. plating (open or SMP)	Not stated	**FN = 7** **Plate = 2**	**Complication**	**FN**	**Plate**	*Operative time (mins)*: FN: 96 +/- 66; Plate: 150 +/- 54 (p=0.007) *Estimated blood loss (mL)*: FN: 40.1 +/- 56.6; Plate: 79 +/- 67.9 (p=0.057) *Elective hardware removal*: FN: 38/50; Plate: 13/32 *Metalwork costs (primary surgery, $)*: FN: 604.52; Plate: 726.30 (462.68 - 939.54) (p=0.11) *Anaesthesia costs (primary surgery, $)*: FN: 902.16 (576.03 - 1228.29); Plate: 1145.16 (876.09 - 1414.23) (p=0.007) *Anaesthesia costs (removal surgery, $)*: FN: 680.03 (393.33 - 966.73); Plate: 815.81 (689.05 - 942.57) (p=0.03) *Fluoroscopy time (mins)*: FN: 2.5 +/- 1.1; Plate: 3.3 +/- 1.7 (p=0.21) *Operative time (removal surgery, mins)*: FN: 54 +/- 60; Plate: 79.8 +/- 24 (p=0.02) *Estimated blood loss (removal surgery, mL)*: FN: 13.3 +/- 18.1; Plate: 50.4 +/- 41.7 (p=0.01) *Fluoroscopy time (removal surgery, mins)*: FN: 0.14 +/- 0.16; Plate: 0.56 +/- 0.56 (p=0.04)
					Infection	NR	NR	
					Limb length discrepancy	1	1	
					Malunion	3	1	
					Non-union	0	0	
					Prominent metalwork	1	0	
					Implant failure	0	0	
					Revision surgery (unplanned)	1	0	
					Other	1	0	
					Mortality	NR	NR	
Chen et al (2018) USA Retrospective observational study	**n=58** *Age*: mean = 7.7 +/- 2.0 *Sex*: 43 male; 15 female *Weight*: not reported *Fracture types*: 21 comminuted; 16 transverse; 13 oblique; 8 spiral *Severity*: 0 open; 58 closed	**FN: 28** **Plate: 30** SMP vs. FN	22 months	**FN = 10** **Plate = 6**	**Complication**	**FN**	**Plate**	*Operative time (mins)*: FN: 52; Plate: 94 (p<0.001) *Estimated blood loss (mL)*: FN: 88; Plate: 100 (p<0.001) *Elective hardware removal*: FN: 23/28; Plate: 24/30 *Operative time (removal surgery, mins)*: FN: 30; Plate: 62 (p<0.001) *Estimated blood loss (removal surgery, mL)*: FN: 0; Plate: 75 (p=0.08)
					Infection	3	4	
					Limb length discrepancy	0	0	
					Malunion	0	0	
					Non-union	0	0	
					Prominent metalwork	7	2	
					Implant failure	0	0	
					Revision surgery (unplanned)	NR	NR	
					Other	NR	NR	
					Mortality	NR	NR	
Li et al (2013) USA Retrospective observational study	**n=54** *Age*: mean = 8.2 (range 5 - 12.7) *Sex*: 42 male; 12 female *Weight*: mean = 30kg (range 17 - 50) *Fracture types*: length stable = 10; length unstable = 44 *Severity*: 0 open; 54 closed	**FN: 25** **Plate: 29** FNs (Synthes) vs. plates (open or SMP)	22 months (mean)	**FN = 17** **Plate = 5**	**Complication**	**FN**	**Plate**	Not reported
					Infection	1	0	
					Limb length discrepancy	4	3	
					Malunion	4	1	
					Non-union	0	0	
					Prominent metalwork	3	0	
					Implant failure	NR	NR	
					Revision surgery (unplanned)	2	1	
					Other	3	0	
					Mortality	NR	NR	
Xu et al (2018)	**n=67** *Age*: mean = 8.3 +/- 2.0 (range 5 - 11.9)	**FN: 39** **Plate: 28**	28.5 months (mean)	**FN = 7** **Plate = 4**	**Complication**	**FN**	**Plate**	*Operative time (mins)*: FN: 41.2; Plate: 98 (p=0.021) *Estimated blood loss (mL)*: FN: 8.2; Plate: 70 (p=0.0001)
					Infection	0	0	

China Retrospective observational study	*Sex*: 40 male, 27 female *Weight*: 35.5kg +/- 5.9 (range 25.3 - 49.6) *Fracture types*: length stable = 48; length unstable = 19 *Severity*: 0 open, 67 closed	FNs (Synthes) vs. open LCP plating (Synthes)			*Limb length discrepancy*	2	3	
					Malunion	2	1	
					Non-union	0	0	
					Prominent metalwork	3	0	
					Implant failure	NR	NR	
					Revision surgery (unplanned)	0	0	
					Other	NR	NR	
					Mortality	NR	NR	

Key: FN: flexible nail, DCP: dynamic compression plate, SMP: sub muscular plate, LCP: locking compression plate, NR: not reported, mins: minutes, mL: millilitres, $: dollars.

Outcome analysis

Primary outcome (any complication)

Pooled data from the five included studies showed that complications (any) occurred 47 times in patients treated with flexible nails comparted with 17 in those treated with plating. The overall incidence of any complication was 14.3% higher if treated with flexible nails. Relative risks were calculated, finding that the overall relative risk of any complication was 2.13 (95% CI 1.28, 3.53) and that this was statistically significant (p=0.0035).

Secondary outcomes (individual complications)

Secondary outcomes, individual post-operative complications, are outlined in Table 2. This table outlines the number of studies that reported on each individual complication as well as the incidence of each complication.

Complication	Number of studies	Incidence (n)		Incidence (%)	
		Flexible nails	Plating	Flexible nails	Plating
Infection	4/5	5/124	4/102	4.0	3.9
Limb length discrepancy (>1cm)	5/5	7/174	7/134	4.0	5.2
Malunion	5/5	14/174	3/134	8.0	2.2
Non-union	5/5	0/174	0/134	0.0	0.0
Prominent metalwork	4/5	14/142	2/102	9.6	2.0
Implant failure	3/5	0/110	0/77	0.0	0.0
Unplanned revision surgery	3/5	3/114	1/89	2.6	1.1
Other	2/5	4/75	0/61	5.3	0.0
Mortality	0/5	0/0	0/ 0	0.0	0.0

Complication	Number of studies	Incidence (n)		Incidence (%)	
		Flexible nails	Plating	Flexible nails	Plating
Overall (any)	5/5	47/174	17/134	27.0	12.7

Table 2: Incidence of complications occurring after flexible nails vs. plating.

It is evident that the most frequent complications were malunion, prominent metalwork and limb length discrepancy. Rates of individual complications from the five studies were again pooled and relative risks were calculated using the same methods as outlined above. These results are displayed in Table 3.

Complication	Number of studies	Relative Risk	95% CI	Significance level
Infection	4/5	1.20	0.33, 4.36	p = 0.7822
Limb length discrepancy (>1cm)	5/5	0.77	0.28, 2.14	p = 0.6168
Malunion	5/5	3.59	1.05, 12.25	**p = 0.0409**
Non-union	5/5	0.77	0.02, 38.63	p = 0.8966
Prominent metalwork	4/5	5.39	1.25, 23.31	**p = 0.0241**
Implant failure	3/5	0.70	0.01, 35.04	p = 0.8596
Unplanned revision surgery	3/5	1.89	0.20, 17.87	p = 0.5767
Other	2/5	6.94	0.38, 127.85	p = 0.1923
Mortality	0/5	0.77	0.02, 38.63	p = 0.8966
Overall (any)	5/5	2.13	1.28, 3.53	**p = 0.0035**

Table 3: Relative risk calculations (alpha <0.05; 95% confidence intervals)

There was a statistically significant increased relative risk of malunion (angulation; malrotation) of 3.59 (95% CI 1.05, 12.25) when patients were treated with flexible nails compared with plating (p=0.0409). There was similarly a statistically significant increased relative risk of prominent

metalwork of 5.39 (95% CI 1.25, 23.31) for flexible nails compared with plating (p=0.0241). No other individual complication showed statistically significant differences.

Unplanned revision surgery in those who underwent treatment with flexible nails included revision for prominent metalwork (2), and manipulation under anaesthesia for knee stiffness (1), compared with epiphysiodesis (1) for a 3cm limb length discrepancy in the plating cohort. All cases of infection were managed non-operatively with antibiotics alone.

Other complications in those treated with flexible nails included knee flexion contracture (1), knee stiffness (1), saphenous nerve paraesthesia (1), and skin maceration (1). No other complications were reported patients who underwent treatment with plating.

Secondary outcomes (operative variables)

Operative time (minutes): 4/5 studies assessed operative time at primary surgery. Estimated total operative time for flexible nails versus plating was calculated based on the mean operative time and the number of cases in each cohort. Proportional durations of operative times were then calculated, with 42.2% of time spent performing flexible nails relative to 57.8% of time performing plating. This 15.6% difference was found to be of statistical significance, confirming that undertaking flexible nailing required a shorter operative duration compared to plating (95% CI 3.59, 26.90; p=0.0110). The relative risk of operative time was 0.73 for flexible nails (95% CI 0.72, 0.75; p<0.0001).

Estimated blood loss (millilitres): 3/5 studies assessed estimated blood loss at primary surgery. Estimated total blood loss for flexible nails versus plating was calculated based on the mean blood loss and the number of cases in each cohort. Proportional estimated blood loss volumes were then calculated, with 38.8% of blood loss occurring during flexible nailing relative to 61.2% occurring during plating. This 22.4% difference was also statistically significant, confirming that

undertaking flexible nailing resulted in smaller volumes of blood loss compared to plating (95% CI 8.64, 34.95; p=0.0014). The relative risk of estimated blood loss was 0.63 for flexible nails (95% CI 0.62, 0.65; p<0.0001).

Elective hardware removal: 2/5 studies cited that their centres routinely offered elective metalwork removal to their patients once the fractures had healed. This was taken up by 78.2% of patients with flexible nails and 59.7% of patients with plates. Applying the Chi-squared test, this produced a difference of 18.5% (95% CI 3.20, 33.16; p=0.0179) (Chi-squared 5.606, DF 1). Both studies found that the operative time (minutes) and estimated blood loss (millilitres) was statistically significant, in favour of flexible nails at the time of removal surgery. One of these two studies, Allen *et al*[21], also found fluoroscopy time (minutes) at elective removal surgery to be of a statistically significant shorter duration in favour of flexible nails. The relative risk of elective hardware removal was 1.27 for flexible nails (95% CI 0.90, 1.79; p=0.1696).

Surgical costs ($): This was only analysed in the study by Allen *et al*[21]. They found statistically significant difference in the cost of anaesthesia fees in the USA during the primary surgery (p=0.007) and elective removal of hardware surgery (p=0.03) in favour of flexible nails. Metalwork/implant prices for the primary surgery were not statistically significant. Further figures are available in Table 1.

Discussion

This is a comprehensive and up-to-date systematic review of the literature comparing the complications and surgical variables in children aged 5 to 12 years old who have undergone treatment of diaphyseal femoral fractures with either flexible nails or plating techniques. There is presently no prospective randomised trial data on this subject matter, and only five observational studies met the eligibility criteria which detailed 308 diaphyseal femoral fractures in 306 patients, of which 174 were treated with flexible nails and 134 were treated with plates.

47 complications occurred after treatment with flexible nails (27% complication rate), compared with 17 complications after plating (12.7% complication rate). The relative risk of having any complication between flexible nails and plates was 2.13 (95% CI 1.28, 3.53), indicating an increased risk of complications if treated with flexible nails, and this was statistically significant (p=0.0035). Although it is clear that complication rates are high in both treatment groups, this finding demonstrates that operating surgeon who prefers to use flexible nails may wish to give consideration to plating techniques in order to reduce the risk of post-operative complications.

Secondary outcome analysis also found a statistically significant increased risk of malunion and prominent metalwork when this cohort are treated with flexible nails compared to plating techniques. All five studies reported data on malunion, and four studies reported data on prominent metalwork. Flexible nails were shown to have significantly increased relative risks of 3.59 (95% CI 1.05, 12.25; p=0.0409) and 5.39 (95% CI 1.25, 23.31; p=0.0241) for malunion and prominent metalwork respectively, compared to plating. It must be recognised, therefore, that this modality of treatment carries this significant risk of malunion and prominent metalwork, and the operating surgeon should consider these when deciding which treatment is optimal to suit each patient and their fracture pattern on a case-by-case basis.

The relative risks for infection, unplanned revision surgery and ‘other’ were all increased for flexible nailing techniques; however, the relative risks were reduced for limb length discrepancy, non-union

and implant failure. None of these outcomes were of statistical significance. Of note, some complications were not reported across all five studies; therefore, the relative strength of the findings must be interpreted cautiously.

Although more complications occurred in patients undergoing flexible nailing, the surgical variable data found this treatment modality to be superior in terms of certain operative features: shorter operative duration times (p=0.0110), smaller volumes of estimated blood loss (p=0.0014), and lower cost of anaesthesia fees (p=0.007). This suggests that flexible nailing may offer increased safety to patients in terms of duration of anaesthesia, volume of blood loss, and cost of surgery when compared to plating.

Existing literature focusses on children under-5 or over-12 years old. Numerous series for the latter cohort have documented the well-recognised post-operative complication of malunion at varying rates ranging from 7-60%[6,27,30-31]. This is more prevalent in the form of angular malunion rather than rotational malunion. Contributing factors can include age, body weight, fracture pattern, nail size and nail material[32]. Available literature suggests that the upper limits for avoiding undue complications through use of flexible nails are patients who are aged 12+ years, patients who weigh 50+ kilograms[33], or patients who have length-unstable fractures[11]. This differs from the findings of our review, which would suggest that the upper age limit may be lower than previously thought.

The key difficulties that remain appear to be that: 1) there does not appear to be consensus definition of what constitutes a malunited femur in children aged between 5-12 years old; 2) what timeframe post-injury should malunion be diagnosed (and how much time for remodelling should be permitted first); and 3) what degree of malunion in this cohort are we willing to accept. Undoubtedly, many surgeons will have their own acceptable timeframes and degrees of angulation that they are willing to work within.

Limitations

The greatest limitation of this systematic review is the lack of high-quality evidence available for examination. No RCTs comparing the complications of children aged 5 to 12 years old undergoing treatment of diaphyseal femoral fractures with either flexible nails or plating techniques were identified, which inherently implies that the results of this review are subject to selection bias and confounding.

All five included studies were observational, and the risk of bias assessment found all five studies to carry serious risks of bias (see Appendix 2). The retrospective nature of four of the included studies increased the risk of reporting and classification biases, and was potential for measurement errors (for example, measuring malunion and limb length discrepancy can be subject to inter-observer variability). The one prospective study included in this analysis was deemed to have critical omissions in its reporting of data.

There were suggestions of a lack of homogeneity amongst the outcomes recorded (for example, two of the five studies did not provide data on implant failures rates or unplanned revision surgery rates); and follow-up periods were not equal, which may have influenced the outcome data recorded (for example, metalwork may become prominent or symptomatic over a more prolonged period of time, and may not be recorded if the follow-up period is only three months). Some studies included low-grade open fractures, which may have been managed differently to the closed fractures; and some studies utilised two different plating techniques (open versus sub-muscular) together, thus increasing the number of variables which could affect outcomes. As such, the results of the study should be interpreted with caution.

Conclusions

This review identified a significantly increased risk of any complication when diaphyseal femoral fractures in children aged 5-12 years old are treated with flexible nails compared to plates. Secondary analysis identified significantly increased risks of malunion and prominent metalwork in particular. The findings of this review should be used to supplement the current AAOS guidelines[5] in this cohort which are currently lacking evidence-based detail. The quality of data in this field remains low, and therefore we propose a multi-centre prospective randomised controlled trial to determine if either treatment is superior would be justified.

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