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Flexible intramedullary nailing Vs. plate and screws in the treatment of diaphyseal femoral fractures in children: Meta-analysis & systematic review

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Abstract
Background: Femoral diaphysis fractures provide a risk of morbidity in paediatric patients. Numerous fixation techniques have been devised, although there exists only little data to support their usage. This systematic study aimed to evaluate the clinical results of flexible intramedullary nailing with plate and screws in treating femoral diaphyseal fractures in children aged 5 to 10 years.
Methods: We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines when performing our study as we searched PubMed, Scopus and Web of Science databases from inception to February 2023 for eligible articles to be included in our study. Criteria for inclusion had been articles comparing the elastic intramedullary nailing technique with the plate and screws technique in children. We involved all types of observational studies (cohort, case-control, and cross-sectional) in addition to randomized controlled trials. The RoB 2 tools assessed the risk of bias.
Results: A total of 268 articles were identified, with 14 studies meeting the eligibility criteria. Quality assessment revealed that four RCTs had low risk of bias, while three had high risk, and one had some concerns. Among observational studies, three were of high quality, and two were of moderate quality. Intramedullary nailing was associated with significantly decreased operation time, lower blood loss, and shorter hospital stay compared to the plate and screws technique ($p < 0.05$ for all). Additionally, the intramedullary technique demonstrated faster healing time ($p = 0.001$). However, no significant differences were found between the two techniques in terms of limb length discrepancy ($p = 0.66$) or Flynn score ($p = 0.75$). Intramedullary nailing was linked to a higher incidence of complications, with an odds ratio of 3.09 ($p = 0.03$).
Conclusions: The usage of intramedullary nails in treating of femoral diaphyseal fractures in children from 5 to 10 years old is associated with better outcomes regarding operation time, blood loss, healing time and hospital stay while it is associated with more incidence of complications such as ankylosis and angular deformity compared to plate and screws. There was no difference between the two techniques regarding Flynn score, and limb length discrepancy.

Keywords: Flexible intramedullary nailing, plate and screws, femoral diaphyseal fractures, pediatric fractures, systematic review, meta-analysis

Introduction

Paediatric femoral shaft fractures (FSF) are rare, accounting for < 1% of all paediatric fractures; yet, they impose a considerable cost on healthcare systems and families, since they represent the most prevalent fractures necessitating hospitalisation in children [1]. Such injuries often need extended immobilisation or surgical intervention [2]. Paediatric FSF occur 2.6 times more often in males than in girls. A bimodal distribution has been observed, with the first peak in the 1-3 year age group (typically low energy) and the subsequent peak throughout early adolescence (high energy), accounting for the bulk of these fractures. The predominant causes are falls from heights and road traffic accidents, with a suspicion of child abuse [3].
Stress fractures of the femoral shaft and neck, however rare, are becoming more prevalent in children [4]. A uniform categorisation system for paediatric FSF is unavailable. Fractures are often categorised descriptively according to (I) configuration - transverse, spiral, or oblique, (II) comminution - comminuted or non-comminuted, and (III) open or closed. The predominant fracture type is a simple, transverse, non-comminuted, diaphyseal fracture,

including over 50% of occurrences. In the AO paediatric comprehensive classification of long bone fractures, FSF are categorised, with subcategories a) Simple fractures and b) Unstable patterns [5].

Paediatric FSF often heal quickly and possess significant remodelling capability. Therefore, a broad spectrum of deformities in the first repaired bone is deemed acceptable. The permissible angulation in the sagittal and coronal planes ranges from 30° at birth to 15° at the age of 10 years. Rotational malalignment does not undergo remodelling, and a deformity over 10° in the axial plane is deemed unacceptable. Limb shortening of up to 15 mm may be mitigated in children up to 12 years old with accelerated development. The choice between conservative and operational management of a femoral shaft fracture is influenced by several factors, particularly the patient's age, weight, fracture type, concomitant injuries or polytrauma, and the family's financial position [6].

This work aimed to perform a systematic review comparing the clinical outcomes of flexible intramedullary nailing versus plate and screws in treating femoral diaphyseal fractures in children aged 5 to 10 years.

Patients and Methods

Database searching

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines when pefrfomrming our study as we searched PubMed, Scopus and Web of Science databases for eligible articles to be included in our study depending on the required eligibility criteria.

Eligibility criteria and screening

The articles' search results were evaluated first by title and abstract, followed by full-text screening. The suitable full-text papers were downloaded for further analytical methods. Criteria for inclusion had been articles comparing the elastic intramedullary nailing technique with the plate and screws technique in children. We involved all types of observational studies (Cohort, case-control, and cross-sectional) in addition to randomized controlled trials (RCTs). We exclude studies investigating other techniques, not children population, case-series, case-reports, systematic reviews and meta-analyses.

Data extraction

Using Microsoft Excel sheets, data were extracted including baseline characteristics such as age, gender, sample size, study design, and BMI. Outcomes of the included studies were extracted such as operation time, blood loss, healing time, complications, Flynn score, limb length discrepancy, and hospital stay.

Quality assessment

For observational studies, New Castle Ottawa scale was used for quality assessment. It is a tool made of eight questions with a total score of 9. The score from 0-3 is considered a low-quality study, 4-6 a moderate-quality study and 7-9 as a high-quality study. Regarding RCTs, the Cochrane risk of bias tool (rob2) was utilised to assess the risk of bias among the involved studies. It is composed of three levels which are low risk of bias, some concerns and high risk of bias.

Statistical analysis

We utilised Review Manager version 5. 4 software to performe the meta-analysis and generate the forest plots of the included outcomes. For continuous parameters, mean difference was utilised as an effect size while for dichotomous variables, we used odds ratio for the analysis. Random effect model was implemented and p-value of 0. 05 or less was considered statistically significant.

Results:

The search strategy resulted in a total of 268 articles which became 187 following the removal of duplicates. By title/abstract screening, 27 articles had been included for full-text screening which resulted in a total of 14 [7-10] eligible articles to be involved for the final analysis. Figure 1.

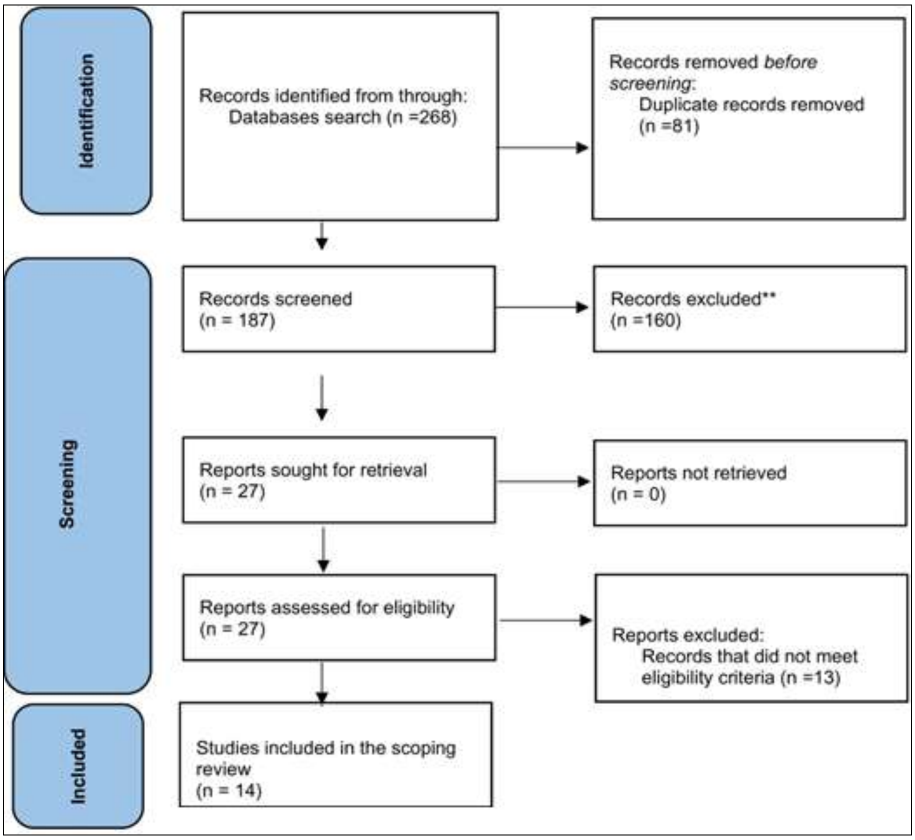


Fig 1: PRISMA flow diagram of the included studies and screening process

Quality assessment

Regarding RCTs, four studies [7-10] were of low risk of bias, three [11-13] of high risk and one [14] had some concerns. Regarding cohort studies, three [15-17] were of high quality and two [18, 19] of moderate quality. One cross-sectional study [20] was of high quality. Figure 2.

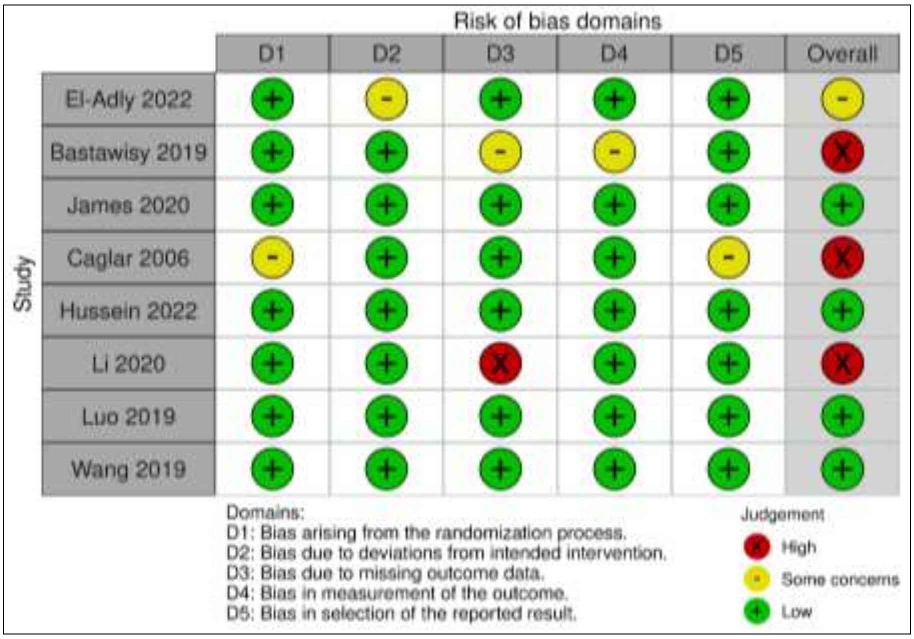


Fig 2: Quality assessment of Cohort and cross-sectional studies using New Castle Ottawa scale (Risk of bias assessment of RCTs using Rob2 tool).

Baseline characteristics: Baseline characteristics of the included studies are shown in table 1.

Table 1: Baseline characteristics of the included studies

Study	Representativeness of the intervention cohort	Selection of the non-intervention cohort	Ascertainment of intervention	Demonstration that outcome of interest was not present at start of study	Comparability of cohorts on the basis of the design or analysis	Assessment of outcome	Was follow up long enough for outcomes to occur	Adequacy of follow up of cohorts	Overall quality
Emet 2023	★	★	★	★	★★	★	★	-	8 (high)
Allar 2016	★	★	★	★	★	-	★	★	7 (high)
Ramseier 2010	★	-	-	★	★	★	★	★	6 (moderate)
Hong 2022	★	★	★	★	★★	★	-	-	7 (high)
Milligan 2020	★	-	-	-	★	★	★	★	5 (moderate)
Cross sectional study	Representativeness of the sample	Sample size	Ascertainment of exposure	Non-respondents	The subjects in different outcome groups are comparable, based on the study designs or analysis, confounding factors are controlled	Assessment of outcome	Statistical test	Overall quality	
Fakoor 2011	★	★	★	★	★	★	★	7 (high)	

Meta-analysis

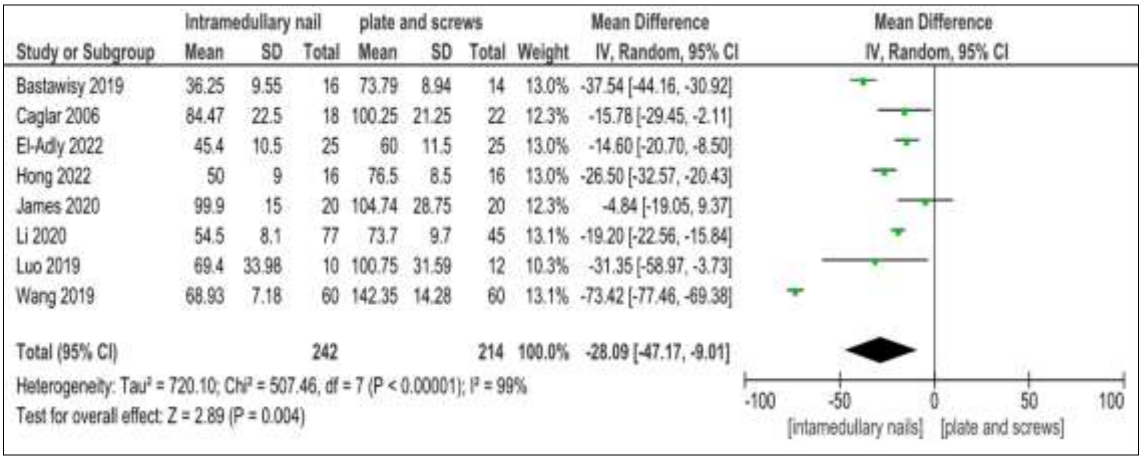
Table 2: Meta-analysis

Study ID	Study Design	Sample size		Age		Gender, (m/f))	
		Nail	Plate	Nail	Plate	Nail	plate
El-Adly 2022	RCT	25	25	7. 96±1. 6	8. 28±1. 62	2/3	18/7
Bastawisy 2019	RCT	16	14	9. 5	9. 3	11/5	10/4
Emet 2023	Cohort	24	16	9. 3±4. 6	9. 3±4. 6	14/10	10/6
James 2020	RCT	20	20	9. 45±3. 41	10. 2±2. 7	13/7	13/7
Allar 2016	Cohort	8	18	10		18 / 8	
Caglar 2006	RCT	18	22	8. 1	8	10/8	16/6
Hussein 2022	RCT	12	12	9. 17±2. 12		15/9	
Fakoor 2011	Cross sectional	7	125	-	-	-	-
Ramseier 2010	Cohort	104	17	-	-	-	-
Hong 2022	Cohort	16	16	8. 4±1. 5	8. 4±1. 5	7/9	7/9
Milligan 2020	Cohort	14	14	9. 7±1. 9	7. 7±1. 8	10/4	11/3
Li 2020	RCT	77	45	8. 1±1. 9	8±2. 2	45/32	16/19
Luo 2019	RCT	10	12	5. 9 ±2. 8		-	-
Wang 2019	RCT	60	60	10. 3	6. 55	38/22	36/24

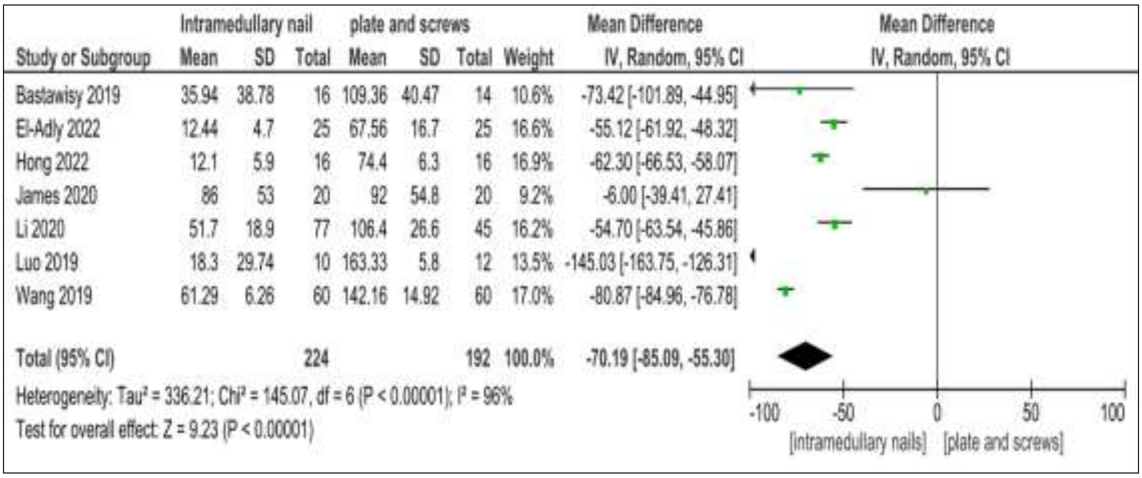
Operation time and blood loss

Intramedullary nails technique was statistically significant associated with less operation time compared to plate and screws with a mean difference of -28. 09 (95%CI: -47. 17 - -9. 01, p<0. 00001. Figure 3 A

Regarding blood loss, it was observed that intramedullary technique produced statistically lower blood loss during the operation compared to the plate and screws technique with a mean difference of -70. 19 (95%CI: -85. 09 - -55. 3, p<0. 00001). Figure 3 B



A)



B)

Fig 3: Forest plot of (A) operation time and (B) blood loss among the study groups

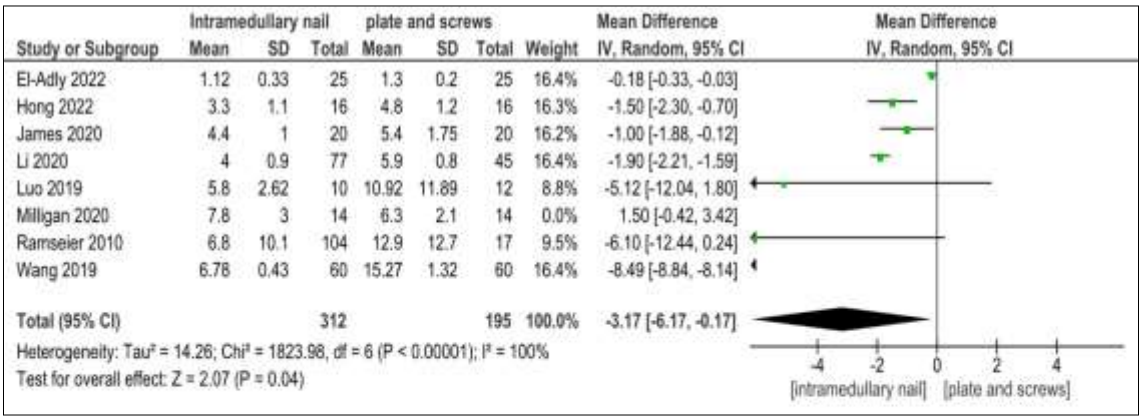
Hospital-stay, healing time, Limb length discrepancy and Flynn score

The intramedullary technique was statistically significant associated with lower length of hospitalisation compared to the plate and screws technique with a mean difference of -3. 17 (95%CI: -6. 17 - -0. 17, p=0. 04). Figure 4 A

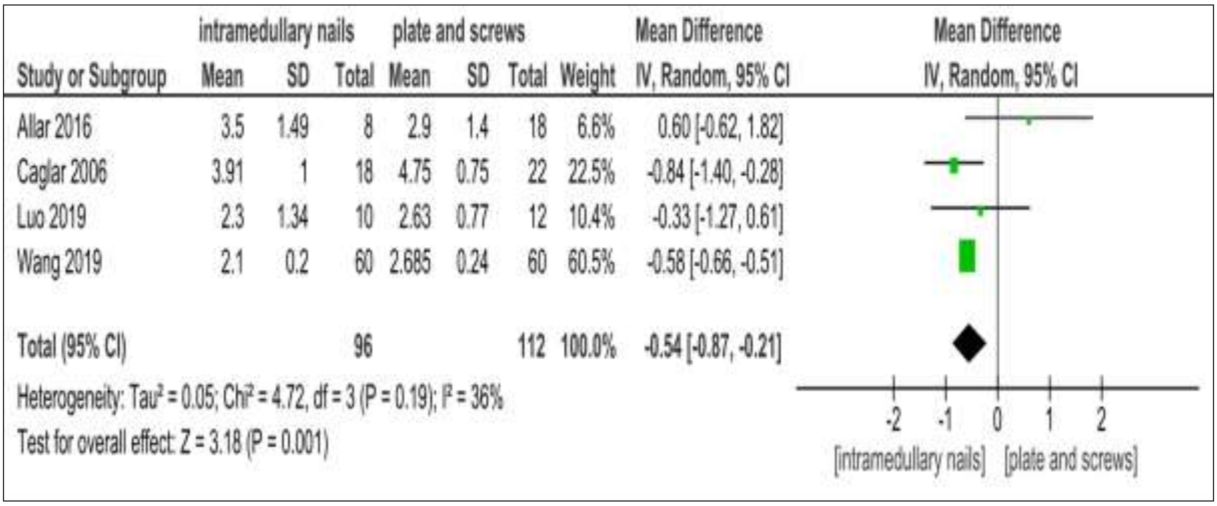
The intramedullary nails technique was statistically significant associated with faster healing time compared to the plate and screws technique with a mean difference of -0. 54 (95%CI: -0. 87 - -0. 21, p=0. 001). Figure 4 B

No statistically significant variation existed between the two groups regarding limb length discrepancy (p=0. 66). Figure 4 C

No statistically significant variation existed between both groups regarding the different domains of Flynn score (Excellent, Satisfactory and poor) (p=0. 75). Figure 4 D



A)



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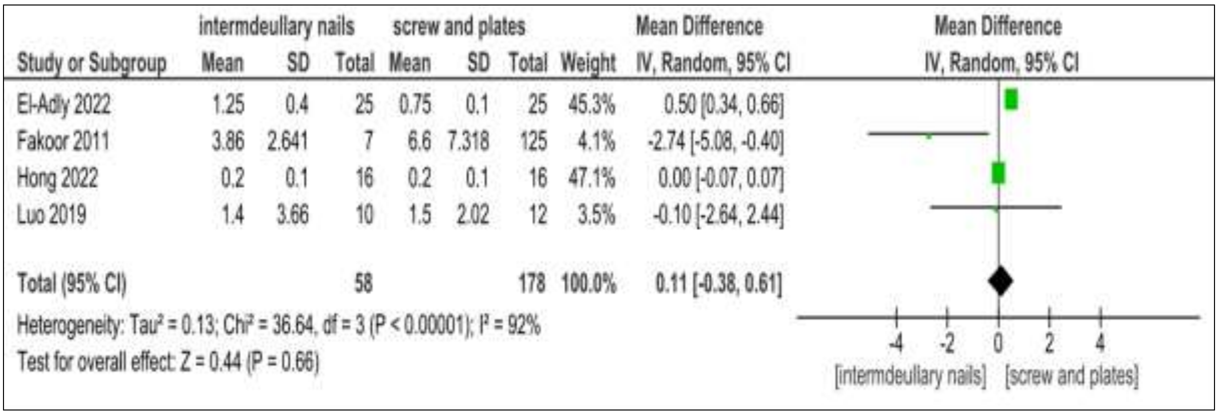
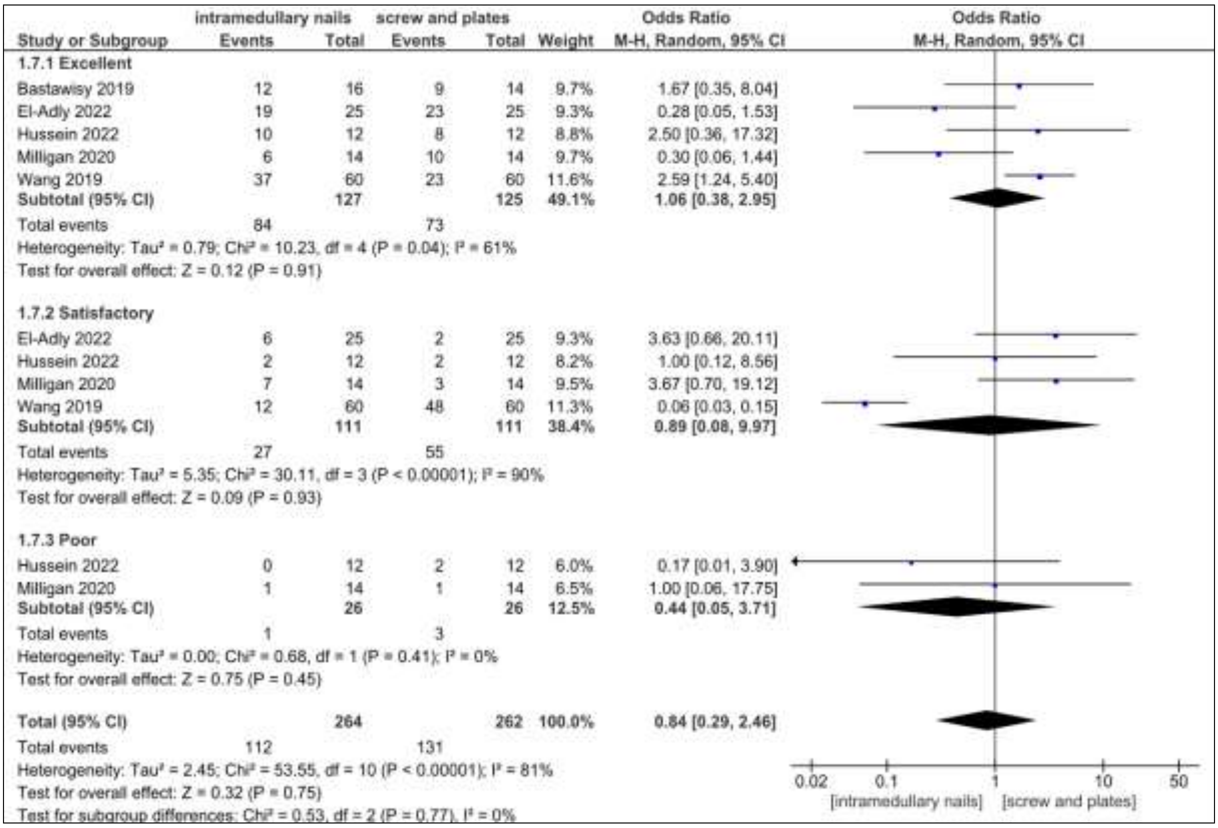


C)



D)

Fig 4: Forest plot of (A) hospital-stay, (B) healing time, (C) limb length discrepancy and (D) Flynn score among the study groups

Complications

Intramedullary nails technique was statistically significant association with higher occurrence of complications compared to plate and screws technique with odds ratio of 3. 09 (95%CI: 1. 1 – 8. 65, p=0. 03). Figure 5.

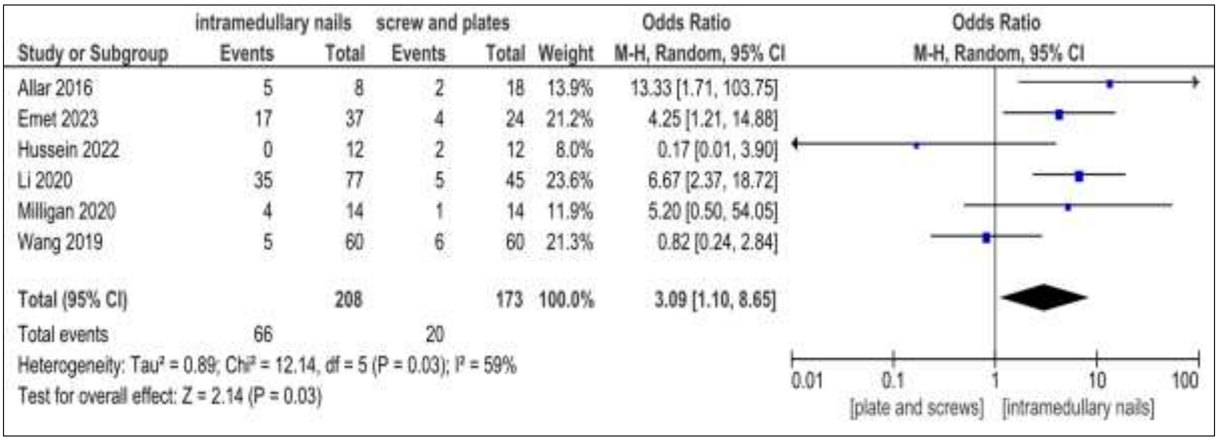


Fig 5: Comparison between the two groups regarding the occurrence of complications

Discussion

There are increasingly more clinical approaches for managing femoral shaft fractures as medical technology advances, but there is still no agreed-upon approach for treating paediatric femoral shaft fractures [21]. According to clinical investigations, conservative therapy took longer time and required lengthier stays in hospitals. Also, the majority of the kids were immature and prone to noncompliance with treatment. As a result, several researchers believed that kids are better to have surgery.

In the beginning, external plaster fixation was attempted, but the fixation strength was insufficient. Since children were frequently uncooperative, different degrees of fracture end displacement could result. Consequences that could last a long time include joint stiffness, malunion, or skin pressure ulcers, all of which would make treatment less effective and diminish quality of life [22]. The most often used procedures for internal fixation are elastic stable intramedullary nailing (IMN) and plate internal fixation, which has lately replaced other modalities [9, 23].

The present study shows favourable outcomes regarding the operation time and the blood loss in the intramedullary nails technique compared to plate and screws.

Reported ranges of 54 minutes for ESIN [24] and 114 minutes for open plating [25] have been stated. Hong reported similar results and showed that the less operating time and the less blood loss are associated with minimal invasiveness in nailing compared to plating.

In terms of blood loss, elastic stable intramedullary nails fared well. According to a study by Luo *et al*. [9] the average blood loss during. ESIN was 18 mL as opposed to 163 mL during plating. Open reduction was not always required, which significantly reduced blood loss. Currently, no other implants, such as submuscular bridge plates, can equal the minimally invasiveness of intramedullary nails.

Although there is debate over the best course of dealing, surgery is preferred for treating pediatric femur fractures between the ages of 5 and 10 years. The most popular choices are elastic nails or compression plates. While elastic nails have an advantage over plates for fixation in that they need less invasion of soft tissues, its main drawback is a higher incidence of instability and misalignment difficulties [26].

The most effective course of action for treating paediatric femur fractures and mobilising the wounded kid is still in debate. When treating children with length-stable femoral fractures, intramedullary elastic nails are frequently used. Sub muscle plating has recently been demonstrated to be a beneficial alternative for managing length- unstable femoral fractures in school-age children, despite the fact that plating is still an effective option for treating femoral fractures due to its ease of administration and early mobilization.

Hong *et al*. [17] investigated the use of triple intramedullary nails technique versus the plate technique. During surgery, alignment, fracture displacement, and stability were evaluated to determine whether a third nail was necessary.

A third intramedullary nail was placed from the lateral incision of the distal femur if the fracture site showed > 1 cm of displacement, translation, or > 15 degrees of angulation. Additionally, in line with the other studies [27], there were no patients in the group of intramedullary nails who had malunion or severe angulation. Children with pathological proximal femur fractures were managed with triple IMN [28]. In addition, difficult FSF in children have been managed with triple nails and a quarter of nails [29, 30]. Triple nails are thus a viable option for paediatric subtrochanteric fractures. The intramedullary nail must push slowly through the restricted area in order to overcome resistance.

Regarding hospital stay, according to numerous reports, the substantial surgical exposure in the plating group and wound dressings may be the reason why hospital stays were shorter in subjects managed with IMN than in subjects treated with plates. More often than not, the patient's financial restrictions had an impact [8].

Regarding Finance, Elastic intramedullary nails are also preferable options from a financial perspective. Nearly half as much money was spent on hospitalisation using the intramedullary nail procedure as it was for plates. The main reason for this was that elastic intramedullary nails were less expensive than plates. According to Luo *et al*. the cost is unrelated to how long the procedure takes. However, there was no discernible difference in implant cost between ESIN and plates in Allen's study [31].

Regarding complications, Our study showed that intramedullary nails technique is associated with higher complication rate compared to plates and screws technique.

The present study showed that the intramedullary nails technique was statistically significant associated with faster healing time compared to the plate and screws technique.

Similar to the present study, Fyodorov *et al* [32], and Andalib *et al* [33] stated that clinical union time was statistically

significant shorter in intramedullary nails technique compared to the plate and screws. Sutphen *et al.* [34] reported on 344 fractures of the femur in pediatrics and compared rigid nailing, intramedullary, and plating with a minimum follow-up of 12 weeks. In comparison to intramedullary nail, they found a statistically significant reduction in the mean-time to union (6 vs. 8 weeks), faster mobilisation (7 vs. 12 weeks), lower rates of malunion, less irritated hardware, and fewer complications with plate fixation.
The present study showed no difference between both techniques regarding limb length discrepancy.
In femoral shaft fractures treated with dynamic compression plates, Ward *et al.* [35] report a (4. 3%) success rate of healing while Eren *et al.* [36] report a (5. 4%) success rate. Ligier *et al.* [37] found (12%) and (8.5%) of limb length discrepancy in patients treated by intramedullary nails, respectively.
Flynn established a scoring system that took into account four factors which are limb length inequality, malalignment, pain, and the occurrence of complications to assess the success of the fixing approach for diaphyseal femoral fractures in children [38].
Our study reported that no statistically significant variation existed between both groups as regards the Flynn score. Different to these findings, El-Adly *et al.* [14] contrasted the flexible IMN and submuscular locked plate using the cluster technique for the fixation of paediatric FSF. Their findings indicated that functional outcomes, as measured by Flynn's score, favoured plating, with 92% of patients achieving great outcomes compared to 76% in the nail group, and no poor outcomes reported in either group. Both methods optimise the advantages of closed treatment while maintaining the biological integrity of the fracture site. Furthermore, locked submuscular plating amalgamates the superior features of surgical intervention, including stability, preservation of proper alignment, early mobilisation, and ease of management.
According to Parikh *et al.* [39] elastic nailing is a significant alternative for treating difficult-to-manage femur fractures. Li *et al.* [13] published a comparison research in 2013 that showed plate fixation to be superior to titanium elastic nails in terms of outcome scores and total complication rate. In a related comparative analysis published in 2018, Xu *et al.* found that plate fixation was a more rigid fixation that was correlated with a decreased complication rate [40]. This comes in accordance with our results.
Hussein *et al.* [8] reported that plating has not been as popular as intramedullary nailing due to plating's worse mechanical characteristics and higher frequency of related infections. The use of closed IMN, which prevents periosteal stripping at the fracture site and preserves the periosteal blood supply, has been found to be particularly compatible with the natural process of healing of periosteal callus formation.
This is the first meta-analysis to investigate the difference between the two main techniques used in diaphyseal humoral fractures in children. We included all available studies in the literature and investigated all the included outcomes to evaluate the differences between the two techniques.
There exist some limitations in the present study including variety among the studies in some of the operating techniques, small sample size in some of the studies, pooling of results in the studies with different study design such as observational studies and RCTs. Another limitation is presented in the statistically significant heterogeneity in some of the outcomes.
The usage of intramedullary nails in managing femoral diaphyseal fractures in pediatrics from 5 to 10 years old is associated with better outcomes regarding operation time, blood loss, healing time and hospital stay while it is associated with more incidence of complications such as ankylosis and angular deformity compared to plate and screws.
There was no difference between the two techniques regarding Flynn score, and limb length discrepancy. The study recommends the use of intramedullary techniques frequently in children 5-10 years old at risk of bleeding complications, for financial issues due to shorter hospital stay and in length stable fractures.
The study recommends the usage of intramedullary techniques frequently in children 5-10 years old at risk of bleeding complications, for financial issues due to shorter hospital stay and in length stable fractures.

Conclusions

The usage of intramedullary nails in the managing femoral diaphyseal fractures in children from 5 to 10 years old is associated with better outcomes regarding operation time, blood loss, healing time and hospitalisation while it is associated with more incidence of complications such as ankylosis and angular deformity compared to plate and screws. There was no difference between the two techniques regarding Flynn score, and limb length discrepancy.

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Nil.

Conflict of Interest
Nil.

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