Acta Orthop. Belg., 2016, **82**, 673-680

REVIEW

A meta-analysis of external fixation and flexible intramedullary nails for femoral fractures in children

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Background : **The purpose of this meta-analysis was to compare the outcomes of external fixation and flexible intramedullary nails for femoral fractures in children between 5 and 15 years of age based on the current evidence.**

Material and Methods : **We searched relevent studies in the following database: Cochrane library, PubMed and EMABASE up to May 2014. All randomized controlled trials, Clinical controlled trials and retrospective controlled studies comparing external fixation and flexible intramedullary nails in femoral fractures of children were included. Data was extracted independently for meta-analysis.**

Results : **Seven trials altogether involving 338 cases of femoral fractures of children treated by external fixation (128 cases) and flexible intramedullary nails (210 cases) were included in the meta-analysis. Results showed that flexible intramedullary nails was superior to external fixation in less time to union , lower postoperative infection rate and refracture rate . It may not increase delayed union, Limb-length discrepancy , pain and bursitis . Both fixations obtained a similar patient satisfaction.**

Conclusion : **Flexible intramedullary nail had greater advantages for the treatment of femoral fractures in children aged 5-15 years, compared to external fixation based on current meta-analysis. This conclusion will ultimately require rigorous and adequately powered randomized controlled trials to be proved.**

Level of Evidence : **level** II

Keywords : flexible intramedullary nail ; external fixation ; femoral fractures ; children ; meta-analysis.

INTRODUCTION

Femoral fractures are among common injuries treated by an orthopedic surgeon in the paediatric age group. Immediate cast application and various forms of traction, external fixation, and internal fixation are currently being used. There are advantages and disadvantages of each method. None of these methods has proven to be superior

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No benefits or funds were received in support of this study.
The authors report no conflict of interests.

at all ages. Femoral fractures in children (younger than 4 years) have been traditionally treated by immobilization in a spica cast, either immediately or after a period in traction. The attention has been focused on the difficulty of caring for children in a body cast for 2-3 months *[8]*. In general, closed reduction and application of a spica cast is an accepted treatment for most femoral fractures for children who are 5 years of age or younger *[4]*. Notably, the older children who are managed with traction and a spica cast may miss several months of school until full union has been achieved. The optimal mode of treatment among the wide variety of surgical and nonsurgical treatment options for children between 5 and 15 years of age continues to be controversial *[2]*. There has been a growing trend towards surgical treatment with widening of the indications to include femoral fractures *[5,11]*. Operative strategies aim at avoiding the adverse physical, social, psychological, and financial consequence associated with prolonged immobilization. Those strategies include external fixation, intramedullary nailing with either rigid or flexible nails *[1,3]*, and plate fixation *[6,17]*. Each procedure caries the risk of certain complications, particularly pin track infection and refracture after external fixation removal or soft tissue irritation and painful bursitis caused by intramedullary nail *[1-3,7,16,18,20]*.

External fixation, does allow for early discharge from hospital, is less cumbersome than the hip spica cast, and can be effective for controlling the fracture position, theoretically leading to reduced rates of malunion *[19,22]*. More recently, short-term immobilization, returning joint range of motion, lack of any stiff joint, short-term hospitalization, and low costs are regarded as advantage of the flexible intramedullary nail. Although the outcomes of external fixation and flexible intramedullary nail for the treatment of femoral fractures in children have been reported *[1,18,20]*. The preferred therapeutic approach is dictated by patient's age, fracture characteristics and characteristic physical activities. It may be needed to investigate whether there is a significant difference between the two fixation in the treatment of femoral fractures in children between 5 and 15 years of age. The pourpose of the present meta-analysis was to compare the outcomes of external fixation and flexible intramedullary nails for femoral fractures in children, including comparison of age, time to union, limb-length discrepancy, infection, pain and bursitis, refracture and patient satisfaction at final review in children between 5 and 15 years of age. We hypothesized that flexible intramedullary nail would be a superior treatment for femoral fractures in children compared with external fixation.

MATERIAL AND METHODS

Search strategy

A computerized search was performed on Cochrane library, PubMed and EMABASE (up to May 2014) for the potentially relevant studies according to the search strategy of the Cochrane Collaboration. Single or combinations of terms were searched as follows: external fixation, external fixator, flexible intramedullary nail, elastic intramedullary nail, femoral fractures. All articles identified as potentially relevant were obtained and reviewed by a research assistant. Also, a manual search of references by this assistant was performed in the identified articles and systematic reviews for any additional eligible articles.

Two reviewers independently evaluated the titles and abstracts of the identified articles. Only full-text articles were eligible and included in this meta-analysis. The inclusion criteria were as follows: (1) prospective randomized controlled trials (RCTs), clinical controlled trials (CCTs) and retrospective controlled studies (RCSs) which compared the external fixation and flexible intramedullary nail were selected. (2) These studies enrolled patients had femoral fractures with a age of 5-15 years. If there were duplicates or multiple publications from the same study, which had overlap in original information, the most complete results should be chosen.

Data extraction

The two reviewers independently extracted seven publications for meta-analysis to a standard

Table I. — The detailed information on basic characteristic of seven studies and methodology assessment score

Authors	Year	Study type	Case (FIN/EF)	Mean age (FIN/EF)	Follow-up (months)	Jadad score
Bar-On, E.et al. *(2)*	1997	RCT	10/10	8.3(5.2-11.1)/9.3(6.9-13.2)	14(12-22)	5.5
Aslani, H.et al. *(1)*	2013	CCT	13/14	8.7±3.7/9.5±3.2	>=12	4.5
Barlas, K.et al. *(3)*	2006	CCT	20/20	9.2(6.8-14.1)/8.2(5.4-12.3)	NA	4.5
Sela, Y.et al. *(18)*	2013	RCS	21/14	9.7/10.6	>=12	2
Wu, Q. Z.et al. *(20)*	2011	CCT	36/31	7.1±1.6/6.5±2.3	12±3	2
Ramseier,L.E.et al. *(16)*	2010	RCS	105/33	12.9/12.9	14.6	3
Clinkscales,C.M.et al. *(7)*	1997	RCS	5/6	15±4/10±1	46.5	2

RCT: prospective randomized controlled trials; CCT: clinical controlled trials; RCS: retrospective controlled studies; NA: not available; FIN: flexible intramedullary nail; EF: external fixation

form. The following variables were extracted from each study: first author's name, publication year, Country, the number of case and control groups. Any disagreement was settled by discussion and a consensus was reached for all data.

Methodological assessment

Methodological assessment conducted using the modified Jadad scale *[14]*. It is an eight-item scale designed to assess randomization, blinding, withdrawals and dropouts, inclusion and exclusion criteria, adverse effects and statistical analysis (Table I). The score for each article can range from 0 (lowest quality) to 8 (highest quality). Scores of 4-8 denote good to excellent (high quality) and 0 to 3 poor or low quality. The critical was conducted by one viewer and verified by another.

Data Analysis

In each eligible study, the relative risk (RR) calculated for dichotomous outcomes and the weighted mean difference for continuous outcomes using the software Stata 12.0, with a 95% confidence interval (CI) adopted in both. Heterogeneity among studies was assessed using I-square (I^2) test, Chi-square (χ^2) test, and Tau-square (τ^2) test. There was no statistical heterogeneity (as judged byχ^2 test $P \geq 0.10$ or $I^2 < 50\%$), When there was no statistical evidence of heterogeneity, a fixed model was chosen; otherwise, a random-effect model was chosen. A $P<0.05$ was considered statistically significant. The outcomes of meta-analysis for age, union time, limb-length discrepancy (LLD), refracture rate, infection rate, pain or bursitis, and patient satisfaction were summarized using forest plot.

Publication bias test

Publication bias was assessed by Begg's test and a funnel plot, a $p<0.05$ was considered significant.

All analyses were performed using the software Stata 12.0 (Stata Corporation, Colledge Station, TX).

RESULTS

A total of 149 potentially relevant articles were retrieved. After reference to titles, abstracts and even full texts, seven published studies *[1-3,7,16,18,20]* with a total of 338 patients met all inclusion criteria. Information on general characteristic of studies and Jadad score was listed in Table I. Total trials scores indicate that the quality of almost half of trials was poor based on current rating system (Table I).

Age of patients

All seven studies *[1-3,7,16,18,20]* provided data of age, but the four studies *[2,3,16,18]* were not eligible for not providing standard deviation (SD). The heterogeneity test indicated a statistical evidence

Table II. — Observations and pooled outcome of meta-analyses.

Observations	NO of studies	Pooled SMD or OR	LL 95% CI	UL 95% CI	P value	χ^2 (p)	I^2 %
Age of patients	3	0.048	-0.406	1.222	0.326	6.01	66.7
Delayed union	2	0.386	0.065	2.290	0.295	1.33	24.8
LLD	5	0.539	0.223	1.301	0.169	3.26	0.0
Pain and bursitis	5	1.418	0.549	3.657	0.471	3.47	0.0
Satisfaction of patients	2	1.125	0.761	1.663	0.555	0.00	0.0

SMD: standardized mean difference; OR: odds ratio; CI: confidence interval; LLD: Limb-length discrepancy

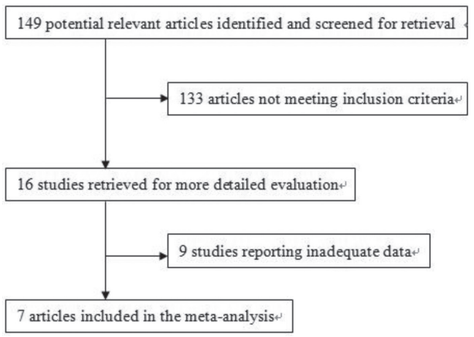

Fig. 1. — Flow chat of study search and selection for the meta-analysis

of heterogeneity (χ^2=6.01, P=0.049, I^2=66.7%). The random-effects model was used. The pooled data indicated that age was no statistical difference between the two groups. (pooled standardized mean difference (SMD): 0.408, 95% confidence interval (CI): -0.406~ -1.222, P=0.326) (Table II).

Time to union

Two studies *[16,20]* provided the data of time to union with mean and standard deviation (SD) and was analyzed. The heterogeneity test indicated a statistical evidence of heterogeneity (χ^2=7.32, P=0.007, I^2=86.3%). The random-effects model was used. The pooled data indicated that the time to union in the flexible intramedullary nail was less than external fixation (pooled SMD: -0.934, 95% confidence interval (CI): -1.837~ -0.031, P=0.043) (Figure 2A).

Delayed union rate

Two studies *[16,20]* provided the data of delayed union rate and was analyzed. The heterogeneity test indicated a statistical evidence of heterogeneity (χ^2=1.33, P=0.249, I^2=24.8%). The fixed-effects model was used. The pooled data indicated that there was no statistical difference in delayed union between two groups (pooled risk rate (RR): 0.386, 95% confidence interval (CI): 0.065~ 2.290, P=0.295) (Table II).

Limb-length discrepancy LLD

Five studies *[1-3,16,18]* provided the data of LLD and was analyzed. The heterogeneity test indicated no statistical significant difference of heterogeneity (χ^2=3.26, P=0.515, I^2=0.0%). The fixed-effects model was used. The pooled data and meta-analysis indicated that there was no statistical difference in LLD between two groups (pooled RR: 0.539, 95% confidence interval (CI): 0.223~ 1.301, P=0.169) (Table II).

Infection rate

Six studies *[1-3,7,16,18]* provided data on postoperative infection rate. It was observed in 205 of 210 femoral fractures managed with flexible intramedullary nail, and in 122 of the 128 fractures managed with external fixation. The heterogeneity test indicated no statistical significant difference of heterogeneity (χ^2=2.63, P=0.756, I^2=0.0%). Data pooled by a fixed-effects model and the meta-analysis indicated a significantly lower rate of

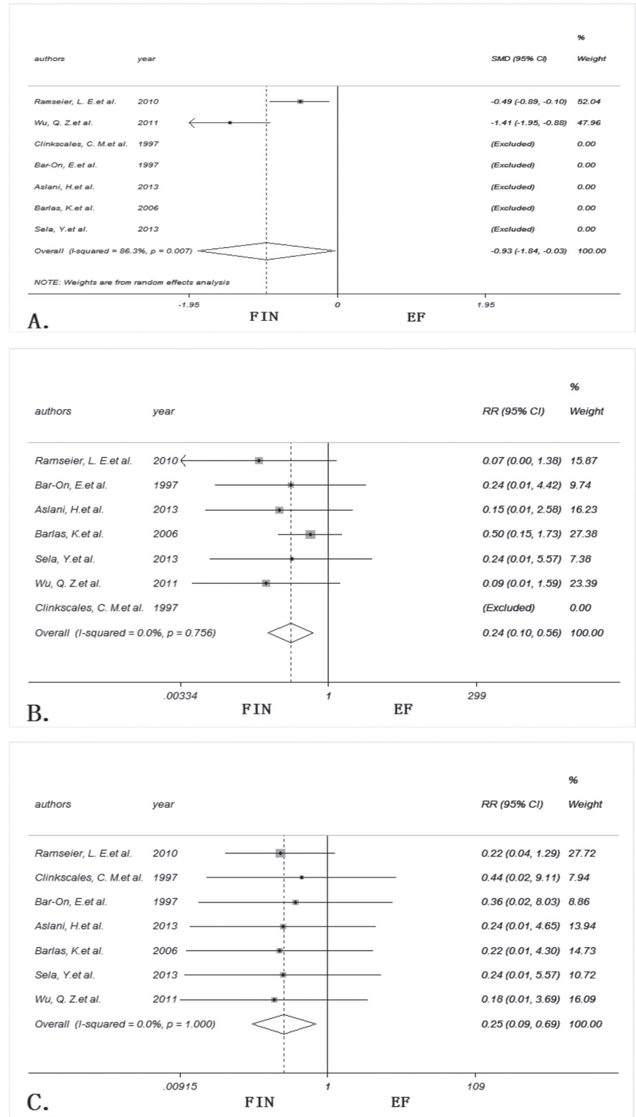

Fig. 2. — Forest plots of the meta-analysis of (A) Time to union, (B) Infection rate, (C) Refracture rate for comparation between two groups. The width of the horizontal line represents the 95% CI of the individual studies, and the square proportion represents the weight of each study. The diamond represents the pooled OR or SMD and 95%CI. OR: odds ratio; CI: confidence interval. FIN: flexible intramedullary nail; EF: external fixation

postoperative infection in flexible intramedullary nail group compared to that in external fixation group (pooled RR: 0.235, 95% confidence interval (CI): 0.099~ 0.561, P=0.001) (Figure 2B).

Refacture rate

Seven studies *[1-3,7,16,18,20]* provided the data of refracture after operation. It was observed in 210 femoral fractures managed with flexible intramedullary nail, and in 128 fractures managed with external fixation. The heterogeneity test indicated an insignificant difference of heterogeneity (χ^2=0.26, P=1.000, I^2=0.0%). Data pooled by a fixed-effects model and the meta-analysis indicated a significantly lower rate of postoperative refracture in flexible intramedullary nail group compared to that in external fixation group (pooled RR: 0.251, 95% confidence interval (CI): 0.091~ 0.694, P=0.008) (Figure 2C).

Pain and bursitis rate

Five studies *[1-3,18,20]* provided the data of postoperative pain and bursitis in two groups. It was observed in 100 of 210 femoral fractures managed with flexible intramedullary nail, and in 89 of the 128 fractures managed with external fixation. The heterogeneity test indicated an insignificant difference of heterogeneity (χ^2=3.47, P=0.483, I^2=0.0%). Data pooled by a fixed-effects model and the meta-analysis indicated that no significantly higher rate of postoperative pain and bursitis in flexible intramedullary nail group compared to that in external fixation group (pooled RR: 1.418, 95% confidence interval (CI): 0.549~ 3.657, P=0.471) (Table II).

Satisfaction of patients

Two studies *[2,3]* reported patient satisfaction. The heterogeneity test indicated an insignificant difference of heterogeneity (χ^2=0.00, P=1.000, I^2=0.0%). Data pooled by a fixed-effects model and the meta-analysis indicated a similar patients satisfaction in two groups (pooled RR: 1.125, 95% confidence interval (CI): 0.761~ 1.663, P=0.555) (Table II).

Publication bias and sensitivity analysis

Funnel plot and Begg's test showed that no significant publication bias was found (Figure 3A) in the studies concerning postoperative refracture (z=1.05, p=0.447). However, a significantly publication bias was fund concerning postoperative infection rate (z=-0.56, p=0.024). Then, sensitivity test was performed to check whether the outcome of infection rate was reliable in the meta-analysis. The results of sensitivity analysis revealed, after excluding the study [3], it did not affect the statistical significant difference of infection rate between the two groups (pooled RR: 0.134, 95% confidence interval (CI): 0.036~ 0.495, P=0.003). No significantly publication bias was fund (z=0.00, p=0.538) after the study [3] was excluded (Figure 3B).

DISCUSSION

This meta-analysis showed that Flexible intramedullary nail had a superior effectiveness for the femoral fractures in children compared with external fixation concerning time to union, LLD, refracture rate, infection rate, pain and bursitis rate and patient satisfaction.

The benefits and harms of different interventions for treating femoral fractures in children and adolescents were discussed, the study did not provide a preferred fixation *[12]*. Developing flexible intramedullary nails have brought large developments in treating pediatric long bone fractures *[21]*. It makes alignment and appropriate rotation possible in treating the fractures. In addition to appropriate stability and elasticity, it can result in a micromotion at the fractured area and strengthen the formation of osseous calculus. These factors may accelerate the union process. However, the study reported the mean union time was not difference between the same in the intramedullary nails group and external fixation group for open femoral fractures *[1]*. In this meta-analysis, the time to union was less in flexible intramedullary nails group than that in external fixation group based on the present evidence. A small incision is used in surgical treatment and there is a very weak

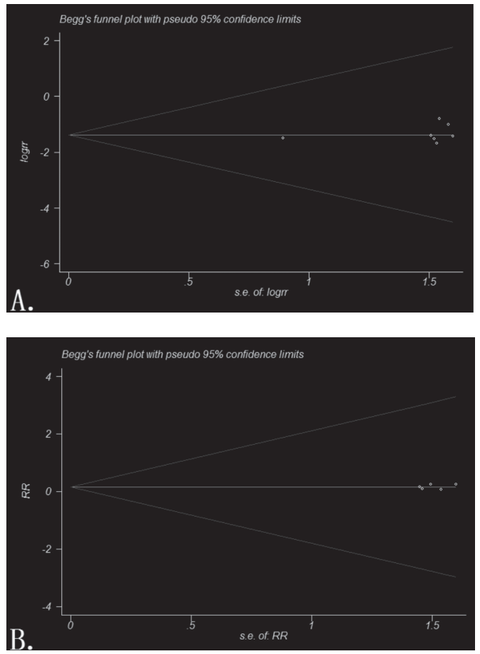

Fig. 3. — Begg's funnel plot for publication bias (with 95% pseudo confidence limits) of the included studies that investigated (A) refracture (p=0.447) and (B) postoperative infection (p=0.538). (Continuity corrected). SE: standard error.

probability of infection *[10,15]*. We fund there was a lower postoperative infection rate in the flexible intramedullary nails group than that in external fixation group in this paper. In fact, a significantly publication bias was fund concerning postoperative infection rate when one study *[3]* was included in this meta-analysis. We fund only this study reported infection in flexible intramedullary nail group and there were 3 infections in 20 patients. Unfortunately, they did not describe the cause of infection in detail in their paper. But, the significant difference of postoperative infection rate was not affected when the study *[3]* was excluded. Therefore, the outcome was credible in this meta-analysis. External fixation was associated with quick stability of long bone fractures and is an effective way in treating open fractures with severe damage of soft tissues, and refracture was regarded as the main complication observed in the external fixator method. The higher refracture rate in external fixation was also fund in this meta-analysis compared to flexible intramedullary nails fixation (Figure 2C). External fixation usually used as a temporary method in adults due to more complications (nonunion, malunion, and infection surrounding the pins) *[9]*. However, the complications (nonunion, malunion) are less seen in children treated with external fixation, and it was used as a definite treatment method in children. Bursitis requiring device removal is the main complication of the flexible intramedullary technique. Bursitis and pain rate was higher in flexible intramedullary nails group than that in external fixation group based on this meta-analysis. The two fixations were associated with specific complications. Nevertheless, not all fractures may be suitable for flexible intramedullary nail fixation. External fixation should be reserved for open or severely comminuted fractures *[2,3]*. The study concluded both external fixator and intramedullary nail method are effective ways in treating high grade open femoral fractures in children and final treatment results are similar *[1]*. In fact, no current single technique is universally applicable to all femoral fractures in children. Combining pins and flexible intramedullary nails is effective in developing more stability and is not associated with more complications *[1]*. Elastic stable intramedullary nailing may reduce recovery time *[13]*. In the present meta-analysis, the same result was also found (Figure 2A). Surgery result in lower rates of malunion in children aged 4 to 12 years, but may increase the risk of serious adverse events *[13]*. The choice of fixation will may remain influenced by the surgeon's preference based on expertise and experience, patient and fracture characteristics, and patient and family preferences *[16]*. Additionlly, these findings of this meta-analysis may guide the surgeons in treating femoral fractures in children.

There were some limitations in this meta-analysis. The number of studies included was not so adequate which just had seven studies involving 338 fractures, and the quality of the trials was generally low for some retrospective studies were

included in this meta-analysis. We intended to perform a subgroup analysis based on the type of fractures (open or close) initially. Unfortunately, not all the studies provided the data and had inadequate outcome data for extraction. Furthermore, other factors such as duration of the operation and hospital stay were reported in a single study, hence, could not be pooled in this meta-analysis. These limitations may reduce the power of our research. The outcomes will ultimately require a rigorous and adequately powered randomized controlled trial (RCTs) to prove.

CONCLUSION

Despite the constraints of the literature, the current available evidence included in this meta-analysis demonstrates that flexible intramedullary nails in the treatment of femoral fractures in children, compared with external fixation, may lead to a less time to union and a lower postoperative infection rate and refracture rate, and may not increase delayed union , LLD, pain and bursitis. Both fixations obtained a similar patient satisfaction. In summary, flexible intramedullary nail had greater advantages for the treatment of femoral fractures in children aged 5-15years, compared to external fixation based on current meta-analysis.

REFERENCES

1. **Aslani H, Tabrizi A, Sadighi A *et al.*** Treatment of pediatric open femoral fractures with external fixator versus flexible intramedullary nails. *Arch Bone Jt Surg* 2013 ; 1 : 64-67.
2. **Bar-On E, Sagiv S, Porat S.** External fixation or flexible intramedullary nailing for femoral shaft fractures in children. A prospective, randomised study. *J Bone Joint Surg Br* 1997 ; 79 : 975-978.
3. **Barlas K, Beg H.** Flexible intramedullary nailing versus external fixation of paediatric femoral fractures. *Acta Orthop Belg* 2006 ; 72 : 159-163.
4. **Carey TP, Galpin RD.** Flexible intramedullary nail fixation of pediatric femoral fractures. *Clin Orthop Relat Res* 1996 ; 110-118.
5. **Canale ST, Tolo VT.** Fractures of the femur in children. *Instr Course Lect* 1995 ; 44 : 255-273.
6. **Caird MS, Mueller KA, Puryear A *et al.*** Compression plating of pediatric femoral shaft fractures. *J Pediatr Orthop* 2003 ; 23 : 448-452.
7. **Clinkscales CM, Peterson HA.** Isolated closed diaphyseal fractures of the femur in children: comparison of effectiveness and cost of several treatment methods. *Orthopedics* 1997 ; 20 : 1131-1136.
8. **Dencker H.** Wire traction complications associated with treatment of femoral shaft fractures. *Acta Orthop Scand* 1964 ; 35 : 158-163.
9. **Griffet J, Leroux J, Boudjouraf N *et al.*** Elastic stable intramedullary nailing of tibial shaft fractures in children. *J Child Orthop* 2011 ; 5 : 297-304.
10. **Ligier JN, Metaizeau JP, Prevot J.** Closed flexible medullary nailing in pediatric traumatology. *Chir Pediatr* 1983 ; 24 : 383-385.
11. **McCartney D, Hinton A, Heinrich SD.** Operative stabilization of pediatric femur fractures. *Orthop Clin North Am* 1994 ; 25 : 635-650.
12. **Madhuri V, Dutt V, Gahukamble AD *et al.*** Interventions for treating femoral shaft fractures in children and adolescents. *Evid Based Child Health* 2014 ; 9-4 : 753-826.
13. **Madhuri V, Dutt V, Gahukamble AD *et al.*** Interventions for treating femoral shaft fractures in children and adolescents. *Cochrane Database Syst Rev* 2014 ; 7 : D9076.
14. **Oremus M, Wolfson C, Perrault A *et al.*** Interrater reliability of the modified Jadad quality scale for systematic reviews of Alzheimer's disease drug trials. *Dement Geriatr Cogn Disord* 2001 ; 12 : 232-236.
15. **Pankovich AM, Tarabishy IE, Yelda S.** Flexible intramedullary nailing of tibial-shaft fractures. *Clin Orthop Relat Res* 1981 : 185-195.
16. **Ramseier LE, Janicki JA, Weir S *et al.*** Femoral fractures in adolescents: a comparison of four methods of fixation. *J Bone Joint Surg Am* 2010 ; 92 : 1122-1129.
17. **Sink EL, Hedequist D, Morgan SJ *et al.*** Results and technique of unstable pediatric femoral fractures treated with submuscular bridge plating. *J Pediatr Orthop* 2006 ; 26 : 177-181.
18. **Sela Y, Hershkovich O, Sher-Lurie N *et al.*** Pediatric femoral shaft fractures: treatment strategies according to age--13 years of experience in one medical center. *J Orthop Surg Res* 2013 ; 8 : 23.
19. **Skaggs DL, Leet AI, Money MD *et al.*** Secondary fractures associated with external fixation in pediatric femur fractures. *J Pediatr Orthop* 1999 ; 19 : 582-586.
20. **Wu QZ, Zhang J, Lan SH.** Clinical outcomes of elastic intramedullary nail fixation and external fixation for the treatment of pediatric femoral shaft fractures. *Zhongguo Gu Shang* 2011 ; 24 : 146-148.
21. **Wright JG, Wang EE, Owen JL *et al.*** Treatments for paediatric femoral fractures: a randomised trial. *Lancet* 2005 ; 365 : 1153-1158.
22. **Yandow SM, Archibeck MJ, Stevens PM *et al.*** Femoral-shaft fractures in children: a comparison of immediate casting and traction. *J Pediatr Orthop* 1999 ; 19 : 55-59.