Titanium elastic nails versus AO plating in pediatric femoral fractures: a prospective randomized study

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The Egyptian Orthopedic Journal; 2018 supplement (2), December, 54: 67-75

Abstract

Background
Femoral shaft fracture is a common pediatric injury for which variable methods of treatment are used. We randomize a study to asses 2 operative methods

Patients & Methods
From 2009 to 2013, we treat 56 patients with fracture shaft femur. Patients age was 4 -12 years, there were 38 boys and 19 girls. The injury was in left sided in 25 patients while 31 patients were right sided. The first group, 28 patients were treated with titanium elastic nails (TENS) including 19 males and 9 females , The other 28 patients were treated with open reduction and internal fixation using narrow AO plates including 18 males and 10 females. Clinical and radiographic follow up was done in regular intervals (2 weeks, 6 weeks, 3 months, 6months and 1year) and the Final clinical and radiographic results were evaluated using Flynn et al (2001) scoring system.

Results
In the TENS group, 18 patients had excellent results and 10 patients had good results with minor complications. Union achieved with average 8.4 weeks (rang 6 - 12 weeks).In the plating group, 17 patients had excellent results, 8 patients had good results with minor complications and three patients had poor results in form of re-fracture after metal removal, severe infection that resolved after later metal removal and debridement and sever infection reaching the bone. Union achieved with average 9.6 weeks rang 6 - 14 weeks.

Conclusion
TENS is a simple, reliable, effective and minimally invasive method of treatment of pediatric femoral fractures.

Keywords
TENS, Elastic nails, femoral fractures, plating in children.

Introduction

Diaphyseal femoral shaft fractures are a common pediatric injury[1]. Different methods of treatment have been practiced for this decapitating injury. These methods are dependent on many factors, the main of which is the age of patient. There is general agreement that femoral fractures in children up to 4 years of age must be treated conservatively[2].And those above the age of 16 are nowadays candidates for locked intramedully nailing. Treatment in Children between 4- 16 years is a controversial issue[3], and the debate is which method to choose from either traction followed by spica , open reduction internal fixation using plates and screws or the less invasive method of elastic intramedullary nails. Every method has its own pros and cons.

We prospectively randomized a trial to compare the outcome of both open reduction internal fixation and the use of titanium elastic nails to treat such fracture.

Patients and Methods

Between 2009 and 2013, a total of 56 patients with fracture shaft femur were admitted to our hospital. Patients with age above 4 years and those who do not exceed 12 years were included in this study. The study includes 37 boys and 19 girls. The left side was affected in 25 patients. The right side was affected in 31, no patient suffered bilateral fracture femur in this series.

Of the total 56 patients 28 patients, were treated with titanium elastic nails (TENS) including 19 male and 9 female. The other 28 patients were treated with open

reduction and internal fixation using narrow AO dynamic compression plates including 18 male and 10 female.

The mechanism of trauma was Road traffic accidents in 24 patient, falls in 29 patients and Heavy object trauma in 3 patients. Associated injuries were found in 4 cases 2 with head injury and another 2 cases with abdominal injury

Study design:

We design our study as a prospective randomized trial to compare the results of two operative methods of treatment of pediatric femoral fractures in the age group 4-12 years old by using either TENS or AO narrow plates and screws.

Patient Semple

A total of 56 patients were included in this study. We designed our study to include patients ageing above 4 years and not exceeding 12 years old who suffered recent traumatic closed femoral shaft fracture. Patients with extreme proximal or distal femoral fractures closer to epiphyseal plate , patient open femoral fracture and those with old or late presented malunited fracture were excluded from this study

Documentation and follow up

Full records for every child were saved including name, age, sex mechanism of injury, and any associated injuries. Also Fracture nature, type, and level. In addition to time to fixation, operative time, size of the nail, and any intra-operative complications and blood loss. Finally records of Post operative data (length of hospital stay, type of post-operative immobilization, time to union, time to metal removal, any post implant removal complications, and the length of the follow up period), and any residual complications.

All patients were followed up clinically and radiographicly in regular intervals (2 weeks, 6 weeks, 3 months, 6months and 1 year) for assessment of hip, and knee motion, presence or absence of postoperative infection and any complications till complete bone healing , remodeling and then later metal removal. Radiographic follow-up included anteroposterior and lateral radiographs every clinic visit for checking alignment, any loss of reduction, duration and quality of bone healing and implant related complications. The Metals were removed after clinical and radiographic union. Patients were followed up for mean duration of 10.51 months (range 6- 17 months).

Assessment:

By the end of the follow up period after full clinical and radiographic bone healing, all patients were assessed clinically for residual pain, limping, range of motion of hip and knee joints, functional daily activities, limb-length discrepancy, and any rotational malalignment of the injured extremity. Radiographic assessment was done for alignment, quality of bone healing, and to measure limb-length discrepancy.

Final clinical and radiographic results were evaluated using Flynn etal (2001) scoring system[4] (Table 1)**.**

Table 1: Flynn scoring system

	Excellent results	**Satisfactory results**	**Poor results**
Limb-length inequality	< 1.0 cm	< 2.0 cm	> 2.0 cm
Malalignment	5 degrees	10 degrees	> 10 degrees
Pain	Non	Non	Present
Complication	Non	Minor and resolved	Major and lasting morbidity

Surgical technique and post operative care

Surgical technique of TENS

Under general anasthesia the patient is supine on the standard translucent orthopedic table after a single prophylactic dose of antibiotic, A 1-2 cm longitudinal incisions on the lateral and medial supracondylar ridges are done 2 cm proximal to the distal femoral physis . The soft tissue is minimally dissected to reach the bone. A suction drain trocar is used as a curved awel to slaintly open the femoral cortex avoiding the risk of soft tissue endangering and slippage associated with the use of drill bit with good control

on the handle. in a retrograde manner using a T-handle the slightly hand curved nail with a suitable size is introduced in a retrograde manner by rotation movements of the wrist and under fluoroscopic control pushed to the fracture site , paying utmost care to avoid penetration of the contra lateral cortex specially with the use of hammering . The fracture is manipulated until reduction can be achieved and the nail is continued to the proximal femur where the lateral one should stop just distal to the greater trochanter physis and the medial one should aim and anchor the neck of the femur. The largest possible diameter should be used; usually preoperative determination is planned using the diameter of the isthmus as the guide to estimate the nail size that should be around 40% of the isthmus diameter. Finally the two nail construct should be aligned and faced and the maximum curvature of the nail should be as near as possible to the fracture site. Care is taken to assess the alignment and radiographic reduction and special attention should be paid to the rotation of the limb, Calcar direction, and avoidance of the epiphyseal plate. The distal end of both nails are cut short outside the bone and bent away to facilitate later removal and then embedded in the soft tissue. Closure of the incisions and application of hip spica for one three weeks to alleviate pain, oedema and ensure non weight bearing of the child is done.

Surgical technique of plating

Under general anesthesia, on a standard table the patient is supine. After preparation, a postero-lateral approach using a muscle splitting approach with minimal soft tissue dissection and periosteal elevation to avoid devitalization or excessive callus formation is performed. Manipulation to achieve reduction, correction of angulation and length restoration is tried and then applications of 4.5 AO narrow dynamic compression plate applying the same AO fixation principles. Closure in layers is used over a suction drain. No intra-operative X-ray was needed. Hip and knee active exercises were allowed immediately postoperatively.

Results

The average operative time in the TENS group was 35 minutes while it was 55 minutes in the plating group. As regard to hospital stay, unless the patient had other associated injury he/she was discharged on the 2nd day postoperative in the TENS group while the patient discharged in the 3rd postoperative day in the plating group. The mean union time in the TENS group was 8.4 weeks while it was 9.6 weeks for the plating group.

There was an anterior angulation in 5 cases (17.8%) (But less than 10 degrees) in the TENS group, however no case of anterior angulation was reported in the plating group. Rotational malalignment was reported in 6 cases (21.4%), less than 15° in half of them in the TENS group while No rotational malalignment was reported in any case of the plating group.

Limb length discrepancy was found in 18 cases (64.2%) in the TENS group which was less than 1 cm in final follow-up, while 15 patients (53.6 %) suffered limb length discrepancy in the plating group that was 1.7 cm average .

There were 4 cases (14.2 %) of irritation bursa around the nail insertion but no reported case of infection in the TENS group while 2 cases (7. 1%) of infection was reported in the plating group, the first case had severe infection that started after 6 weeks when union has occurred and we continued with the plate till complete union then metal removal and debridement was done after which infection resolved. The second case came with severe infection reaching the bone and not respond to medical treatment so we decided to remove the metal and debridement then external fixation was applied for 6 weeks.

In our study we faced no cases of nail bending or refracture of the bone after removal in the TENS group while one case (3.5%) refractured after plate removal for which replating was done. No blood transfusion was needed in the TENS group while blood transfusion was needed in 8 cases (28.6 %) in the plating group and a unit of blood was ready in all cases.

There was slight limitation of knee motion in 4 cases (14.2 %) due to nearby nail insertion in the TENS group while there were 3 cases (10.7%) of hip or knee limitation of motion in the plating group. Weight bearing was allowed as soon as callus was observed across the fracture site usually at 6 week. Full weight bearing was achieved gradually depending on radiographic progression to union with average time 6 to 12 weeks in this series. An additional observation in this study is that the union rate is more rapid in children less than 10 years old.

Table 2: Flynn scoring system of Our Results

Results	Elastic rods	Plating
Excellent	18	17
Good	10	8
Poor	Zero	3

Table 3: Comparative results of using elastic rod or plating

ITEM	Elastic rod	Plate
Mean operative time	35 min	55 min
Blood transfusion	No	8 Cases (28.6%)
Painful bursa	4 cases (14.2 %)	No
Intraoperative X-ray	Yes	No
Mean union time	8.4 weeks	9.6 weeks
Anterior angulation	5 cases (17.8%) but less than 10 degrees	No
Rotational malalignment	6 cases (21.4%), less than 15°	No
Limb length discrepancy	18 cases (64.2%) < 1 cm	15 patients (53.6 %) Average 1.7 cm
Knee joint motion	4 cases (14.2 %) but was slight limitation	3 cases (10.7%)
Infection	No	2 cases (7. 1%)
Refracture after	No	1 case (3. 8%)
Flynn score	100%	89.2%

Table 4: Master sheet of cases of fracture femur fixed by elastic nails

Number	Age	Sex	Side	Mechanism of Injury	Associated injuries	Time to fixation (days)	Nail Technique closed semi-Open - Open	Operation Time (minutes)	Post operative immobilization	Time to union (Weeks)	F.U. Period (months)	Time to metal removal (month)	Complications	Score
1	6Y	F	Rt	FOG	No	1	Closed	35	H.S.	8	6	5	No	Ex.
2	4Y	F	Lt	MCA	Splenectomy	4	Semi open	45	H.S.	6	7	4	No	Ex.
3	4Y	F	RT	MCA	No	4	Closed	40	H.S.	6	6	4	No	Ex.
4	8Y	M	Rt	FOG	No	1	Closed	35	H.S.	10	8	5	No	Ex.
5	9Y	F	Rt	MCA	No	1	Closed	30	H.S.	8	9	5	No	Ex.
6	5Y	M	Rt	FOG	No	1	Closed	35	H.S.	8	7	4.5	Minor	G
7	5Y	F	Lt	HOT	No	1	Closed	25	H.S.	6	8	5	No	Ex.
8	6Y	M	Rt	FOG	No	1	Closed	35	H.S.	8	9	6	Minor	G
9	9Y	M	Rt	FOG	No	1	Closed	35	H.S.	10	9	5	Minor	G
10	8Y	M	Rt	FOG	No	1	Closed	40	H.S.	10	10	5	Minor	G
11	8Y	M	Rt	MCA	No	1	Closed	35	H.S.	`10	9	4	No	Ex.
12	8Y	M	Rt	FOG	No	1	Closed	35	H.S.	10	6	3	No	Ex.
13	5Y	M	Rt	FDS	No	1	Closed	20	H.S.	8	6	3	No	Ex.
14	4Y	F	Lt	FOG	No	1	Closed	30	H.S.	6	7	3	Minor	G
15	8Y	M	Rt	MCA	No	1	Closed	35	H.S.	10	11	4	No	Ex.
16	6Y	M	Rt	MCA	No	1	Closed	40	H.S.	10	7	4	No	Ex.
17	5Y	M	Lt	FOG	No	1	Closed	35	H.S.	8	6	4	No	Ex.
18	7Y	F	Rt	FOG	No	1	Closed	45	H.S.	8	8	4	Minor	G
19	5Y	M	Rt	FOG	No	1	Closed	35	H.S.	8	6	5	Minor	G
20	8Y	M	Lt	FOG	No	1	Closed	35	H.S.	10	11	6	No	Ex.
21	9Y	M	Rt	FOG	No	1	Closed	25	H.S.	10	9	4	Minor	G
22	10Y	M	Lt	MCA	No	1	Closed	40	H.S.	12	8	5	No	Ex.
23	6Y	M	Lt	FFH	Head Trama	4	Closed	40	H.S.	8	7	4	No	Ex.
24	11Y	F	LT	FOG	NO	1	Closed	35	H.S	12	11	7	NO	G
25	5Y	M	R	FOG	NO	1	Closed	40	H.S	6	6	5	NO	Ex
26	9Y	F	R	MCA	NO	1	Closed	25	H.S	10	9	6	NO	G
27	5Y	M	LT	MCA	NO	1	Closed	40	H.S	6	10	7	NO	Ex
28	6Y	M	LT	FOG	NO	1	Closed	35	H.S	8	7	6	NO	Ex

Table 5: Master sheet of cases of fracture femur fixed by plating

Number	Age	Sex	Side	Mechanism of Injury	Associated Injuries	Time to fixation (days)	Operation time (minutes)	Post-OP Immobilization	Time to union (Weeks)	F.U. Period (month)	Time to metal removal	Complications	Score
1	10 Y	M	Rt	MCA	No	1	50	No	12	14	12m	No	Ex.
2	10 Y	F	Lt	MCA	No	1	60	No	12	9	6m	No	Poor
3	8 Y	F	Lt	MCA	Head trauma	5	60	H.S.	8	15	12m	No	Ex.
4	10 Y	F	Lt	FFH	No	1	55	No	12	13	12m	No	Ex.
5	9 Y	M	Rt	MCA	No	1	60	No	10	14	12m	No	Ex.
6	9 Y	F	Lt	FFH	No	1	65	No	10	15	12m	No	Ex.
7	10 Y	F	Rt	MCA	No	1	60	No	12	14	12m	No	Ex.
8	9 Y	M	Lt	FFH	No	1	55	No	8	12	10m	No	Ex.
9	8 Y	F	Rt	MCA	No	1	60	H.S.	10	12	10m	Minor (resolved)	Good
10	8 Y	M	Lt	MCA	No	1	55	No	8	10	8m	No	Ex.
11	10 Y	M	Rt	FOG	No	3	55	H.S.	10	10	3m	Deep infection ex fix	Poor
12	5 Y	M	Lt	FOG	No	1	55	H.S.	8	14	12m	No	Ex.
13	9 Y	M	Rt	FOG	No	1	55	No	10	10	8m	No	Good
14	7 Y	M	Rt	HOT	NO	1	65	H.S.	8	12	10m	No	Ex.
15	9 Y	M	Lt	FOG	No	3	65	No	12	15	12m	Minor (resolved)	Good
16	10 Y	M	Rt	FOG	No	1	60	No	10	10	8m	Frx. Afte, MR Re plating	Poor
17	6Y	M	Lt	FOG	No		40	No	8	13	12m	no	Ex
18	8 Y	F	Lt	MCA	No	1	55	No	10	11	8m	Superfical infection	Good
19	4 Y	M	Lt	MCA	No	1	50	H.S.	8	10	8m	No	Ex.
20	10 Y	M	Rt	MCA	Liver tear	4	65	No	10	14	12m	No	Ex.
21	9 Y	M	Lt	MCA	No	1	60	No	10	14	12m	Minor	Good
22	10Y	M	Lt	MCA	No	1	40	No	12	17	15m	no	Ex
23	8 Y	F	Rt	MCA	No	1	60	No	12	13	10m	Minor	Good
24	9Y	M	RT	MCA	NO	1	40	No	10	14	12m	no	Good
25	9Y	M	RT	FOG	NO	1	45	No	12	21	18m	no	Ex
26	7 Y	F	LT	FOG	NO	1	55	No	8	14	12m	No	Ex.
27	8Y	F	LT	HOT	NO	1	40	No	10	15	12m	no	Good
28	7 Y	M	RT	MCA	NO	1	55	No	8	11	8m	no	Ex.

Discussion

Fracture of the femoral shaft is a common injury in children for which the ideal choice of treatment has remained a constant challenge .The ideal treatment of that injury defined by Staheli [5] as the one that controls alignment and length, does not compress or elevate the extremity excessively, is comfortable for the child and convenient for the family, and causes the least negative psychological impact possible.

Treatment varies with the age and size of children, associated injuries and local practice[6]. Early primary spica cast treatment or following traction has been used however it resulted in many complications such as limb-length discrepancy, angulations, rotational deformity, psychological and economic complications[7-9] .

Pollak et al [10] reported shortening and angulation that required repeat reduction or other treatment in 50% of closed, high-energy femoral shaft fractures in children younger than 10 years of age. External fixation has been historically the treatment of choice used for polytrauma patients and is also effective for closed and isolated open fractures however, risks include pin-track infections, delayed union, nonunion, loss of knee range of motion, and refracture [11, 12]

Comparing external fixator and elastic rod as a line of treatment; Baron et al[11] reported better results with the elastic rods than external fixator as regards return to school, full range of nearby joints, and early union. They reserved external fixator for open or severely comminuted fractures. Nearly Buech-senschuetz [13] reported the same results. Solid antegrade intramedullary nailing had resulted in avascular necrosis of the femoral head, trochanteric epiphysiodesis, and coxa valga [14-16]

AO compression plates for fixation of femoral shaft fractures in children and adolescents have been reported by many authors. Good fracture healing without leg length discrepancy after compression plating of femoral fractures in children aged 6 to 16 years was reported by Ward et al[17] with average healing time 11 weeks and limb length discrepancy in 25%. of patients .They recommended compression plate fixation for patients with severe head injury or multiple traumas. Hanson et al[18] reported healing of all fractures treated by plating in series of patients with a mean age of 11 years, without angulation or rotation ,with a mean overgrowth of 7 mm and with no restricted hip or knee motion . In our series all patients treated using plating achieved union in average of time was 9.6 weeks with no case of anterior angulation or Rotational malalignment figure 1 a,b,c .

Plating has its own disadvantages such as the need for another operation to remove the plate and the poor cosmetic appearance of the scar left by the incision, moreover the reported higher degrees of overgrowth in comparison to that associated with intramedullary fixation [1] Breakage of the plates is far less important in children than adults, because femoral shaft fractures heal so rapidly during childhood Although rare, stress fracture may occur through the screw holes during the first few months after plate removal. We had one case (3.5%) refractured after plate removal for which replating was done. Infection was reported in 7% of our patients. Significant overgrowth up to 1.7 cm was reported in53.6% of patients. Blood transfusion was needed (28.6 %) our patients.

The ideal device to treat femoral fractures in pediatric population should be a simple, load sharing internal splint, allowing early mobilization while maintaining length and alignment for several weeks until bridging callus forms, without risk on the epiphyseal blood supply [8, 13, 19, 20]. TENs were found to promote healing by limiting stress shielding in addition to their biocompatibility without metal sensitivity reactions [8, 21, 22]

Several authors reported good results using elastic stable intramedullary fixation Ligier et al [22] reported excellent results with the use of elastic stable intramedullary nails

Heinrich et al[21] in a prospective study of seventy-eight diaphyseal femur fractures, noted mild varus or valgus angulation (11%) and mild anterior or posterior malalignment (8%). minimal rotational malalignment of an average 8 degrees was noted in 10.2% However, 89% of the children had equal leg lengths at follow-up. In our TENS series we noted anterior angulation in 17.8% but less than 10 degrees and Rotational malalignment was reported 21.4%, less than 15° in half of the cases. Limb length discrepancy was found in 64.2% which was less than 1 cm in final follow-up,

In a 31 femoral shaft fractures case series Oh et al[23] children used retrograde flexible intramedullary nailing and found that the average time for union was 10.5 weeks .There was one broken nail , but no infection or refractures. There was no limb-length inequality exceeding 1 cm and no malunion. They feel that femoral fractures in patients aged 5–10 years can be safely treated with retrograde flexible intramedullary nailing with minimal risk of surgical complications. In our series the The mean union time was 8.4 weeks figure 2 a,b,c.

Flynn et al[24] in a 50 prospectively evaluated cases found that the most common encountered problem

has been irritation at the nail insertion site 18 % of cases . in our series 14.2 % of our patients had irritation bursa around the nail insertion.

Titanuim elastic nails are easily applied in a retrograde manner without opening the fracture site or stripping the periosteom so they do not lead to overgrowth unless in the invitible case of transverse fracture Only reported overgrowth was 0.5 cm in our study . they have the pitfall of poor control of rotational stability so we exert extreme care being during intraoperative limb positioning and a post operative hip spica was applied in all cases.

Figure 1: a.Preoperative radigraph of a 8 years old child b.full union achieved after AO narrow plating c. after implant removal

Figure 2: a.Preoperative radigraph of a 6 years old child b.full union achieved using plating TENS c. after nails removal

Conclusion

Despite the good rotational control, the lack of need to radiation exposure and the early start of postoperative rehabilitation, the use of plating is still complicated by the need of blood transfusion, the more trauma to the muscles and the elevated risk of infec-

tion. So it has to be reserved for cases with head trauma and those who are polytraumatized to facilitate nursing and early rehabilitation. Titanium elastic nails has the advantages of being simple, biological , easy to applicate , less invasive , has less operative time with no need to blood transfusion . Additionally it has shorter time to union and minimal growth disturbance of bone. The only pitfall is the poor rotational control and the need for intraoperative irradiation.

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