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Outcomes of Treatment of Diaphyseal Femur Fracture Using Titanium Elastic Nail Fixation in Children of Eastern Nepal: A Prospective Study

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Abstract:

- ***Background and Objectives:***

The management of femoral shaft fractures in pediatric age has always been a subject of discussion. In this study, we are ascertaining the functional outcomes following the use of Titanium Elastic Nails for diaphyseal femoral fractures in children.

- ***Material and Methods:***

This prospective observational study was performed on 23 patients of age 5 to 15 years with diaphyseal femur fracture who were operated and fixed with intramedullary TENS in the Department of Orthopedics, BP Koirala Institute of Health and Sciences from May 2020 to April 2021. Patients were evaluated to ascertain the functional outcomes of titanium elastic nail fixation in diaphyseal fracture of femur in pediatric age group using Flynn's scoring criteria.

- ***Result:***

All 23 patients were evaluated for a period of 6 months. Radiological union in all cases were attained in a mean time of 14.61 weeks. Average duration of hospital stay was 4.3 days. Limb length discrepancy and malalignment were notable in none of the cases. The results were excellent in 21 patients (91.3%), satisfactory in 2 (8.7%) and poor in zero patient(0%) at 6 month period.

- ***Conclusion:***

Based on these results, TENS is a safe, mini-invasive, reliable, rapid and efficacious method for the management of diaphyseal femur fractures in children.

Keywords: *Femur Fracture, Diaphyseal, Pediatric, Outcomes, Titanium Elastic Nail System.*

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I. INTRODUCTION

Femoral shaft fracture is a debilitating injury in children[1]. Diaphyseal femur fractures represent 1.7% of all fractures in children[2]. The mechanism of injury is usually high energy, like a fall or road traffic accident. The fractures are commonly located in shaft region, and demands for operative management in most cases[3]. Intramedullary interlocking nail fixation is the mainstay of treatment in case of adult femoral shaft fractures. Likewise, the femoral shaft fractures in infants and toddlers are managed by spica casting, but the management of femur fractures in children is debatable.

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Current treatment options for paediatric femoral shaft fracture include early spica cast application, traction, external fixation devices, submuscular plate fixation, elastic titanium nails and rigid nails[4]. The main disadvantages with different types of traction and plaster cast application are inability of the child to resume daily activities and school as a result of long period of bed rest and the increased financial burden due to long duration of hospital stay. Over a course of time, it has been found that the outcome of children with diaphyseal femur fracture is not always favorable with conservative management[4]. Patients in the paediatric age group (5-15 years) are more prone to limb length discrepancy, angulation, malrotation and malunion who have adopted nonoperative interventions [5,6,7].

Femur fractures in children account for 9.8% of fractures seeking operative interventions; up to 76% of these fractures lie in shaft region, and 62% of them are fixed with elastic titanium nails, while plate fixation is performed in only 10% of the cases[9]. Operative management is advisable in femur fractures in children of 6-14 years age group, as this provides early mobilization, reduced duration of hospital stay, and allow early attainment of school and routine activities[10-12].

Operative management of femur fractures in children include external fixator, submuscular plate fixation, rigid and elastic intramedullary nail fixation. There are pros and cons of every method and there is no technique which can be declared ideal and most effective. In comminuted fractures, additional aid with external fixator may be needed along with Elastic Stable Intramedullary Nailing System (ESIN), while compression plating provides stable fixation at the cost of extensive soft tissue damage. Elastic nailing is mini invasive and better for the fractures of middle two-third of the diaphysis[13].

Surgical management contributes to eliminate social, physical and psychological burden to the patient and his family[14]. Although external fixators provide good stability and early mobilization, they are usually not preferred because of the likelihood of pin tract infection and refracture[15]. Moreover, weight bearing is usually delayed and are mostly performed in case of open fractures or fractures with severe comminution. Antegrade intramedullary nailing is obsolete as there is high risk of avascular necrosis with this technique[16]. Plate fixation results in extensive soft tissue damage, high blood volume depletion, prolonged immobilization and is more prone to infection.

The ideal treatment modality for femoral diaphyseal fracture in children should act as load sharing internal splint, promoting rapid mobilization without compromising length and alignment for weeks till the adequate callus formation occurs, also should not damage the blood vessels supplying the growing physis. Titanium elastic nailing system (TENS) has all the properties and internal fixation of diaphyseal fracture by TENS is getting more popular and has been more preferred alternative to other nonoperative and operative treatment methods among the children of 5-16 years. The biomechanical principle of TENS depends on its symmetrical bracing action provided by the two titanium nails bearing against three points inside the metaphysis of long bone. It contributes to adequate stability to the fractured bone, allowing rapid mobilization and swift integration to the daily and routine activities of the patients, with minimum complications.

Results from different studies have demonstrated that TENS fixation assists in early mobilization, less chances of avascular necrosis, minimal damage to physis and less prone to re-fracture. Similarly, as a mini invasive technique, TENS fixation neither damages periosteum nor disturbs fracture hematoma as a result of which there is minimum chances of infection and loss of osteogenic tissues. Although the literature mentions about these several advantages of TENS fixation, it has not been validated in our setting. Hence this study was performed to ascertain the clinical and functional outcomes, effectiveness and efficacy of TENS fixation in diaphyseal femur fractures in children.

II. RESEARCH METHODOLOGY

A prospective observational study was conducted in the Department of Orthopaedics, B.P. Koirala Institute of Health Sciences, Dharan, Nepal, over a period of 1 year from May 2020 to April 2021. Ethical clearance was obtained from the Institutional Review Committee of BPKIHS, Dharan (IRC/1650/019) on 15th May 2020.

The technique was well explained including complications and prognosis and informed consent was acquired from each patient's parent. Children of age 5 to 15 years with mid shaft fracture of femur were enrolled. Patients who refused to give consent or presenting with open fractures (Gustilo Anderson grade II and II) or neurovascular compromise or pathological fractures or neuromuscular disorders were excluded. A thorough history including demographic profile, methodology, pertinent clinical and radiological information was recorded in preset pro forma. Immediate skin traction application was done in Emergency Department and patients were scheduled for operative intervention after pre-anaesthetic checkup (PAC) clearance. Wound was inspected on second postoperative day and patient were discharged and asked for follow up at 2 weeks, 6 weeks, 3 months and 6 months at Orthopaedic outpatient department (OPD).

All the cases were operated by retrograde titanium elastic nailing system. They were fixed with two elastic nails of equal diameter – one from lateral entry point and the other from medial entry point. Patients were kept in fracture table with hip and knee in extension on the affected side and opposite hip was flexed, abducted and externally rotated and knee flexed. Entry point was marked 1-2 cm proximal to the distal femoral physis under the fluoroscopic guidance. A skin incision was made at the marked entry point and a bone awl was used to enlarge the Medullary cavity at the same level on both sides of the femur shaft.

The diameter of nail was determined as 30-40% of the diameter of isthmus which was measured radiologically as the narrowest diameter on anteroposterior and lateral X-ray

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image. Nails of measured size were pre-bent and advanced into the medullary cavity. Fracture was reduced using F-tool under image guidance and manipulation. The lateral titanium nail was driven up to the metaphysis of greater trochanter whereas the medial one was advanced up to the neck of femur or lesser trochanteric area. Nails were inserted in such a way that both nails cross the fracture site concurrently and rotational alignment was maintained. The ends of nail were cut flushing with the metaphyseal flare without bending the ends. Postoperative X-ray was taken on 1st postoperative day and immediate complication was assessed and patients were discharged on 2nd postoperative day after wound inspection (and if found satisfactory).

Patients were followed up in OPD in 2 weeks, 6 weeks, 3 and 6 months and X-rays were done to assess the radiological outcome at every follow up apart from first visit at 2 weeks. The wound was inspected and sutures were removed at the end of 2 weeks. Postoperative physiotherapy and mobilization was initiated by trained physiotherapist on individual basis and patients were encouraged for gradual weight bearing depending upon the fracture stability, degree of reduction achieved and rate of fracture union.

The main aim of the study was to ascertain the functional outcomes of titanium elastic nail fixation in diaphyseal fracture of femur in children using Flynn's scoring criteria.

Table 1 Flynn's Scoring Criteria

Parameter	**Functional Outcomes**		
	Excellent	***Satisfactory***	***Poor***
Limb Length Discrepancy	<1cm	<1-2 cm	>2cm
Malalignment	<5 Degrees	<5-10 Degrees	>10 Degrees
Pain	Absent	Absent	Significant
Complications	Absent	Minor and resolved	Major with long lasting morbidity

The sample size estimation was based on a previous study[24] which reported the excellent outcome of TENS fixation 82.5% and with a permissible error of 20% and considering 10% loss to follow up, sample size was caclulated as 23 using one sample proportion technique.

Data were entered in Microsoft Excel 2013 and converted into a Statistical Package for social sciences (SPSS 11.3) for statistical analysis. Proportion, percentage, mean, standard deviation was calculated. Tabular presentation was also made.

III. RESULT

Initially 30 patients were considered for eligibility in this study. Out of 30 patients, 7 patients were not meeting the inclusion criteria (2 had re-fracture, 3 had Gustilo Grade II open fractures and 2 had pathological fracture) and they were excluded. A total of 23 patients were included and underwent TENS fixation and follow up was conducted for 6month time duration and subsequently analyzed.

In this study, the number of male and female patients were 15 (65.2%) and 8 (34.8%) respectively. Most of the patients lied in the age group 5-10 years accounting 18 (78.3%) whereas there were only 5 (21.7%) in the age group 11- 15 years, the mean age being 9.13±1.66 yrs. Most of the patients presented with injury to the right thigh, which was 15 (65.2%) whereas only 8 (34.8%) patients had injury to left thigh.

The time taken to present after injury was 1.48±0.665 days, injury to surgery time was 3.13±0.920 days while duration of hospital stay was 4.30±0.7.03 days. The average duration of surgery was found to be 62.70±7.778 min. Intraoperative blood loss was found to be 38.48±10.383ml. The average VAS score for pain in the immediate post-operative period was 4.13±1.058.

Out of total cases, 21 (91.3%) patients did not develop any complications, 1 (4.35%) patient developed superficial infection while there was 1 (4.35%) case of bursitis. The case of superficial infection required a course of oral antibiotics but didn't require debridement or admission. The case of bursitis required symptomatic treatment.

Fracture was united in 18 (78.3%) patients by 12 weeks while it was observed by 24 weeks in another 5 (21.7%) patients. The average duration of fracture union was 14.61±4.061 weeks. Twenty patients had full range of motion (0-140 degree) while 3 cases had mild restriction of flexion (0-120 degree) but none had moderate or severe restriction during knee flexion at final follow up at 6 months.

All cases had limb length discrepancy of <1 cm and < 5 degree of malalignment. Among the 23 patients analyzed at 3 and 6 months, the functional outcome evaluated by Flynn's Scoring system was excellent in 20(86.95%) patients, satisfactory in 2 (8.7%) patients and poor outcome in 1 (4.3%) case at 3 months whereas 21 (91.3%) cases had excellent outcome and 2 (8.7%) cases had satisfactory outcome and none of the cases had poor outcome at 6 months period.

Table 2 Functional Outcomes Using Flynn's Scoring Criteria

Functional Outcome	**Time Duration**	
	At 3 months	***At 6 months***
Excellent	20 (86.95%)	21 (91.3%)
Satisfactory	2 (8.70%)	2 (8.7%)
Poor	1 (4.35%)	0

IV. DISCUSSION

While pediatric femur fractures are frequently seen in our hospital's emergency room, there are no established guidelines or protocols for their management, despite significant research in this area[36]. Femur fractures in children under 5 years are often effectively managed with conservative treatment using spica casting[37]. Femur fractures in children older than 15 years are usually managed with interlocking intramedullary nails, leading to few complications[38]. The management of femur fractures in children aged 5 to 15 years remains a topic of debate. For

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children in this age group, with weight below 50 kg and with length-stable fractures, closed reduction and elastic titanium nail fixation are generally considered as more desirable management modality[39].

In our study there was a male predominance; 15 (65.2%) cases were male patients. The predominance of males may be because of their greater engagement in outdoor activities like playing, climbing tree and contact sports in comparison to their female counterparts. In the study by Jolley A et al.[40] there was male predominance (32 in number) as compared to female (28 in number).

Similarly, most of the patients were of 5-10 years, with the mean age being 9.13 years (S.D. 1.66 years). In the study by Olivo et al.[41], the average age was 8.4±2.3 years for cases treated with TENS. Majority of the patients presented with injury to the right thigh, the dominant side. The affected side was right in 15 (65.2%) patients whereas 8 (34.8%) cases were affected on left side. In the study by Arora K K et al.[7] right side was injured in 52 % of cases, 44% had injury on left side and 4% had bilateral injury.

Similarly, the most frequent cause of injury was a fall from height, accounting for 11 patients (47.8%) and 7 (30.4%) patients with fall on ground. In the remaining 5 (21.7%) patients, RTA was the cause of the injury. In the study by Jolley A et al.[40] the most common cause of injury was road traffic accidents (RTA), following which were fall from height and sports injuries. Amongst the 234 patients evaluated by Flynn JM et al.[1], the most common cause of injury was road traffic accidents (RTA) (58.1%) followed by fall on ground (19.6%) and only 28.8% cases presented with fall from height.

Moreover, the average time from injury to surgery was 3.13 days (S.D.0.92 days). Arora K K et al.[7] observed in their study that eighty percent of patients underwent surgery within 2 days of injury, 12% were operated on between 3 to 5 days, and 8% presented after 5 days, with surgery performed on the 7th day.

In this present study, the average time of hospital stay was 4.30 days (S.D. 0.703 days). Vishwanath et al.[4] observed the mean hospital stay was 8.8 days while the average duration of hospital stay was 8.1 days in the study performed by Bhuyan BK et al[24]. The mean duration of surgery (time from skin incision to closure) was 62.70 minutes (S.D. 7.778 minutes). The time period of surgery in the study conducted by Reddy et al.[42] was 83.0 minutes.

The average blood loss was 38.48±10.383 ml and the number of patients requiring blood transfusion was nil. The result was similar to the study of Reddy et al.[42] in which the average blood loss was 45.3±6.58 ml.

Furthermore, the mean duration of fracture union was 14.61±4.061 weeks. In the study by Reddy et al.[42], they found the radiological union in 11.3±1.22 weeks. The mean duration of union was 8.3 weeks in the study by Memeo et al.[30] while it was 11.1 and 8.7 weeks in the study performed by Vishwanath et al.[4] and Saikia et al.[28] respectively.

In our study, significant limb length inequality was not noted. All cases of limb length inequality were ≤ 1cm. In the study by Ho CA et al.[32], 7.6% of the cases had limb length discrepancy > 1cm at 6 months while only 2.19% cases had persistent limb length discrepancy > 2cm. Also, clinically significant malalignment in any plane was not found in patients treated with TENS fixation. Malalignment was <5 degree in all the patients. In the study by Sarkar S et al.[26] varus angulation was found in 4 (5.71%) patients with TENS fixation. Ligier JN et al.[43] reported 11% patients with malalignment who were operated with TENS fixation.

Regarding postoperative complication, there was no complication in 21 (91.3%) patients while there was 1 (4.35%) case of superficial infection and skin irritation each. In a study by Bhuyan BK et al.[24], there were 2 cases of superficial infection and 7 cases of skin irritation. Superficial infection was noted in 4 (1.7%) and 2 (10.5%) cases in the study by Flynn JM et al.[1] and Bar-on et al.[33] respectively. Similarly, 20 (86%) patients had full range of motion (0-140 degree of flexion). Three cases had mild restriction of flexion (0-120 degree). In the study by Arora KK et al.[7] eighty percent of patients achieved a full range of knee movement, while 20% experienced mild restriction in movement. The patients presenting with moderate or severe restriction of movements was nil in our study.

This study showed excellent result in 21 (91.3%) cases whereas satisfactory result in 2 (8.7%) patients. None of the cases had poor outcome. In a study conducted in 40 patients by Bhuyan BK et al.[24], an excellent outcome was observed in 33 patients (82.5%), while 7 patients (17.5%) had a satisfactory result. Similarly, Memeo et al.[30] reported the patients having excellent, satisfactory and poor result as 82% ,14% and 4% respectively.

The lower incidence of surgical wound complications, reduced operative time, minimal blood loss, and quicker recovery with titanium nails in treating pediatric femur fractures, as observed in our study, aligns with findings from other similar studies and case series. This supports titanium elastic nailing as the preferred method for fixing femur fractures in children aged 5 to 15 years. Another treatment option for elastic intramedullary nailing for pediatric femur fractures is fixation with compression plates. While compression plates offer greater fracture stability, they are associated with enormous risk of implant failure[44]. Compression plating is also associated with higher rates of infection, significant soft tissue dissection, disturbance to fracture hematoma and a greater risk of delayed fracture healing[45]. Moreover, it also results into higher chances of stiffness around the knee joint.

To focus on the limitation of our study ,it was a study with a less sample size conducted in a single institution and follow-up was done for a smaller period of time due to which complications like knee stiffness and malalignment were difficult to be assessed appropriately. So, a prolonged study

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period with a greater number of participants is suggested for a more comprehensive assessment and improved management of complications.

V. CONCLUSION

On the basis of these findings, it can be ascertained that the Titanium Elastic Nailing System (TENS) is an excellent approach for treating pediatric femoral diaphyseal fractures. It confers elastic mobility which aids in quick fracture healing and provides stability, making it well suited for early mobilization, with less complications and better results in comparion to other treatment methods. As it favors early weight-bearing, faster union and negligible hindrance to bone growth, intramedullary TENS fixation can be seen as a more physiological management strategy. TENS fixation is a simple, consistent, minimally invasive, effective and physeal-protective technique for the ultimate management of femoral diaphyseal fractures in pediatric age group .

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