Comparison of SIGN Pediatric and FIN nail in Pediatric Diaphyseal Femur Fractures: Early Clinical Results

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INTRODUCTION:

Diaphyseal femur fractures are one of the most common pediatric fractures\(^1\). There are various treatment modalities available to treat these fractures including the Pavlik harness, external fixators, plate and screw devices, intramedullary nails, etc and each has its own advantages and complications\(^2\). The American Academy of Orthopedic Surgeons’s (AAOS) clinical practice guidelines in 2009 for these fractures regarded age as the main factor determining treatment.\(^3\). It was recommended that children less than 5 years should be treated conservatively. Flexible intramedullary nailing was recommended as treatment of choice for children between ages of 5 and 11 years.

Flexible intramedullary nailing requires its own implants, image intensifier, and is also associated with number of complications\(^4\). Poor results have been shown in unstable fracture patterns, obese children (>49kg), children older than 11 years and are associated with complications like loss of length and rotation at fracture site\(^5\). Rigid intramedullary nailing is the treatment of choice for adult diaphyseal femur fractures but its use in the pediatric age group is limited due to complications like avascular necrosis (AVN) of femur head and proximal femoral valgus, amongst other complications\(^6\). Recently, a few authors have reported encouraging results with the use of rigid intramedullary nails without any incidence of AVN\(^7\). The role of the SIGN (Surgical Implant Generation Network) Pediatric nail and SIGN Fin nail is not well described in this regard. The purpose of this study was to compare these two types of rigid intramedullary nails in treating pediatric diaphyseal femur fractures.

Patients and Methods:

Study Design and Study Setting:

After obtaining approval from the hospitals’ Institute Review and Ethics Board (iREB), a prospective case-series study was undertaken at a Level I Trauma Centre; Department of Orthopaedics and Traumatology, Lady Reading Hospital (LRH), Peshawar, PAKISTAN. LRH is a level I centre with 1800+ beds and is the largest hospital in northern Pakistan and it caters for patients from this area in addition to patients from the Federally Administered Tribal areas (FATA) of Pakistan and from Afghanistan. The study was performed from November, 2010 to June, 2012.

Study Sample:
All pediatric patients with OTA-32-type fractures who consented to participate in the study were included. A total of 24 patients were included in the study. The exclusion criteria was femoral diaphyseal fractures in patients less than 5 years or who had attained skeletal maturity, patients who did not consent to participate in the study or were lost to followup.

**Operative Technique:**

Patients were positioned in the lateral position on a standard operating table. A lateral skin incision was performed and the greater trochanter was identified. Reaming to chatter was done using hand reamers. The type of nail was chosen by the operating surgeon depending on canal diameter. Reaming was done until the length of the distal Fin of the SIGN-Fin nail and distal expansion of the SIGN-Pediatric nail; using the marks on hand reamers as an appropriate guide. Closed reduction was preferably performed but open fracture reduction was done in case of previous implant (plate), non-union or if reduction could not be performed by close method. Bone from flutes of the reamers was added the fracture site if open reduction of fracture was done. All fractures were locked proximally. No iliac bone grafting was performed. Neither the image intensifier (C-arm) nor traction table were used for any of the procedures.

Postoperative immobilization modality was dependent on patient compliance, fracture pattern and age of patient. The various options included no immobilization (most commonly given to SIGN-Fin nail group patients), below knee cast with a bar (most commonly given to patients with SIGN-Pediatric nail), and a knee immobilizer postoperatively for 4 weeks. Patients were followed up regularly and were contacted by telephone if they did not come for follow-up. After 4 weeks, patients were encouraged to weight bear as tolerated.

**Data Collection:**

Demographic data was collected from each patient including age, gender, date of injury, date of surgery, time from injury, and any complication from previous treatment (if applicable). Radiographic data included fracture location, fracture classification according to AO/OTA classification. Intraoperative data included nail type and nail diameter. Treatment data recorded weight-bearing status, infection, range of motion (hip and knee), radiographic healing, followup duration and complication (if any).

Patients were asked to come regularly for follow-up. The average follow up period for the study was 70.7 wks (range: 44 wks to 134 wks).
**Data Analysis:**

Data collected were inserted and analyzed using the Statistical Package for Social Sciences 20.0 (SPSS, Inc., Chicago, IL, USA). Results were recorded as frequencies, means ± standard deviations (SD) and p-values. For all purposes, a p-value of <0.05 (95% confidence level) was considered as the criteria of significance.

**RESULTS:**

There were eighteen patients in the study (6 patients did not have any followup). There were 13 male (72%) and 5 female patients (28%). Average age of patients was 10.2 years (6yrs to 13yrs). Average time between injury and surgery was 13 days (1day to 112days). One patient had previous plate fixation and another was previously treated with Kuntschner nail. The average time interval between injury and surgery after excluding these two cases was 6 days (1 day to 20 days).

The SIGN-Pediatric nail was used in 5 patients while the SIGN-Fin nail was used in 13 patients. Both SIGN-Pediatric and Fin nails are FDA-approved, stainless steel nails which are manufactured by SIGN, USA. The Fin nail was not designed for pediatric population but the large canal diameter in our pediatric population encouraged us to use it for treating pediatric femoral diaphyseal fractures.

A comparison of results for both groups is shown in Table I.

### Table I: Comparison of SIGN-Pediatric and SIGN-Fin nail groups

<table>
<thead>
<tr>
<th></th>
<th>FIN NAIL GROUP (n=13)</th>
<th>PEDIATRIC NAIL GROUP (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AGE</strong></td>
<td>11 yrs (Range: 8yrs – 14yrs)</td>
<td>8.2 yrs (Range: 6yrs – 10yrs)</td>
</tr>
<tr>
<td><strong>AVG. NAIL DIAMETER</strong></td>
<td>8.6 mm (Range: 7mm – 10mm)</td>
<td>7.6 mm (Range: 7mm – 8mm)</td>
</tr>
<tr>
<td><strong>AVG. NAIL LENGTH</strong></td>
<td>255mm (Range: 240mm – 280mm)</td>
<td>208 mm (Range: 200mm – 240mm)</td>
</tr>
<tr>
<td><strong>INFECTION</strong></td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td><strong>FULL WEIGHT BEARING</strong></td>
<td>7.07 wks (Range: 3wks – 11wks)</td>
<td>8.4 wks (Range: 6wks – 12wks)</td>
</tr>
</tbody>
</table>
**DISCUSSION:**

Intramedullary fixation of diaphyseal femur fractures has become the standard of care in adults and children. Rigid intramedullary nails showed early promise but later its use was discouraged after reports of complications like avascular necrosis of femoral head, femoral neck valgus, etc. {NEED A REFERENCE HERE FOR THIS STATEMENT} The elastic nail showed promise and is now the standard of care for certain age groups. Its use requires an image intensifier and has been associated with high costs. The use of the elastic nail has been shown to be limited by complications especially in few populations like obese, heavy children, unstable/comminuted fracture pattern {NEED A REFERENCE HERE FOR THIS STATEMENT ALSO}.

The entry-point used in our study was through the lateral aspect of greater trochanter. All patients were full-weight bearing at 7.44 weeks (Range: 3 - 12weeks). Time to full-weight bearing was early in the Fin nail group compared with the Pediatric nail group. This could be because post-operative immobilization was mostly done using a below knee cast with a bar in the latter group. We did not have any patient with complications of AVN, limb length discrepancy, infection, malunion, or neurovascular injury. Gordon et al in a retrospective review of 25 extremities in children with a mean age of 10.5 years and 2 year follow up reported excellent results with rigid intramedullary nailing using a lateral trochanteric approach and did not report any clinically important femoral neck valgus, deformity or narrowing and did not observe avascular necrosis of femoral head in any patient (2).

Keeler et al in a retrospective review of 80 fractures (78 patients) showed excellent results with rigid intramedullary nails and reported no nonunion, delayed union, AVN or clinically important femoral neck valgus or narrowing.\(^8\)

In a recent systemic review by MacNeil et al, the authors compared the site of entry with incidence of AVN in 1277 article; they reported incidence of AVN to be 2% with piriformis fossa as entry point, 1.4% with tip of greater trochanter and did not report any case of AVN with lateral trochanteric entry point.\(^9\)
However, some authors advocate that complications can be minimized with strict adherence to surgical technique and due respect to vascular anatomy of the proximal femur. Kanellopoulos et al in their study of 24 pediatric femur fractures did not report any complication with the tip of greater trochanter as the entry point. SIGN-pediatric and SIGN-Fin have a proximal slot for a screw while the distal end is shaped in a way to interdigitate with bone in the medullary canal. Proximal locking was done in all patients. In a retrospective review by Ellis et al of 107 length unstable femoral shaft fractures treated with locked vs unlocked Enders rod. They found that locked rods had better outcome in terms of shortening and other complications, such as limp, leg length discrepancy, and painful and palpable rods. They also reported a significant migration of unlocked rods in comparison to locked Enders rods.

Biomechanical studies have shown that there is a risk for loss of reduction in both sagittal and coronal planes for transverse midshaft femur fractures which are treated with TEN in heavier children (>45kg). Rigid intramedullary nails are preferred for this indication. No patient in our study was above 45kg and there are no published results of using SIGN-pediatric and Fin nails in this patient population.

Garner et al in a retrospective comparison of flexible nails versus rigid locked nails for length-stable femoral shaft fractures in heavier (>50kg) children did not find any improved outcome in the rigid nail group in terms of complications like malunion and/or leg length discrepancy. However they did report significantly better intraoperative parameters with the titanium elastic nail (TEN) group. They also included treatment costs of both groups which was $11,628 (9402-13,584) for elastic nail group and $10,886 (6564-15,209) for rigid nail group. In our study, there were no patients in either group with weight over 45kgs. We were unable to record intraoperative estimated blood loss and also did not account for patients costs. Cost of individual patient was difficult to ascertain as all nails and some of the intraoperative medicine were given without any cost to the patient but the medicine availability varied at different times. Estimated costs incurred by the patient were between $50 - $200 (excluding implant cost).

The use of SIGN implants obviates the use of image intensifier. This is helpful in reducing the harmful effects of image intensifier to the patient and operating team. There are few studies which have reported intraoperative radiation exposure for elastic nails. Kraus et al reported average radiation time of 70.3 seconds (range: 12-193sec) for 53 femoral diaphyseal fractures. Gamal et al reported average radiation exposure time of 69 seconds (range: 30-135sec) in 73 patients undergoing titatnium elastic nailing of femoral and tibial fractures.
There are no definite recommendations regarding hardware removal in the pediatric population with femur fractures\textsuperscript{16}. Hardware removal after complete fracture healing is common in our setup. It is mainly due to the parents/patients wish to have it removed. There are few studies which have looked at removal or retaining hardware for these fractures in this age group. Morshed et al in a retrospective case series of 24 patients treated with flexible intramedullary nail reported no difference in residual pain symptoms in patients who had hardware removal after fracture healing compared to those patients who had retained hardware\textsuperscript{17}. They also reported that a quarter of patients may require a second procedure for implant removal due to persistent discomfort in 5 years.

Buford et al have shown that the removal of rigid nail is associated with a risk of osteonecrosis if there is extensive dissection at time of implant removal\textsuperscript{18}. In our study, one patient with SIGN-Fin nail wished to have it removed with bone grown over the proximal end. Careful extensive dissection was done and he did not report any adverse outcome even after 4months of implant removal.

The strengths of this study include that it is the first study which has compared use of SIGN-Pediatric and SIGN-Fin nails for pediatric femur fractures. All surgeries were performed by a single surgeon, thus minimizing surgical variability.

The limitations of this study include a small sample size, early results (not following the patients till skeletal maturity), lack of randomization, lack of documenting intraoperative measurements like expected blood loss, etc; [LACK OF A ?????] stringent postoperative protocol and not using functional outcome measures.

In conclusion, SIGN-Pediatric and SIGN-Fin nails have shown to give excellent results with no complications in this small series. Patients need to be followed up until skeletal maturity to ascertain safety of this implant and procedure. Being solid, stainless steel nails; they provide excellent mechanical stability. As they are very economical/free of cost, they become an ideal treatment modality in limited-resource settings. Further large-scale, multi-centre randomized control trials need to be undertaken to ascertain its efficacy and complications.

**REFERENCES:**


