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Evaluation of Complications from Stainless-Steel Flexible Intramedullary Nailing in Children's Femoral Shaft Fractures and Recommendations for Continued Use

Asif Sultan(A,B,C,D,E,F), M Rafiq Bhat(A,B,C), Omar Khursheed(B,C,D), Mubashir Maqbool Wani(C,D,E), Altaf ahmad Kawoosa(B,C,D), Hilal Ahmad Kotwal(D,E,F), Qazi Waris Manzoor(D,E,F)

Government Hospital for Bone and Joint Surgery, Barzulla, Srinagar, Kashmir

SUMMARY

Background. Flexible intramedullary nailing is currently considered the treatment of choice for femoral diaphyseal fractures in school-aged children. The purpose of our study was to critically evaluate and analyze the complications of stainless steel flexible intramedullary nailing in children's femoral shaft fractures.

Material and methods. We conducted a prospective cohort study of 100 children aged 6 to 12 years old (mean age, 8.2 years) with a femoral shaft fracture treated with stainless steel flexible intramedullary nailing from January 1, 2009 to July 31, 2015 and evaluated for complications.

Results. All fractures united in a mean time of 9.2 weeks. Minor complications were noted in 19 patients, and major complications were noted in two patients. The Flynn score was excellent in 74 patients, satisfactory in 23 patients, and poor in three patients.

Conclusions. 1. Stainless steel flexible intramedullary nailing in children's femoral shaft fractures is associated with minimal complications. 2. These complications are not related to the alloy of the implant and are mostly due to the long nail end; these complications can be prevented easily. 3. Stainless steel flexible intramedullary nailing is also cost effective, and we recommend its use be enhanced for the treatment of femoral shaft fractures in children.

Key words: complications, femur fracture, children, flexible intramedullary nailing

BACKGROUND

Femoral shaft fractures are among the more common fractures in children, accounting for about 1% to 2% of all orthopedic injuries and are among leading causes of morbidity in children [1]. Presently, the operative management of femur fractures in school-age children with intramedullary implants (flexible nails) is considered among the best possible options [2-5]. Excellent outcomes with this operative treatment method have been well documented in the current literature [6-11]. The benefits of this treatment approach include earlier mobilization, minimal soft tissue damage, low risk of physeal injury or femoral head osteonecrosis, reduced hospital stays and a more rapid return to school. As a procedure, it is simple and relatively easy to learn [12-14].

Titanium elastic intramedullary nailing has increased in popularity and is now the most commonly used treatment method for femoral shaft fractures in school-aged children [2,13,15,16]. Stainless-steel nails are as effective but are much cheaper alternatives to titanium with a similar safety profile, and we used them in this study [17-19].

Different complications of flexible intramedullary nailing have been described with incidences ranging from 10% to 62% of cases [14,20]. Minor complications do not require further unplanned surgery and include pain with limited knee motion, prominent hardware, delayed union, minor degrees of malunion, transient nerve palsy, and superficial infections [2,14,20-22]. Major complications commonly need a second unplanned surgery and include very prominent hardware, loss of reduction, nerve injuries, and deep infections [2,14,20-22].

The purpose of this study was to critically evaluate and analyze complications associated with the use of stainless-steel flexible intramedullary nails in children's femur fractures and determine whether the use of stainless-steel flexible intramedullary nails should be continued.

MATERIAL AND METHODS

After receiving permission from the hospital ethics committee and signed informed consent from the parents of each child, this prospective cohort study was conducted from January 2009 to July 2015. One hundred femur shaft fractures in children aged six to 12 years (mean age, 8.2 years) were included. The study population was composed of 68 boys and 32 girls. The average body weight was 23.5 kg and ranged from 18 kg to 46 kg. Mechanisms of the injury included falls while playing, falls from heights or bicycle, road traffic accidents, and direct trauma. Patients with pathologic, neurologic disease fractures, bilateral, and open fractures were excluded from the study. Most fractures were surgically repaired within an average of three days after injury. All operations were performed under general anesthesia with the patient supine on a traction table. Under fluoroscopic guidance (using C-arm fluoroscopy), reduction was first performed and checked on both anteroposterior and lateral views. Fractures were fixed using the retrograde method of insertion of flexible intramedullary nails using stainless-steel nails. Two nails were always used, one medial and one lateral, passed just above the distal femoral physis. All fractures were close reduced. The diameter of the stainless-steel nails was predetermined depending upon the size of the medullary canal of femur via radiographs. Both nails used were of the same size and were approximately 40% of the canal diameter at the isthmus level and precontoured according to the location of the fracture. The lever arm of bending was three times the inner diameter of the bone and both nails were symmetrically bent.

Gentle knee range of motion exercises and static quadriceps exercises were started with nonweight-bearing ambulation from the third to the seventh postoperative day as per patient comfort. Patients with transverse fractures were allowed partial weight-bearing at three weeks, but weight bearing was delayed to six weeks in spiral, oblique, and comminuted fractures and progressed to full weight bearing over the next three to four weeks.

Patients were followed-up at two, eight, 12, and 24 weeks postoperatively with clinical and radiographic assessments for fracture union, knee motion, or any complication. Final follow-up was done at one year after the surgery. Patients were assessed clinically and radiographically for any complications, limb-length differences, or deformities.

The results were evaluated using Flynn et al's scoring criteria. In most cases, nails were removed routinely at approximately six months after the primary surgery when the fracture was united clinically and radiologically. In one patient, the nail was removed at five months as it was ulcerating the skin. Several patients had nail removals from seven to 12 months due to their availability at that time.

RESULTS

The most common cause of injury was a fall while playing (43) or a fall from height including bicycle (20), followed by road traffic accidents (29) and direct trauma (8) which included cattle-related injuries in two children. The right side was involved in 67 injuries and left side in 33 injuries. The most common site of fracture was the middle third, noted in 72 injuries, followed by the proximal third in 18 injuries and the distal third in 10 injuries. The transverse type of fracture was the most common injury, seen in 48 cases, followed by oblique fracture in 25 cases, spiral fracture in 19 cases and comminuted fracture in eight cases. Other associated injuries were present in 16 patients, with three ipsilateral both bone leg fractures, five distal radius and forearm fractures, and eight minor head injuries. These associated injuries were managed conservatively with plaster casts.

The average duration of surgery was 55 minutes (range, 30 to 80 minutes). Most of the surgeries were performed on the third day after the trauma (range, three to nine days) and most patients were discharged on the third postoperative day. The mean hospital stay was seven days (range, five to 12 days). All fractures were united within a mean time of 9.2 weeks (range, seven to 13 weeks). The Flynn score was excellent in 74 cases, satisfactory in 23 cases and poor in three cases.

Nail removal was routinely done at approximately six months. In one patient, nails were removed a month earlier (at approximately five months) because it was ulcerating the skin. Some nails were removed later (approximately seven to 12 months) due to social and other nonmedical engagements. Nails were easily removed without any difficulty, but occasionally the incisions made for removal were longer than the incisions made during the primary procedure for insertion. No complications were seen with the nail removal procedure. No case of refracture was seen following nail removal with a minimum follow-up of one year.

COMPLICATIONS

The different complications associated with flexible nailing of the femur seen in this case series are enumerated in Table 1.

Pain at nail insertion site

Pain at the nail insertion site was the most common complication and was seen in 19 of our patients. The pain and irritation were caused by the long and bent nail ends.

Implant prominence

Palpable prominent nail ends presenting as swelling were present in 28 patients, but most of them were clinically asymptomatic. Palpable nail ends with associated bursitis were seen in four patients (Fig. 1). Skin ulceration by the nail end was seen in one patient (Fig. 2). Superficial skin infection was seen in one patient.

Corkscrewing of nails

Corkscrewing or twisting of the nails was seen in two patients postoperatively (Fig. 3, 4A). After discovering the twisting of the nails, due care was taken to prevent it in further cases.

Tab. 1. Complications of flexible intramedullary nailing

Complication	Number (percentage) seen in this series
Pain over insertion site	19 (19%)
Prominent hardware	28 (28%)
Bursitis	4 (4%)
Corkscrewing of nails	2 (2%)
Skin ulceration	1 (1%)
Superficial infection	1 (1%)
Deep infection, osteomyelitis	0
Knee stiffness	15 (15%)
Varus	8 (8%) (6º-10º)
Valgus	4 (4%) (5º-8º)
Procurvatum	19 (19%) (7º-19º)
Recurvatum	1 (1%) (2º)
External rotation deformity	5 (5%) (<10º)
Internal rotation deformity	0
Lengthening	10 (10%) (<1cm)
Shortening	8 (8%) (<2cm)
Non-union, delayed union	0
Proximal nail migration with neck penetration	2 (2%)
Distal nail migration	0
Ectopic bone formation over nail insertion site	1 (1%)
Nail breakage	0
Knee synovitis, hematoma	0
Refracture	0
Neuropraxia, nerve palsy	0
Reoperations other than nail removal	0

Proximal nail migration and neck penetration

Two patients had asymptomatic migrations of the nail proximally with penetration of the neck after the fracture union and were seen at the time of routine nail removal at six months (Fig. 4A,B,C).

Stiff Knee

The range of motion of the knee in a functional arc was achieved in an average of nine weeks. Fifteen patients had varying degrees of stiffness of the knee when evaluated at six months (limitations of 10° to 20°) prior to nail removal. Pain at the nail insertion site limited further movements. No stiffness or limitation in knee motion were seen after nail removal.

Bone formation over nail end

One patient had ectopic bone formation over one nail end at the insertion site, which presented as rounded asymptomatic and nontender swelling (Fig. 5, 6).

Fig. 1. Clinical photograph showing case with prominent hardware and bursitis

Fig. 2. Clinical photograph of the knee showing skin ulceration and superficial infection

Fig. 3. Anteroposterior and lateral radiograph showing corkscrewing of nails with fracture union

Deformity

Varus and valgus malalignment (in the coronal plane) occurred in 12 patients. Eight patients had varus angulation between 6°and 10° (Fig. 5,7), and four patients had valgus angulation between 5° and 8°. Nineteen patients had an average of 9° (range, 7° to 19°) angulation anteriorly in the sagittal plane (procurvatum; Fig. 6). Recurvatum (posterior angulation in the sagittal plane) of 2°was seen in one patient (Fig. 7). External rotation deformity of less than 10° was seen in five patients. No internal rotation deformity was seen in any patient.

Limb length discrepancy

Limb length discrepancy at the 12-month follow-up was clinically insignificant and ranged from -2 cm to 1 cm. Ten patients had lengthening of approximately 1 cm, and eight patients had a reduction in length averaging 1 cm with one patient experiencing 2 cm shortening. However, none of the children or their parents was aware of the discrepancy in limb length.

DISCUSSION

Femoral shaft fractures in school-aged children are now commonly managed by operative fixation with flexible intramedullary nails, the accepted standard treatment for these fractures [2]. It is a physiological

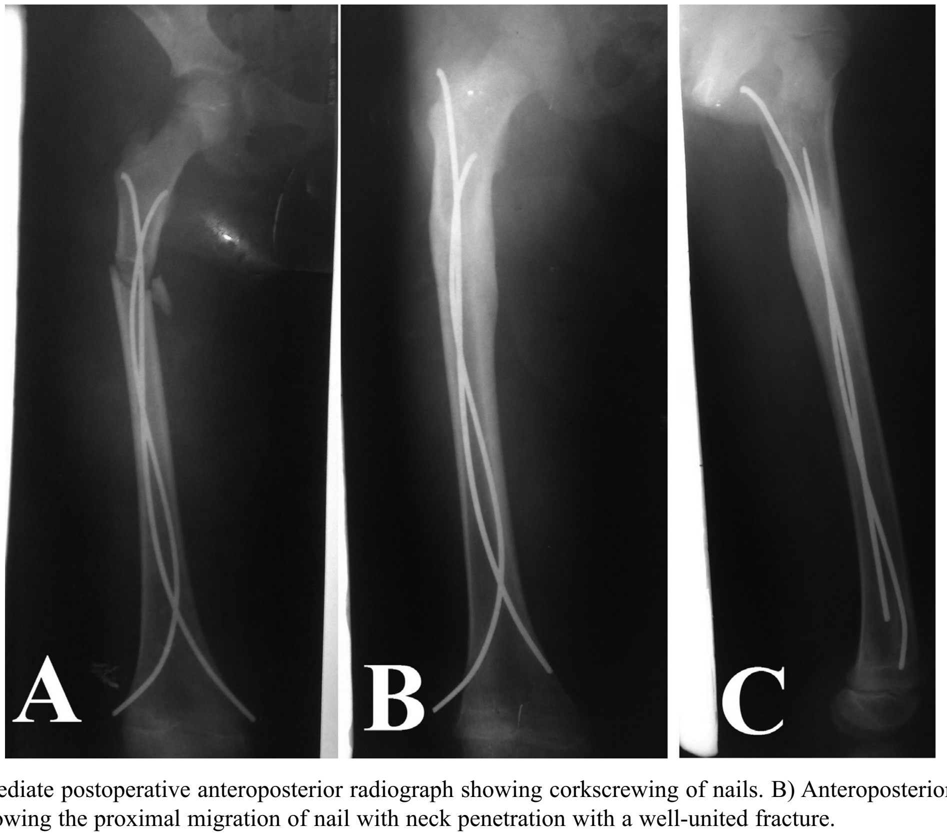

Fig. 4. A) Immediate postoperative anteroposterior radiograph showing corkscrewing of nails. B) Anteroposterior and C) lateral radiographs showing the proximal migration of nail with neck penetration with a well-united fracture.

Fig. 5. Anteroposterior radiograph showing varus deformity and ectopic bone over nail end.

Fig. 6. Lateral radiograph showing procurvatum deformity and ectopic bone over nail end.

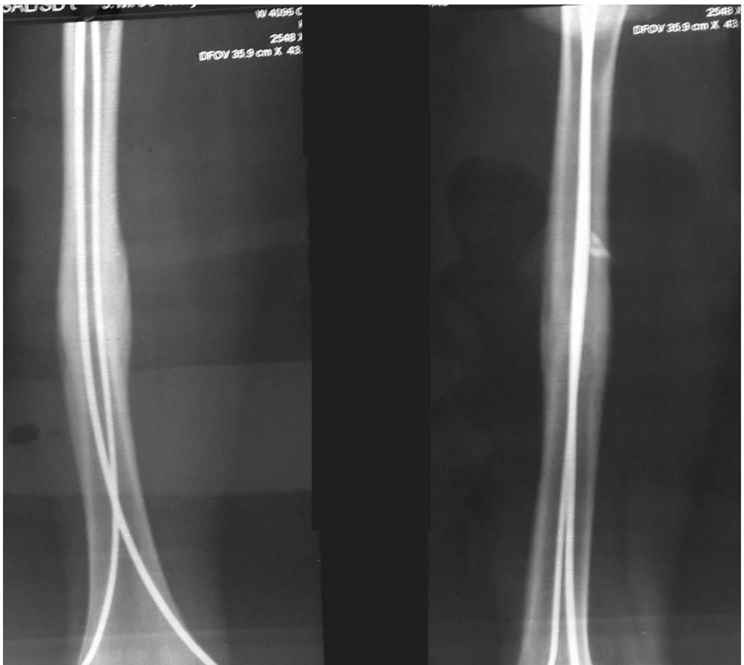

Fig. 7. Anteroposterior and lateral radiograph showing varus and recurvatum deformity

method of treatment as it allows for early weight-bearing with rapid healing and the least disturbance in bone growth of the available methods [23].

Nail end related complications

The most frequent complications associated with the use of flexible intramedullary nailing are nail end-related and include pain at the nail insertion site, implant prominence, and skin ulcerations which arise from skin irritation due to the extraosseous long portion of the nail. Pain at the nail insertion site has been seen in almost all studies and is due to nails being bent earlier in the process to facilitate removal [2,3, 18,22, 23]. We noted many complications due to nail ends in the initial period. To avoid complications related to the nail end, our nails were laid over the femoral metaphyseal flare without being bent and were cut shorter (approximately 1 cm to 2 cm). Putting the nails flush to the metaphyseal flare of the distal femur avoided skin irritation due to the long nail later in the series.

We had one case of skin ulceration and superficial infection due to the long nail. Ulceration was seen in more cases in previous series due to more bending of the nails. Superficial and deep infections have been reported mostly due to skin ulceration because of longer, prominent nails [2,13,18,23,22]. No deep infection or osteomyelitis was seen in our series.

The method of cutting the nails short and allowing them to lay flush to the metaphyseal flare prevents skin irritation, pain, ulceration, and infection and improves knee motion. It is also advisable to use a guillotine nail cutter, which provides a clean and blunt cut without producing sharp edges (which can also irritate skin even if nail end is short and not bent). Cannulated impactors can be used to push the nail at the end while still leaving a long enough (10 mm to 15 mm) end for an easier subsequent removal. One should always palpate nail ends before closure to check for prominence and any hindrance in knee movements [22].

One can also prevent pain and ulcerations at the nail end by using an end cap as it tends to protect the skin from any irritation, and this has been effective in maintaining length in unstable fractures [24,25]. We did not use end caps in any of our patients.

Knee stiffness was seen in 15 patients, but the functional range of motion was achieved in all patients in a mean time of nine weeks. Stiffness was associated with long nail ends and pain at nail sites. Long nails also irritated the vastus medialis and vastus lateralis muscles and can block the iliotibial tract, thus resulting in restriction of knee motion [26]. This limited range of motion of the knee resolved completely in all cases after nail removal.

Corkscrewing of the nails during flexible intramedullary nailing has been reported previously [26]. It causes torsion on the nails around their long axes opposite to each other and is usually more pronounced in the second nail. This results in permanent damage to the contour of the nails and causes loss of the effective internal tension of the nails, reducing the stability of the construct [26]. Corkscrewing was seen in two patients in the present series. It was recognized postoperatively in both cases but the fractures healed well without issue. No additional splint or cast was applied. In both cases, weight bearing was delayed for six weeks. Subsequently, due care was taken during surgery to prevent this by passing both nails simultaneously in small increments and avoiding twisting or rotation of the nails by more than 180°.

Proximal nail migration and neck penetration were seen in two cases. Although rare, it has been reported previously [18,22,27]. One case of sciatic nerve neuropraxia has been reported but was resolved after the nail was repositioned [22]. Our cases were asymptomatic with no penetration in early postoperative radiographs. Both these patients had nail diameters smaller than the optimal 40% of medullary canal diameter. The nails were removed proximally. Operators are recommended to use large nails and have proper fluoroscopy in use during surgery, and attention should be focused on the proximal extent of the nails beside the fracture site in both the anteroposterior and lateral projections. The nails should be directed medially (not in an anterior or posterior direction), which is best seen on lateral projections. It is also recommended that if the nail penetrates the femoral neck region intraoperatively, the nail should be repositioned rather than keeping it short in the same track [27].

Distal nail migration is more common and usually requires reoperation [2,14,18,22]. We had no case of distal nail migration in our series. This problem of nail migration usually does not arise if the fracture is stable and properly sized nails are used [24]. Studies have reported that the use of end caps prevents this distal nail migration because they stop the nail from coming out [24,25].

Angular deformities following intramedullary nailing have been reported and are usually due to the use of mismatched nails or comminution at the fracture site [2,22]. The use of nails with different diameters, as is sometimes done during difficulty passing the second nail, produces asymmetric forces resulting in angulation at the fracture in the direction determined by the larger nail. Therefore, both nails should be of the same thickness. Other factors leading to malalignment include the corkscrewing of nails, abnormal asymmetrical curvature in both nails, and the use of small diameter nails [22].

We had some cases of angular malalignment in both sagittal and coronal planes, but these were not clinically significant and did not need surgical intervention. The reduction of the fracture and the comminution were important factors for abnormal angulations.

Rotational asymmetry of less than 10°was seen in five patients and was insignificant. A previous study reported that higher malunion rates are seen in titanium nails as compared to similarly designed stainless-steel nails [17].

Nonunion and delayed union following intramedullary nailing have been reported and usually result from the use of thin nails [3,13,18]. This gives less rigid fixation, and the resultant excessive motion at the fracture site due to thin nails causes nonunion. One study reported that the replacement of 2-mm nails with 3.5-mm nails in a patient with nonunion following intramedullary nailing resulted in union in eight weeks [3]. None of the patients in our series developed delayed union or nonunion even though stainless-steel nails are stiffer than titanium nails.

Limb length discrepancies in the present study at a minimum one-year follow-up ranged from a reduction in length by 2 cm to a lengthening of 1 cm. The discrepancy was not apparent to the children or their parents. Several studies have reported a limb length discrepancy of approximately 1 cm without any clinical significance [2,3,14,18,22]. Mutimer et al. [28] reported more lengthening in children aged four to eight years in his series of 17 children aged four to 14 years. One study reported a small mean lengthening of 1.2 mm at a mean follow-up of 22 months, but there were two cases of significant limb lengthening which required epiphysiodesis [23]. This overgrowth may be due to increased vascularity associated with fracture healing rather than any compensatory mechanism [28]. True leg lengths were measured with a tape from the anterior superior iliac spine to the medial malleolus with the pelvis squared, and any discrepancy was measured using the blocks method to eliminate any evident pelvic tilt by palpation of the iliac crests. These clinical methods of limb measurement are sensitive to leg length discrimination, and routine radiographic follow-up is not necessary unless clinically indicated because it gives unnecessary radiation exposure [28].

Shortening (a reduction in length) is also seen in intramedullary nailing due to some overlap at the fracture with some angulation and in those patients who are noncompliant with nonweight-bearing orders [28]. Shortening can be prevented by using end caps and thick diameter nails [24,25].

Ectopic bone formation over the nail end was seen in one of our cases and presented as a smooth swelling without any pain or tenderness, measuring 2 cm × 2 cm. This has not been reported in previous studies. This bone formation may be due to the continuous irritation of muscle by the nail end. This swelling was alleviated at the time of nail removal by utilizing a larger incision and additional dissection. The use of end caps may prevent the formation of ossification over the tips of the nails and tends to facilitate the removal of nails by protecting their ends from callus formation [24].

Nail removal has been routinely recommended starting at 6 months and onwards by many authors [2,18]. We routinely removed nails in all patients; most were removed by 6 months and others were removed later due to personal engagements. Only one patient required an early nail removal as it had ulcerated the skin. No case of nail breakage or refracture after nail removal was seen in our series. Nail removal was done without much difficulty or complications in our study.

The choice to continue using stainless-steel nails in our study was due to many reasons, with the principal reason being that they provide equally good or better results than titanium nails [17,29]. Stainless-steel nails are more rigid and provide better resistance to recall forces than titanium nails [24]. They are also four times cheaper than titanium nails, and orthopedic surgeons must recognize cost containment is one of their responsibilities while also avoiding potential increases in complications or compromising patient outcomes, which was exactly achieved in this study [30].

We had excellent results with stainless flexible intramedullary nails with reasonable complications unrelated to the nature of the alloy used at a conside rably lower price than the titanium option. Therefore, we recommend the continued use of stainless-steel flexible intramedullary nails for the fixation of fe mo ral shaft fractures in children aged six to twelve years old.

CONCLUSIONS

1. Stainless steel flexible intramedullary nailing in children's femoral shaft fractures is associated with minimal complications.
2. These complications are not related to the alloy of the implant and are mostly due to the long nail end; these complications can be prevented easily.
3. Stainless steel flexible intramedullary nailing is also cost effective, and we recommend its use be enhanced for the treatment of femoral shaft fractures in children.

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Adres do korespondencji / Address for correspondence
Asif Sultan, MBBS, MS, Asst. Professor
Government Hospital for Bone and Joint Surgery
Barzulla, Srinagar, Kashmir.190005, e-mail: drasifsultan@yahoo.com

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