

# Stabilization of Open Femoral Fractures with The SIGN Intramedullary Nail: Treatment Protocol and Early Clinical Results

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## ABSTRACT

*Objective* To evaluate the effectiveness of SIGN-Nail (Surgical Implant Generation Network®) for the treatment of open femoral fractures.

*Study design* Case-Series.

*Place & Duration of study* Department of Orthopaedics and Traumatology, Lady Reading Hospital Peshawar, from September 2010 to June 2012.

*Methodology* Patients with open fractures of femur were included in the study. Femoral IM nailing was done using SIGN (Surgical Implant Generation Network®) nail with standard SIGN-technique with hand reaming without using bone-grafting or image intensifier. Patients were evaluated for infection, radiographic parameters, range of movements, time to weight bearing (partial and complete) and complications or revision surgery, if needed.

*Results* There were a total of twenty-two (21 male and 1 female) patients in this series. The mechanism of injury was gunshot in 12, bomb blast in 4 and road traffic accident in 6 cases. Seventeen (77%) patients had Gustilo Type IIIa fracture, 3 (14%) patients had Type IIIb fracture and two (9%) patients had Type II fracture. The average time from injury to surgery was 13.8 days (range 2 to 35 days). Two patients developed surgical site infection. The frequency of infection in Type IIIa fractures was 5.8% (1/17) and in Type IIIb fractures 33% (1/3). In follow up all patients had greater than 90 degrees flexion at the knee joint. Twenty patients (91%) were full weight bearing at 4 months. Two revision surgeries were done. Bone grafting plus exchange nailing was done in both the patients to achieve union.

*Conclusion* Use of SIGN-nail is an effective treatment modality in treating open fractures of femur with excellent fracture healing.

*Key words* Femur nailing, Open fracture femur, SIGN Nail.

## INTRODUCTION:

The management of open long bone fractures can be challenging even for the most experienced trauma surgeons. The treatment can be associated with complications such as infection, nonunion, malunion and amputation.<sup>1</sup> It is the initial management of such fractures which determines the ultimate outcome.<sup>2</sup>

The indications for treating open femur fractures with intramedullary nails and the timing of such procedures remain controversial.<sup>3</sup> Deep infection, intramedullary sepsis, osteomyelitis and infected nonunion represent some of the concerns that have been raised over the years.<sup>4</sup> Other authors have advocated the use of external fixation followed by delayed definitive internal fixation.<sup>5</sup> The role of the SIGN (solid) nail for the management of open femoral fractures remains obscure. The purpose of this study therefore was to report on the algorithm and clinical results of open femoral fractures treated with the SIGN-IM nail.

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**METHODOLOGY:**

A prospective case-series was undertaken at a Level I Trauma Centre; Department of Orthopaedics and Traumatology, Lady Reading Hospital Peshawar from September 2010 to June 2012. The inclusion criteria were open femur fractures (Gustilo Type I-IIIc), femoral fractures stabilised with reamed SIGN-IM nailing, and those who were regularly followed for a minimum of 6 months period. Patients with closed femoral fractures and the open fractures initially stabilised with external fixation, were excluded. The Gustilo et al classification system was used to classify open fractures.<sup>6</sup> The OTA/AO classification was used to classify the fracture pattern.<sup>7</sup> Overall injury severity was assessed using the injury severity score (ISS).<sup>8</sup>

Patients on arrival were managed according to the Advance Trauma Life Support (ATLS) protocol. Tetanus immunization and broad-spectrum antibiotics were given to all the patients. Surgical debridement with copious irrigation of open wounds was done at the time of admission if required. Radiographs were taken following application of splints. Patients were kept in skeletal traction from time of admission till surgery. Fractures were reduced either by open or closed reduction, depending on the fracture pattern and time since injury. There were no absolute criteria for performing either antegrade or retrograde nailing. Generally, distal femur fractures were treated with retrograde nailing and proximal / middle third fractures with antegrade nailing. SIGN nailing was performed by standard SIGN technique with hand reaming.<sup>9</sup> Bone from flutes of the reamers was added to the fracture site if open reduction of fracture was done. All fractures were locked both proximally and distally with interlocking screws. No iliac bone grafting was performed. Image intensifier (C-arm) was not used for any of the procedures. Antibiotics were given to all the patients and continued postoperatively for two weeks.

Data were collected at the time of surgery and every follow up visit by performing physical examination and radiographs. Parameters recorded and analysed were signs of infection, mode of weight bearing status (partial/full weight bearing), knee range of motion, complications (if any) and status of bridging callus across the cortices in the radiographs. Union was described as full weight bearing without any thigh pain and having bridging callus across at least 3 cortices on plain radiographs. Delayed union as the absence of progressive fracture healing for 3 consecutive months with / without thigh pain and non-union as the absence of healing after six months with / without thigh/fracture site pain. In

addition to radiographic and symptomatic assessment of fracture healing, a novel technique of "Squat and Smile" was used to assess fracture healing. Patient who could squat without any pain with greater than 150 degrees of knee flexion were labelled as healed.

Data was entered into SPSS 18.0 (SPSS, Inc., Chicago, IL, USA). Fisher's Exact test was applied to test the association between categorical variables. Results were recorded as frequencies, means  $\pm$  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:**

A total of 26 patients met the inclusion criteria but four were lost to follow-up. There were 21 males and 1 female patients with a mean age of 27.7 year (range: 19-52 year). The mechanism of injury was gun shot in 12 cases, road traffic accident in 6 cases and bomb blast injuries in 4 cases. The fracture was in proximal-third in 4 cases, middle-third in 7 cases and in distal-third in 11 cases. OTA/AO classification system was used to classify fractures.<sup>10</sup> Seventeen patients (77%) had Gustilo Type IIIa fracture, 3 patients (14%) had Type IIIb fracture and 2 patients (9%) had Type II fracture. Injury severity score (ISS) ranged from 11 to 36 (mean = 22.6).

Six patients had associated bowel injuries for which laparotomy was performed before nailing and during this period, the patients were on traction. Two out of six patients presented primarily to our hospital while four were referred for orthopaedic intervention from other hospitals. One patient developed acute respiratory distress syndrome after surgery (injury to surgery time: 10 days). Three patients had associated sciatic nerve injuries. Three patients had multiple fractures; one had ipsilateral tibia fracture, one had ipsilateral neck of femur fracture and one had fractures of radius, ulna and humerus. One patient, who had debridement delayed for greater than 24 hours also had contralateral type IIIc fracture for which he underwent trans-knee amputation.

Antegrade femur nailing was done in 9 cases (41%) while retrograde femur nailing was performed in 13 cases (59%). The average nail diameter was 10.0mm (range: 9mm – 11mm) while average nail length was 353.6mm (range: 320mm – 400mm). The average time from injury to debridement was 10.5 hours (range: 2 hours to 96 hours). One patient had delay of 96 hours while another had a delay of 41hours. Excluding these two outlier delays, the average time

from injury to debridement for the remaining 20 patients was 4.7 hours. There were 11 delayed primary skin closures, 6 primary skin closures and in 5 patients the skin was allowed to close by secondary intention. The average time from injury to surgery was 13.8 days (range: 2 - 35 days). This delay was mainly due to late presentation of patients to our hospital and / or multiple debridements before definitive procedure. The average follow up period for the study was 70.7 weeks (range: 44 weeks – 134 weeks).

Two patients (2/22) developed surgical site infection; one was superficial and pus grew *Staphylococcus aureus* and the other one was deep with *Escherichia coli* on culture result. The superficial infection settled down with a course of antibiotics whereas the deep infection necessitated debridement and irrigation once and then nail removal after complete bone healing. Both of these patients sustained fractures in bomb blast incident to distal femur. They were full weight bearing at 16 and 14.8 weeks respectively after surgery (average time: 14.36 weeks). No patients developed discharging sinus or osteomyelitis.

All patients had greater than 90 degrees flexion at the knee joint. Three patients had knee flexion less than 140 degrees. Retrograde nailing was done in these patients. They needed manipulation under anesthesia to regain full flexion at the knee joint. Twenty patients (91%) had fracture union and were full weight bearing at 4 months. They were also able to 'squat and smile'.

One patient (with IIIa injury) developed nonunion for which iliac crest bone grafting with exchange

Fig I (A): Preoperative x-ray of a 24 year old patient with Gun Shot Wound : AO 32-C3



Fig I (B): X ray at Follow up (38 Weeks)



nailing was done and the patient was full weight bearing 3 months after surgery. Exchange nailing with bone grafting was done for one patient with implant failure. This was a 45 year old gentleman who had gunshot injury to distal femur (IIIa), fixed with retrograde nail. Revision surgery was carried out and the patient was full weight bearing 4 months later. At final review, there was no evidence of infection, nonunion and malunion in any of the patients. All patients were full weight bearing with greater than 150 degrees of flexion at the knee joint and could "squat and smile".

**DISCUSSION:**

Intramedullary nailing is the treatment of choice in closed diaphyseal fractures of femur.<sup>11</sup> Its use however in treating open femoral fractures is controversial. Previous reports on the management of open femoral fractures reported high complication rates while others reported encouraging results.<sup>12</sup> The advances made in antibiotic treatment and the better understandings of debridement techniques have resulted in decreased incidence of infection.<sup>13</sup> Appropriate antibiotic coverage and early debridement is an essential component of management of such fractures.<sup>14</sup> In our study, all but two patients had early debridement and antibiotics were administered. Harley et al in his retrospective review of 215 open long bone fractures reported that time between injury and debridement was not a significant factor in developing an adverse outcome.<sup>13</sup> In our study, patients who developed infection had debridement and antibiotics administered within 5 hours after injury.

This can be due to the reason that rate of infection is more associated with severity of injury, open fracture type rather than timing of debridement.<sup>13,15</sup>

Early wound coverage is of paramount importance in the management of open fractures. In this study there were 11 delayed primary skin closures. Gopal et al reported good results with immediate internal fixation and early soft-tissue cover, but their case series was for tibial open fractures.<sup>16</sup> In this study, there was an average delay of about 2 weeks between injury and surgery. This delay was mainly due to late presentation and/or initial management for more severe chest/abdominal/head injuries. Morshed et al in a study of over 3000 patients concluded that fixation of femoral shaft fractures in patients with multiple system involvement had reduced mortality if the fixation is delayed for more than twelve hours. They also reported that the subgroup of patients with abdominal injuries had the most significant reduction in mortality.<sup>17</sup> Patients in our study were placed on traction during the time from admission to nailing surgery. Park et al reported good results using NPWT followed by delayed soft tissue coverage.<sup>18</sup> In this study this was not followed.

In this case series, retrograde nailing was performed more often compared to antegrade nailing. Greater trochanteric entry point was used for antegrade approach. Stannard et al reported no significant difference in functional hip outcome after one year of surgery between piriformis fossa and greater trochanteric entry point but did report significant improvement in intraoperative parameters (operation time, incision length, fluoroscopy use, etc) with greater trochanter as entry point.<sup>19</sup> In this study, there were more distal femur fractures compared with middle or proximal shaft fractures, hence retrograde approach was preferred. In addition, retrograde approach offered the added benefit of applying tourniquet during some part of surgery and hence resulted in decreased blood loss compared with antegrade approach.

Infection, along with its sequela is the major concern regarding early intramedullary fixation of femoral shaft fractures. Implant material, design and insertion techniques are important factors. SIGN nail is different from commonly used nails (which are cannulated, hollow) as it is a solid, stainless steel nail and comes with its own unique assembly of target arm with which both proximal and distal interlock screws can be placed without using the image intensifier. Horn et al in an experimental study compared infection resistance amongst solid, hollow and cannulated nails; and found out that solid nails

offered a significant; greater than twofold resistance to infection.<sup>20</sup> This can be because of less surface area for biofilm to be attached. We used hand reamers in all cases and the bone obtained from flutes of reamers was put in the fracture site. This technique is physically demanding for the surgeon but it also reduces chances of thermal necrosis and other complications.<sup>21</sup> O'Dwyer et al in a study on tibial fractures found hand reaming to be significantly superior to power reaming in terms of earlier union rates.<sup>22</sup> In our series, one patient (4.5%) had non-union. There were no cases of malunion or limb length discrepancy. Green et al reported high complication rates in their study of open femur fractures. They reported overall infection rates of 9%.<sup>4</sup> Singh et al reported infection rate of 4% and nonunion rate of 9%.<sup>10</sup>

#### CONCLUSION:

SIGN intramedullary nailing of open femur fractures performed 48 hours after injury is safe with excellent union rates and fewer complications provided adequate initial debridement and early antibiotic administration are done.

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