MANAGEMENT OUTCOME OF CLOSED FEMORAL SHAFT FRACTURES BY OPEN SURGICAL IMPLANT GENERATION NETWORK (SIGN) INTERLOCKING NAILS

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Background: Many hospitals in our country lack surgical expertise and operating room facilities like image intensifier and fractures table to carry out closed interlocking nails (ILN) in femoral shaft fractures. But availability of Surgical Implant Generation Network (SIGN) interlocking nails & nailing instrumentation have made open ILN of these fractures possible at very basic level of our health care system. We have carried out open SIGN nailing in patients with closed fractures of shaft femur without the use of image intensifier. Result for fracture union was evaluated both clinically and radio-logically, and graded at 8 months (32 weeks) after treatment by Thoressen's criteria. **Methods:** An experimental study of open SIGN nailing was carried out on 47 patients with fractures shaft of femur who had been admitted to our tertiary care hospital from January 2006 to December 2007. Inclusion criteria were adult patients older than 16 years with closed fractures of the shaft femur, and have presented within a week of the injury, and have not had any previous surgical treatment for the fracture. Malnourished patients and patients with open, pathological fractures and non union cases were excluded from the study. A standard protocol was followed on all patients, which is describing below. The data obtained was analysed using SPSS. **Results:** The union rate was 97.83% in open nailing at 32 weeks after surgery and the Mean±SD time to union was 19.65±5.19 weeks (ranges from 16–32 weeks).We obtained excellent results in 39 patients (83.33%), good in 4 patients (8.50%), fair in 3 patients (6.38%) and poor in one (2.12%). **Conclusions:** The open SIGN nailing, without the use of image intensifier, for treatment of closed fractures of shaft femur achieves excellent result in term of fracture union. Results obtained are comparable to the results of closed interlocking nailing, requires less expertise and resources, and its use is recommended for long bones fracture care at the very level of our health care system.

Keywords: SIGN nailing, Interlocking nailing, Image intensifier, Closed femoral shaft fracture, image intensifier

INTRODUCTION

Femur shaft fractures, like many other bony joint injuries, have become more common in Pakistan due to ever rising incidence in motor vehicle accident (MVA), fire arm and bomb blast injuries and falls. The non-operative methods of treatment like Plaster of Paris, external fixation and skin traction have been carried out less frequently except in very young patients or where operative facilities are unavailable. Operative treatment in the form of plating, nailing, and external fixation is still being carried out for these fractures in many parts of the world.

Result for fracture union was evaluated both clinically and radio-logically, and graded at 8 months (32 weeks) after treatment by Thoressen's criteria.[1] Closed reduction and intramedullary nail fixation, as has been proposed by the Kuntscher *et al*, is most biological way of treating fractures of the shaft of femur.[2] Evolution to Interlocking Nailing for treating these fractures became possible and popular due to the advent of image intensifier (II) and surgical techniques. Closed ILN using image intensifier for fixing these fractures is a standard practice around the world now.[3]

However many factors like less surgical expertise, non-availability of Image Intensifier and fracture table for closed ILN led to resurgence in the use of open Intra-medullary nails for treatment of these fractures.[4] This has become an efficient and cost effective way of early disposal of these patients in the resources hit and unequipped hospitals. Least to mention is the avoidance of radiation in combination with other proven benefits of open SIGN nailing.[5,6] Yet more, free of cost availability of SIGN[4] interlocking nails which use a simple external jig for interlocking, were the driving forces to study open SIGN nailing of these fractures in our hospital. This treatment modality of open SIGN interlocking nailing for these fractures can be easily carried out in many hospitals in Pakistan without the need for much surgical expertise or image intensifier and yet attaining the most cost effective benefits with acceptable disadvantages/complications for the method of treatment.

MATERIAL AND METHODS

Forty-seven consecutive cases of fractures shaft of the femur admitted to the Department of Traumatology

and Orthopaedic Surgery, Ayub Teaching Hospital, Abbottabad, Pakistan, were included in this hospital-based experimental study from January 2006 to December 2007, and their informed consent were obtained for the procedure. Inclusion criteria were adult patients older than 16 years with closed fractures of the femoral shaft, and had presented within a week of the injury, and did not have any previous surgical treatment for the fracture. Malnourished patients and those with open fractures, pathological fractures and fractures non-union were excluded from the study. Properly established protocols were used for the treatment of these patients.[7]

Following treatment guidelines were used for these fractures. Pre-operative plain radiographs were obtained to determine fracture configuration as per Winquest & Hansen's classification.[8] Fracture fixation was done using SIGN interlocking nails and instrumentation. The SIGN nails were inserted according to the manufacturer's instructions. All patients were intravenously given 1 gm of prophylactic Cefazoline and 120 mg of Gentamicin at the induction of anaesthesia.

Following technique for OPEN ante-grade SIGN nailing was used. All patients were given Spinal or General anaesthetic for the procedure. Ordinary operation tables were used for surgery. Patients were positioned either lateral or postero-lateral for fracture exposure. Open reduction of the fracture, hand reaming, nail sizing, assembly preparation, and nail insertion ante-grade/retrograde were performed as per instructions of the SIGN nails manufacturer. Distal screw insertion through the external jig first, and then proximal screw insertion for static locking were performed in all cases. Fixation assembly was removed, and wound closure done. All SIGN nails were statically locked.

A uniform post operative care and follow-up was adopted for all the patients. Antibiotics, as has been mentioned above, were continued intravenously for a total of 5 days. Plain x-rays were taken to assess and/or confirm quality of fracture reduction and position of SIGN nails, and also for record keeping and case reporting purposes as well. Static quadriceps exercises, knee bending and non-weight bearing ambulation were started on first post operative day in the physiotherapy department. Non weight bearing ambulation with the help of crutches was started and continued till the appearance of callus on X-rays during follow-up. This was followed by partial weight bearing ambulation using one crutch was permitted for another 3 weeks. Full weight bearing was allowed only on the radiological evidence of callus consolidation.

Treatment outcome was analysed regarding fracture healing, joint movements, and implant failure. For this purpose, these patients were post-operatively followed at intervals of 2 weeks, 6 weeks, 3 months, and then monthly thereafter regularly for a total of 12 months. Patients were discharged as soon as their condition allowed. The criteria of classification applied was as proposed by Thoressen *et al*, with the addition of non-union at 8 months or nail breakage as criteria for a poor result (Table-1).[1] The out come of fracture union at 8th months were graded as Excellent, Good, Fair and Poor. Clinical criteria of union included absence of pain and local tenderness on stressing the fracture site or full bearing weight of the operated limb. Radiological healing of the fracture was defined as presence of callus around the fracture circumference with density similar to that of adjacent cortex, or obliteration of fracture line, whichever was earlier. Healing of the fracture was considered complete when both clinical and radiological criteria of union were fulfilled to the satisfaction of the authors and the independent observer. Delayed union was recorded when the fracture united between 4 and 6 months, while non-union was noted when union had not occurred after 8 months of treatment. All of our patients were followed-up for at least 12 months. The results were analysed using the SPSS, version 11.

Table-1: Criteria for classification of results (Modified from Thorsen *et al*[1])

Criteria	Results			
	Excellent	**Good**	**Fair**	**Poor**
Malalignment of femur (degrees)				
Varus/Valgus	5	5	10	>10
Antecurvatum/Recurvatum	5	10	15	>15
Internal Rotation	5	10	15	>15
External rotation	10	15	20	>20
Shortening of femur (cm)	1	2	3	>3
Knee motion (degrees)				
Flexion	>120	120	90	>90
Extension deficit	5	10	15	>15
Pain/Swelling	None	Minor	Significant	Sever
Non-union/Nail breakage	Absent	Absent	Absent	Absent

RESULTS

The age of the patients included in the study ranged from 16–67 years with median age of 37.05±12.84 years, and male to female ratio is 3:2. There were 22 right sided femur fractures and 25 left sided femur fractures. Fracture sites were proximal shaft in 13, middle shaft in 22, and distal shaft in 12 cases. Fracture type per Winquest and Hansen's Classification[8] were as in Table-2.

Table-2: Type of Fracture

Type of Fracture	Number	Percent
Type I	12	25.5
Type II	19	40.4
Type III	10	21.3
Type IV	6	12.8
Total	47	100.0

Table-3: Gender distribution

Gender	Number	Percent
Female	19	40.4
Male	28	59.6
Total	47	100.0

The fracture union rate in the study was 97.83% at 32 weeks after surgery and the Mean±SD union time was 19.65±5.69 weeks (range: 16–32 weeks). Delayed union, i.e., union between 17–24 weeks postoperatively, occurred in 16 patients (34.04%) and one patient (2.12%) had non union at >32 weeks. The break up of union according to time is shown in Table-4.

Table-4: Union time in weeks

Union Time	Number	Percentage
16 weeks	26	55.31
20 weeks	9	19.14
24 weeks	7	14.89
32 weeks	4	8.51

As to range of motion of the knee at 8th months from surgery, 38 patients (80.85%) had full knee motion from 0–130 degree, 6 patients (12.76%) had range of motion from 0–90 degree and 3 patients (6.38%) had knee range of movements from 0 to 60 degree.

The clinico-radiological evaluation was done at 8 months after surgery and the final observations were made according to the criteria by Thoressen *et al.*[1] We obtained excellent results in 39 patients (83.33%), good in 4 patients (8.50%), fair in 3 patients (6.38%) and poor in 1 (2.12%).

Majority of the patients complained of pain at the fracture site and knee this was treated with analgesia. Overall there were 19 complications and we divided them into per-operative and post operative complication.

Table-5: Characteristics of the fracture in study

Parameters	Results
Total number of fractures	47 (100%)
Age range of the patients	16–67 years
Mean±SD of age	37.05±12.84 Yrs
Side of the fractures	
Right side	22 (46.80%)
Left side	25 (53.19%)
Femoral Shaft Fracture	
Proximal Shaft	13 (27.65%),
Middle shaft	22 (46.80%),
Distal shaft	12 (25.53%)
Male to female ratio	3:2
Most common type of fracture as per Winquest & Hansen classification: Type-II	19 (40.4%)
Union rate at 32 weeks post surgery	97.83%
Mean±SD union time	19.65±5.19 weeks
Union time range	16–32 weeks

Table-6: Pre- and Post-operative Complications

Complication	Number	Percentage
Per-operative Complication(s)		
Anaesthesia	0	0
Longitudinal bones split	2	4.25
Misplaced distal screw	5	10.6
Post-operative Complication(s)		
Superficial Infection	2	2.25
Deep Infection	4	8.51
Distal screw Breakage	2	4.25
Knee stiffness	3	6.38
Non-union	1	2.12

DISCUSSION

Motor vehicular accidents are the commonest cause of mortality and morbidity in people aged 20–50 years. Not surprisingly then, one finds these fractures of shaft femur more common in younger age group. Orthopaedists in many poor countries like Pakistan are duly concerned as to the appropriate treatment modality of many bony joint injuries including these fractures of femur. The prevalent practice in many hospitals in these poor countries is use of now almost obsolete Kuntscher's nail for stable shaft femur fractures around the isthmus of femur while the unstable fractures are often treated by ORIF with plate. Almost all open fractures are offered ex-fixation.

However fractures care has evolved through the development of new generation intra-medullary interlocking nails and more trained surgical expertise. These interlocking nails fixation is now the prevalent standard for treating these stable and unstable, closed or open, fractures of long bones around the world. These are routinely performed in developed countries and involve the use of an image intensifier and fracture table which are expansive and mostly un-available in many third world countries like Pakistan. Thanks to SIGN organization whose free of cost all time availability of SIGN instrumentation and SIGN nails with its easy to use external jig for interlocking screw insertion without the use of II and fracture table, all these problems have been circumvented. Successful interlocking nailing using the method will not only improve the quality of fracture care, but avoid intra-operative ionizing radiation to both patients and the surgeon. This study attempts to determine that interlocking nails that do not require fluoroscopy to set locking screws (SIGN nails), can be used to provide fixation of these fractures in resource poor hospitals with comparable or optimal results to previous methods.

There were 47 cases in this study, majority, i.e., 67.67% of the total, were young males between 16 to 50 years of age. This has also been found in the study of Grosse *et al*[9] and other studies.[4,10] The ratio of factures femoral shaft in male to female is 3:2 as compared to 2:1 found in the study of Innocent CI *et al.*[4] The reason of increased frequency of these fractures in females in our study is poverty which has compelled these unskilled women for working to earn bread and butter for their families side by side with the males.

In our study, these closed fractures were classified as per Winquist and Hansen's classification[8] for comminution. Twelve patients had type I, 19 had type II, 10 had type III, and 6 had type IV femoral shaft fracture. We have high frequency of type II fracture in our study.

None of the patients in our study were operated within 24 hours of the injury due to factors like late arrival of the patients to the hospital from far off areas and lack of operating facilities in the emergency department of the hospital. Majority of the patients (76.76%) were fixed between 5th and 7th days.

Fracture union rate achieved at 32 weeks after the surgery was 97.83% while 34.04% cases had delayed union of the fracture. This is comparable to the result of the Wilber and Evans study.[11] The mean union time for these femoral shaft fractures in our study was 23.5 weeks which is comparable to the result of other studies. The average healing time of femoral shaft fractures after closed interlocking nailing is quoted by various authors as 4.5 months[12], 16 weeks[1] 17 weeks[13], and 18 weeks[14]. Our study also supports the Basumallick *et al*[15] citation that average healing time in femoral fracture 23.45 weeks which validate our study results.

Common complications of SIGN nailing in our study was infection, knee joint stiffness and misplacement of distal locking screws which are also reported in other studies.[4,7,10] All these were amicably resolved.

CONCLUSIONS

The gold standard of treatment for long-bone fractures is closed interlocking nail fixation under image intensifier. However, main drawbacks of the closed ILN are cost of the nail and availability of image intensifier and fracture table in the operating room. Open SIGN interlocking nail fixation has solved these problems and has the added advantage of reduced cost to the patients while, at the same time ensuring high quality fracture care comparable to any in the developed countries. Proficiency in the use of the SIGN interlocking nail instrumentation will come with practice. We therefore conclude that, with the aid of external jigs and slot finders, interlocking can be achieved without an image intensifier and is recommended to be carried out in all basic level hospitals in poor resource setting.

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