

Outcome of surgical implant generation network nail initiative in treatment of long bone shaft fractures in Kenya

O.O. Soren, MBChB (Moi), MMed (Orthopaedics) (Makerere), Consultant Orthopaedic Surgeon, Embu Provincial General Hospital – Embu Kenya, P.O. Box 20665-00100, Nairobi, Kenya, Email: Soren2001us@yahoo.com

ABSTRACT

Background: Closed interlocked intra-medullary nailing (IM), the standard method of treating of long bone shaft fracture, has been a dream to most resource poor hospitals like Kenyan regional hospitals. Surgical implant generation network (SIGN) initiative employs use of external jigs and slot finders instead of expensive fluoroscopy and fracture table to achieve interlocked IM nailing. This study describes the authors experience and analysis of outcome of this initiative.

Objective: To describe applicability of the SIGN initiative in fracture care in a Kenyan hospital.

Setting: Embu Provincial Hospital, Kenya.

Methods: Seventy eight consecutive patients with 20 tibia and 60 femur fractures were done SIGN interlocking nail at Embu Provincial Hospital, Kenya between December 2005 and December 2007. Patient demographic, fracture characteristics and outcome measures of locked nail rate, duration of surgery, hospital stay, complication rate, weight bearing time and union time and rate were prospectively studied.

Results: Male to female ratio was 3:1 and the age range was 18 to 82 years. There were 63 closed and 17 open fractures of which 57/80 (71.25%) recent fractures, 12/80 (15%) non-unions, 6/80 (7.5%) mal-unions and 5/80 (6.25%) due to failed plating. There were 18/80 (22.5%) retrograde femur, 42/80 (52.5%) Antegrade femur and 20/80 (25%) tibia cases done. Interlocking was achieved in 76/80 (95%) of the cases. Surgical duration was 60 -180 minutes and hospital stay was one to three weeks post intervention. Complications included superficial infection 4/80 (5%), deep infection 2/80 (2.5%) and screw loosening 4/80 (5%). Time to union averaged 18 1/2 weeks with a union rate of 93%.

Conclusion: SIGN initiative a valuable technology in shaft fractures fixation with comparable results and is applicable in the resource poor hospitals.

Significance: Initiative is an effort in provision of equality of fracture care worldwide.

INTRODUCTION

Prior to the use of surgical stabilization, femoral fractures were associated with high incidence of morbidity and mortality (1). IM nailing as proposed by Küntscher and with many subsequent contributions by other surgeons, is the best treatment for most femoral shaft fractures. By controlling length and rotation, locked IM nail has expanded indications for IM nailing to virtually all fracture patterns of the shaft (2-5). The healing rates with such treatment is as high as 99% (6-9) However, image intensifier is required to achieve interlocking in most cases. Unavailability of

this in resource poor setups has led to the invention of external jig systems used to achieve interlocking. SIGN has employed this with comparable success (10). The common methods of internal fixation of fractures in peripheral setup in Kenya are use of plates and Küntscher nail (11). SIGN technique, initially introduced in Uganda, was propagated in to Kenya mainly in resource poor hospitals, and has changed long bone fractures' management and outcomes.

The goal of this study was to describe applicability of the SIGN initiative in fracture care in a Kenyan hospital.

MATERIALS AND METHODS

Patients: Seventy eight patients with 60 femur and 20 tibia fractures were prospectively done SIGN locked IM nail between December 2005 and December 2007. Patient demographics, cause of injury, fracture pattern and indication for intervention that included recent fractures, non union, mal-union and implant failure of either femur and/or tibia shaft fracture were studied. Preoperatively assessment of patients included routine laboratory, X rays and consent forms. Post-operative management included antibiotics, check X rays and physiotherapy. Patients were discharged on non weight bearing crutches and initially followed at two weekly intervals then every month. Fifty five (55) patients were followed beyond 30 weeks post-operatively. 51 patients healed while four had complications and needed re-operation. Twenty five were lost to follow-up and union not assessed.

Implant characteristics and procedure: SIGN nail is a solid nail with a 5 degree bend in proximal 5 cm. It has two dynamic locking slots distally and one dynamic and one static slot proximally. The diameters vary from 8mm to 12mm and the length from 280mm to 420mm. It was initially designed for tibia but its use has been extended to femur and humerus. Interlocking is achieved with the help of external jig, sleeves and slot finders. Operation was done on flat theatre table with the patient supine and a sand bag either below the operated hip or knee. In antegrade femur approach nail is inserted through the tip of the greater trochanter. Retrograde femur approach is through the intercondylar notch non articular area. Tibia approach is through para-patella incision 1cm below the joint line. Fracture reduction was done open in most cases except for a few cases of fresh tibia fractures. All fractures were reamed and drilled by hand.

Clinical outcome: Interlocking rates, duration of surgery and fracture healing indices including; non weight bearing time, partial weight bearing time, knee range of motion, serial monthly X-rays and complications were collected at follow up visit by the surgeon. A fracture was considered united if there was bridging callus on two cortices of two views of X-rays and the patients had painless weight bearing.

Statistical analysis: This was done using SPSS version 10 to derive descriptive statistics.

RESULTS

Patient demographics: Patients' age ranged from 18 -82 years [mean 41; SD 23.19]. The Male to Female ratio was 3:1 [58:20].

Mechanism of Injury: Road Traffic Accidents was the leading cause of fractures at 81% and other as shown in Table 1.

Table 1
Cause of fractures

	Frequency	(%)
RTA	65	81.3
Fall	9	11.3
Assault	3	3.8
Gunshot	3	3.8
Total	80	100

Fracture patterns varied from simple non-displaced transverse fractures to segmental and comminuted fractures with proportions (Table 2).

Table 2
Fracture types

Fracture type	Femur		Tibia		Total
	No.	(%)	No.	(%)	
Closed	57	90.5	6	8.5	63
Open Gustillo II	1	12.5	7	87.5	8
Open Gustillo II	1	16.7	5	83.3	6
Open Gustillo IIIA	1	33.3	2	66.7	3
Indication for SIGN nail					
Recent fracture	41	71.9	16	28.1	57
Mal Union	5	83.3	1	16.7	6
Aseptic non union	9	75	3	25	12
Other implant failure	5	100	0		5
Fracture pattern					
Simple non displaced	2	66.7	1	33.3	3
Simple displaced	49	76.5	15	23.5	64
Segmental	8	72.7	3	27.3	11
Comminuted	1	50	1	50	2

Table 3
Surgical approaches

	Frequency	(%)
Antegrade femur	42	52.50
Retrograde femur	18	22.50
Tibia	20	25.00
Total	80	100

Duration of surgery: The surgical duration ranged from 60–180 min with mean of 105; S.D 25.63.

Post operative hospital stay: The duration of post operation stay in hospital ranged from 3–22 days; mean 10.07; standard deviation (S.D) 4.00; mode 10 days.

Table 4
Knee range of motion at discharge

Degrees	Frequency	(%)
Up to 45	3	3.8
Above 45 up to 90	57	72.5
Above 90	18	23.8
Total	78	100

Partial weight bearing: Majority of patients (78%) could partially bear weight on crutches between 4 and 6 weeks as indicated in Table 5.

Complications: Complications are as shown in Table 6.

Table 5
Weight of crutches

	Duration in weeks						
	2	3	4	6	8	10	
Femur	2	1	33	15	5	3	
Tibia	2		10	3	4		
Total	4	1	43	18	9	3	
	7%		78%			15%	

Table 6
Complications

Complications	Antegrade femur	Retrograde femur	Tibia antegrade	Total
Superficial infection	0	1	3	4
Deep infection	1	0	1	2
Screw loosening	4	0	0	4
Other	1	0	0	1
Total	6	1	4	11

Infection rate was 6.5%. Superficial infection cases healed with antibiotics and dressing. The two deep infection cases required nail removal, irrigation and external fixation.

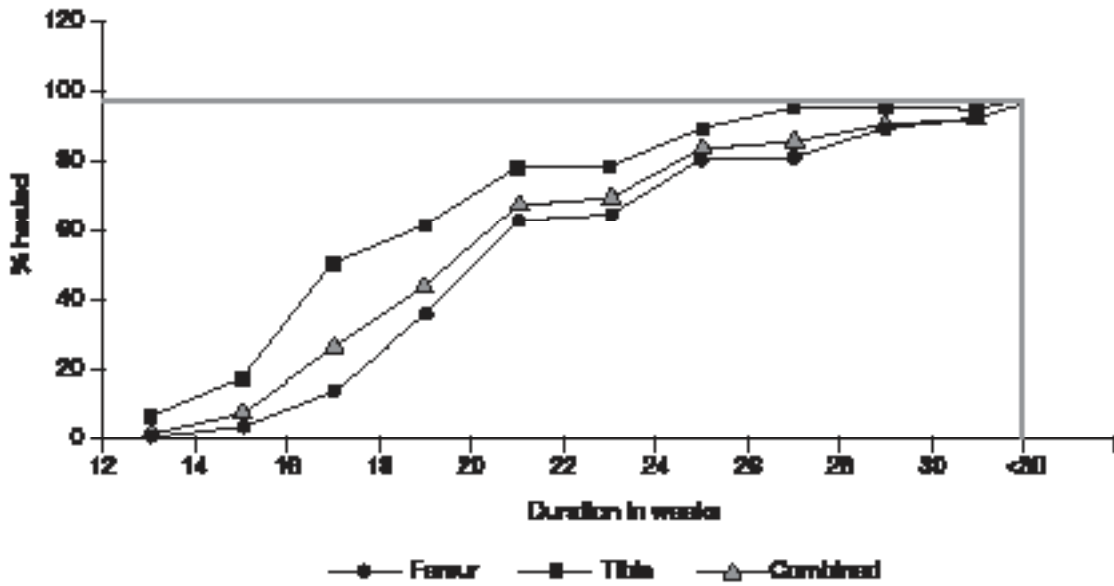
Table 7
Painless weight bearing in weeks versus surgical approach

SX approach	Painless weight bearing time in weeks							Total
	12	14	16	18	20	24	30	
Antegrade femur	0	6	4	9	3	0	1	23
Retrograde femur	4	5	0	0	1	1	0	11
Tibia antegrade	6	5	3	1	2	0	0	17
Total	10	16	7	10	6	1	1	51

Table 8
Statistical summary painless weight bearing in weeks

	Femur fractures	Tibia fractures
Minimum	14 weeks	12 weeks
Maximum	30 weeks	26 weeks
Mean	18.5 weeks	18 weeks
Mode	20 weeks	16 weeks
S.D	11.37	11.61

Figure 1



Fifty one out of 55 patients with complete follow up records healed with radiological evidence and clinically painless weight bearing. Mean healing duration was 18.5 weeks. Range was 12 to 30 weeks. Healing rate was 93% $([51/55] \times 100\%)$.



Figure 2: *Tibia SIGN nail fixation*

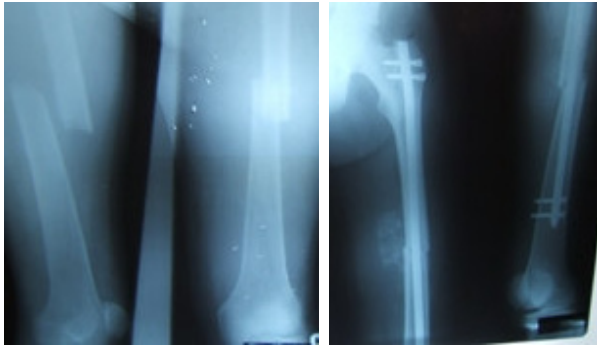


Figure 3: Antegrade SIGN nail fixation

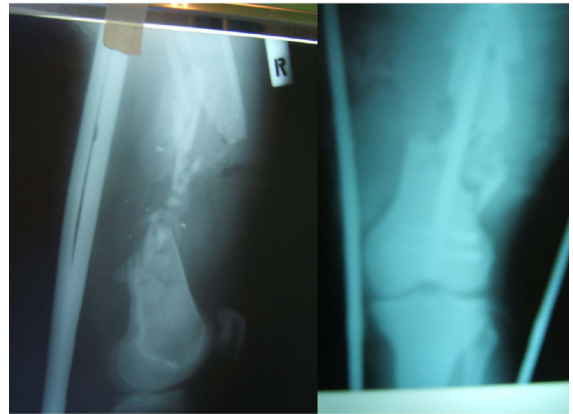


Figure 4: Segmental femur antegrade SIGN nailing



Figure 5: Retrograde SIGN nail fixation



Figure 6: Gunshot distal femur SIGN nail fixation

DISCUSSION

Despite the success of closed locked intramedullary nail in the treatment of long bone shaft fractures with healing rates as high as 99% (6-9), the availability of locked IM nail has remained elusive to most surgeons practicing in the developing countries. Management of femoral and tibia shaft fractures has evolved slowly in the developing countries due to lack of equipment needed to perform closed IM nailing. Most patients in peripheral hospitals are treated with conservative methods of tractions and plaster cast. Surgical stabilization of fractures in peripheral hospital has been shown to be possible (7). However the outcome has been affected by among other factors implant failure. Muyembe reported that Kutscher nail and plate and screws were the commonest implant used in peripheral hospital to stabilize shaft fractures and that implant failure was not unusual (7). The slow evolution to application of standard methods of treatment of femoral and tibia fractures has lead to patients in the third world have prolonged morbidity, hospital stay and worsening economic status (7,11).

Conventionally closed locked intramedullary nailing requires the use of fluoroscopy and fracture tables in addition to the implants. Fluoroscopy is unavailable in most resource poor hospitals in the third world (6). Kutscher nail that forms the basis of modern day IM nailing is what is mostly used in resource poor hospitals. It does not control rotation and not applicable to the distal and comminuted fractures of femur (5). An invention of a locked IM nailing system that can be used without fluoroscopy and fracture table has been long awaited for. SIGN IM nailing system that was initially designed for tibia shaft fractures has proved handy and applicable to surgeons in the developing world in the quest to provision of equality of fracture care with encouraging results. Applicability of SIGN IM nail without fluoroscopy and to tibia, retrograde femur and antegrade femur approaches with the use of the same jig system and same nail design is cost effective and relevant to resource poor set ups like Kenyan peripheral hospitals. Ikemi *et al* (6) have shown that IM nailing can be achieved with the use of external jig and slot finders and the union rates as high as 90% can be achieved in 18 weeks post intervention. Similarly, this study has shown that interlocking can be achieved in 95% of the time and that 93% union rate can be achieved with a mean duration to union of 18.5 weeks. This compares to reported cases done with closed IM nailing methods.

Despite the wide variability in patients and fracture characteristics, SIGN IM nail was effective in stabilization fractures as shown in this study. The mean patients' age of 41 years strongly calls for prompt return to work and not prolonged hospital stay as was seen with traditional methods of fracture treatment. The versatility of one type of nail being applicable to different fracture types and different approaches of insertion is suitable in resource poor hospitals.

Road traffic accidents is the leading mechanism of injury resulting in fractures in this study. This correlates to reports in literature both in developing and developed countries. The increase in road traffic in the developing world calls for invention of appropriate techniques to deal with injuries arising thereof in order to reduce the morbidity and mortality (11). Several studies have reported the importance of fracture haematoma in fracture healing and hence the advocacy for closed IM nailing (3,4,8). However, there is need to open the fracture site during SIGN IM nailing as it is a solid nail. Most fractures are also fixed several days from date of injury in peripheral hospital like ours. The effect of this to healing rate and complications was not clear as the healing rate (93%) was comparable to reported cases done closed (4,5,12).

Operative time (Mean 105; Range 60-180 minutes) compares to the operation time as reported in centers using fluoroscopy. Several SIGN IM nailing can thus be done in a limited period as is the case in our hospital.

The Impact of SIGN IM intervention was evident through early discharge from hospital, weight bearing, healing and return to pre-morbid status. Hospital stay for patients done SIGN IM locked nail (3-22 days; mean ten days) was remarkably reduced compared to the patients treated by traditional methods of traction (42-84 days; mean 62 days). Majority (78%) of patients could partially bear weight between four and six weeks. These surgically stabilized patients could therefore get back to their socio-economic activities earlier.

The complications encountered with this intervention included superficial (four patients) deep infection (two patients), screw loosening (one patient) and Peri-implant fracture (one patient). The infection rate of 6.5% is not uncommon in a peripheral hospital like ours. The infection rate for Orthopaedic surgery ranges from 1% to 12.5% (15,16). The superficial infections were managed by antibiotics and dressing with iodine. Deep infection necessitated nail removal, irrigation antibiotics prolonged use and external fixation. The peri implant fracture was re fixed with a longer nail.

The final outcomes of SIGN IM nail initiative of 93% healing rate and mean duration to union of 18.5 weeks is encouraging and compares to Ricci *et al* (15) reported mean of 13 weeks to union and Ikemi *et al* (6) mean of 19 weeks to union of fractures treated by different IM nails. Follow up of our patients need to continue to assess the impact further.

CONCLUSION

Interlocking IM nailing can be achieved with the use of external jig and slot finders. SIGN initiative has provided SIGN IM locked nail that is versatile and can be applied in treatment of femur and tibia shaft fractures with good outcomes. This initiative can go a long way in provision of equality of fracture care in resource poor countries.

STUDY LIMITATIONS

Functional outcomes were not fully assessed and long term follow up is required to make comparative conclusions.

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