

# Treatment of Nonunion of Long Bone Fractures With Surgical Implant Generation Network Nail

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## ABSTRACT

- Objective** To evaluate the efficacy of surgical implant generation network (SIGN) nail in treatment of nonunion of long bone fractures.
- Study design** Descriptive case series.
- Place & Duration of study** Orthopedics Unit Mercy Teaching Hospital, Peshawar Medical College Peshawar, from June 2009 to December 2011.
- Methodology** The study included 50 patients of age 15 year to 70 year of either sex and established nonunion after either surgical or nonsurgical intervention. All patients were managed by reamed SIGN nail and bone graft was performed. The follow up was done for the union. The data was analyzed with SPSS version 14.
- Results** There were a total 50 patients with 46 (92%) males and 4 (08%) females. Mean age was 34.84 year. Average duration of nonunion was 16.16 months (range 06-48 months). Among 50 cases tibia was involved in 30 (60%), femur in 16 (32%) and humerus in 4 (08%). Thirty-eight (76%) cases were operated before SIGN nailing, with 16 (32%) having external fixator, 14 (28%) intramedullary nailing and 8 (16%) DCP. Twelve (24%) cases were managed conservatively. Average follow up was 21.12 (range 6-31) months. Fort-six (92%) cases were united fully in follow up, 2 (4%) were infected, 1(2%) had broken implant and 1 (2%) was persistent nonunion case.
- Conclusion** Results of reamed solid intramedullary nail were good in terms of union and stability.
- Key words** SIGN nail, Nonunion, Intramedullary interlocking nail, Implant failure.

## INTRODUCTION:

A bone union following fracture is defined as clinically having no pain, tenderness, need of assistance for movement; and radio-graphically, as trabeculae having passed through the fracture gap or the solid cortical callus having bridged both the fragments. Nonunion is defined as a fracture that has not healed after six months of treatment or repeated surgeries performed to achieve union.<sup>1</sup>

Developments in fracture treatment are improving

as there are innovation in implants design, quality, and its availability, but still complications of nonunion of long bone fractures are faced. It is sometime difficult to assess from fracture geometry whether the applied way of treatment will result in union or need additional procedures for nonunion are required. Repeated surgeries are a cause of considerable pain and disability in these patients because of stiffness of neighboring joints, deformity and limb length discrepancy.

Factors responsible for nonunion include failure of the biology (high-energy injuries with devascularization), host related factors (nicotine use, vascular diseases, other co morbidities), failure of mechanics (improper stabilization), or treatment (iatrogenic devascularization). In cases of previous surgery on the limb, there should always be the

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suspicion of infection as the cause of nonunion.<sup>2</sup> Nonunion can be associated with significant morbidity, instability and functional impairment.

Treatment of long bone fracture is still a dilemma. Interlocking nail is best for femur, good for tibia, may be useful in humerus but not suitable for radius and ulna. Bone graft augments healing process. Early redo surgery must be considered in such cases because of manageable rate of complications.<sup>3</sup> Treatment for nonunion includes eradication of infection, bone grafting, stable fixation, osseous transplants, use of electricity capacitative coupling, direct electrical current, inductive coupling, pulsed ultrasound and many others. Converting external fixator or dynamic compression plating to intramedullary nailing, exchange nailing, bone grafting are the most common surgical methods for the promotion of bone healing.

One method to treat nonunion includes reamed intramedullary SIGN nail. This method achieves the two basic principles of treatment: stable fixation of the fracture and physiologic inter-fragmentary compression by early weight bearing. Surgical Implant Generation Network (SIGN) was formed in 1999. The SIGN solid, stainless steel nail was designed for use in the tibia and it is strong enough for slots rather than holes, to accommodate the interlocking screw. The nail is straight but the proximal and distal ends of the nail have a 9 and 1.5 degree apex posterior bend, respectively. The nail is used for femoral intramedullary (IM) nailing and these 2 bends create an effective radius of curvature, which closely approximates that of the normal human femur.<sup>4</sup> In this study we report the results of SIGN nail in the treatment of nonunion of long bone fractures.

#### METHODOLOGY:

This case series study was conducted at the Department of Orthopedics Mercy Teaching Hospital, Peshawar Medical College, Peshawar, from June 2009 to December 2011. Patients of both sexes and age more than 15 year with diagnosis of established nonunion of long bones were included. Established nonunion was defined as no clinical or radiological evidence of bony union after 6 months for tibia and humerus and 9 months for femur. Exclusion criteria were infected nonunion or infected delayed union as determined by biochemical or clinical markers and inappropriate site of fracture for intramedullary nailing.

All patients were operated using SIGN interlocking nails and instrumentation, which was donated by the SIGN organization (Richland WA, USA) for the

help of poor people. Open reduction of fracture was performed and fibrous tissue was excised. Previous implants if any, were removed and hand reaming was done. Fracture was fixed with SIGN nail along with bone graft. No image intensifier was needed in all cases in this technique. Postoperatively patients were mobilized non-weight bearing with crutches. Follow up ranged from 6 months to 18 months. The data were analyzed with SPSS version 14.

**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 8 mm to 12 mm and the length from 280 mm to 420 mm. Interlocking is achieved with the help of external jig, sleeves and slot finders. Operation was done on flat theatre table with the patient in lateral decubitus position for femoral shaft fracture and supine for tibial and humeral shaft fractures. In antegrade femur approach nail is inserted through the tip of the greater trochanter. Retrograde femur approach is through the intercondylar notch in nonarticular area. Tibia is approached through the patellar tendon incision. Fracture reduction was done in open fashion. All fractures were reamed and drilled by hand.

#### RESULTS:

There were a total 50 patients with 46 (92%) males and 4 (08%) females. Mean age was 34.84 year (range 15-70 year). Average duration of nonunion was 16.16 months (range 06-48 months). Forty-four (88%) were closed fractures in primary injury, 4 (8%) were Gustilo's and Anderson classification type II and 2 (4%) were Gustilo's and Anderson classification type III open fractures.

Among 50 cases tibia was involved in 30 (60%), femur in 16 (32%) and humerus in 4 (08%) cases. In all 12 (24%) cases had nonunion in proximal shaft, 28 (56%) had in middle shaft and 10 (20%) cases had nonunion in distal shaft. Thirty-eight (76%) cases were operated before SIGN nailing. Sixteen (32%) had external fixator, 14 (28%) intramedullary nailing and 8 (16%) had DCP. Twelve (24%) were managed conservatively. Forty-six (92%) cases had atrophic nonunion and 4 (8%) had hypertrophic nonunion on radiographic appearance.

Average follow up was 21.12 (range 6-31) months. Forty-six (92%) cases united fully in follow up, 2 (4%) were infected in which nail was removed after signs of healing and 1(2%) had persistent nonunion in which exchange nailing was done and 1(2%) had broken implant in which redo surgery performed.

**DISCUSSION:**

Incidence of nonunion following post traumatic long bones diaphyseal fractures is reported to be 5-10%.<sup>5</sup> Nonunion is prevented if fractures managed with a minimal gap, adequate stability and sufficient nutritional supply.<sup>6</sup> No published data on use of SIGN nail in nonunion fractures of long bones is found. SIGN nail provides stability against rotation, bending and axial loading, helps in mobilization and early weight bearing. Conventionally closed locked intramedullary nailing requires the use of fluoroscopy and fracture tables in addition to the implants. Kutscher nail that forms the basis of modern day IM nailing does not control rotation and is not applicable to the distal and comminuted fractures of femur.<sup>7</sup> SIGN IM nailing system that was initially designed for tibia shaft fractures has proved handy. Applicability of SIGN IM nail without fluoroscopy and to tibia, retrograde 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. Ikemi et al 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.<sup>8</sup> In this study at an average follow up of 21.12 months 46 (92%) cases were united fully. This compares to reported cases done with closed IM nailing methods.<sup>7</sup> In another study by Ricci et al healing rate was comparable and mean duration of union was 13 weeks.<sup>9</sup>

In a study by Chia-Wei Yu et al a union rate of 91.7% and the union period of median 4 months was reported.<sup>10</sup> The fracture union rate in the study of Razaq M et al was 97.83% at 32 weeks after surgery with mean union time of 19.65±5.69 weeks in the treatment of femoral shaft fracture with SIGN nail.<sup>11</sup> In one study by Shroeder JE et al average time of union for nonunion femoral shaft fractures with exchange nail was 16 weeks and union rate was 86%.<sup>12</sup>

A one-stage procedure with SIGN nail had advantage over external fixation, like good effective joint mobilization, thus improving local musculature and blood supply with aid of regular exercise. This can promote healing of bone with control of infection. The SIGN tibial nail, despite its slightly smaller diameter, can provide similar construct stiffness and stability, when compared to a larger hollow nail for stabilization of tibial shaft fractures.<sup>13</sup>

It has been shown that reamed intramedullary nailing of lower extremity long bone fractures significantly reduces rate of nonunion and implant failure in

comparison with non-reamed nailing.<sup>14</sup> In this study reamed SIGN nail was used in all cases along with bone grafting to achieve union. SIGN nail for open fractures of tibia has been used with average union time of 22 weeks.<sup>15</sup> Shah, Ram K et al conducted a study on infected nonunion. The goal of control of infection and bony union was achieved in 213 (85%) cases after a single procedure. The mean time for union was 4 months (range, 2–6 months).<sup>16</sup> In index study one (2%) case of broken implant due to persistent nonunion and two (4%) cases with infection lead to removal of nail. In one (2%) case of non-union exchange nailing was done.

**CONCLUSIONS:**

SIGN nail has advantage of mobilization and early weight bearing and showed promising results because of its better strength, better accuracy in distal locking thus improved union rates. This technique has a low complication rate. It has the added advantage of reduced costs to the patient. Technique was performed without fluoroscopy and no postoperative bracing was needed.

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