SIGN Interlocking Nail for the Treatment of Infected Nonunion

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Summary: Chronic infection of bone with nonunion and/or bone defects is traditionally treated by a 2-stage procedure involving initial debridement and antibiotic delivery for control of infection and then definitive internal fixation for fracture stabilization. The external fixators have been used to provide stability in the presence of active infection.

A technique of Surgical Implant Generation Network (SIGN) solid interlocking nail is used in the femur and tibia bones after thorough irrigation and debridement at the same stage. Although not most suitable for all infected nonunions and/or segmental bone defects, this technique is particularly useful for patients who are poor and hence cannot afford multiple surgeries and are not ideal candidates for external fixation and for those who do not want to have an external fixator applied.

This technique was used in a series of 250 patients from multiple centers. The goal of control of infection and bony union was achieved in 213 (85%) cases, 165 cases after a single operation, and 48 cases after additional interventions. In the remaining 37 (15%) patients, the goal of control of infection was achieved with stable nonunion, which were taken care of by standard procedure of bone grafting after control of active infection. Four patients needed exchange nailing to another thicker SIGN nail for continued infection and implant loosening. Subsequently complete control of infection could be achieved in these cases.

From the total, 14 fractures went on bone healing despite persistent infection, with or without sinuses. Early removal of nail after union and thorough debridement made them free from infection. But 7 cases are still coming at follow-up with infection but pain-free functional limb, that is, persistent infection even after fracture union.

In summary, control of infection and stability to promote union has traditionally been provided by 2 separate procedures, which have proved to be efficacious in the past. However, both these goals can be achieved with 1 surgical procedure in a variety of scenarios in our limited circumstances, using the technique of SIGN solid intramedullary nail. This 1-step surgical procedure eliminates the complications that can occur secondary to the use of external fixation and bone transport. It may also reduce the morbidity of 2 surgical procedures and inpatient admissions required for the two-stage procedures or for the application and removal of external fixators to that of a single procedure and inpatient admission. Additional procedures may be required with both treatment methods for achieving control of infection, bony union, or soft tissue coverage.

Key Words: antibiotics—infection—nonunion—SIGN intramedullary nail.

The problems in infected nonunion include multiple sinuses, osteomyelitis, bone and soft tissue loss, osteopenia, adjacent joint stiffness, complex deformities, limb-length inequalities, and multidrug-resistant polybacterial infection. Bone gap and active infection are the crucial factors relating to treatment and prognosis. The gaps larger than 4 cm most likely cannot be effectively bridged by corticocancellous bone grafting. If the limb has intact distal circulation and sensation, limb salvage and reconstruction generally is preferable to amputation, especially in the femur. The fracture generally unites if adequate debridement of the nonunion site is done with fracture stabilization and bone grafting, if necessary.

The treatment of nonunion in the presence of infection presents with the dual problems of controlling infection and providing stability. Various factors contribute to infected nonunions, including open fractures, infection after internal fixation, chronic osteomyelitis with pathologic fractures, and surgical debridement of infected bone. Traditionally, the treatment strategy consists of surgical debridement with local and systemic antibiotic delivery and then a second procedure for stability, generally either internal or external fixation. Special reconstructive procedures and soft tissue procedures might also be necessary. Local antibiotic therapy is a useful technique that results in high local concentrations of antibiotics with minimal systemic levels. The method in the form of antibiotic-impregnated polymethylmethacrylate beads is used in the treatment of osteomyelitis and open fractures. The antibiotic impregnated polymethylmethacrylate beads are very costly and not readily available in our poor countries.

With the goal of avoiding more than one procedure in these patients, we present our novel single-procedure technique of treatment with a Surgical Implant Generation Network (SIGN) solid interlocking nail, which provides stable internal fixation and thereby control of infection at a most cost-effective way in our underfinanced and resource scarce countries.

SURGICAL TECHNIQUE

The surgical technique involves a series of steps, each of which is critical for successful results. The first step is careful preoperative evaluation of culture and sensitivity results from sinuses or biopsy and radiographs. Full-length standing anteroposterior view radiographs are obtained of both lower extremities of all patients with the use of a 51-inch x-ray cassette with the x-ray source placed at a distance of 10 feet and the beam centered on the knee. This technique yields 5% magnification. Additional anteroposterior and lateral view radiographs of the
involved bone are obtained, and the preoperative measurements of the length and diameter of the interlocking nail are calculated by using these radiographs and the SIGN nail templates. For the femur, the distance from the piriformis fossa to 1 cm proximal to the top of the intercondylar notch is used as the length of the nail. Alternatively, the distance from tip of the olecranon to the tip of the little finger of the same patient is used to measure the total length of the intramedullary (IM) nail in femur. For the tibia, the length of the nail is from the proximal tibial articular surface to 1 cm proximal to the ankle plafond.

The second step involves thorough debridement of the infected bone and soft tissues and then copious lavage with normal saline. All the nonviable and infected tissues, including the skin, soft tissues, and bone, undergo debridement until bleeding viable tissue is present at the resection margins (the Paprika sign in the case of bone). Inadequate debridement leaves nonviable or infected tissue secluded from the microcirculation, resulting in recurrence of infection despite local and systemic antibiotic delivery. This in turn facilitates biofilm formation, which protects the pathogens from antibiotics and host defense mechanisms. Specimens are obtained of the bone, soft tissues, and any purulent material present and are sent for routine and special (aerobic and anaerobic) cultures. After the bone debridement, the shortening of 1 to 3 cm was accepted to achieve union.

The third step is the insertion of the SIGN interlocking IM nail under sterile conditions in the operating room and following standard techniques of gentle hand reaming to accommodate standard SIGN nail, preferably thicker to fit into the medullary canal by hand driving only. The SIGN nail was not necessarily tight fitting and 1 or 2 proximal or distal locking screws were used, but at least 1 at each end of nail.

The wounds were closed in layers as far as possible without any tension on the skin and in the cases of deficient skin or soft tissue delayed closure by skin grafting were done.

The type and duration of antibiotics were dependent on culture and sensitivity report until infection was controlled.

We do not insert bone graft in the presence of acute infection. Bone graft is more effective once the infection is controlled.

Exchange nailing, if necessary, is done generally to a larger nail for additional stability if the infected nonunion has been converted to a nonunion without infection or the infection has extended into the medullary canal causing the IM nail loosening. If there is no infection and union has occurred, the IM nail can be left in situ permanently. If both infection and

<table>
<thead>
<tr>
<th>TABLE 1. Age and Sex Distribution of Patients</th>
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</tr>
<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<th>TABLE 2. Type of Fracture</th>
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<tr>
<td>Age Group</td>
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<tr>
<td>-----------</td>
</tr>
<tr>
<td>15–24</td>
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<td>25–34</td>
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<tr>
<td>35–44</td>
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<tr>
<td>45–54</td>
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<tr>
<td>&gt;55</td>
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<tr>
<td>Total</td>
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<tr>
<th>TABLE 3. Type of Primary Treatment in Open Fractures</th>
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<tbody>
<tr>
<td>Primary Treatment</td>
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<tr>
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</tr>
<tr>
<td>Conservative</td>
</tr>
<tr>
<td>External fixator</td>
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<tr>
<td>Internal fixation</td>
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<tr>
<td>Total</td>
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nonunion persist, the IM nail is exchanged for another nail, generally 6 to 8 weeks after the index surgery.

If removal of SIGN IM nail is indicated, it is performed in a standard fashion.

**MATERIALS**

A total of 280 cases were collected retrospectively from 3 centers in Dhaka, Kathmandu, and Blantyre for this study where SIGN IM nails were used during a period of 8 years (2000 to July 2007).

The inclusion criteria were infected nonunion of femur or tibia. Infection was defined as the presence of bacteria in the bone and soft tissues as shown by sinuses, pockets of pus, intermittent fevers and pain, and radiographic changes of sclerosis, lucency, and periosteal reaction with or without sequestra. Nonunion was defined as failure to allow pain-free full weight-bearing and absence of mature bridging callous in 2 radiographic plains, 6 or more months after fracture.

Of the collected 250 cases (from total 280), 235 cases arose after standard fractures and 15 after pathologic fractures in patients with chronic osteomyelitis. Of the fractures 200 were open, which had been treated conservatively (86 cases), by external fixation (76 cases), and by internal fixation (38 cases). In 35 patients the original insult was a closed fracture which had developed an infected nonunion after an attempted internal fixation (Tables 1 and 2).

But only 250 cases of infected nonunions and chronic osteomyelitis of femur and tibia in 93 females and 157 male patients (age range, 15–65 years) obtained full follow-up of (say) 12 months or more. (Table 3). Two hundred patients had an infected nonunion, and 48 patients had segmental defects ranging from 1 to 3 cm after initial debridement and the bones were shortened to achieve end to end union without bone grafting. Although 5 patients with more than 4 cm defects were excluded from the study, the other 2 patients with defects of more than 4 were treated by bone shortening. Thirty patients were classified as B hosts with systemic or local tissue compromise such as diabetes, HIV disease, or peripheral arteriopathy, and 220 were classified as A hosts with no systemic or local compromise. No data on smoking habits were collected. Average follow-up was 14 months (range, 7–40 months) some follow-up is 7 months, but others who defaulted at 9 months were excluded.

Thirty patients were lost to follow-up after 9 months, having achieved control of infection and stable nonunion and so they were excluded from the study.

All 250 patients (excluding the 30 lost cases) were followed up regularly on a monthly basis and on each follow-up the wound was inspected, blood tests for C-reactive protein and erythrocyte sedimentation rate were done, and x-rays were done to monitor the control of infection and advance of bone union.

**RESULTS**

In 70% of patients the C-reactive protein and erythrocyte sedimentation rate returned to normal within 3 to 6 weeks’ time, but in 30% of patients, they remained elevated without any clinical signs of infection for a longer period. This might have occurred secondary to the patient’s other medical comorbidities, which included renal insufficiency, diabetes, and multiple sclerosis.

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). In the remaining 37 (15%) patients, the goal of control of active infection was achieved with stable nonunion, which was taken care of by standard procedure of skin and bone grafting after control of active infection.

There were 4 cases of nail and/or screw loosening due to persistent infection for which exchanged SIGN nailing was done. There were only 2 cases of nail breakage because of nonunion.

Thus, the goal of bony union with infection control was revised to reflect the cases with infection control and skeletal

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**TABLE 4. Results and Complications**

<table>
<thead>
<tr>
<th>Item</th>
<th>No Cases</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Bony union and control of infection</td>
<td>213</td>
<td>85.2</td>
</tr>
<tr>
<td>Bony union with persistent infection</td>
<td>30</td>
<td>12.0</td>
</tr>
<tr>
<td>Bony union with recurrent infection</td>
<td>7</td>
<td>2.8</td>
</tr>
<tr>
<td>Nail/screw loosening</td>
<td>4</td>
<td>1.6</td>
</tr>
<tr>
<td>Nail/screw breakage</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>Additional procedures</td>
<td>150</td>
<td>60.0</td>
</tr>
</tbody>
</table>

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**FIGURE 1.** Case 1. Infected nonunion distal femur treated by retrograde SIGN nailing.
stability with nonunion sufficient for ambulation in 213 patients. Bony union was achieved in 85% of the 250 patients where the final goal for the patient was to achieve bony union and infection control. Of the 250 patients, 60% needed additional procedures (1–3 procedures), like curettage of sinus, wound debridement, and bone grafting, to achieve the goals of control of infection and bony union.

In 7 cases low-grade recurrent infection persisted despite healing of fracture. Infection could be eradicated after removal of nail and debridement which included reaming and canal lavage after removal.

**DISCUSSION**

Jain and Sinha¹ reviewed 42 consecutive patients with infected nonunion of the long bones. These patients were categorized into 2 groups. Type A was infected nonunion of long bones with nondraining (quiescent) infection, with or without implant in situ; type B was infected nonunion of long bones with draining (active) infection. Both were classified further into 2 subtypes: (1) nonunion with a bone gap smaller than 4 cm or (2) nonunion with a bone gap larger than 4 cm. Single-stage debridement and bone grafting with fracture stabilization were the methods of choice for Type A1 infected nonunions. Adequate debridement, fracture stabilization, and second-stage bone grafting provided desirable results in type B1 infected nonunions. Distraction histiogenesis was the preferred procedure for type A2 and B2. However, the autogenous nonvascularized fibular graft and posterolateral bone grafting for the tibia could be good treatment options in selected cases.

Infected nonunions and segmental bone defects demand treatment methods that offer control of infection and provide stability to the bone to promote union. Surgical debridement and use of local and systemic antibiotics help in achieving control of infection. Local delivery of high concentrations of antibiotics achieves control of infection whereas avoiding systemic complications of antibiotic use. Various methods of local antibiotic delivery are used, including antibiotic cement and spacers, bioabsorbable delivery vehicles such as calcium sulfate and synthetic polymers.²⁻⁷ Various synthetic bioabsorbable delivery vehicles are being developed to avoid the need for second surgical procedures for removal of antibiotic cement beads and, in some cases, to promote bony union.⁸⁻¹⁴

The use of guide rods coated with antibiotic-impregnated cement prepared by using chest tubes as molds has been reported as the first stage of treatment in infected nonunions.¹⁵ However, this approach requires removal of the cement-coated rods after 6 weeks and insertion of IM nails for providing stability to the nonunion. Our technique was developed based on these observations with the goal of combining the 2 procedures into a single surgery.

We believe that skeletal stability is critical in infection control and that IM nailing offers a more stable configuration than external fixation. Additionally the IM nail is preferable in rehabilitation, increasing local blood flow to assist local healing and optimizing final functional outcome.

The use of an Enders or Kuntscher nail coated with antibiotic-impregnated cement has been reported,¹⁶,¹⁷ but these nails would not provide adequate stability to achieve union of infected nonunion in all cases. Two-stage surgery for arthrodesis in cases of chronic infection after total knee arthroplasty was reported by Bose et al.¹⁸ The first stage consisted of debridement and the use of antibiotic-containing beads, and the

**Problems and Complications**

Four patients required exchange nailing with another IM nail for continued infection. Infection control was achieved in 243 of the 250 patients and the remaining 7 continued with infection at the last review. Bony union was achieved in 85% of the 250 patients where the final goal for the patient was to achieve bony union and infection control. Of the 250 patients, 60% needed additional procedures (1–3 procedures), like curettage of sinus, wound debridement, and bone grafting, to achieve the goals of control of infection and bony union.

In 7 cases low-grade recurrent infection persisted despite healing of fracture. Infection could be eradicated after removal of nail and debridement which included reaming and canal lavage after removal.

![Figure 2](image_url)

**FIGURE 2.** Case 2. Infected nonunion treated by SIGN nailing and bone grafting.
second stage consisted of IM nail insertion. A prolonged period of immobilization with no weight bearing is necessary between these 2 stages.

In our patients, the combination of good bone stability and debridement provided the environment for eradication of infection, promotion of bone union, and improved mobility with immediate partial to full weight bearing (Fig. 1).

The external fixators have been used for the treatment of infected nonunions. This is more pertinent in cases of femoral nonunions than in cases of tibial nonunions.21 Moreover, some patients do not consent to the use of external fixators because of cosmetic or cultural reasons. Additionally, some patients are not ideal candidates for the use of external fixators because of poor compliance with treatment, including pin site care, lack of sanitation at home, or because of obesity.

FIGURE 3. Case 3. Infected nonunion with gap more than 4 cm treated by bone shortening and SIGN nailing.
which increases the risk of pin site infections. These patients can directly benefit from the IM nail method.

The presence of implants promotes both adherence of microbes and biofilm formation, and it adversely affects phagocytosis, thereby facilitating development of infection. Thus, if further surgical procedures on the limb are necessary, we use this opportunity to remove the infected IM nail together with the biofilm and exchange with a standard SIGN nail. If a nonunion persists but the infection is eradicated, a SIGN interlocking nail is used. We do not practice routine removal of these nails unless indicated for further surgical procedures for infection control or unless the patient requests removal of the nail (Fig. 2).

The control of infection and stability to promote union has traditionally been provided by 2 separate procedures, which have proved to be efficacious in the past. However, both these goals can be achieved in most of the patients with 1 surgical procedure in a variety of scenarios using the technique of an antibiotic-cement-coated IM nail. But it remains a very costly treatment in our setup.

It has been traditionally recommended to use bone grafts only after control of infection, however, vancomycin-impregnated cancellous bone grafting is reported as a safe method for the treatment of infected tibial nonunion. We also followed the traditional method of corticocancellous bone grafting after infection control but without vancomycin.

First acute shortening and later distraction osteogenesis is a safe, reliable, and successful method for the treatment of tibial nonunion with bone loss of more than 4 cm, and it has shown a lower rate of complication. However, large defects require complex reconstructive procedures, such as distraction osteogenesis and vascularized bone grafting. In 2 cases of bone defects of more than 4 cm, the bones were shortened and fixed with an interlocked nail. Thus the limb was saved and the function was restored with the addition of a shoe raise (Fig. 3).

Retention of the IM nail is performed if the fixation is stable and the infection is under control. External fixation is most suitable for uncontrollable osteomyelitis or infected nonunion. We also believe that in extreme cases of widespread bony sepsis a more traditional external fixation approach may still be indicated.

A one-stage procedure with SIGN nail had additional advantage over external fixation like good effective joint mobilization and thus improvement of local musculature and blood supply by regular exercise can promote healing of bone with control of infection (Fig. 4).

In summary, control of infection and stability to promote union has traditionally been provided by 2 separate procedures that have proved to be efficacious in the past, although often requiring several adjunct procedures. However, both of these goals can be achieved in the patients with 1 surgical procedure in a variety of scenarios by using the technique of SIGN solid IM nail. These are cases that would have alternatively required circular external fixation and bone transport to achieve adequate stability and bone union. This 1-stage surgical procedure eliminates the complications that occur secondary to the use of external fixation and bone transport. It may also reduce the morbidity and above all the cost of 2 surgical procedures and inpatient admissions required for the 2-stage procedures or for the application and removal of external fixators to that of a single procedure and inpatient admission. Additional procedures may be required with both treatment methods for achieving control of infection, bony union, or soft tissue coverage.

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REFERENCES


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