Achieving locked intramedullary fixation of long bone fractures: technology for the developing world

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Received: 7 June 2012 / Accepted: 9 July 2012 / Published online: 31 July 2012
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Abstract Eighty per cent of severe fractures occur in developing countries. Long bone fractures are treated by conservative methods if proper implants, intraoperative imaging and consistent electricity are lacking. These conservative treatments often result in lifelong disability. Locked intramedullary nailing is the standard of care for long bone fractures in the developed world. The Surgical Implant Generation Network (SIGN) has developed technology that allows all orthopaedic surgeons to treat fracture patients with locked intramedullary nailing without the need for image intensifiers, fracture tables or power reaming. Introduced in 1999, SIGN nails have been used to treat more than 100,000 patients in over 55 developing world countries. SIGN instruments and implants are donated to hospitals with the stipulation that they will be used to treat the poor at no cost. Studies have shown that patients return to function more rapidly, hospital stays are reduced, infection rates are low and clinical outcomes excellent. Cost-effectiveness

analysis has confirmed that the system not only provides better outcomes, but does so at a reduced cost. SIGN continues to develop new technologies, in an effort to transform lives and bring equality in fracture care to the poorest of regions.

Introduction

Data from the World Health Organisation [16] and studies on the global burden of musculoskeletal injuries and disease [23] suggest the disease burden attributable to musculoskeletal injuries, as measured by disability-adjusted life years (DALYs), is large relative to that of communicable diseases and accelerating globally [20, 22, 23]. The reports also show that the largest proportion of this burden is borne by the developing world where trauma care systems are least developed [40]. By 2030, road traffic injuries alone are predicted to become the third largest contributor to the global burden of disease [25]. Low- and middle-income (LMICs) countries will probably bear the brunt of this projected increase as the number of motorised vehicles and kilometres of paved roads rapidly grow, in combination with alcohol use, poor vehicle maintenance, poor traffic regulations and enforcement, deficient prehospital care and lacking infrastructure, material and human resources, to provide adequate trauma care [1, 31, 41].

Worldwide, there are an estimated five million deaths annually from accidental injuries, with close to 95 % occurring in developing countries [26]. More than 85 % of road traffic accidents occur in developing countries, and there are almost twice as many injury-related deaths compared with high-income countries—89 per 100,000 versus 51 per 100,000 [4]. Road traffic accidents often result in high-energy injuries

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and the incidence of long bone fractures can be expected to dramatically increase concomitant with this growing pandemic. The dimensions of the growing musculoskeletal disease and injury burden have been well documented [22, 23]. Tibia and femur fractures are the most common of the non fatal long bone injuries following road traffic accidents, accounting for 15 % of skeletal injuries sustained [30]. Sequelae of the neglect to treat, or of treatment itself [15], often present as malunion, nonunion, shortening or post compartment syndrome contractures following these fractures. Statistics hold that five to 50 times more patients are left with temporary or permanent disability for every death [22, 23]. Extremity injuries are presumed to be a major contributor to the number of permanently disabled [2, 3, 8, 28, 29].

The problem is especially severe in the younger population. Data collected in 2001 showed that greater than 30 % of the disease burden in the developing world occurs in men between the ages of 15 and 44 years [22]. Injuries attributable to road traffic accidents, violence and self-inflicted wounds account for the greatest proportion [33]. In children aged between five and 14 years, falls are reported as one of the leading causes of musculoskeletal disability [20]. Disability in this population is especially catastrophic. Young men often carry the ultimate responsibility of acting as primary wage earner in societies where physical labour predominates and skilled professional positions are scarce. Disabilities that render an individual incapable of gainful employment following a long bone fracture perpetuate the cycle of poverty.

In the developed world long bone fractures are commonly treated with intramedullary (IM) nailing and the literature is replete with studies purporting the many benefits over conservative treatment [6, 11, 19, 37–39]. Nonsurgical treatment of femoral shaft fractures is associated with increased length of hospital stay [37] and higher incidence of morbidity and mortality [11]. Functional outcomes are improved for both femur [19, 37, 39] and tibia [9, 17, 21, 38] fractures treated with IM nailing versus conservative methods. Despite this knowledge, skeletal traction or closed reduction and casting remain the standard of care in many low-income countries where resources are limited. Lack of image intensifiers, power reaming and fracture tables had previously precluded the use of interlocked IM nailing even when available.

What follows is a review of the Surgical Implant Generation Network (SIGN) IM nailing system, a technological innovation that has allowed the treatment of long bone fractures in the face of previously insurmountable barriers posed by austere environments.

Surgical Implant Generation Network

The SIGN (Richland, WA, USA) IM nailing system was designed specifically to overcome obstacles commonly faced

in such settings. It allows stable, rigid, interlocked IM fixation without the need for fracture tables, intraoperative image intensifiers or power reaming, allowing surgical management of long bone fractures otherwise untreatable by standard interlocked IM nailing techniques used in the developed world. Interlocking the proximal and distal ends of the nail controls rotation, prevents shortening and allows the patient to be mobilised immediately out of bed without fear of losing the reduction (Fig. 1). Skeletal traction and casting were commonly used as the standard of care in these settings, and a host of complications accompanied their use [13, 27].

The SIGN nail was designed as a solid stainless steel implant. Closed reduction and nailing over a guide wire is thus impossible. Since many fractures present late, an open reduction is necessary anyway, and for fresh fractures the exposure is kept to the minimum necessary for the surgeon's finger to guide the tip of the nail in the distal fragment. The decision was also guided by the inherent difficulties in removing titanium nails, the higher likelihood of incarceration and lower material costs with little compromise in biomechanical properties [5]. The nail is approved by the Food and Drug Administration (FDA) for use in the USA. Though providing a low-cost implant that can be distributed in the developing world, there has been no compromise in the quality, materials or manufacturing process.

Designed as a straight tibia-type nail (Figs. 1 and 2) with a 9° apex posterior bend in the proximal end and a 1.5° bend in the distal end, the implant can also be used in the femur and humerus. The interlock apertures have been designed as vertically oriented oval slots, and not holes, to facilitate axial compression with loading at the fracture site to promote healing. Hand reamers are used to widen the canal, negating the need for a consistent electrical supply and power reamers. The technological innovation that bypasses the need for intraoperative fluoroscopy is a rigid targeting side arm which allows accurate blind drilling of the proximal and distal interlocks for screw insertion (Fig. 3). While locating the distal interlocks can still be technically challenging in complex comminuted fracture types, methods

Fig. 1 SIGN IM nail. Target arm (*top*) attaches at the head of the nail (*bottom*) and allows the surgeon to accurately locate the distal interlocks of the nail using the slot finder (*left*) for blind drilling and screw placement

Fig. 2 Segmental tibial fracture pre-op anteroposterior (a) and lateral (b) views. Immediate post-op following fixation lateral (c) and anteroposterior (d) views

have been described to achieve successful interlocking in the most complicated of fracture patterns [32].

Fig. 3 Nail illustration showing IM placement with target arm attached to nail head and allowing for blind drilling and placement of distal interlocking screws

The nail's use has been effectively employed in the treatment of diaphyseal fractures of the femur [35], tibia [18] and humerus [12] as well as ankle arthrodesis [24]. Both antegrade (from the greater trochanter) or retrograde (from the knee joint) approaches are possible for femoral fixation further expanding its potential for use. Since the same nail and screws are used for femur, tibia and humerus, right and left, the inventory is kept to a minimum. The greatest utility to date has been in the femur which accounts for 58 % of the cases in which the nail has been used (Fig. 4), followed by tibia and humerus fractures, which account for 39 and 3 % of cases, respectively.

As of late 2011, SIGN reported 36,454 IM nail operations registered in the SIGN online surgical database (SOSD) [42]. A total of 55 LMICs participate in the SIGN programme with over 200 active hospital sites (Fig. 5). Participation is dependent on prior training in surgical technique and continued data submission of surgical cases to the online database. The data collection system is an integral piece of the programme. Reporting of cases is obligatory for resupply, and shipments of nails and screws are sent after 20 cases are reported, at no

Fig. 4 Pre- (a) and post-op (b, c) X-ray films showing the SIGN nail used for femoral shaft fracture fixation. Locking of both the proximal (b) and distal (c) fragments is demonstrated

Fig. 5 SIGN is currently active in over 55 LMICs with more than 200 hospital sites using the technology on a regular basis

extra costs [7]. The SOSD further provides for academic exchange amongst SIGN surgeons, continued education and scientific analysis of the relatively young technology. Initial studies on clinical outcomes [35, 42] and cost-effectiveness [14] purport the benefits of the nail thus far.

It has yet to be seen if the validity of the SOSD data will facilitate larger scale and more comprehensive outcome studies. An inherent limitation in this population is the consistent collection of follow-up data. In the developing world patients seldom return to clinic if feeling well, and paying out of pocket for follow-up radiographs is low priority when already living far below the poverty line.

Case studies

The SIGN nail has been in use since 1999. Questions regarding clinical outcomes and importantly cost-effectiveness of the intervention have begun to be answered. Initial descriptive and comparative analytic studies have shown that it is not only of clinical benefit but is also cost-effective. The following three published investigations have lent evidence to the SIGN nail's success thus far.

Outcome studies

Sekimpi et al. [35] published in the *Journal of Bone and Joint Surgery* the clinical results of 50 consecutive patients treated with SIGN nails for closed femoral shaft fractures in Kampala, Uganda. The mean age of the study group was 31 years, with 74 % male patients. The mean time to surgery was 13.2 days post injury. As was previously mentioned, road traffic injuries account for many of the long bone fractures occurring in the developing world. This cohort fits this expected norm with 44 (88 %) of the femur fractures in this group the result of road traffic accidents. All patients were followed for a minimum of six months or until fracture healing occurred.

A single surgeon performed all 50 nailing procedures. Antegrade and retrograde approaches to the femur were used in 54 and 46 % of cases, respectively. All 50 fractures

went on to heal at six months with two requiring nail dynamisation (removal of screws at one end of the nail to allow compression at the fracture with axial loading) at three months for delayed union. Forty-six fractures healed within the commonly accepted margin of ten degrees of malalignment. Two healed with over ten degrees varus malalignment and two with over ten degrees of valgus malalignment. No patient experienced a leg length discrepancy of more than two centimetres.

Technically, the nail was inserted without difficulty in 48 patients, and in two patients a screw missed the nail at the distal insertion site which was only noted on follow-up radiographs. Neither of these were of any consequence, both patients going on to heal their fractures uneventfully by six months. The mean time from admission to surgery was 13.2 days, and the mean time from surgery to hospital discharge was 6.9 days. It is presumed that the overall length of stay was significantly less than the usual six to eight weeks of traction treatment for these fractures. Previous investigators looking at Perkins traction in 53 femur fractures in Sierra Leone reported that mean duration of traction was 45 days and hospital length of stay 52 days. It can be assumed that similar scenarios are commonplace in Uganda. The authors concluded that “the SIGN intramedullary nailing system promotes predictable healing of closed femoral shaft fractures in a resource-poor setting.”

In 2011, Young et al. [42] published results on the infection rates for all femur and tibia cases logged in the SOSD prior to October 2010. At the time of review the SOSD contained data on 34,361 lower extremity SIGN IM nail surgeries in 55 LMICs since 2003. The overall follow-up rate (% of IM nail procedures with at least one registered follow-up visit) in the database was 18.1 %. Preliminary analysis of all cases found infection rates ranged from 0.7 % for femur fractures to 1.2 % for fractures of the tibia. With the exclusion of surgical cases without a documented follow-up from the analysis, the rates of postoperative infection ranged from 3.5 % for femoral fractures to 7.3 % for tibial fractures.

Given the overall low follow-up rate of 18.1 %, the authors conducted a secondary analysis to determine the relationship between follow-up rates and risk of infection. Results showed increasing follow-up rates correlated with increasing risk of infection though only to a level of follow-up of 5 %. In countries with follow-up rates surpassing 5 % there was no statistically significant increase in infection with increasing follow-up when using generalised additive regression models.

As with all studies, limitations exist, and the overall low follow-up rate may have hindered the ability of the authors to accurately determine the rate of infection in the SOSD study population. That being said, the true infection rate probably resides somewhere between the two ranges, 0.7–3.5 % for femur fractures and 1.2–7.3 % for tibia fractures.

Overall it can be concluded that the infection rate is low, and though higher than in high-income countries, the rates are comparable. Considering the clinical context, the rates found in the Young et al. study are probably acceptable in LMICs where the incidence of open fractures, late presentation, nonunions, malnutrition and immunosuppression stack the odds against successful surgery uncomplicated by infection. One also needs to consider the treatment alternatives, where many more do better with surgery than with traction, and the overall final disability with surgery is much less than with traction, even when surgical complications are included.

Published data on IM nail procedures conducted in LMICs are scarce. The analysis of the SOSD was the first study of this magnitude to attempt to lend evidence to the true infection rates following IM nailing procedures. What is thought to contribute to the presumption that exceedingly high rates of infection exist are largely from anecdotal accounts and exceedingly high infection rates published by other surgical specialists in LMICs. In an attempt to dissuade this common sentiment, Young et al. conclude in stating “However, the abundance of chronic osteomyelitis, late-presenting infected open fractures, and badly done internal fixation that one can experience in these settings should not let us conclude that properly done surgery, in correctly selected patients, with modern equipment, by well trained surgeons will have poor results.”

Cost-effectiveness

Gosselin et al. in 2009 [14] looked at the cost-effectiveness of implementing SIGN nails in a provincial trauma hospital in Cambodia for the treatment of femur fractures. Previously, the standard of care was Perkins skeletal traction. A comparative analysis of the costs incurred for the treatment of 50 patients with skeletal traction and 37 with SIGN IM nails was undertaken. Study groups were similarly matched for age and fracture severity. The authors concluded that the calculated cost to the patient of skeletal traction was US \$1,107 and US\$888 per patient in the nailing group, a difference of US\$219. Hospital length of stay was considerably different between the two groups. The skeletal traction group averaged 52 days, while patients treated with IM nailing had an average hospital length of stay of 35 days, most of it because of delay in surgery. Weight-bearing status at time of discharge was also evaluated with 57 % of surgical patients full weight-bearing and 16 % in the traction group. Discrepancy in the rates of fracture union between the two groups was also noted. Patients with a minimum of 16 weeks (mean 6.5 months) of radiographic follow-up were pooled for comparison; 92 % of patients in the nail group showed radiographic evidence of healed fractures, while only 74 % in the traction group were radiographically healed at 16 weeks. Further, 22 % in the traction group were diagnosed as nonunions.

Discussion

Fourteen years since first introduced, SIGN is just beginning to impact the treatment and outcomes of the millions of fractures that occur in poverty-stricken and conflicted areas of the world. Keen insight and technological ingenuity have allowed for locked IM nail fixation of long bone fractures in the face of previously insurmountable barriers. An estimated 100,000 patients have been treated since 1999, and the number of surgeons soliciting the organisation to bring SIGN technology to their hospitals continues to grow. Orthopaedic surgeons in developing countries now have the ability to provide patients an improved method of fracture care with the benefits of earlier weight-bearing, lower incidence of complications and higher rates of union that accompany locked IM fixation. Previously treated with suboptimal methods, patients found themselves fraught with long hospital stays, high risk for complication and poor outcomes. Bringing equity in fracture care to the developing world, SIGN is transforming the lives of musculoskeletal injury survivors that would otherwise run the high risk of lifelong disability.

Beyond the deficiency of material resources, speculation was that infection and prohibitive costs would never allow successful implementation of locked IM technology in austere environments. The commonly held beliefs that high rates of infection would outweigh any potential benefits are slowly being dispelled. Early investigations on high infection rates following caesarean section (38 %) and hysterectomy (20 %) in the gynaecological literature [34] and surgical site infections (19 %) in the general surgery literature [10] gave orthopaedic surgeons reason for concern, though initial studies on infection following SIGN IM nailing procedures have shown rates below 7 % can be achieved, and less than 3 % are likely in select fracture types. Further studies have shown that clinical outcomes are excellent and complications are low.

Improved clinical outcomes alone at a reasonable cost increase should drive the introduction of alternative patient care technologies. The reality is that in developing countries hospitals are sorely under-resourced and policymakers have not come to appreciate the benefits of improved fracture care. Cost-effectiveness of the SIGN system was therefore of utmost importance in its design and implementation.

Subak and Caughey [36] previously described three measures of cost-effectiveness analysis (CEA) in which one intervention is deemed more cost-effective than a competing alternative: (1) it is less costly with an equal or better outcome, (2) it is less costly with a worse outcome, but the added benefit of the alternative is not worth the extra cost, or (3) it is more costly with better outcomes, and the added benefit is worth the added cost. The first of these measures is by far the most desirable to achieve. SIGN has been shown to be highly cost-effective, fulfilling both criteria to successfully meet the first measure, achieving both better clinical

outcomes and doing so at a lower cost than skeletal traction or conservative methods. Transformational technologies that are not cost-effective have little chance for long-term implementation in the developing world. It is therefore the authors' recommendation that any new technologies to be introduced are assessed for cost-effectiveness in comparison to the competing alternatives.

While the SIGN network of surgeons and hospitals continues to grow, new directions are being sought to improve fracture care in new and innovative ways. Plans to engineer new products are actively being developed. Hip fixation devices, bone transport systems and improved clamping systems could all prove to have great impact in furthering fracture care in these settings.

Conclusions

SIGN nails have transformed the lives of over 100,000 patients who have fallen victim to injury. It has proven a safe, cost-effective and easy to learn and to teach technique, which addresses common problems with high rates of permanent disability when treated conservatively. The supply chain is sustainable, at no costs to patients or surgeons, and the necessary resources, both human and material, are minimal. When used for appropriate indications, there is no doubt this simple technology lessens the acute and chronic suffering of injured patients and their families. As the network of SIGN surgeons and hospital sites continues to grow, the impact that will be made on long-term disability rates will be tremendous. With the success of the developing world IM nail technology, new technologies with the potential for great impact are actively being developed. Until equality in fracture care is achieved for the poorest regions of the world, the SIGN mission will continue.

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