Review Article

Future Directions for Assisting Orthopedic Surgery in the Developing World

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Summary: Although Surgical Implant Generation Network (SIGN) has made continuous progress toward achieving its mission over the last 10 years, significant work remains. We envision 3 main areas for future growth: research, education, and technologic development. There is a dearth of information regarding the incidence of musculoskeletal injury, types of treatment used, and resultant outcomes in developing countries. With adaptation the SIGN Database has the potential to be used for this purpose. Clinical trials and cost-effectiveness studies are also needed. Expertise in business development is important to create sustainable solutions in the long-term. Academic studies are also needed. Expertise in business development is important to create sustainable solutions in the long-term. Academic partnership through SIGN has been a powerful tool for improving orthopedic care abroad and has potential to expand. Technologic development is at the foundation of SIGN’s success to date. A number of projects are currently underway to develop low-cost alternatives suitable for use in low-resource settings.

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The mission of Surgical Implant Generation Network (SIGN) is to “create equality in fracture care throughout the world.” Over the last 10 years, our implants have facilitated a more complete and rapid recovery from long-bone fracture for over 50,000 of the world’s poorest victims of trauma. Yet, there is an unknown but substantial number who remain without proper fracture care. This review is intended to share our thoughts on future directions for SIGN and the orthopedic community to address these unmet needs.

We felt it fitting that the summary be written by a young orthopedic resident with an academic background in public health and a more veteran surgeon with hands-on experience treating patients in over forty of the world’s poorest countries. Future progress for SIGN requires an appropriate balance between the big-picture analysis and methods used in global health and the common-sense problem solving based on direct observation that has been the foundation of SIGN’s success to date. Both approaches are represented in this article and have a role to play in addressing the emerging epidemic of trauma.

RESEARCH
Orthopedic Trauma Registries

Taken separately, funding for orthopedic research and global health are growing significantly. However, there remains little funding for research and program development to address unmet needs in orthopedic care in the low and middle-income country setting. Unfortunately, advocating for greater investment in programs to improve orthopedic care is difficult in the absence of basic epidemiologic studies to establish the burden of both traumatic and nontraumatic musculoskeletal problems. The dramatic growth of SIGN and the unceasing demand for implants suggest that the burden of long-bone fractures is significant, but in general, global data on the burden of conditions amenable to orthopedic intervention are lacking.

The 2000 Burden of Disease Project, commissioned by the World Bank, which is widely cited by advocates of injury prevention and treatment programs, contained very limited data about fractures and made significant assumptions about their impact. For example, only femur fractures were considered to have any impact on long-term disability, with all other fractures assumed to have mild impact for a few months duration in all cases. Furthermore, estimates of incidence for entire continents were often extrapolated from a few small studies. This is not a criticism of the project, but rather a reminder that fundamental work is needed to determine what level of resource allocation is warranted and to assist in obtaining support for it.

The extensive network and existing data collection system already established by SIGN offer a relatively low cost avenue to estimate the burden of fractures. However, the SIGN database in its current form allows only limited inference in this regard. The first issue is that data are only collected for fractures treated with SIGN implants. It therefore excludes long-bone fractures treated conservatively or with other implants in addition to missing fractures outside the diaphysis of the tibia, femur, and humerus. Program participation and data quality also suffer because it is time consuming for surgeons devoted to their busy clinical practice. This is compounded by poor internet bandwidth.

Most or all of these barriers are feasible to overcome with some investment of time and money. However, a “chicken or egg” dilemma arises when funding is sought for this purpose. How do we make a case to allocate resources for an orthopedic trauma registry without the very data that the registry would provide? SIGN has explored common sources of global health funding for such a project but had limited success. Perhaps rather than asking the global health community to take an interest in orthopedics, the orthopedic community could begin to take leadership roles in global health.

There are other trauma registries in many low and middle-income countries that are a first step toward understanding the incidence of fractures, but perhaps more important than incidence is an understanding of the treatment received and resultant outcomes. For example, the number of femur fractures that occur by region is undeniably important, but perhaps more pertinent is the fraction that are treated by traction, plates, and intramedullary nails. These data would be highly informative both for determining how resources could be allocated and in convincing policy-makers that musculoskeletal injury is a relevant global health issue.
We believe the SIGN database is uniquely suited to be adapted for this purpose given the breadth of its existing global network. New technologies such as PDA-based systems for data entry and reports prepared offline are currently being explored. With investment in information technology research and development, this is an area with significant potential for growth.

Clinical Trials

Ultimately, a full understanding of clinical outcomes requires high-quality comparative trials. In light of the tremendous heterogeneity in patient populations treated by SIGN and the broad spectrum of resources available at each program, generalizing results from high-income countries can hardly be assumed. Among the greatest challenges is achieving an adequate follow-up rate when returning to clinic is costly to the patient, both in terms of the direct costs of medical services and the indirect costs of travel and missed work. However, if funding could be obtained, follow-up could potentially be improved through subsidized care and small monetary incentives to participating patients.

The second issue is reliable data collection. This could be addressed by modest funding for medical students or other trained health care professionals to perform on-site data collection. Many SIGN surgeons would be happy to host a medical student who would help them conduct a clinical study, but relying on local resources to perform all aspects of a clinical study is unlikely to succeed given the existing constraints of time and money.

There is a never-ending list of clinical dilemmas for SIGN surgeons that would benefit from further study. Examples are the appropriate number of interlocking screws to use according to fracture type. Many proximal femoral shaft fractures may benefit from 2 rather than 1 interlocking screw to reduce varus collapse as shown in Figure 1. Alternatively, these fractures might benefit from supplemental fixation, such as the plate SIGN has developed to treat intertrochanteric fractures. Another area of uncertainty encompasses the appropriate indications for primary intramedullary nailing in patients at high-risk for infection. There are just a few examples of a multitude of important questions that could be explored.

In addition to the effectiveness of orthopedic interventions, cost is a critical component of policy decisions, particularly in the resource-constrained setting of many developing countries. Cost-effectiveness analyses can be run in parallel with a clinical trial or conducted secondarily. Results from such a study are useful in advocating for investment in an intervention and allow comparison across many different prevention and treatment strategies. Given the perceived high-cost of surgical intervention and implant technologies, this is an important aspect of improving global orthopedic care. In 2 recent publications, Gosselin and colleagues illustrated that both trauma centers as a whole and the SIGN nail system specifically are cost-effective interventions in Cambodia.

Patient Safety

It is of the utmost importance to SIGN that in our pursuit of equality in fracture care, we do no harm. In addition to clinical outcomes, we must find other markers to determine quality of care at each program. We have begun to explore the possibility of surveying programs on a variety of factors ranging from time to debridement for open fractures to sterile practices in the operating room. The goal would not be to withdraw support or penalize struggling programs, but rather to identify areas where we can improve safety in a meaningful way through education or resource allocation.

Among the greatest concerns to any orthopedist implanting foreign material to heal a fracture is infection. The SIGN database contains data on infectious complications including depth of infection, treatment, and outcome as well as the severity of the soft tissue injury. We hope to correlate survey results to these data in an effort to identify factors that play the greatest role in reducing these complications.

Innovative Business Models

A skill set that is crucially needed but beyond the scope of most orthopedists is a thorough understanding of business model development, particularly in the low-income country setting. Creation of sustainable methods for delivering high-quality care is crucial to lessening the global burden of musculoskeletal disease. SIGN has made remarkable progress in this regard through charitable donation alone, but growing or even maintaining the current supply of implants is challenging, especially in the current economic climate.

Social entrepreneurship is a relatively new concept that relies on free-market principles to address social needs rather than emphasizing profit. Relevant examples are Aurolabs and Aravind, both established in India to improve cataract care.

Aurolabs manufactures intraocular lenses at low-cost and sells them to Aravind, a network of cataract surgery centers that operates on a sliding scale payment system. Using the combination of high-volume local manufacturing and tiered pricing, more than 70% of patients receive care free or at low cost. At the same time both the hospital system and the manufacturing plant are thriving without reliance on outside funding. Granted, there are significant differences between orthopedic and ocular implants in terms of the underlying diseases being treated and manufacturing needs, but it may be feasible for a similar framework to be developed for SIGN and other orthopedic technologies to achieve better care in a sustainable manner.

EDUCATION

Education plays a substantial role in accomplishing SIGN’s vision. An important guiding principle is that knowledge does not flow one-way from rich to poor. Rather, many important innovations in both technique and technology have been learned from the skilled SIGN surgeons who strive to find...
ways to improve patient care without the benefit of expensive technologies. An important forum for this discourse is the SIGN conference, held yearly at the company headquarters in Richland, WA. The conference includes lectures by surgeons from all backgrounds, ranging from the president of the OTA to surgeons from Latin America, Sub-Saharan Africa, and Southeast Asia. It is also an opportunity to learn and perfect technique through Sawbones and other hands-on workshops.

Regional SIGN Conferences are also held throughout the year, which are another excellent venue for exchange of knowledge between surgeons from around the world. In addition, the strongest advocates for using SIGN are the surgeons themselves. The number of requests to start programs inevitably increases after a regional conference.

Recently there has been increasing interest from academic programs wanting to become involved in educational partnership with developing world surgeons. As an example, in the last 2 years there have been flap workshops at Duke and the University of Southern California (see Figure 2). Next year University of California, San Francisco has offered to host the flap course. Feedback from participants in these workshops indicated that newly learned skills were put directly into use to treat open fractures and other severe wounds. The network SIGN has developed lends itself to assisting academic orthopedic programs interested in developing overseas partnerships.

The educational efforts of SIGN are not always directed overseas. Another goal of the company is to mentor young people interested in working in impoverished countries. In many cases, this involves encouragement and support for research projects related to new surgical technologies. We have served as mentors for bioengineering classes at Johns Hopkins and Georgia Tech. Projects completed include negative pressure wound therapy and a bone transport system that utilizes a motor placed on the interlocking screws of the SIGN nail. This year we will mentor Georgia Tech biomechanical engineering students who will look at ways the shoe sole affects stresses in the knee and fracture healing. We hope these studies will decrease incidence of osteoarthritis and speed healing of fractures of the tibia.

TECHNOLOGIC DEVELOPMENT

As a manufacturing company, engineering and innovative thinking are at the core of what SIGN does. In a recent issue of “Clinical Orthopaedics and Related Research,” Hansen and Bozic discussed the power of disruptive innovations, which increase the availability of technology through reducing costs of existing devices rather than developing new technologies at higher cost. This captures the mentality of SIGN engineers who are continually seeking affordable solutions to challenges faced in treating fractures. The following are several areas SIGN is exploring where innovative solutions are needed.

Nonunions

There are an estimated 100,000 nonunions per year in the United States. The proportion of fractures that fail to progress to union may be even higher in developing countries where many long-bone fractures are treated with traction or plate fixation (see Figure 3) and infection rates may be higher. SIGN has begun a study with the Washington State University Department of Biomechanical Engineering to determine whether silver can be coated on stainless steel to prevent bacterial infection. This might be a valuable tool in treating patients with high-risk or even established infection. The article in this issue by Shah demonstrates the first step toward using the SIGN nail for infected nonunions. Silver has the potential to further improve results.

Bone Loss

Addressing bone loss is a challenge even when an abundance of high-tech tools are available. During the last 2 SIGN conferences Ilizarov technique has been taught, which is addressed further in the article in this issue by Linh. SIGN has also developed a novel mechanism to motor the transported bone using the SIGN nail without the need for Ilizarov. Unfortunately, funding has not been available to pursue this further.

Negative Pressure Wound Therapy

Negative pressure wound therapy has been a very beneficial development for patients with severe soft-tissue injuries in Western countries. Surgeons in developing countries have innovated ways to accomplish the same method. A surgical
residents in the Philippines designed a pump which is being adapted for use in other developing countries. Work remains in perfecting the design to allow proper drains, foam covering, and suction pressure, but early developments are promising. Wound vacuums may be especially valuable for SIGN programs because they help to isolate open and closed wounds on frequently crowded hospital wards.

**Drill Covers**

Many SIGN programs use commercial battery-operated drills in the operating room. Not only do they reduce operating time, but they are actually cheaper than surgical hand drills in most cases. In the past these drills have been sterilized by trying to cover with cloth, soaking or even wiping with alcohol. Scott Nelson, MD, working in the Dominican Republic, has contracted with local women to make a more sophisticated drill cover. Combined with an extension for the drill chuck developed by Randall Huebner of Acumed, this may help preserve sterility in the absence of proper surgical drills. Along the same lines, we are collaborating with Joel Gillard, of Acute Innovations, to determine the optimum drill speed to be used for these tools in different densities of bone.

**Femoral Neck Fractures**

Femoral neck fractures are a frequent cause of disability in developing countries where hemiarthroplasty and total hip replacement are cost-prohibitive. We are exploring ways to achieve reduction and fixation with a lower incidence of non-union and avascular necrosis. The compression screws used in the SHC, the hip fixation device for intertrochanteric fractures, are a starting point. We are also considering methods to add fixation to the lateral cortex to improve biomechanical stability in comminuted fractures of the proximal femur.

**Enhancing Conservative Treatment**

There are several fractures where conservative management often offers an equal chance of successful outcome without the risks of surgical intervention. An example is closed tibial shaft fractures, which have been treated successfully in fracture braces. We have begun to explore the cost of manufacturing prefabricated braces similar to the concept originated by Sarmiento. If this can be achieved at a relatively low cost, this may be a good alternative to SIGN nailing for many patients. Early price estimates suggest that up-front costs for manufacturing fracture braces are high, but the per part price may be less than surgical implants. The greater challenge may be improving clinical follow-up, which is important to achieve satisfactory outcomes for many conservatively treated fractures.

Patient education is another area where there are opportunities to improve care. Simple written instructions that are language and culture-appropriate would be a straightforward and low-cost way to assist often busy surgeons who must also manage knee, shoulder, and back problems. Whereas joint replacement or arthroscopic procedures may not be realistic for these patients in the near future, a well-outlined conservative treatment plan might benefit many patients. The SIGN network would be a rapid way to distribute such materials.

**CONCLUSION**

This article covers a wide-range of topics that are either current projects or future opportunities for assisting orthopedic care in developing countries. It is hoped that some element of the article may resonate with each reader and provide an avenue to make a contribution or inspire a new idea. The public health model utilizes careful surveillance, assessment of the problem, and a calculated intervention on a population level. This is emphasized more in the research component of the article. The technology section represents a more pragmatic approach. It emphasizes solutions rather than spending time quantifying the problem when it is readily apparent to those spending time among the populations most affected. The optimal strategy is likely some combination of both philosophies.

It is our hope that other orthopedic surgeons will join us and contribute to the care of trauma patients over the world. Not only do the many victims of trauma need your help, but it can be a tremendously rewarding and self-fulfilling endeavor. With each new SIGN program, a cascade of positive change begins. Surgeons rise to become experts in their hospitals. Hospitals become regional teaching centers. SIGN surgeons often train others from their country or region. This has wide ramifications as we consider the impact we can make on a major global problem. Of all those who might recognize this impact and possess the skill-set to help sustain it, none are greater than current members of the orthopedic community.

**REFERENCES**