SIGN Surgeons Drive Innovation to Heal Victims of Trauma in Developing Countries

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Road traffic accidents, conflicts and natural disasters injure 20 million people every year. Ninety percent of those injured live in developing countries and earn less than $2 per day. They live day to day and so, when injured, have no reserves to buy the implants necessary to stabilize their fractures. Patients with long bone fractures lie in traction for several months, unable to earn a living for their families. Government hospitals lack funding to provide nursing care, so families move into the hospital wards to provide care for the patient. This disruption of family life causes the family unit to spiral further into poverty, affecting three generations. This poverty is longstanding if the patient, who is the breadwinner, has a poor result from treatment.

Impetus for SIGN

After seeing a patient who had been in traction for three years due to inability to pay for his implants, Surgical Implant Generation Network (SIGN) founder Dr. Lewis Zirkle realized that teaching orthopaedics in developing countries *must* be accompanied by a consistent supply of implants that can be used with the available facilities. He decided to start a charitable organization whose purpose is to design, manufacture and *donate* orthopaedic implants for use in developing countries. SIGN's vision and mission is to create equality of fracture care by providing orthopaedic training in use of intramedullary nail and interlocking screw fixation to surgeons, and donating the instruments and implants for use in treating the poor. In SIGN programs, patients with open fractures are taken to surgery for wound debridement and insertion of the SIGN IM Nail, if indicated, on a timely basis. Closed fractures are also treated on a timely basis, allowing discharge within three days rather than spending months in traction.

Criteria for Achieving Interlock

The biggest challenge is locating the distal slot in the nail without using a C-arm—and many government hospitals in developing countries do not have C-arms. SIGN engineers had to develop mechanical targeting devices to locate the distal slot without the use of such equipment. The slot finder, used in conjunction with the target arm, allows the surgeon to use his tactile senses to confirm location of the distal slot for insertion of the interlocking screw. More than 140 hospitals in 50 developing countries are using the SIGN IM Nail system and have successfully treated 40,000 patients since 1999.

SIGN Surgeons Drive Innovations

When SIGN began in 1999, Dr. Zirkle had taught orthopaedics in Vietnam for more than ten years. During that time, he developed a deep respect for the local surgeons' abilities and wanted to give them the first opportunity to use the SIGN IM Nail system. He chose two of the busiest hospitals as pilot programs to test whether an intramedullary nail device would be accepted by local surgeons and their patients. The Vietnamese surgeons accepted the challenge. They made many suggestions for new instruments to aid in more accurate and efficient location of the distal interlock. Within two years, the two pilot programs grew to ten hospitals using the SIGN IM Nail system on a regular basis.

The SIGN IM Nail system was originally designed as a tibia nail.

SIGN surgeons quickly began to extend the indications for its use. On one trip to Vietnam, Dr. Zirkle was presented with a challenging case. A young Vietnamese woman had sustained a "floating knee" in a motorcycle accident. Surgeons first stabilized the tibia with a SIGN nail, and then placed a second SIGN nail through the same incision into the distal femur to fix the segmental femur fracture. (See Exhibit 1.) At that time, retrograde use of an IM Nail device was not common. Many surgeons were concerned that it would result in loss of knee flexion. Dr. Tan, in Hanoi, studied patients who had been treated with the retrograde approach to the femur. He found that patients did not lose knee flexion if the surgeon manipulated the knee after the nail and interlocking screws were placed.

Exhibit 1: First SIGN retrograde femur case. Patient presented with floating knee fracture. She is standing on the operated leg at six weeks post-op.

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Dr. Quang from Binh Duong province was first to use the antegrade approach to inserting the SIGN nail in the femur. When these x-rays appeared on the database, Dr. Zirkle and the SIGN engineers considered redesigning the nail. They collaborated with Battelle, an international research laboratory, to confirm that the bend in the SIGN nail was appropriate for the antegrade femur approach. The engineers used Mimics software to model the canal of the bone and converted these results to SolidWorks to study the nail/bone construct. The SIGN database, which began in early 2004, now contains 11,200 femur reports compared to 8,000 tibia reports.

Dr. Antao from Mumbai, India began using the SIGN nail in the humerus when a patient presented with a seven-year-old nonunion of the humerus. The patient had undergone five operations to attempt healing of the fracture, but all failed. Dr. Antao decided to use the SIGN nail. He sent pre-, post- and follow-up x-rays and clinical photos of the patient that demonstrated complete functional and x-ray healing. (See Exhibit 2.) With this surgery, the SIGN IM Nail system became the first universal IM Nail Interlocking Screw System used for tibia, femur and humerus and designed specifically for use in developing countries.

Exhibit 2: First SIGN humerus surgery. Patient presenting with seven-year-old nonunion of humerus, treated after five operations by SIGN nail.

SIGN's Next Orthopaedic Challenge

SIGN donates implants to hospitals with the proviso that the surgeons record their cases on the SIGN surgical database. These reports are reviewed by Dr. Zirkle and U.S. surgeons. About two years ago, it became apparent that SIGN surgeons were using the SIGN nail for fractures in the proximal femur including intertrochanteric fractures. (See Exhibit 3.)They were very skillful in placing the interlocking screws into the femoral head. We felt that the SIGN system could be modified to provide better stability in hip fractures. This desire was intensified during a recent trip to an Afghanistan hospital where we saw 20 patients lying in traction with hip fractures. After three weeks, they were sent home in body casts.

We have been aided by many individuals and organizations during the process of designing and testing the new SIGN Hip Construct (SHC). SIGN engineers worked in conjunction with PATH (a Seattle-based non-profit organization that focuses on technical solutions to improve lives in developing countries. To learn more, visit www.path.org.) and Dr. Allan Tencer from the University of Washington to develop a bench testing fixture that replicates the normal human gait. The SHC System has maintained reduction after 200,000 cycles of fatigue testing with increasing weight to 2,150 newtons during flexion and extension. These tests have provided valuable data to validate the design. SIGN is on target to go into production of the SHC later this year.

Exhibit 3: Unstable intertrochanteric fracture treated by SIGN nail

SIGN's Future

This year, SIGN will provide training, educational opportunities and implants to nearly 4,000 SIGN surgeons in 50 developing countries. Those surgeons will treat 13,000 to 15,000 patients injured by traffic accidents, conflicts or natural disasters. Thousands more are injured and need orthopaedic treatment each year. We can reach more patients by increasing the pace at which we start new programs, and by increasing the types of fractures that can be treated with SIGN implants. Our goal is to provide training and equipment to allow SIGN surgeons to annually treat 100,000 fracture patients by 2013.

The 7th annual SIGN conference will be held at SIGN headquarters from September 17 to 20, 2008. SIGN surgeons from around the world will presnt their orthopaedic experiences with the SIGN nail and other devices. U.S. and overseas surgeons will present workshops and talks on long bone, hip and pelvic fractures, Ilizarov and Ponseti techniques, and other trauma related topics. The SIGN conference connects U.S. and overseas surgeons who collaborate to start new programs. Discussions that arise from workshops on SIGN techniques and the new SHC system will generate many new innovations.

Please visit our website at www.sign-post.org or write to us at signcom@sign-post.org to learn more about volunteering or donating to SIGN. Volunteering allows trauma surgeons to meet and interact with dedicated surgeons throughout the developing world. A $100 donation makes a life-changing difference to a patient as it covers the cost of implants, while a donation of $20,000 provides the instruments and implants necessary to start a program to treat the poor.

Jeanne Dillner is Chief Executive Officer of SIGN, a non-profit organization that designs, manufactures and donates patented, FDA-cleared orthopaedic implants to hospitals in developing countries. Ms. Dillner regularly travels to assist Founder and President, Lewis G. Zirkle Jr., M.D., with the training of the surgeons on the SIGN IM Nail System. Doctors are now using this system in more than 140 hospitals in 50 developing countries, and have given more than 40,000 patients a chance to resume normal activities. Ms. Dillner can be reached at jeanne@sign-post.org.

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