Development and Biomechanical Testing of the SIGN Hip Construct

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Summary: The SIGN hip construct (SHC) was developed to treat stable and unstable intertrochanteric fractures in low and middle income countries. The design was based on previous hip stabilization devices with specific adaptations to accommodate the unique challenges encountered in resource-limited settings. Specifically, our goal was to enable operative stabilization of all intertrochanteric hip fractures without the aid of C-arm imaging. The SHC evolved through 3 years of bench testing prior to clinical use. As more clinical challenges were identified, we anticipate the testing and incorporation of new ideas to improve functionality and overall structural performance of the device. This article presents the design strategy and development of the SHC as well as a fatigue gait simulator that was used to evaluate the performance of the construct.

Key Words: biomechanical testing—sign hip construct—intertrochanteric fractures—fatigue.

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There has been a progression of innovations in treating hip fractures from the Smith-Petersen and Jewett nails to the sliding hip screw (SHS) and more recently, to intramedullary devices. Despite these advances, internal fixation devices for hip fractures have yet to find the optimal approach for all fracture configurations.1–4 Each of these implants is an attempt to balance collapse of the fracture with rigid stability. Fracture collapse has the benefit of interfragment apposition and compression whereas rigid stability is the traditional goal of internal fixation. We have learned that achieving this balance is critical to successful treatment of hip fractures.

The SHS was an attempt to attain this balance by allowing collapse of the fracture to create compression between the proximal and distal fragments.5 The design works well for stable fractures, but unstable fractures are prone to excessive collapse, resulting in leg length discrepancy and implant cut-out.6–9 The intramedullary hip screw (IMHS) utilizes the nail itself to prevent excessive collapse, but cut-out from the femoral head remains problematic. Regardless of their efficacy, both the SHS and the IMHS rely on real-time image guidance to be placed safely, which makes them unfeasible for the resource limited hospitals of the developing world.10

MOTIVATION FOR THE SIGN HIP CONSTRUCT

The inspiration for the SIGN hip construct (SHC) occurred in a similar manner as the early inspiration for Surgical Implant Generation Network (SIGN). During many visits to SIGN programs to teach the technique for the standard nail, one of us (L.G.Z.) observed wards full of patients with hip fractures being treated in skeletal traction then placed in a body cast. Due to the absence of an affordable implant suitable for resource-constrained hospitals, these patients could never undergo surgery. In contrast to the hip fractures treated in high income countries, these patients are often young with high-energy unstable fractures sustained in road traffic accidents. This ultimately led to an ongoing process of adapting the original SIGN system for the treatment of extracapsular hip fractures.

Significance: High-energy fractures in young people must have robust stabilization.

THE DESIGN PHASE

In North America, the choice of fixation is based primarily on a binary classification of the fracture as stable or unstable. Unstable fractures may be further defined by obliquity of the fracture line and presence of comminution of the lesser trochanter, lateral trochanteric wall, or both.11,12 The goal with the SHC was to design and manufacture a hip fixation device that could be used for both stable and unstable fracture patterns and inserted without using fluoroscopic image guidance.

Evidence suggests fixation devices that securely stabilize the femoral head as well as the junction of the proximal screw in the nail result in very stable fixation.6 However, there is a trade-off because fixed angle devices do not allow for variations in size of the proximal femur. To achieve the goal of a universal device for use in low and middle income countries, SIGN sought to develop a design that can accommodate the many hip sizes around the world. Diverse anatomy of the proximal femur is noted in several studies made up of localized cohorts of different ethnicities, but to the authors’ knowledge, a worldwide biometric analysis of proximal femur anatomy has not yet been conducted.13–15 These observations led to the following priorities to guide the design process.

Definite criteria

● The implant can be used in both stable and unstable hip fractures.
● Insertion can be done without C-arm using a reliable, repeatable technique.
● The technique is transferrable to surgeons in low and middle income countries (ie, feasible to teach and learn in a relatively short time-frame given prior orthopedic training).
● The device must accommodate variation in the anatomy of the proximal femur.

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Relative criteria

- Existing SIGN technology is used as much as possible.
- Large holes in the lateral trochanteric wall, which may serve as stress risers, are avoided.
- The implant is smaller than conventional implants to reduce damage if placed in the wrong position.
- The fixation is sufficiently stable to allow early weight bearing, which is important in settings where physical therapy and close clinical follow-up are rarely available.
- Compression of the fracture site is achieved before rigid fixation is inserted.

Significance: Definition of the design criteria is imperative to measurement of relative success.

DEVELOPMENT OF THE SHC

Initially, we started with the existing SIGN nail and interlocking screw system and attempted to fix fractures created in a Sawbones foam femur (P/N:1130-27, Pacific Research Laboratories, Vashon Island, WA). Through an iterative process with a simple load-to-failure test that mimicked a single legged stance, a great deal was learned about the modifications necessary to treat fractures of the hip based on observation of failure modes and failure load measurements (Fig. 1).

Significance: Load-to-failure testing provides information in the preliminary design stages.

The first problem encountered was rotation of the nail for placement of the interlocking screw to account for the variability in femoral anteversion across individuals and populations. The standard SIGN nail has a 9 degree proximal bend. After the standard nail was inserted, rotation to direct the interlocking screws into the femoral head created hoop stresses in the femoral neck postfixation. This hoop stress was noted qualitatively as a 2- to 3-mm rotational movement of the femoral head after the nail rotation and interlocking screw placement in a foam Sawbones femur. It is likely that this hoop stress would not have been noticed qualitatively if a full strength bone had been used for initial SHC development. The first modification was therefore to decrease the proximal bend to 6 degrees. This change decreased the postrotation hoop stress in the femoral neck to a level that was not measurable at postconstruct installation. Whereas it is possible that the observed hoop stress is a contributing factor to the femoral neck fractures seen in some populations of IMHS patients, future biomechanical evaluation is needed to validate this mechanism as causal. Another modification considered, but ultimately discarded, was to add an arc of radius to better match the nail to the anterior bow of the femur. Similar to the 9 degree proximal bend, it was discovered that adding a radius of curvature caused significant hoop stresses when the nail was rotated to direct the interlocking screws toward the center of the femoral head. This iteration was also qualitatively evaluated as described previously. These early observations led to a straight nail with a 6 degree proximal bend to allow the nail to be more freely rotated during insertion.

Significance: Forced rotation of a nail with a proximal bend or shaft radius of curvature results in hoop stresses that may cause an iatrogenic fracture during insertion.

Further experimentation demonstrated that putting 2 interlocking screws into the femoral neck (using the technique of the standard SIGN nail) did not leave enough space to add the compression screws that were considered necessary for stable fixation. To create space in the femoral neck, the more distal of the 2 proximal apertures on the standard nail design was removed. Flats were then machined parallel to the axis of the single remaining proximal interlocking screw hole. These flats allow clearance for 2 compression screws to enter the neck without striking the nail during placement. The goal was to insert the anterior compression screw first to compress and stabilize the fracture before the rest of the implant was placed. The compression screws were designed with differential thread pitch between the distal and proximal ends, which results in a predictable amount of compression at the fracture site.

Significance: The SHC has a smaller proximal nail diameter and a larger proximal interlocking screw than the standard nail. Two compression screws that do not pass through the proximal nail can be placed by hand without C-arm and account for variations in proximal femur anatomy.

To address the issue of transverse fractures in the lateral trochanteric wall, a variable angle connector rod was designed to connect the interlocking screw to a unicortical screw. The idea was to create a tension band. For reasons of cost and ease of use, this was later changed to a plate with equal functionality. Figure 2 shows the final design of the SHC proximal

FIGURE 1. Early compression load-to-failure setup.
fixation construct, including the connector plate. The lateral connector plate described from this point forward is a later and further optimized iteration of the original connector rod described here.

The value of distal fixation of the nail was proven in bench testing. The initial design used a fin nail (Fig. 3), which interdigitates with the femoral canal via compression fit. This worked well in practice in Cambodia and Myanmar, but there was concern that the fin would not adequately engage the larger canals of African patients. To address this, a second nail was designed without a fin that could accept a distal interlocking screw (Fig. 4). This also meant revising the target arm to include the option for placement of distal fixation. The downside of interlocking is that there may be a higher-risk of femoral fractures due to creation of a stress riser, which has been an issue with other IMHS designs. Ultimately, it was felt that providing both options would add flexibility for the treating orthopedic surgeon is familiar with in typical practice. A new iteration of the clamp has recently been completed and is currently being manufactured.

Significance: Distal fixation of the nail is important for the overall stability of the construct.

REDUCTION CLAMPS

Given the importance of fracture reduction in overall stability of any hip fixation construct, instruments to achieve and maintain the reduction were heavily emphasized during the development of the SHC. It was felt that the existing clamps were either too difficult to apply or failed to provide compression in the proper plane. Using an iterative process with rapid prototyping, a more effective and ergonomic clamp was designed (Fig. 5). The clamps are much easier to insert through a small incision and can be secured using motions that an orthopedic surgeon is familiar with in typical practice. A new iteration of the clamp has recently been completed and is currently being manufactured.

Significance: Reduction clamps are necessary when a fracture table cannot provide traction and rotation.

BIOMECHANICAL TESTING

Once a suitable implant configuration was achieved, initial bench testing was repeated with the simple load to failure test using a hydraulic jack and donated polyurethane foam femurs from Pacific Research Laboratories (Fig. 1). The information from these initial tests was valuable to develop a qualitative understanding of failure modes. For example, it was noted that the head of the compression screws migrated superiorly as the construct approached failure. This was addressed with a plate designed to fit between the interlocking screw and the posterior compression screw to serve as a buttress. Although prominence of the plate was originally problematic, this was resolved with successive iterations of the design. Furthermore, early testing demonstrated the distinct advantage of having the threaded screw heads for fixation into the lateral cortex. Overall, the load-to-failure testing system was invaluable in comparing early design iterations of the hip construct.

Ultimately, it was recognized that although early bench testing was helpful, a more sophisticated testing apparatus was needed before using the implant clinically. This testing was achieved through a collaborative effort between SIGN, Program for Appropriate Technology in Health (PATH) (an international non-profit organization), and Allan Tencer from the University of Washington Orthopedic Science Laboratory. The collective expertise of Dr. Tencer and engineers at PATH and SIGN, bolstered by funding from PATH, led to the design and fabrication of a low-cost fatigue testing apparatus for use by SIGN engineers.

Significance: Although load-to-failure testing was valuable in the early design process of the SHC, fatigue testing was necessary to understand the failure modes associated with more physiologic loading.

To avoid complicating our discussion of the SHC design and development process, the design specifications of the fatigue testing apparatus have been included in an appendix. The general concept was to design an apparatus that would mimic the forces associated with ambulation on a hip implanted with the SHC. This was accomplished using the test setup shown in Figures 6 and 7, which utilizes a vertical load simulating body weight applied cyclically to the femoral head in synchronization with flexion and extension. Measurement of the inferior displacement of the femoral head facilitates calculation of the construct modulus, ultimate strength, and failure rate (μm/1000 sec) in addition to the opportunity to evaluate construct changes in real-time.

Because of the challenges in acquisition and high variabili-
ity in mechanical properties of fresh-frozen cadaver specimens, the fourth-generation Sawbones composite femur (P/N: 3406) was selected for biomechanical fatigue testing. These composite femurs exhibit similar structural properties to cadaver bone. Composite bones provide an advantage over cadaver bone for biomechanical tests as they have low inter-specimen variability and are readily available, cost efficient and have no special handling requirements. Prior to testing, a fracture was created in either a stable or unstable pattern by cutting the cortex with a Dremel (Robert Bosch Tool Corporation, Racine, WI) and then fracturing the cancellous foam with blunt force to create some interdigitation between fragments. Once fractured, the composite bone was implanted with the SHC and fixtured as described in the appendix.

Significance: Each iteration of the SHC is fatigue tested in an apparatus that mimics the physiologic loading associated with progressive ambulation. The Sawbones model allows for a highly repeatable protocol reducing the number of tests needed to evaluate each new design iteration.

To date, well over a million cycles of fatigue testing have been performed on the SHC using this gait-mimicking fatigue test machine. Each round of testing is used to examine a different hypothesis about the design and its fatigue resistance in a specific fracture pattern. Examples of the data sets obtained through testing are seen in the appendix. To date, four conclusions have been made related to SHC installation using this model.

1. Rigid distal fixation is necessary for highly unstable fractures.
2. The fin nail (Fig. 3) achieves adequate distal fixation when the femoral canal is narrow enough for the fin to fully interdigitate.
3. The lateral connector plate is valuable for fractures with an unstable lateral wall, but it may add unnecessary complexity in other patterns, including those with posteromedial comminution.
4. When the lateral connector plate is needed, linking the
proximal interlocking screw to a separate unicortical screw results in no loss of biomechanical stability compared with the original design linking the interlocking screw to the posterior compression screw. This simplifies the design and installation of the SHC for fractures with an unstable lateral wall.

Through discussion with experts in the field, literature searches on biomechanical test methods, and a review of both the American Standards of Testing and Materials and International Organization of Standardization standards, it was observed that there is no universally accepted or consistent test standard for biomechanical testing of hip fracture constructs. Comparisons in the literature between different implants for stabilization are not consistent, particularly with regard to biomechanical test setup and loading conditions. Implants are tested in cadaveric and synthetic femurs that are setup with different degrees of adduction to simulate a single legged stance or physiological stance phase during walking. Load application varies between in vivo trajectories to vertical with the femoral shaft with or without a combination of axial, torsion, and bending. However, the largest source of variation appears to be the loading criteria, where a series of cyclic tests are conducted prior to a static load to failure with resultant displacement measurements that individualize and isolate each fracture type, fracture reduction, proximal femur anatomy, and the fixation principle of allowing fractures to collapse into a stable state, experimental studies of fixation performance rely on an accurate simulation of physiological loading to evaluate each construct. Haynes et al, concluded that static testing in comparison to dynamic loading does not accurately represent the clinical performance for the SHS, thus misinterpretation may occur for either the benefit or detriment of the fixation system. This emphasizes the importance of a standardized test method to unify fixation performance.

The design of the testing apparatus used for the SHC was loosely based on a design by Dr. Allan Tencer used for comparing fixation methods for basi-cervical femoral neck fractures. However, because of the heterogeneity in testing methods, it is impossible to make comparisons to results of studies of other implants. Unlike many other medical and nonmedical devices, there is no standard for preclinical biomechanical testing of hip fixation. In the absence of a standard, it is difficult to determine how the SHC compares to other devices used to treat intertrochanteric fractures. As a result of this shortfall, we are currently in the process of proposing development of an American Standards of Testing and Materials standard for hip fracture implant testing based on the SHC fatigue testing apparatus and the Sawbones composite femur model.

Significance: There are no accepted standards for biomechanical testing of hip fixation devices. A validated standard would allow preclinical comparison of the biomechanical stability of new and existing implants.

In addition to the critical role that bench testing can play in implant design, we feel it is relevant to address the value that such a testing process can have in orthopedic education. Through bench testing, much was learned about the forces acting to deform a hip fracture during ambulation, and the strengths and weaknesses of each implant used to resist these forces. As work hour restrictions lessen the opportunities to learn from direct clinical exposure, it may be worth considering the value of ex-vivo implantation and bench testing. With a simple Sawbones model and a hydraulic press, one can learn a great deal about the strengths of one implant relative to another or the importance that a subtle difference in screw placement can have on achieving rigid internal fixation.

Significance: A great deal can be learned about surgical technique and characteristics of different implants through ex-vivo implantation and load-to-failure testing.

CONCLUSIONS

Through an iterative process of trial and error using bone analogs and biomechanical fatigue testing, we have developed a novel device for the treatment of intertrochanteric hip fractures in low- and middle-income countries. We believe all the initial “definite” design criteria were met, but, several important questions remain to be explored by both biomechanical and clinical study. For example, we are currently working to determine the indications for the lateral connector plate based on the stability of the fracture. We feel confident that it is unnecessary for stable fractures, but among the unstable fracture types, it is possible that it can specifically be reserved for fractures with involvement of the lateral trochanteric wall.

From a broader perspective, we hope to translate the lessons learned from the SHC project into a standard for biomechanical testing of all hip fixation devices. Review of the literature has shown that little convincing biomechanical data exists with regard to the repair of unstable intertrochanteric fractures. Given the ease of use and low cost of our testing apparatus, it is our hope that it will have a role in further defining appropriate repair of these difficult to treat fractures.

In addition to guiding the design process, the biomechanical testing process resulted in a successful substantial equivalence determination of the SHC by the Food and Drug Administration.

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APPENDIX

Cyclic Fatigue Test Machine Design

The testing apparatus was designed using SolidWorks (SolidWorks Corp., Concord, MA) and fabricated at PATH in Seattle, WA. The final design consists of an aluminum load frame with pneumatic actuators mounted to achieve forces approximating normal gait (Figs. 6, 7). A force vector equivalent to upper body weight is applied to the femoral head at an angle of 7 degree from vertical in the coronal plane by a large vertically oriented pneumatic cylinder. The force acts through a Delrin plastic acetabulum at a physiologic angle.

The fixture cut distal-end of the femoral shaft is mounted in a polyvinylchloride cylinder and filled with polymethylmethacrylate using a fixture that creates a 5 degree varus angle in the coronal plane. Once the polymethylmethacrylate is cured, the femur is mounted to a ball-transfer (Fig. 7). A computer numerically controlled machined molydneum disulfide filled nylon track for the ball transfer serves as a guide through the normal physiologic range of motion encountered with ambulation. Coupled with the potted femoral varus angle, the combined load is offset 12 degree from the axis of the femoral shaft in the coronal plane. A smaller, horizontally
FIGURE 8. Loading profile through a single flexion extension cycle at each of the three progressively increasing loads.

Phase 1: 0 to 5000 Cycles
Peak load 900N
(1x Body Weight)

Phase 2: 5000 to 10,000 Cycles
Peak load 1250N
(1.4x Body Weight)

Phase 3: 10,000 to 20,000 Cycles
Peak load 1500N
(1.6x Body Weight)

FIGURE 9. Example of data output for fracture configuration and design iteration comparison.
mounted pneumatic cylinder provides the force necessary for flexion and extension of the femur.

Fatigue Testing
Cyclic testing with 30 degrees of flexion and 10 degrees of extension was conducted at a rate of 1 Hz.31,35 During testing, inferior displacement of the femoral head was measured by a linear transducer inside the vertical pneumatic actuator. Failure was determined as displacement of the femoral head greater than 5 mm. A load cell mounted in-line between the pneumatic cylinder and the acetabulum measured the force applied to the femoral head and tracked the loading profile to assure concurrence with accepted standards defined by Bergmann et al. in 2001.16 A typical loading pattern through one cycle of flexion and extension at each of the progressively increasing loads is shown in Figure 8. Load and displacement data were collected in Labview (National Instruments, TX) and exported to Microsoft Excel (Redmond, WA) for further analysis. Figure 9 gives an example of the data output available for direct comparison of different fracture configurations and design iterations.

The testing protocol is as follows:

1. Install potted femur into standardized test machine and add preload to take up any construct laxity.
2. Graduated loading protocol:
   - 0 to 5000 cycles at 890 N (1 × body weight),
   - 5 to 10,000 cycles at 1246 N (1.4 × body weight),
   - 10,000 to 20,000 cycles at 1468 N (1.6 × body weight).
(Note: 20 K cycles = 6 weeks of ambulation [~480 steps/d]19)
3. Test stopped at displacement > 5.00 mm or 20 K cycles
4. Load to failure testing parameters:
   - 979 N preload,
   - Loading rate = 10 lbs/min,
   - Failure = displacement > 5 mm.

The above test protocol and the fatigue test frame allow for calculation of the construct modulus, ultimate strength, and failure rate (μm/1000 sec) in addition to the opportunity to evaluate construct changes in real-time.

REFERENCES


