A biomechanical comparison of the Surgical Implant Generation Network (SIGN) tibial nail with the standard hollow nail

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Introduction

SIGN (Surgical Implant Generation Network) was created in 1999 as a humanitarian, non-profit corporation with a goal to provide improved health care and appropriate orthopaedic treatment of fractures at little or no cost to people in need throughout the developing world.21 The SIGN tibial system is a solid intramedullary nail (IMN) with interlocking capability through a mechanical aiming device that enables the placement of proximal and distal interlocking screws without the need for image guidance.

More than 3000 orthopaedic surgeons use the SIGN system on a daily basis to treat long bone fractures largely caused by road traffic accidents. Since 1999, >26,000 patients have been treated with the SIGN intramedullary femoral or tibial nail. Majority of these nails are inserted without reaming and the use of an image intensifier. SIGN has been unable to perform a comprehensive analysis of union rates or complications, given the difficulties in obtaining follow-up data in the suboptimal healthcare environment of developing countries.

Intramedullary nailing of tibial shaft fractures is generally accepted as the standard treatment.1,2,4,10,12,14 In developed countries, in part because of easy access to intraoperative fluoroscopy, most commercially available tibial nails are hollow. These are cannulated systems that can be used for reamed and unreamed techniques, enabling nail insertion over a guide wire. Few studies have compared the biomechanical characteristics of solid and hollow nails.3,18 More recent series have demonstrated union rates of ~90% for tibia fractures treated with SIGN nails,13,19 similar to union rates reported for reamed hollow nails.5,8,15,16

However, despite its widespread use, there is no published data on the biomechanical properties of the SIGN nail. Therefore, this study aimed to compare the mechanical stiffness of the SIGN tibial nail with a standard hollow tibial nail.

Materials and methods

Construct design and fracture model

Two IMN construct groups with 10 specimens each (n = 10) were created using third-generation, medium-sized (380 mm) left
tibial synthetic composite bones (Sawbones, Pacific Research Laboratories, Inc., Vashon, WA, USA). The use of Sawbones for mechanical testing is well established and minimises the variation in stiffness found in cadaveric bones with differences in age and bone quality. A 3 cm gap was created 18.5 cm proximal to the plafond, to simulate a comminuted mid-shaft tibia fracture (AO/OTA42-C3). All osteotomies were performed after intramedullary nailing by an experienced orthopaedic trauma surgeon.

**Implant design and instrumentation**

The Sawbones were instrumented using either a SIGN or a Smith and Nephew Russell–Taylor (RT) tibial nail (generously provided by SIGN, Richland, WA, USA and Smith and Nephew Inc., Memphis, TN, USA, respectively). The SIGN nail was a solid stainless steel nail measuring 9 mm × 345 mm, while the RT nail was a hollow titanium nail measuring 10 mm × 345 mm (Fig. 1). Both systems had proximal and distal interlocking capabilities via 4.5 mm cortical screws. The SIGN interlocks had threaded heads.

After reaming the medullary canal 1.5 mm over the respective nail diameter, nails were inserted according to standard tibial IMN techniques. In the SIGN system, proximal and distal cross-locks were inserted using a specifically designed aiming device, while distal cross-locking in the RT system was carried out using the free-hand technique with an image intensifier. Following intramedullary nailing, all Sawbones were osteotomised as described previously.

**Mechanical testing**

For mechanical testing, the proximal and distal ends of each tibia were mounted in custom-built polymethylmethacrylate (PMMA) moulds conformed to the tibial plateau and the plafond, respectively. The position of the tibia in the mould was such that the line of action for the load went through the central axis of the construct, simulating the mechanical axis of the tibia. The specimens were supported by a ball-bearing proximally and distally in the testing machine to avoid uncontrolled torque or bending. The model was then placed on the loading platform of a materials-testing machine (Instron 5800 R, Canton, MA, USA) for mechanical testing (Fig. 2). For torsional testing, the specimens were proximally held in a custom mould and distally secured in a chuck, with the tibial axis in line with the axis of rotation (Fig. 3).

**Fig. 1.** The Russell–Taylor (RT) nail (A) was a hollow titanium nail measuring 10 mm × 345 mm, while the SIGN nail (B) was a solid stainless steel nail measuring 9 mm × 345 mm. Both systems had proximal and distal interlocking capabilities via 4.5 mm cortical screws.

**Fig. 2.** For axial and cyclical axial testing, the proximal and distal end of each tibia was held in a PMMA mould and supported by a ball bearing in the materials testing machine to avoid uncontrolled torque or bending.
Axial loading

The constructs were loaded in compression at a displacement rate of 10 mm min\(^{-1}\). After stabilising the construct with a preload of 100 N, axial loading was performed in a displacement control mode. Testing was stopped when 500 N was reached.

Torsional loading

The specimens were preloaded to 5 N m and each construct was torqued to a maximum of 20 N m at a rate of 20 N m/\(\min\). Testing was stopped when 20 N m was reached.

Cyclical axial loading

This loading protocol was previously described for the mechanical evaluation of fracture constructs.\(^{17,22}\) It consisted of increments of 10 cycles starting with 500 N. The load for each successive increment was increased by 500 N, to a maximum load of 2500 N, with 10 s of rest between each increment. The preload and baseline load after each cycle was 100 N. Testing was conducted in a displacement control mode at 0.75 mm s\(^{-1}\) and was performed until either 2500 N was reached, or visual loss of fixation occurred. This method of cyclical testing was used to compare the influence of nail design on construct stiffness, and to assess its contribution to reversible and irreversible (plastic) deformation.

Data recording and statistical analysis

Data analysis was performed to determine stiffness values and plastic deformation for each sample. For axial testing, a load–displacement curve was plotted for each construct (Microsoft Excel, Seattle, WA, USA) and the stiffness was calculated as the slope of the initial and linear region of the loading curve. For torsional testing, stiffness of the construct was measured using the linear portion of the load and angular displacement data. Finally reversible and irreversible deformation in cyclical axial loading is shown in a typical time–displacement curve of the nail construct (Fig. 4). Plastic deformation was calculated by subtracting the amount of displacement present prior to the start of the first cycle (500 N) from displacement present after the final cycle (2500 N). Total deformation was recorded after the last testing cycle.

An unpaired \(t\)-test was performed using StatView (SAS Institute Inc., Cary, NC, USA) to determine possible significant differences in axial and torsional stiffness, as well as plastic deformation between each group. The level of significance was defined as \(p \leq 0.05\).

Results

Axial and torsional loading

No visual loss of fixation occurred in either the axial or the torsional loading groups. The mean axial stiffness for the SIGN nail constructs was 47% higher than mean stiffness for the RT nail constructs (Table 1). While this represented a statistically significant difference in axial loading (\(p < 0.001\)), a difference of only 9% in stiffness was found between the two groups in torsional loading (\(p = 0.221\)).

Cyclical axial loading

After each set of loading cycles, the amount of irreversible/plastic deformation increased significantly more in the SIGN nail group than in the RT group (Table 1). No visual loss of fixation occurred in either group. The mean plastic deformation was calculated by subtracting the amount of displacement present at the beginning of the 500 N cycles, from the displacement present at the end of the cycles.

Table 1

<table>
<thead>
<tr>
<th>Tibial nail</th>
<th>RT ((N=10))</th>
<th>SIGN ((N=10))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axial stiffness (N/mm)</td>
<td>Mean 1290.77 SD 90.43</td>
<td>Mean 1897.29 SD 103.98</td>
</tr>
<tr>
<td>Difference</td>
<td>606.52</td>
<td></td>
</tr>
<tr>
<td>Torsional stiffness (N m/degree)</td>
<td>Mean 1.24 SD 0.08</td>
<td>Mean 1.13 SD 0.06</td>
</tr>
<tr>
<td>Difference</td>
<td>0.11 (\leq 0.021)</td>
<td></td>
</tr>
<tr>
<td>Total deformation (mm)</td>
<td>Mean 2.58 SD 0.09</td>
<td>Mean 3.14 SD 0.32</td>
</tr>
<tr>
<td>Difference</td>
<td>0.56 (\leq 0.108)</td>
<td></td>
</tr>
<tr>
<td>Plastic deformation (mm)</td>
<td>Mean 0.63 SD 0.06</td>
<td>Mean 1.63 SD 0.31</td>
</tr>
<tr>
<td>Difference</td>
<td>1 (\leq 0.006)</td>
<td></td>
</tr>
</tbody>
</table>

RT: Russell–Taylor; SD: standard deviation.

* Unpaired \(t\)-test.
2500 N cycles. Even though the total deformation was statistically not significant between the two groups (p = 0.108), the SIGN constructs had 159% more irreversible deformation than the RT constructs (p = 0.006).

Discussion

Intramedullary devices have become the gold standard for the treatment of tibial shaft fractures. In the fracture model we have presented, a comminuted fracture with a shaft defect was simulated without the possibility of bony contact. Therefore, our loading model primarily tested the stability of the bone-implant construct, where interfacing of the proximal and distal fragment was achieved through the locking system. Based on this model system, our primary findings were that compared to the RT nail construct, in the SIGN nail construct: (1) axial stiffness was significantly greater, (2) torsional stiffness was not significantly different, and (3) plastic deformation, but not total deformation was significantly greater.

The mechanical properties of the IMN are influenced by their torsional and bending rigidities, which in turn are reflective of material and structural properties of the implant. The radius of the nail is the chief determinant of its stiffness, influencing the calculated bending stiffness to its fourth power. In this study, the stiffness of the bone-implant unit was mainly influenced by the diameter and profile of the implant. We compared a solid 9 mm stainless steel SIGN nail with a hollow 10 mm titanium RT nail. According to our results, the RT nail demonstrated a higher mean torsional stiffness and a lower total deformation than the SIGN nail. These differences, although statistically not significant, may be explained by the larger nail diameter. However, despite the structural differences (i.e., the smaller diameter), the SIGN nail was axially significantly stiffer than the RT nail, possibly secondary to its solid stainless steel design. Previous biomechanical studies have demonstrated that solid tibial nails have a greater axial and torsional stiffness than hollow nails of the same diameter.\(^3\)\(^18\)

For torsional loading studies presented herein, it is perhaps not surprising that the stiffness of the two nail constructs were comparable. For a solid shaft subjected to a torque \(T\), it can be shown that vast majority of the torque is resisted by the outer region of the shaft.\(^1\)\(^11\) For the case of a solid shaft (of diameter \(c\)) and similar shaft consisting of only the outer region (i.e. missing the inner core of radius \(0 \text{ to } c/2\), \(\sim 94\%\) of the torque is resisted by the outer region with the remaining \(6\%\) of \(T\) resisted by the inner core. Therefore, considering at least for torsion that the biomechanical properties are not altered substantially by the change in cross-sectional area, other factors must be considered that are perhaps less related to patient care directly, such as manufacturing simplicity for solid-shaft nail systems versus overall material costs.

This study had several limitations. Even though the two nail constructs were controlled for reaming and locking systems, the nail diameters were different. This may have accounted for the differences in construct stiffness with regard to axial and torsional loading. However, considering the diameters were comparable in size, we believe this effect was minimal. Further, although two types of locking screws were employed in this study (with and without a threaded head), the screws were seated rigidly in the respective bony cortices, and load was effectively transferred through the nails in the experiments described herein. Thus, differences in locking-screw effects were considered minimal with respect to differences in structural properties of the nails. Finally, an inherent limitation of biomechanical studies is their inability to accurately reproduce both the internal and external loading environment of the tibia. Although this model did not take into account the actual muscle forces acting in the tibial diaphysis, we feel that it was appropriate for comparing the relative stability and stiffness of the two construct groups.

In conclusion, our biomechanical data demonstrated that the SIGN tibial nail, despite its smaller diameter, can provide similar construct stiffness and stability, when compared to a larger hollow nail for stabilisation of comminuted tibial shaft fractures. Additional research may be needed to further investigate the clinical relevance of the biomechanical differences found in this study. Nevertheless, the SIGN nail continues to be successfully used in developing countries as a low-cost option and alternative to standard hollow IMNs for tibial shaft fractures.

Conflict of interest

The authors did not receive any outside funding or grants in support of their research for or preparation of this work. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity.

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References