

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

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## ABSTRACT

**Objective:** In developing countries, tibial shaft fractures are frequently stabilised using Surgical Implant Generation Network (SIGN) nails. Despite widespread use throughout the world, little is known regarding their biomechanical properties. This study aimed to compare the mechanical stiffness of the SIGN tibial nail with a standard hollow tibial nail.

**Methods:** A fracture gap model was created to simulate a comminuted mid-shaft tibia fracture (AO/OTA42–C3) using synthetic composite bones. The constructs were stabilised with either a 9 mm solid SIGN nail or a 10 mm hollow Russell–Taylor nail. Both nail systems were interlocked proximally and distally. Following fixation, the specimens were loaded in axial, torsional, and cyclical axial modes to calculate construct stiffness and irreversible (plastic) deformation.

**Results:** The mean axial stiffness for the SIGN nail constructs was 47% higher than mean stiffness for the RT nail constructs ( $p < 0.001$ ). The difference in torsional stiffness was not statistically significant. However, the SIGN group demonstrated 159% more irreversible deformation than the Russell–Taylor group ( $p = 0.006$ ) for the loading parameters studied.

**Conclusion:** The SIGN tibial nail, despite its slightly smaller diameter, can provide similar construct stiffness and stability, when compared to a larger hollow nail for stabilisation of tibial shaft fractures.

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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.<sup>21</sup> 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.<sup>1,2,4,10,12,14</sup> 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.<sup>3,18</sup> More recent series have demonstrated union rates of ~90% for tibia fractures treated with SIGN nails,<sup>13,19</sup> similar to union rates reported for reamed hollow nails.<sup>6,8,15,16</sup>

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 and cyclic deformation of the SIGN tibial nail with a standard hollow tibial IMN system. Studies were conducted using synthetic composite bones and a tibial fracture model system under a variety of compressive and torsional loading regimes.

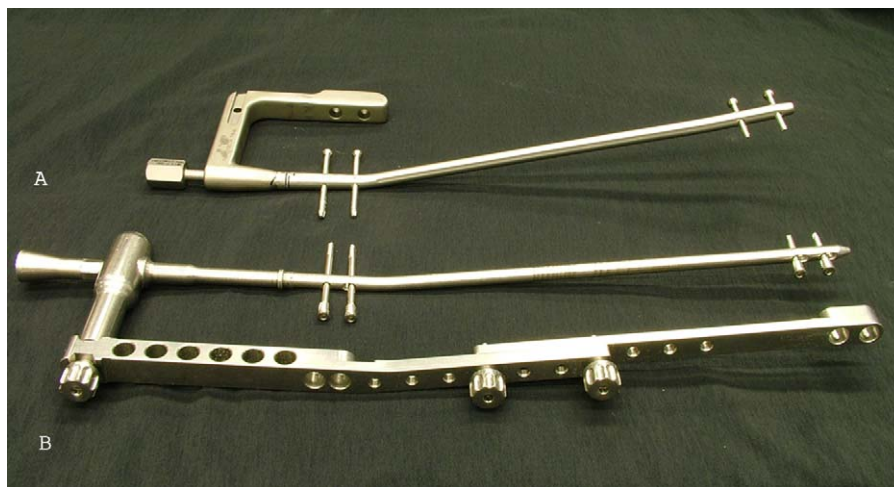
## Materials and methods

### 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

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

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.<sup>7,9</sup> A  $3\text{ cm}$  gap was created  $18.5\text{ cm}$  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  $9\text{ mm} \times 345\text{ mm}$ , while the RT nail was a hollow titanium nail measuring  $10\text{ mm} \times 345\text{ mm}$  (Fig. 1). Both systems had proximal and distal interlocking capabilities via  $4.5\text{ mm}$  cortical screws. The SIGN interlocks had threaded heads.

After reaming the medullary canal  $1.5\text{ mm}$  over the respective nail diameter, nails were inserted according to standard tibial IMN techniques.<sup>20</sup> 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.<sup>5</sup> 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).

Mechanical testing was conducted in axial and torsional loading, two biomechanical critical loading modes acting on the tibia during normal physiological activities, in addition to axial cyclic loading. Significantly, torsion and axial loading were accomplished first within the linear elastic regime to ultimately compute stiffness values, and then subsequently in cyclic axial loading. The order of testing for torsion and axial loading within the elastic regime for each specimen was determined randomly to preclude any unforeseen testing-order bias.



**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.

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