INTRODUCTION:

The orthopaedic community has become increasingly cognizant of the disparity that exists in healthcare throughout the developing world(1). Annually, there are nearly five million deaths worldwide due to traumatic injuries, a number approximating that of HIV/AIDS, malaria and tuberculosis combined(2). Motor vehicle trauma accounts for a large proportion of these deaths, and for every death there are many more left permanently disabled. In developing nations, significant rural-to-urban population shifts and industrialization are causing significant increases in the number of industrial and motor vehicle accidents. These trends are expected not only to continue but to accelerate substantially.

Of all long bone fractures sustained during accidents tibial fractures are the most common(3). In developing countries the optimum treatment method for complex fractures of the tibia remains controversial. Options for stabilization include cast immobilization, external fixation, open reduction and plate fixation, and intramedullary (IM) nailing. IM devices have become the most popular implant choice in developed nations(4). However, the significant costs and the equipment required to place IM nails have made their use challenging in the developing world.

In 1999, the Surgical Implant Generation Network (SIGN) of Richland, Washington, was created as a non-profit humanitarian organization aiming to provide quality orthopaedic equipment and care at little or no cost to developing nations in need. To date, more than 36,000 patients have been treated with the SIGN IM femoral or tibial nail(2). The SIGN tibial system is a solid IM nail with interlocking capability. Proximal and distal interlocks are placed using a mechanical aiming device thereby eliminating the need for costly, cumbersome and largely unavailable C-arm systems.

A recent series published by Shah et al demonstrated a 90% union rate in open tibial fractures treated with the SIGN system(4). To our knowledge, no previous study has evaluated the mechanical properties of the SIGN tibial nail system. The purpose of this study was, therefore, to elucidate the mechanical properties of this solid nail and compare them with those of a commonly used North American hollow nail.

MATERIALS AND METHODS:

A fracture gap model, 3cm wide and 18.5 cm proximal to the plafond, was created using tibial synthetic composite bones to simulate a comminuted mid-shaft tibia fracture (AO/OTA42-A3). Unreamed fracture fixation was achieved using either a 9mm x 340mm solid SIGN 661 tibial nail or a 10 mm x 34.5 mm Russel-Taylor tibial nail with two proximal and distal interlocks, respectively. Mechanical testing was performed using a materials testing machine (Instron 5800 R, Canton, MA) with main outcome measures being stiffness in axial and torsional loading, as well as total and irreversible (plastic) deformation in cyclical axial loading. Testing was stopped after either a visual loss of fixation or a sudden change in construct stiffness, as reflected by the load-displacement curve.

For torsional loading tests the constructs were preloaded to 5 Nm and then torqued to a maximum of 20 Nm at a rate of 20 degrees/min. Axial loading was assessed by loading the construct in compression at a loading rate of 100 N/s. After stabilizing the construct with a preload of 100 N, axial loading was performed to a maximum load of 500 N. Cyclical axial loading consisted of 10 incremental 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 seconds of rest between each increment. The preload and baseline load after each cycle was 100 N. Testing was conducted at a loading rate of 100 N/s. For axial and torsional testing, a load-displacement curve was plotted for each construct and the stiffness was calculated as the slope of the initial region of the curve. Plastic deformation was calculated by subtracting the amount of displacement present at the start of the first cyclical axial cycle (500 N) from displacement present after the final cycle. Total deformation was recorded after the last testing cycle. A one-way analysis of variance (ANOVA) was performed to determine statistically significant differences in axial and torsional stiffness and plastic deformation between each group. The level of significance was defined as P<0.05.

RESULTS:

Mechanical testing was successfully performed on 10 SIGN nail models and on 10 Russel-Taylor (RT) constructs. All tests were run to completion and no catastrophic hardware failures occurred.

The torsional stiffness test revealed no statistically significant difference between the SIGN nail and the RT nail. The mean torsional stiffness of the SIGN nail was 1.125 ± 0.057 Nm/degree, while mean torsional stiffness for the RT nail was 1.242 ± 0.079 Nm/degree (p=0.223).

Under axial loading the SIGN nail showed significantly more stiffness than the RT nail. The mean axial stiffness for the SIGN construct was 1897.29 ± 103.98 N/mm, whereas the mean axial stiffness for the RT construct was 1290.78 ± 90.43 N/mm (p=0.001).

Cyclic loading protocols revealed that plastic deformity was significantly greater in the SIGN nail than in the RT nail. Plastic deformity was -1.627 ± 0.31mm for the SIGN construct and -0.633 ± 0.056mm for the RT construct (p=0.006). However, total deformity for the two nails was not significantly different. Total deformity for the SIGN nail was -3.14 ± 0.322mm and for the RT nail it was 2.577 ± 0.094mm (p=0.108).

DISCUSSION:

In the developed world, IM fixation has become somewhat of a gold standard for treatment of both open and closed fractures of the tibial shaft. A recent study by Bhandari et al. surveyed more than 400 North American and international orthopaedic surgeons. They found that over 95% preferred to use IMN for treatment of both high energy and low energy tibial shaft fractures(5).

The SIGN nail provides the developing world with access to IM technology at little or no cost. The efficacy of this construct in vivo has already been confirmed(6). Our study further elucidates the exact mechanical properties of this solid nail. In direct comparison to a standard hollow nail we have shown that the SIGN nail is stiffer under axial loading. This result is not surprising given the solid nature of this device. However, this axial stiffness does not appear to correlate with deformation under cyclical loading. Despite its solid nature, the SIGN nail exhibits significantly more plastic deformity than its hollow counterpart. Interestingly, total deformity for the two nails was not significantly different and neither construct experienced any catastrophic failures.

Although some statistically significant differences exist between the SIGN nail and the RT nail, the SIGN construct appears to have the biomechanical potential for strength and longevity. As developing economies grow and expand, the incidence of traumatic injuries will continue to rise. The availability and efficacy of the SIGN nail will allow surgeons in the developing world to provide gold standard care to their trauma patients.

REFERENCES:


