Original Article

Are Stainless Steel Elastic Nails the Solution to Heavier Children with Femoral Shaft Fractures?

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Abstract

Background: The use of titanium elastic intramedullary nails for the treatment of femoral shaft fractures, in children weighing ≥45 kg, has been questioned due to the increased rates of malunion. Our aim was to see if the mechanical properties of stainless steel elastic nails provided enough fracture stability to justify their use in heavier children. **Materials and Methods:** Twenty pediatric femoral Sawbones®, fixed with titanium or stainless steel elastic nails, were tested. The bending stiffness and moments of the constructs were calculated at increasing loads, along with the angle of fracture deformation. From these estimates of maximum permitted body weight for each nail type were extrapolated. **Results:** Steel nails created significantly stiffer constructs than titanium in both the coronal and sagittal planes ($P < 0.0001$). Steel nails allowed bigger sagittal bending moments before losing acceptable alignment, compared to titanium ($P < 0.0001$). However, in the coronal plane, the difference was not statistically significant ($P = 0.457$). The estimated body weights extrapolated in the sagittal plane were 45 and 61 kg, in titanium and steel, respectively. In the coronal plane, they were 42 and 44 kg. **Discussion:** As steel has nearly twice the Young's modulus of titanium, it seems logical that fractures fixed with steel nails would be stiffer and fail at higher loads. However, it is unclear why steel did not outperform titanium in the coronal plane. A theory was proposed that unequal nail slip from the insertion sites might be a contributing factor to these findings. **Conclusion:** Pediatric femoral shaft fractures fixed with elastic steel nails provide significantly stiffer constructs than those fixed with titanium. However, there is an increased risk of malunion in the coronal plane, in children weighing ≥45 kg, regardless of material used, possibly due to unequal nail slip at the distal entry points.

Keywords: Biomechanical study, elastic nailing, pediatric femoral fractures

Introduction

Femoral shaft fractures account for 1.6% of all pediatric fractures.[1] In children <5, traction, spica casting, bracing, or combinations of these techniques have become the most established forms of treatment.[2] In older children, nonoperative treatment methods have been shown to give unacceptable rates of malunion, and longer inpatient stays.[3,4] In 1988, Ligier *et al*. showed that elastic nails could provide sufficient intramedullary splintage to resist fracture displacement, without compromising femoral head or physeal biology.[5-7] Elastic stable intramedullary nailing (ESIN) is now the most common form of the treatment of diaphyseal femoral fractures in children with open physes.[8,9]

Currently, titanium alloy nails are the most widely used in the UK, but they have shown unacceptable rates of malunion in children weighing over 45 kg.[8,10] As childhood obesity rates in the UK continue to rise,[11,12] the greater Young's modulus of stainless steel may provide a better alternative in heavier children.[7]

In this study, titanium and steel nails were compared, through a biomechanical saw bone model, to see if one nail material was superior at resisting bending forces. The data was then used to give an estimate of maximum permitted body weight, in transverse femoral fractures, for each nail material.

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Materials and Methods

Bone-nail construct setup

Twenty pediatric femoral Sawbones® (Vashon Island, WA, USA) were tested; 10 using stainless steel nails (medical grade 1.4441-316 LVM); 10 using titanium alloy nails (medical grade Ti-6Al-4V-ELI). Each had a translucent hard outer plastic cortex with a 9.0 mm medullary canal and synthetic trabecular bone filling the proximal and distal thirds. All implants were T2 kids system Stryker® (Kalamazoo, MI) 3.5 mm × 450 mm flexible nails.

Nails were prebent, using a template to ensure equal nail curvature, then inserted in a retrograde manner. The proximal tip of the medial and lateral nails lay in the femoral neck, and greater trochanter, respectively. The apex of each nail lay at the fracture site.

Transverse fractures were made 170 mm proximal to the center of the intercondylar notch.

The bone was placed in a four-point bending jig, with the bottom rollers 100 mm from the intercondylar notch and greater trochanter tip, and the top rollers 25 mm either side of the fracture. Aluminum squares, glued onto the bones at the roller sites, were used during coronal bending to prevent the bone rotating. These were not used in the sagittal tests as rotation was not an issue due to the saw bone anatomy.

The jig was placed into a Zwick/Roell (Ulm, Germany) Z050 compression machine linked to a computer. The top roller base plate was attached to the compression machine's load cell, while the bottom rollers base unit was fixed to the machine's base. The compression machine was used to apply a downward vertical force.

The bones were positioned so that for sagittal bending tests, an anteroposterior force was applied. For coronal bending tests, a mediolateral force was applied [Figure 1].

Testing

The aim of each test was as follows:

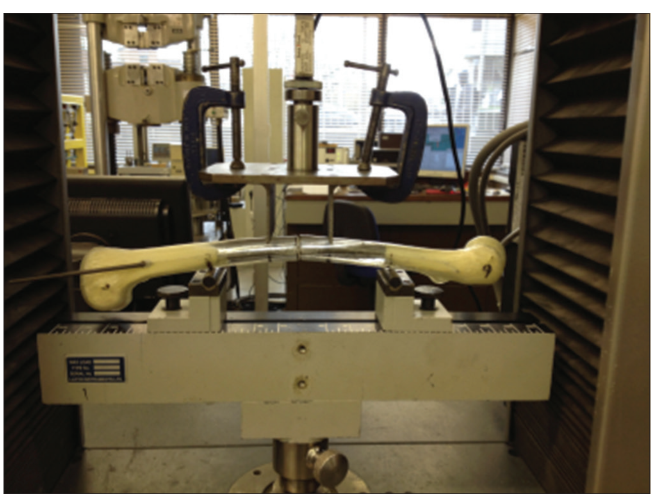

Figure 1: Loaded femur stabilized with titanium nails

1. To establish the angle of deformation of the bone-nail construct at a given applied load
2. To calculate the residual plastic deformation once the load has been removed
3. To calculate the bending stiffness of the construct.

Deformation of the femur beyond 15°–20° in the sagittal plane and 10° in the coronal plane, at the point of fracture union, is considered a poor outcome.[10,13,14] We measured the bending moment (BM) the bone-nail construct plastically deformed beyond 10° and 15° in the coronal and sagittal planes, respectively. Estimates of the maximum body mass permitted for that nail material can then be extrapolated using the BMs measured.[10]

Testing sequence

The bone was first preloaded to 10 N to secure the bone in the jig. Then, for each bone-nail construct, the distance between the load cell and the machine base was recorded. A set load was then applied, and the downward displacement of the load cell was calculated. As the load cell was fixed to the top rollers, the displacement of the load cell equaled that of the rollers [X_1 – Figure 2]. As the distance between the top and bottom rollers was fixed (Y = 50 mm) the θ_1 angle could be calculated using the equation: $\theta_1 = Y/X_1 \sin^{-1}$, where $2\,\theta_1$ = the deformation angle on loading.

The residual displacement was then calculated once the jig was returned to preload levels [X_2 – Figure 3]. The angle of plastic deformation could subsequently be calculated: $\theta_2 = Y/X_2 \sin^{-1}$, where $2\,\theta_2$ = the deformation angle after unloading.

The construct was initially loaded to 20 N and then increased, in 20 N increments, for each loading-unloading cycle until the angle of plastic deformation (θ_2) was equal to the angle of malunion (10° and 15° in the coronal and sagittal planes, respectively).

Calculating bending moments

As the load cell is fixed centrally between the top rollers, we know for applied load *n* (in *N*), each roller exerts *n*/2. Thus, the BM at the fracture site was calculated using the following formula: BM = 50 *n*/2 (N/mm).

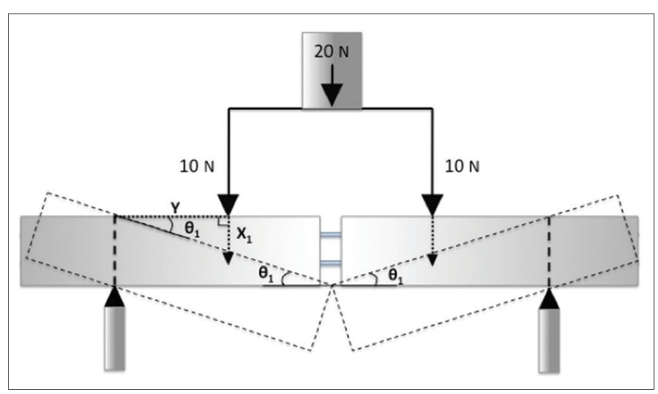

Figure 2: Schematic diagram demonstrating how θ_1 and X_1 were calculated

Estimating maximum body mass

A previous study by Li *et al*. correlated femoral BMs, in sawbones fixed with titanium nails, with estimated body mass. Using Li's calculations, sagittal and coronal BMs at malunion (BM, in N/m) were used to estimate maximum permitted body mass (M, in kg). These were calculated using the formula, M = BM/(32 × g) in the sagittal plane, and M = BM/(35 × g) in the coronal plane (g = gravity, 9.81 ms^{-2}).

Calculating bending stiffness

Using the following equation, the bending stiffness (K, in N/mm) of the construct at the fracture site was calculated: $K = n/(Y_2 \times \sin\theta_1)$.

Statistical analysis

Mean and standard deviation (SD) values were calculated for BMs at malunion, estimated body mass at malunion and bending stiffness. Using these data unpaired *t*-tests were carried out to compare to the two materials, using GraphPad QuickCalcs (Graphpad ®, San Diego, CA, US). $P < 0.05$ was deemed statistically significant.

Results

The mean sagittal BM resulting in plastic deformation >15° in the titanium model was 14.2 Nm (SD = 1.26 Nm). This correlated to an estimated body mass of 45.2 kg at malunion. In the stainless steel model, the mean sagittal BM, at 15° plastic deformation, was 19.1 Nm (SD = 0.82 Nm). Giving an estimated body mass of 60.8 kg, this meant the stainless steel model was significantly more resistant to BM s, compared with titanium, in the sagittal plane ($P < 0.0001$, 95% confidence interval [CI] −6.45 to −3.35).

In the coronal plane, the mean BMs leading to plastic deformation greater than 10° was 14.3 Nm (SD = 1.03 Nm) and 15.1 Nm (SD = 2.04 Nm), for titanium and steel, respectively. These results correlated to estimate maximum body masses of 41.7 and 44.0 kg, for titanium and steel, respectively, which were not statistically significant ($P = 0.457$, CI −3.16 to 1.56) [Figure 4].

In both the sagittal and coronal plane stainless, steel was significantly stiffer. Mean sagittal plane bending stiffness was 21.1 and 29.9 N/mm in titanium and steel, respectively ($P < 0.0001$, CI 7.5 to 10.1). Mean coronal plane bending stiffness was 26.1 and 32.6 N/mm, in titanium and steel, respectively ($P < 0.0001$, CI 5.1 to 7.9). Figures 5 and 6 demonstrate load-displacement curves for constructs using both materials in the sagittal and coronal planes. Results are summarized in Table 1.

Discussion

Titanium was the material of choice in the early studies of ESIN as steel was thought to be too stiff, running the risk of straightening out the normal curvatures seen in pediatric bone.[5] However, more recent clinical studies have shown steel may not only be as good as titanium in maintaining fracture alignment,[15] but even superior.[15] Lohiya found no statistical difference in malunion between children treated with steel and titanium nails.[13] Wall found patients treated with titanium were nearly four times more likely to heal with malunion.[13] Reporting on ESIN, Hunter suggested the greater Young's modulus of steel nails might be useful in older and obese children, who are at greater risk of malunion.[7] This study sought to calculate the BMs at which steel and titanium nails would plastically deform to unacceptable levels, and from this

Table 1: Demonstrating means±standard deviations of bending moments at malunion, estimated body mass and bending stiffness in both groups, during sagittal and coronal testing

	Titanium	Stainless steel	*P*
Sagittal testing			
Bending moment at malunion (Nm)	14.2±1.2	19.1±0.8	<0.0001
Estimated body mass at malunion (kg)	45.2±4.0	60.8±2.6	<0.0001
Bending stiffness (N/mm)	21.1±3.7	29.9±1.7	<0.0001
Coronal testing			
Bending moment at malunion (Nm)	14.3±1.0	15.1±2.0	0.457
Estimated body mass at malunion (kg)	41.7±3.0	44.0±6.0	0.457
Bending stiffness (N/mm)	26.1±2.2	32.6±3.4	<0.0001

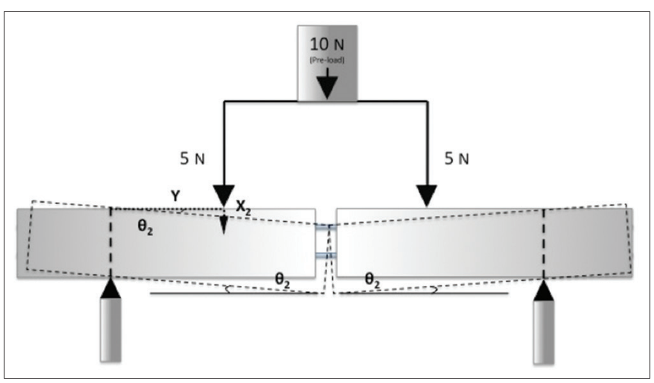

Figure 3: Schematic diagram demonstrating how θ_2 and X_2 were calculated

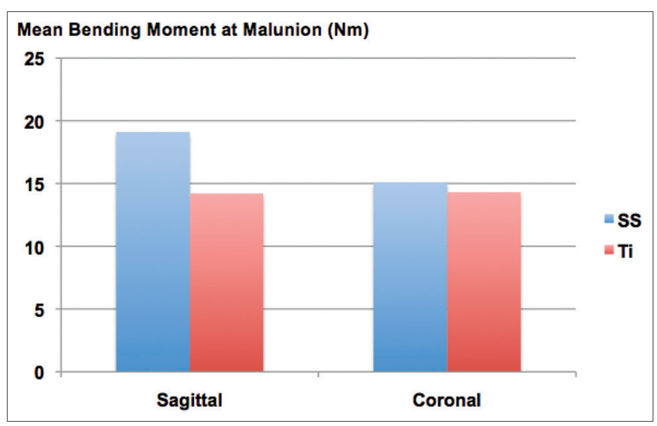

Figure 4: Chart showing the mean bending moment at malunion for titanium and steel models, in both sagittal and coronal planes

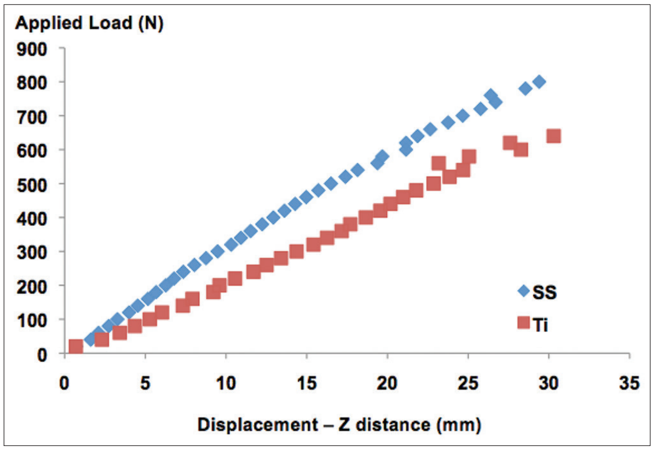

Figure 5: Scatter plot showing the relationship between load and displacement for both stainless steel and titanium bone nail constructs, in the sagittal plane

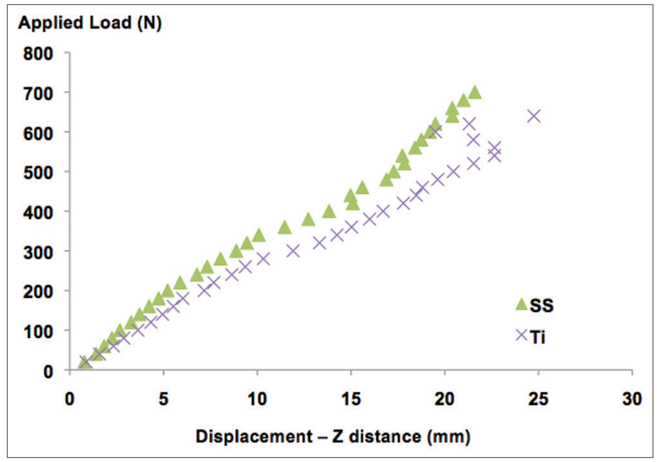

Figure 6: Scatter plot showing the relationship between load and displacement for both stainless steel and titanium bone-nail constructs, in the coronal plane

extrapolate an estimate of maximum body weight permitted for each nail material, testing Hunter's hypothesis.

Duda developed an analytical model estimating the BMs across the femur during normal gait.[16] Their model calculated femoral BMs as a ratio of body weight. Li later used this data to convert BMs, calculated from a four-point bending model, into estimates of body weight. They calculated from this that femoral fractures, fixed using titanium nails, were likely to lose acceptable alignment, in children weighing over 45 kg which correlated closely with a clinical studies,[8,10] suggesting a biomechanical model using pure BMs can give clinically relevant estimates of the maximum permitted body weight. In this study, mean sagittal and coronal BMs causing significant plastic deformation in the titanium group were 14.2 and 14.3 Nm, respectively. These were converted into estimated body weights at malunion of 45 and 42 kg, correlating closely with previous studies. This supports evidence that titanium nails are not suitable for use in femoral shaft fractures in children weighing over 45 kg and gives credence as to the efficacy of the biomechanical model used in this study.

Does stainless steel provide a useful alternative in heavier children?

With rising childhood obesity rates across the UK,[12] the problem of femoral shaft fractures in children weighing over 45 kg, with open physes, is likely to become an increasing issue.

In this study, the bending stiffness of bones fixed with steel nails was significantly greater than in those fixed with titanium, in both the coronal and sagittal planes. These data are supported by a study carried out by Kaiser, which showed spiral femoral fractures fixed with steel nails were significantly stiffer, than those fixed with titanium, in four-point bending, torsional and axial compression tests.[17] Considering the material properties of medical grade stainless steel and titanium alloys, these findings should not be surprising.[18] Stainless steel has nearly twice the Young's modulus of titanium. However, Mahar *et al*. compared axial compression and torsional stiffness of femoral saw bone fractures, fixed with titanium and steel nails,[19] finding paradoxically that titanium nails created significantly stiffer constructs. They suggested the lower Young's modulus of titanium allowed greater nail deformation in the canal, leading to a larger area of nail contact, and therefore increased frictional forces across the fracture.[19] Later, Perez confirmed greater nail contact area in titanium nails, using finite element analysis.[20] However, as the laws of dry friction show that frictional force is independent of the contact area between two sliding objects, we can confidently state that the increased contact area seen in titanium nails will not increase the frictional forces between the nail and bone. In addition, the fracture stability, created by ESIN, is not dependent on frictional forces. Instead, the fracture is stabilized due to the equal and opposite BMs of both nails.[21]

In both, the aforementioned studies axial fracture gap closure was used to calculate construct stiffness. However, ESIN was initially designed to allow some movement in the axial direction, promoting bridging callus, while preventing coronal and sagittal movements.[21] In our study, bending stiffness was used to judge fracture stability, as greater movement in a direction perpendicular to the femoral axis is more likely to lead to malunion, resulting in a clinically poor outcome.

What is the maximum permitted patient body mass, in children treated with stainless steel nails?

Increasing body mass causes greater axial load through the femoral head, which in turn creates greater BMs across the femur. These can lead to implant failure, through plastic deformation of the nails within the canal correlating with higher rates of malunion.[8]

Currently, the suggested maximum patient body mass for femoral shaft fractures treated with titanium nails is 45–49 kg.[8,10] However, to the best of our knowledge, there is no current advised maximum patient body mass for children treated with steel nails.

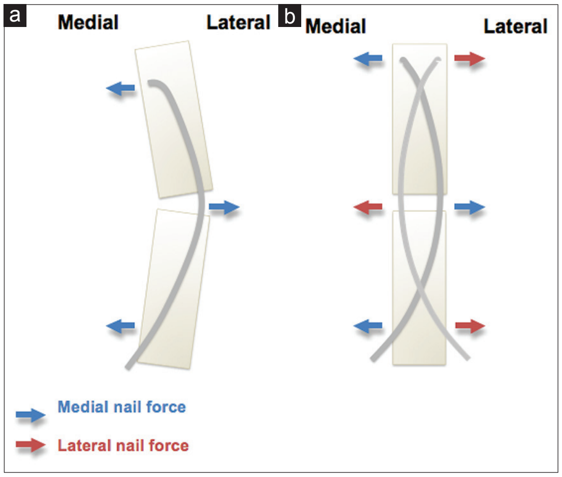

Figure 7: Schematic diagram showing how nail slip can result in reduced curve height and therefore reduced intramedullary bending moments: a. shows an unbalanced single nail construct; b. shows a balanced two nail (double 3-point bending) construct

In this study, the mean sagittal BM causing unacceptable plastic deformation in the steel group was 19.1 Nm. This correlated with a body mass of 60.8 kg, significantly greater than the 45 kg permitted by the titanium group ($P < 0.0001$). However, such a difference was not seen in the coronal plane tests where the mean BM causing unacceptable plastic deformity was 15.1 Nm in steel nails, correlating with a body mass of 44 kg, just 2 kg greater than that seen in titanium nails ($P = 0.457$). More detailed analysis showed some bone-nail constructs using steel well outperformed those fixed with titanium. For example, the maximum coronal BMs achieved at malunion were 18.5 and 16 Nm, in the steel and titanium groups, respectively. However, in the steel group, the spread of results, in the coronal plane, was much greater (SD steel = 2.04; SD titanium = 1.25), and the lowest recorded coronal BM causing malunion was found (13 Nm). One potential explanation could be the effect of entry point nail slip. Perez showed that steel nails were more likely to slip out of the distal entry points during loading.[20] As more nail slips out of the bone, the potential height of the nail curve decreases, therefore decreasing the BM caused by the elastic propensity of the nail [Figure 7]. If both nails encounter an equal amount of slip, the BMs created by each nail remain equal, and the construct remains balanced. However, if one nail slips more than its counterpart, the BM in that nail would be comparatively reduced, creating an unbalanced construct, and therefore, loss of reduction [Figure 8].

As each nail is inserted parallel to the coronal plane, there is potential that during coronal bending, the laterally nail disproportionately slips. Once the force is released, the deformity remains, not due to plastic deformation of the nails, but due to the disproportionately higher BM now produced by the medial nail. Although it is likely that nail slip occurs during the sagittal tests, the sagittal BM is in a plane perpendicular to the curves of both nails, resulting in equal amounts of slip, maintaining a balanced construct. In this study, nail slip was not measured, but this hypothesis could form the basis of further research.

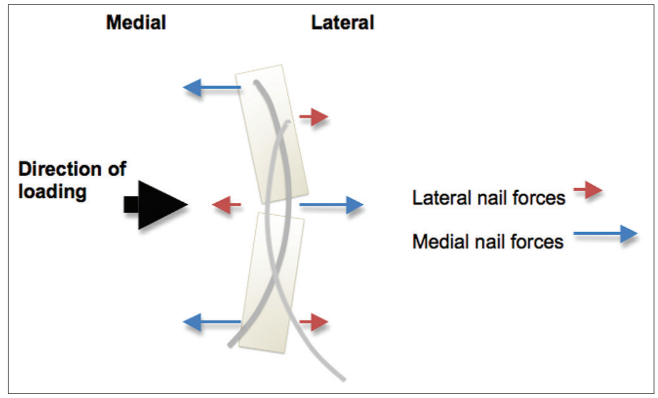

Figure 8: Schematic diagram showing the bending moment mismatch that may occur following nail slip

Conclusion

This study suggests that pediatric femoral shaft fractures fixed with elastic steel nails provide significantly stiffer constructs than those fixed with titanium. However, there is an increased risk of malunion in the coronal plane, in children weighing ≥45 kg, regardless of whether titanium or steel nails are used, possibly due to unequal nail slip at the distal entry points.

Financial support and sponsorship

Nil.

Conflicts of interest

Though I received no funding for this project I would like to state Stryker (US) provided ESIN kit, nails and the sawbones free of charge. However they had no other role including no role in study design or submission for publication.

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