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Citation

Abstract
Purpose Titanium elastic nails are widely used in the treatment of femoral shaft fractures in children. The standard technique employs the retrograde insertion of two curved nails, with the apex of the curve at the fracture site. This study examines the biomechanical stability of this configuration of titanium elastic nails in segmental femoral fractures, an injury which is often high-energy and therefore inherently unstable. The stability of a new nailing technique is also tested, using an additional third nail inserted antegrade. Methods A model of a segmental femoral fracture was created in four synthetic femora. Two were fixed with the standard two retrograde nails and two with the third antegrade nail. A fifth was used as a control. Each was tested with axial, torsional and bending loads and the deflection measured. Result Minimal deviation of the models occurred under physiological loads in all forms of loading. There was statistically significant increased torsional and bending stiffness using the three-nail technique compared with the standard two-nail technique. Conclusion Titanium elastic nails in the standard two-nail retrograde system can provide a stable mechanical construct for the fixation of segmental femoral fracture. The use of a third nail inserted antegrade increased the stability in bending and torsion, however theoretically it carries a potential risk of splitting the femoral canal and creating subtrochantric fracture especially if the canal fill exceeds 80%. Accordingly we do not recommend the use of the three-nail system described in this study as a routine choice. Clinically Titanium elastic nail provide sufficient stability to avoid prolonged period in traction. Post-operative bed rest might be recommended to allow the development of early callus formation that further increase the stability of the fracture and allow weight bearing.

INTRODUCTION
The incidence of femoral fractures in children is 20 in 100,000 in the United States and Europe (Poolman et al 2006) [11]. Sixty-eight percent occurred in children of 6-18 years of age and sixty-five percent of these fractures involved the femoral shaft (Loder et al 2006) [6]. Titanium elastic nails (TENs) are the treatment of choice for skeletally immature children older than 6 years with a transverse fracture in the middle 60% of the femoral shaft (Sander et al 2001) [12]. This form of fixation works as an internal splint that maintains alignment and length, whilst allowing micro-movement at the fracture site to occur, encouraging callus formation (Ligier et al 1988) [5].

The principle requires two curved titanium nails to be inserted retrograde bilaterally. The nails are pre-curved so that the height of the curve is three times greater than the diameter of the medullary canal (Mazda et al 1997) [9]. Each nail provides three-point fixation: the nail entry point, the apex of the curve, and the tip of the nail, where it is embedded into the cancellous bone. Stability is ensured by the bone, through cortical end-to-end reduction, and by the surrounding soft tissue.

Recent biomechanical studies have tested the stability of a variety of alternative nail configurations in differing fracture types (Table 1). None have examined the stability of TEN’s when used in segmental fractures. This type of injury is often high-energy and therefore inherently unstable due to fracture pattern and associated soft tissue stripping (Winquist & Hansen 1978) [14]. Their nature offers further challenges due to the difficulty, if not impossibility, of placing the apex of the nail’s curve at the fracture site. Therefore, the purpose of this study was to assess the stability of TEN’s in the fixation of oblique segmental femoral fractures, using both the standard technique described above and an as yet untested nail combination that employs a third nail inserted antegrade in addition to the two retrograde nails.

Figure 1

Table 1: A comparison between this study and recently published papers on the biomechanical stability of TENs in paediatric femoral fractures

<table>
<thead>
<tr>
<th>Author</th>
<th>Biomechanical Tests</th>
<th>Sample Size</th>
<th>Bone Model</th>
<th>Nail Diameter</th>
<th>Fracture Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flick et al [1]</td>
<td>Axial Tension</td>
<td>10 femora (5 each group)</td>
<td>Synthetic bone (Sawbone®)</td>
<td>3.5mm</td>
<td>Transverse Comminuted</td>
</tr>
<tr>
<td>Gryn et al [2]</td>
<td>Tension</td>
<td>20 femora (5 each group)</td>
<td>Synthetic bone (Sawbone®)</td>
<td>4.0mm</td>
<td>Transverse Comminuted, Oblique Butterfly Spiral</td>
</tr>
<tr>
<td>Mahler et al [3]</td>
<td>Bending Tension</td>
<td>10 femora (5 each group)</td>
<td>Synthetic bone (Sawbone®)</td>
<td>3.5mm</td>
<td>Transverse Comminuted</td>
</tr>
<tr>
<td>Keely [4]</td>
<td>Bending Tension</td>
<td>3 femora (1 for each TEN configuration)</td>
<td>Machined tube made of Tufnol®</td>
<td>3.0mm</td>
<td>Transverse</td>
</tr>
<tr>
<td>Abolalek et al [5]</td>
<td>Axial Bending Tension</td>
<td>5 femora (2 in each group + 1 control)</td>
<td>Synthetic bone (Sawbone®)</td>
<td>4.0mm</td>
<td>Segmental</td>
</tr>
</tbody>
</table>

MATERIALS AND METHODS

TYPE OF NAIL

This study used Titanium Elastic Nails (Synthes Inc., Paoli, PA, USA). These are flexible titanium alloy nails. The nails used measured 4.0 mm in diameter by 440 mm in length. Synthes’ literature does not recommend the use of their elastic nails in unstable fractures such as long, oblique spiral fractures and multifragmentary fractures (Synthes® Website) [13].

BONE MODEL

The models were produced using third generation Sawbone® femora (Pacific Research Labs Inc., Vashon Island, WA). Studies on such composite bones have shown biomechanical similarity to cadaveric human bone (Heiner & Brown 2001) [3]. The length of the femur is 380 mm with a 12 mm canal diameter, which corresponds to the upper range of our target population. The segmental fracture pattern was created by using a power saw to cut two fracture lines at 45° from the longitudinal axis of the femur, both in the same plane. The fracture lines divided the shaft into three equal segments. Four femora were divided into two groups, each containing two femora. One group received two nails and the other received three nails. One femur was left intact as a control.

The insertion technique for the retrograde nails involved an entry point approximately 2 cm proximal to the growth plate bilaterally, as would be the case in vivo. A 4.5 mm drill bit was used at 45° to the axis of the shaft toward the medullary canal. The elastic nails were pre-contoured to three times the diameter of the medullary canal. The apex of the bend was at the level of the centre of the middle segment. The nail tips sat at the level of the greater trochanter laterally and at the midpoint of the femoral neck medially.

One group of femora then received an additional nail inserted antegrade. The entry point for this was at the tip of the greater trochanter. Again a 4.5 mm drill bit was used at 45° but the nail was inserted without pre-bending. The antegrade nail was advanced until it reached the distal crossing point of the retrograde nails. Final position of the nails was verified with radiographs (Fig. 1).

MECHANICAL TESTING

Biomechanical tests were conducted in the Centre for Orthopaedic Biomechanics at the University of Bath in the UK. Each model was tested in bending (antero-posterior [AP], medio-lateral [ML] and latero-medial [LM]), torsion (internal rotation [IR] and external rotation [ER]) and axial loading. Results were recorded in terms of deflection (mm) against load (N). Each test was repeated five times, allowing the bone model to rest between tests.

Axial loading was carried out using Instron® 4301 and 4303 tensile and compression testing machine (Instron, High Wycombe, Bucks, United Kingdom). All samples were loaded to 500 N. In order to examine the effect that the middle femoral segment had on the stability of the construct, one femur in each group was chosen to have its middle segment removed to mimic a highly comminuted fracture. The model was then subjected to repeated axial loading. Load against displacement data were obtained in text format.
from the Instron machine, which by using the Instron Software Series 9, was imported to Excel spreadsheets (Microsoft Corporation). One femur from each nail group was then tested to failure. As in previous work (Fricka et al 2004) [1], failure was defined as 5mm shortening.

Bending and torsion tests were performed using a jig specifically designed for each test similar to that in Miles et al study (Miles et al 1994) [10]. In both tests the proximal femur was secured in an aluminum block machined to accommodate the shape of the head and greater trochanter. The gap was filled with Wood’s metal, a low temperature casting alloy, to ensure a secure fixation. In the bending tests, a dial gauge was attached at a standard point (fig. 2a) and load applied by weights on a hanger attached to the distal femur. Deflection in mm was measured against load applied. In the torsion tests, a metal plate was fixed to the femoral condyles (fig. 2b) and secured at the center of rotation with a metal post that allowed rotation but prevented bending. The angle of twist (θ) in degrees was measured and torsional stiffness expressed in Nm/degree. The angle of twist θ was calculated as angle θ = \tan^{-1}(d/A) where d is the vertical deflection, measured at a distance A from the axis of rotation. Stiffness = F.B/θ (Nm/degree).

Both in bending and torsion tests, load were applied manually in five increments to a maximum load of 42 N.

DATA ANALYSIS AND STATISTICAL METHODS

Load against displacement data from the above tests were entered into spreadsheets using Microsoft Excel. From these, a load-displacement graph was produced for each test, as well as obtaining the mean displacement and the standard deviation. The gradient from each graph was calculated using the Excel software. This gradient represented the stiffness in N/mm for bending and axial tests and the torsional stiffness in Nm/degree for the torsion tests. These figures were used to compare stability between models.

Generalising estimating equations (GEE) were used to fit a linear model to the data to examine the relationships between the nail systems and control group. This form of analysis allowed the data to be grouped by sample to take into account the clustering from the five repetitions of each test. For each GEE model, an equal-correlation model was assumed for the within-group correlation and robust standard errors were used. The GEE models were constructed within a standard statistical software package (STATA v8.2, StataCorp LP, College Station, TX, USA). In each case the conventional exchangeable correlation structure was used to adjust for within sample correlation.
Paired t-tests were applied to investigate the differences between samples of the same nail system, and between axial loading of models with and without the middle segment.

**RESULTS AND OBSERVATIONS**

**BENDING**

The 3-nail system had significantly higher bending stiffness compared to the 2-nail system (Table 2): AP bending increases 1.14 N/mm (95% CI 0.69-1.59) (p<0.001); ML bending increases 1.60 N/mm (95% CI 0.73-2.47) (p<0.001); LM bending increases 1.92 N/mm (95% CI 1.17-2.66) (p<0.001).

As would be expected, both the 2-nail and 3-nail systems showed significantly lower bending stiffness compared to the intact sample in AP, ML and LM bending (p<0.001 for all comparisons).

**Figure 4**

Table 2: AP Bending Stiffness Test results (N/mm).

<table>
<thead>
<tr>
<th>Test</th>
<th>Intact Sample</th>
<th>2-nail system</th>
<th>3-nail system</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13.5135</td>
<td>0.38320</td>
<td>0.68125</td>
</tr>
<tr>
<td>2</td>
<td>13.9860</td>
<td>0.42103</td>
<td>0.66283</td>
</tr>
<tr>
<td>3</td>
<td>14.3265</td>
<td>0.55267</td>
<td>0.73209</td>
</tr>
<tr>
<td>4</td>
<td>14.3471</td>
<td>0.48974</td>
<td>0.76952</td>
</tr>
<tr>
<td>5</td>
<td>14.3265</td>
<td>0.35959</td>
<td>0.66283</td>
</tr>
<tr>
<td>Mean</td>
<td>14.1</td>
<td>0.49684</td>
<td>0.83131</td>
</tr>
<tr>
<td>SD</td>
<td>1.32274</td>
<td>0.04286</td>
<td>0.02556</td>
</tr>
</tbody>
</table>

**TORSION**

The 3-nail system (Table 3) had IR torsion stiffness of 0.206 N/degree (95% CI 0.137-0.275) greater than the 2-nail system (p<0.001).

The 3-nail system had an ER torsion stiffness of 0.260 N/degree (95% CI 0.078-0.441) greater than the 2-nail system (p=0.005).

Again, both systems had significantly less stiffness compared to the intact sample in internal and external rotation (p<0.001 for all comparisons).

**Figure 5**

Table 3: Torsional (IR) Stiffness results (N/m/deg.)

<table>
<thead>
<tr>
<th>Test</th>
<th>Intact Sample</th>
<th>2-nail system</th>
<th>3-nail system</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.5463</td>
<td>0.53032</td>
<td>0.39012</td>
</tr>
<tr>
<td>2</td>
<td>2.311248</td>
<td>0.565</td>
<td>0.31308</td>
</tr>
<tr>
<td>3</td>
<td>2.851171</td>
<td>0.06085</td>
<td>0.109</td>
</tr>
<tr>
<td>4</td>
<td>2.777197</td>
<td>0.74659</td>
<td>0.11664</td>
</tr>
<tr>
<td>5</td>
<td>2.830189</td>
<td>0.05474</td>
<td>0.11220</td>
</tr>
<tr>
<td>Mean</td>
<td>2.633252</td>
<td>0.061211</td>
<td>0.11642</td>
</tr>
<tr>
<td>SD</td>
<td>0.245214</td>
<td>0.008907</td>
<td>0.004844</td>
</tr>
</tbody>
</table>

**AXIAL LOADING**

There was no evidence of a statistical difference in the axial stiffness between samples fixed with the 2- and 3-nail systems (p=0.669) (Table 4).

**Figure 6**

Table 4: Axial Stiffness Test results (N/mm)

<table>
<thead>
<tr>
<th>Test</th>
<th>Intact Sample</th>
<th>2-nail system</th>
<th>3-nail system</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1395.3</td>
<td>762.8</td>
<td>1219.6</td>
</tr>
<tr>
<td>2</td>
<td>1500.4</td>
<td>836.9</td>
<td>1316.3</td>
</tr>
<tr>
<td>3</td>
<td>1516.5</td>
<td>852.2</td>
<td>1326.3</td>
</tr>
<tr>
<td>4</td>
<td>1514.7</td>
<td>869.9</td>
<td>1265.3</td>
</tr>
<tr>
<td>5</td>
<td>1487.5</td>
<td>837.4</td>
<td>1204.9</td>
</tr>
</tbody>
</table>

Both the 2-nail and 3-nail systems had significantly lower axial stiffness compared to the intact sample (p=0.002, p<0.001 respectively).

No failure (5 mm shortening) was encountered in any sample, testing up to 500 N of axial compression, representing the full weight of a 49 kg child. In all fractured samples tested with the middle segment present, the maximum shortening was only 1.0 mm at 500 N. In addition, when the middle segment was removed to represent a highly comminuted fracture, the maximum shortening was 2.27 mm when loaded to 500 N.

When testing the models to failure (i.e. a shortening of 5 mm), which only achieved after removal of the middle segment of the shaft from the samples, 760N was required in the 2-nail model and 1164 N for the 3-nail model.

Removing the middle segment of the shaft in 2-nail and 3-nail system shows significant reduction in axial stiffness, for example a paired t-test showed that sample 4 which is a part of the 3-nail system had a 195 N/mm (95% CI 157-233) reduction in axial stiffness after the removal of the middle segment of the femoral shaft (p<0.001). This indicates that the presence of the middle segment played an important part in the axial stability, a factor that might be difficult to replicate in vivo.

There were significant intra-group differences in axial stiffness between models fixed with the same system (Table 4). For the 2-nail system, one femur had a reduced axial stiffness of 420 N/mm (95% CI 338-501) compared to the other (p<0.001). For the 3-nail system, one femur had a reduced axial stiffness compared to the other of 264 N/mm (95% CI 214-315) (p<0.001). The causes of this variation in
shortening are likely two-fold. The first is due to longitudinal closure of the fracture gaps followed by transverse gliding of the segments at the oblique fracture lines as load increases (Fig. 3). Subtle variations in the surface roughness of the fracture line potentially lead to differing engagement of the fracture surfaces and altered resistance to further load. The second is the fact that bending deformity cannot be entirely discounted, especially considering the natural bowing of the femur.

An interesting behaviour was observed during testing to failure of the models after the middle segment was removed. An audible noise was noted that coincided with spikes on the deflection/load graphs. The most plausible explanation was that during axial loading the curvature of the nail increased. This caused greater contact of the nails with the inner cortex, which then seemed to be suddenly reduced due to minute slippage of the nails at the entry points, thus causing further shortening of the sample. This process seemed to repeat itself as indicated by the regular audible noise, which continued until the experiment terminated. This has been named the ‘Pistoning Phenomenon’ by the authors and is detailed in (Figure 4). It should be noted that this effect only occurred at forces above normal physiological load.

DISCUSSION

The ability of TENs to provide stability in oblique segmental fractures was demonstrated by the fact that none of the models failed when axial forces in excess of physiological load were applied. We might argue that the models were inherently stable once reduced as only minute amount of shortening was allowed on axial loading tests. However these models shows satisfactory stability even when the middle segment was removed to resemble a highly comminuted fracture with extensive soft tissue stripping. Much information was learnt about the behaviour of segmental fractures when fixed with TENs, importantly the fact that shortening can occur without nail end protrusion, by transverse sliding of the fragments upon one another (Fig. 3) as well as via increase in the curvature of the nails.

The most commonly reported complication of TENs is skin irritation at the nail entry site (Luhman et al 2003) [7]. This is often due to the surgeon allowing for easy later removal by leaving longer nail ends and bending these ends away from the cortex. This will be worsened by nail end protrusion. The pistoning phenomenon, described for the first time in this study, shows that nail end protrusion does not occur in a continuous motion as axial load is applied, but rather incrementally in a cyclical fashion as explained earlier. In addition, this effect only occurs in the presence of large fracture gaps, which allow the main fragments on either side of the fracture to collapse towards each other. In addition, a greater load is required beyond the normal physiological load to achieve the initiation of pistoning.
Adding a third nail in an antegrade manner has no effect on the behaviour of a model of an oblique segmental femoral fracture subjected to axial load. This fact has been confirmed when the middle segment removed and the 3 nail model subjected to axial loading again. This is due to the fact that the two retrograde nails maintain their curvature and their relationship to each other without interference from the third antegrade nail.

However, the third antegrade nail has a significant effect when the same model is subjected to rotation and bending forces. This is likely to occur because the nail works as a canal-filling agent. Furthermore, the torsional stiffness obtained in this study for the two-nail system compared favourably with a previous study testing TENs in simple oblique femoral fracture (Gwyn et al 2004) [2], providing further weight to the argument of the suitability of this fixation technique in segmental oblique fracture.

There was variation in axial stiffness between models fixed with the same nail system, possibly due to differences in hand bending of the nails and in the surface roughness of the fracture lines created with the saw. A small sample size also limited this study. While axial loading was conducted in a more controlled manner using testing machines, bending and torsion were tested manually. The authors consider the consistency of results achieved upon repeated testing validated the methods used.

We anticipate that inserting a third nail in antegrade direction in vivo as augmentation to the standard 2-nail system will be a difficult task as we found during our tests. There is also the potential risk of bone splitting due to increased hoop stress if the antegrade nail is forced in the femoral canal. What is more there is also the possibility of creating a stress riser at the antegrade nail entry point which might lead to subtrochanteric fracture.

Children with different age will have different femoral canal diameter and only accommodate nail sizes which should represent 40% of their canal diameter according to the elastic nail manufacture manual (Synthes® Website) [13]. The standard 2-nail system should achieve a maximum 80% canal fill. Smaller nail diameter than 4.0 mm used in our study will naturally have less torsional and bending stiffness and might fail to reproduce satisfactory results compared to ours. However (Kiely, 2002) [4] used 3.0 mm nail size in his study and he was able to demonstrate satisfactory bending and torsion stability in his models.

In conclusion, this study suggests that TENs in the standard 2-nail retrograde system offer a valid treatment option for the fixation of segmental oblique fracture of the femur in children, even in cases of severe comminution. Despite the increase in the bending and torsional stiffness by adding a third nail inserted in antegrade manner we do not recommend the use of this technique in vivo due to the potential risk of shaft splitting and subtrochanteric fracture. However should a third nail is used the total canal fill of the 3 nails combined should not exceed 80% or each nail diameter in this situation should represent about 26% of the femoral canal diameter.

In clinical setting it is our practice to avoid early weight bearing following the use of TENs in the treatment of paediatric femoral fracture due to pain and muscle spasm in the immediate period after surgery. We recommend the start of weight bearing to be delayed until the appearance of early callus formation at three to four weeks time following the fixation. This in fact will further support the TENs that function eventually will become redundant once the callus fully consolidate.

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