International Journal of Research in Orthopaedics
Debnath UK et al. Int J Res Orthop. 2016 Dec;2(4):280-285
http://www.ijoro.org

DOI: http://dx.doi.org/10.18203/issn.2455-4510.IntJResOrthop20164001

Original Research Article

Three different interlocking intramedullary nails for unstable reverse oblique inter-trochanteric fractures: a bio-mechanical comparative study

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Received: 04 October 2016
Accepted: 24 October 2016

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ABSTRACT

Background: Biomechanical testing, intramedullary devices have proven advantageous over the extramedullary devices in the management of unstable intertrochanteric fractures. Reverse oblique type of intertrochanteric fractures are highly unstable and intramedullary nails are currently the method of internal fixation. The currently available nails seems to provide rotational, axial and angular stability, but biomechanical analysis of the strain pattern in the bone and implant in this type of fracture is lacking. The aim of this experimental study was to analyse the strain in three different long femoral nail-bone units under physiological loading when implanted in Saw bone model after creating a reverse oblique intertrochanteric fracture.
Methods: A total of 12 sawbones were divided into 4 equal groups. Group 1 was intact saw bones and was used as controls. Group 2, Group 3 and Group 4 were implanted with Depuy, Stryker and Synthes nails respectively after creating a reverse oblique intertrochanteric fracture. All the four groups were axially loaded with 100 N increments until physiological loads. The strain patterns were measured at the posteromedial cortex and the peak strains were extracted at partial weight bearing i.e. 500 N and full weight bearing physiological loads i.e. 1000 N.
Results: There was no significant difference in peak strains among the groups at partial loads. However at 1000 N loads the peak strain in the DePuy nail-bone unit was significantly high compared to the other two nail-bone units and the controls.
Conclusions: These results question the safety of immediate full weight bearing following surgery when treating the reverse oblique unstable fractures with DePuy intramedullary nails. A period of partial weight bearing following fixation of reverse oblique fractures would be wise when using DePuy nails.

Keywords: Unstable intertrochanteric fractures, Reverse oblique fractures, Intramedullary nail, Sawbone model, Peak strain

INTRODUCTION

The incidence of unstable intertrochanteric fractures is increasing and they constitute one fourth of all intertrochanteric fractures in the elderly.[1] Reverse oblique fractures form a distinct variety of unstable fractures. In these fractures, the aim of achieving the functional goals of the patients relies on the fracture reduction and adequacy of the fixation. The choice of implant for this group of fractures has been a topic of debate. Any chosen implant should allow full weight bearing as soon as the fracture is stabilised. This allows a faster patient recovery, rehabilitation and reduces the morbidity and mortality. Intramedullary fixation aims to achieve this goal subject to the influence by other variables such as implant design, fracture reduction, surgical technique etc. Hitherto, on biomechanical testing, intramedullary devices have proven advantageous over the extramedullary devices in the management of these unstable intertrochanteric fractures.[1-3]

Recently, for a reverse oblique intertrochanteric fracture an intramedullary device has become the preferred implant. When implanted in an unstable intertrochanteric fracture an intramedullary nail is close to the centre of axial loading resulting in a short lever arm and a lower bending moment. The fixation failures in the last three decades have led us to appreciate this distinctive reverse oblique fracture configuration. The surgical techniques have been refined and various designs of the intramedullary nails have evolved. The lessons learnt from the older generation nails led the manufacturers to engineer the current generation nails that overcome these problems.

The current-generation femoral intramedullary nails available in the market differ mainly in their proximal morphology and the mode of fixation of the femoral head. PFNA is the cephalomedullary device of the Synthes®. This nail has a helical blade inserted by impaction without tapping. Trochanteric nail from the DePuy® has a lag screw and a derotation screw, which need pre-drilling and tapping. The Dyax nail is a Stryker® product that has a lag screw, which needs pre-drilling, and a set screw to prevent movement of the lag screw. Currently the trochanteric entry point is preferred to the piriform fossa entry point.[4] All these nails have proximal bend and has been designed for insertion through the tip of the greater trochanter. These nails are deemed to provide rotational, axial and angular stability for the fracture.

Our aim was to assess the strain patterns of these three different designs when experimentally tested with physiological axial loads. We created a reverse oblique intertrochanteric fracture in the Sawbone models and evaluated the strain distribution in the proximal femur when implanted with these three different nails.

METHODS

Specimens

Twelve identical large size fourth generation composite Sawbones (Model 5293, Pacific Research Labs Inc., Vashon, WA) were used for our experiments. These Saw bone models have a cortex made up of a mixture of short glass fibres and epoxy resin, pressure injected around a cancellous core material made up of polyurethane foam. These models provide a uniform and consistent test bed with the same physical and biomechanical properties as the human adult femur.[5]

Experiment

The twelve sawbones were randomly divided into four equal groups. Sawbones were prepared according to the surgical techniques provided by the manufacturers. Group 1 was unimplanted and these intact sawbones were used as controls. Other groups had femoral head fixation as follows; Group 2 was fixed with lag screw and an antirotation screw (DePuy nail). Group 3 was fixed with lag screw and a set screw (Stryker nail). Group 4 was fixed with helical blade (Synthes nail).

Steps in the preparation of bone

Sawbones were held in a rigid clamp fixed to a firm surface. A guide wire was introduced into the medullary canal through the entry point created with an awl on the tip of the greater trochanter. Sawbones were optimally reamed over a guide wire using the trochanteric entry point. An unstable reverse oblique fracture was created at a pre-marked identical area using a saw and was simulated in each Sawbone. The postero-medial buttress involving the lesser trochanter was removed using a milling machine to make the fracture configuration more unstable.

Group 2 sawbones were implanted with the 130^{o} DePuy nails of 360 mm length × 11 mm diameter. The femoral head fixation was achieved with a lag screw of 100 mm length × 10.5 mm diameter and a de-rotation screw of 95 mm length × 4.5 mm diameter as given in Table 1.

Group 3 saw bones were fixed with 130° Stryker nails of 360 mm length × 11mm diameter and the femoral head was fixed using a lag screw of 100 mm length × 10.5mm diameter. A set screw to lock the lag screw was applied through the proximal end of the nail as given in Table 1.

Group 4 sawbones were fixed with 130°Synthes nails of 360 mm length × 10 mm diameter with impacting of a helical blade of 100 mm length to fix the femoral head as shown in Table 1. All the nails were distally locked with two locking bolts after fracture reduction as given in Table 1.

Table 1: Showing baseline characteristics of different groups.

Group 1	Group 2	Group 3	Group 4
Unreamed Unimplanted Intact Saw-bones	DePuy nails 130^{0} 360 mm × 11 mm Lag screw 100 mm × 10.5 mm Derotation screw 95 mm × 4.5 mm	Stryker nails 130^{0} 360 mm × 11 mm Lag screw 100 mm × 10.5 mm	Synthes nails 130^{0} 360 mm×10 mm Helical blade 100 mm

A large sized acetabular component of a total hip arthroplasty was used to simulate the acetabulum. The articular cartilage was simulated using 6 mm thick Sorbothane sheet (70 durometer). This was attached to the inside of the cup using cyanoacrylate adhesive as shown in Figure 1. A nylon strap was used to create an artificial abductor mechanism for the hip joint. One end of the nylon strap was fixed to the greater trochanter with screws. The other end of the strap was ran through a ball bearing firmly fixed to an aluminium plate thereby creating a lever mechanism. By levering, the strap was tensioned to create an abductor force equivalent to half of the joint reaction force. The acetabular cup was free to rotate against the lever. The distal end of the femur was fixed to a metal platform using screws and a central peg was fitted into the predrilled intramedullary cavity in the intercondylar notch. The plate was supported on a spherical bearing, allowing it to pivot freely as in Figure 2. The postero-medial portion of the proximal femur was painted with white paint and then fine black speckles were applied over the white paint. The deformation of these black speckles at various loads was the basis for strain measurements.

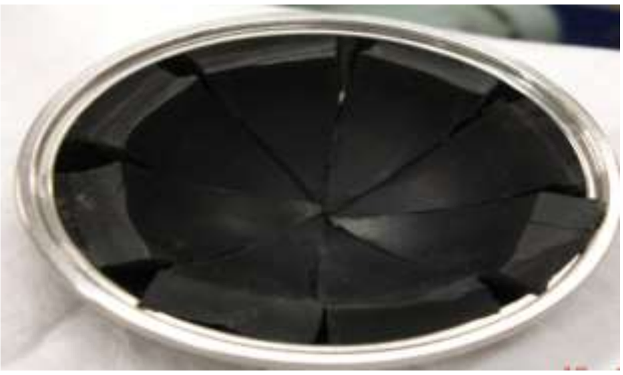

Figure 1: Photograph showing the simulated acetabulum and the articular cartilage.

For loading the sawbone specimens, a Dartec 9500 servo hydraulic machine with a capacity of 5kN (Dartec, Leominster, UK) was used as in Figure 2. The loads on the specimens were increased gradually in 100N increments until the physiological load was reached (1000 N-applied load, producing a joint reaction force of 2000 N). This axial load was applied via the distal femoral shaft to the hip joint thereby approximating the joint reaction force one might experience in rising from or lowering into a chair.

To measure the strain patters in the posteromedial cortex a Limess digital image correlation system was used. This consisted of two high-resolution digital video cameras and a computer. The software used was VicSnap for image capture and Vic3D for digital image correlation (Correlated Solutions Inc, USA). This software has the ability to identify areas with matching pixel patterns in the images from the two cameras. Hence, it calculates the position and movement of each area on the surface. In dynamic failure situations, images are acquired at 225000 frames per second in a burst of 32 images for a polymer edge cracked beam subjected to impact loading. This enabled the stress intensity factor (SIF) to be followed over 140µs from the point of contact. The measurement field sizes are 10-100 mm^2 with accuracy for displacements of 0.01 pixels and accuracy of strain 200 µ strains. Strain distribution could then be calculated from the displacement gradients. The strain in the vertical direction was plotted as colour contours and the peak strains in regions of interest were extracted for further analysis.

Figure 2: Photograph showing the mechanical testing of the Sawbone model using Dartec 9500 servo hydraulic machine.

We used SPSS version 20 (Chicago, Illinois, USA) for statistical analysis. The null hypothesis used for the statistical analysis assumed that there was no difference in the strain patterns between the 4 groups. We performed a student t-test to obtain p values ($p < 0.05$ as significant difference).

RESULTS

We found that most of the strain was concentrated below the fracture site on the medial cortex in groups 2, 3 and 4 as given in Figure 3. In Group 1, the strain was fairly uniform along the posteromedial cortex, but there were variations which are presumably associated with differences in cortical thickness and shape. We found an increased strain in all other groups when compared to group 1 at physiological loads as presented in Table 2. The mean peak strain in Group 1 was -0.00576 (-0.00483 to -0.00690), in Group 2, -0.01787 (-0.01320 to -0.02040), in Group 3, -0.00897 (-0.00594 to-0.01078) and in Group 4 was -0.00758 (-0.00531 to -0.00985). The abductor mechanism failed at 800 N load in one of the Synthes nail bone units when the greater trochanter was avulsed. Although the rest of the nail bone unit in this specimen was intact, we replaced the unit for loading as it was no longer possible to apply the abductor load.

The mean peak strains were increased in Depuy nail-bone unit by 210%, in *Stryker* nail-bone unit by 56% and in Synthes nail-bone unit by 36% when compared to Group 1. Table 2 shows the statistical significance of these peak strains among the groups. The peak strain in Group 2 was significantly increased with *p* values of 0.029, 0.041, and 0.050 in comparison to Group 1, Group 3 and Group 4 respectively. Whereas, the differences in peak strains among Group 1, Group 3 and Group 4 were not significant as seen in Table 3.

The mean strains in various groups at 500 N loads (1000 N joint reaction force), are mentioned in Table 4. The statistical significance of the differences in the strain patterns among different groups at 500 N loads is mentioned in Table 5.

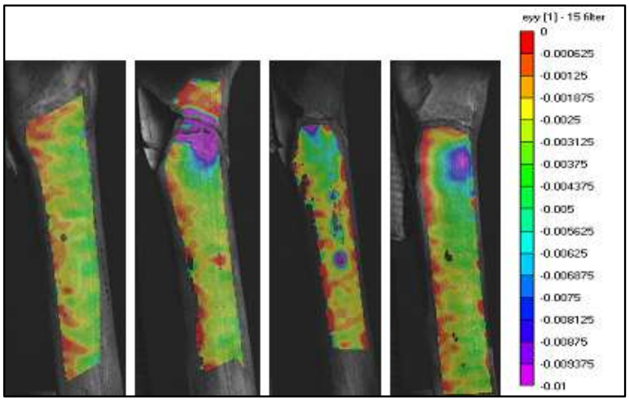

Figure 3: Photograph showing the strain patterns in the posteromedial cortex in the four different Sawbone models. Note the colour coded strain measuring scale provided.

Table 2. Showing peak strain patterns in the poster medial cortex in different groups.

	Group 1 (Unimplanted intact bone)	Group 2 (DePuy)	Group 3 (Stryker)	Group 4 (Synthes)
	-0.00483	-0.02000	-0.00594	-0.00985
	-0.00690	-0.02040	-0.01020	failed
	-0.00555	-0.01320	-0.01078	-0.00531
Mean	-0.00576	-0.01787	-0.00897	-0.00758
SD	0.001051	0.004046	0.002643	0.003210

Table 3: Showing the statistical significance (P value) of difference of strains at physiological loads among different groups.

	Group 1 (Unimplanted)	Group 2 (DePuy)	Group 3 (Stryker)
Group 2 (DePuy)	0.029		
Group 3 (Stryker)	0.159	0.041	
Group 4 (Synthes)	0.567	0.050	0.663

Table 4: Showing peak strain patterns in the poster medial cortex in different groups at 500 N loads (1000 N joint reaction force).

	Group 1 (Unimplanted Intact bone)	Group 2 (DePuy)	Group 3 (Stryker)	Group 4 (Synthes)
	-0.002556	-0.002039	-0.00282	-0.002801
	-0.00403	-0.00723	-0.004658	-0.00204
	-0.004403	-0.004285	-0.005695	-0.003691
Mean	-0.003663	-0.004518	-0.004391	-0.002844
SD	0.009076662	0.002603332	0.00145598	0.00082634

Table 5: Showing the statistical significance (P value) of difference of strains at 500 N loads among different groups.

	Group 1 (Unimplanted)	Group 2 (DePuy)	Group 3 (Stryker)
Group 2 (DePuy)	0.637		
Group 3 (Stryker)	0.517	0.946	
Group 4 (Synthes)	0.331	0.383	0.203

DISCUSSION

Reverse oblique fractures are of great concern to orthopaedic surgeons. Intramedullary devices have become the standard implants of choice to stabilise these fractures. An intramedullary device is very close to the calcar, subject to less tension, and is more stable compared to extramedullary device.[6] The highest compressive strain occurs at the postero-medial aspect reaching a value of -10467 µ. The postero-medial cortex, being the compression side of the femur, takes most of the strain during weight bearing esp. during walking.

Although compression forces at the fracture site help fracture union, a balance between compression and fracture stability provides an optimal environment for healing.

The mathematical estimates derived from gait laboratory observations made in a patient walking on the level with an instrumented implant has shown peak resultant force in the range of 2.5 to 3.5 times body weight.[11,12] This roughly equates to around 1500 to 2000 N. An intramedullary implant should at least be able to withstand these forces in order to let the patient fully weight bear. Hence, we extracted peak strains at two different loads i.e. 2000 N to simulate the full weight bearing and 1000 N to simulate the partial weight bearing. The vertical component of the hip joint reaction at peak reaches 236% of body weight during heel strike. In average, during the stance phase, hip joint reaction is around 110% of body weight.

We found that the strain pattern at full weight bearing loads i.e. 2000N is higher in all the nail bone units compared to intact femur. The Lag screw – antirotation screw design (Depuy) was the one to perform least and the difference between that and the intact normal bone was statistically significant.

When loaded with partial loads of 500 N the strain distribution was not significantly different (table) among the groups. Thus, it shows that these nails could be safe enough for partial weight bearing. However, the practicality of partial weight bearing following surgery is a challenge to both the patient and the physiotherapist and it is not reproducible.[7] The validity of partial weight bearing regimes has been questioned.[7] Many a times, it is not successful to mobilise an elderly demented patient with non-weight bearing. Moreover, the whole purpose of treating with intramedullary nail is lost. Hence, the aim should always be to mobilise full weight bearing following fracture fixation. Ideal implants should allow full weight bearing without compromising the fracture stability.

In our study, at physiological loads the lesser strains in the Stryker nail-bone unit could be attributed to the usage of a set screw, which makes it a fixed angle device. The fixed angle nature of this implant is more rigid and shares more strain resulting in less strain distribution along the posteromedial cortex. We used 10 mm diameter Synthes nails in this study and compared with 11 mm diameter nails of DePuy and Stryker. The reason being that 10 mm is the largest diameter Synthes nail distributed to us. Although we used 10 mm Synthes nails, the peak strains were less in these compared to the two nail-bone units. The reason for this could be the helical blade, which fixes better in the head and distributes stress over a greater area when compared to the sliding screw.[8,9] However, the greater trochanter was avulsed in one of the Synthes nail-bone units at 800 N load. This was due to cracking of the cortex during the impacted insertion of the helical blade, which occurred in all the three samples and caused weakening of the proximal metaphysis.

The failure of one of the Synthes constructs and the occurrence of cracking of greater trochanter in the other two may be presumably due to the behaviour of the Sawbone material. It is difficult to draw firm conclusions about the likelihood of such cracking *in vivo*. Although the Sawbone material has similar strength and stiffness to human cortical bone, its fracture toughness has not been shown to be equivalent, and it is possible that it will crack more easily. However, the widespread cracking observed in this study does suggest a possible danger, particularly in osteoporotic bone, and this should be investigated further. Therefore, caution would be advisable to prevent such cracking *in vivo* especially where bone quality is poor.

The DePuy nail produced increased peak strains in the medial cortex, below the fracture site, and this appeared to be associated with high load transfer through the fracture on the medial side. There are several possible explanations for this. The fixation of the screw in the head may be less effective, resulting in movement or subsidence and hence increased compression medially. Alternatively, the stiffness of the nail may be less resulting in a greater share of the load being carried by the bone. Further measurements are required to determine which of these effects was responsible for the observed increase in proximal strain. Since the observed strain concentration was localised immediately distal to the fracture site, it was probably caused by poor fixation in the head and not by differences in the stiffness of the nail.

In our experiment, we assessed the strain distribution on the femur. The higher the strain distribution, the greater the force going through the bone at any given load. A fractured bone in the elderly is usually osteoporotic. Therefore, any implant used ideally would allow fracture healing without compromising the stability. Although our results suggest that Synthes and Stryker nails are superior to DePuy nails in terms of strain distribution pattern, the quest for an ideal implant continues.

The limitations of the study were the following:

- Unknown component of force imparted by the individual muscles attached around the proximal femur.
- Further the strain pattern observed was under static conditions and not simulated walking.
- Number of tested units were only 3 in each group
- There is no correlation of the results with clinical outcome of all three nails.

- A priori route was followed which assumes that high strains are may be deterrent to healing.

CONCLUSION

The peak strains in the three nail bone-units were high when compared to intact bone controls at physiological loads. The increased strains in the Stryker and the Synthes nail-bone units were not significant compared to intact bone controls. The peak strain in the DePuy nail-bone unit was significantly high compared to the other two nail-bone units and the controls. There was no significant difference among various groups at partial loads. These results question the safety of immediate full weight bearing following surgery when treating the reverse oblique unstable fractures with DePuy intramedullary nails. A period of partial weight bearing following fixation of reverse oblique fractures would be wise when using DePuy nails.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

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Cite this article as: Debnath UK, Maripuri SN, Subramanian KN, Mohanty K. Three different interlocking intramedullary nails for unstable reverse oblique inter-trochanteric fractures: a bio-mechanical comparative study. Int J Res Orthop 2016;2:280-5.