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Comparative study of trochanteric fracture treated with the proximal femoral nail anti-rotation and the third generation of gamma nail

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ABSTRACT

Objectives: To compare the results between the proximal femoral nail anti-rotation (PFNA) and the third generation gamma nail (TGN) in the treatment of trochanteric fractures.
Methods: Between April 2007 and May 2008, 107 consecutive patients older than 60 years with trochanteric femoral fractures were treated with PFNA or TGN. The preoperative variables including patient age, gender, fracture classification, walking ability and American Society of Anaesthesiologists (ASA) rating of operative risk were summarised. Operative time, fluoroscopy time, blood loss, and any intra-operative complication were recorded for each patient. Follow-up was undertaken at 3, 6, and 12 postoperative months, and yearly thereafter. Plain AP and lateral radiographs were obtained at all visits. All changes in the position of the implant, complications, or fixation failure were recorded. Hip range of motion, pain about the hip and the thigh, walking ability score and return to work status were used to compare the outcomes.
Results: There were 55 patients in the PFNA group and 52 in the TGN group. The two groups were comparable with regard to the preoperative variables. The mean follow-up time was 17.5 months (range 12–24). Patients treated with a PFNA experienced a shorter fluoroscopy time and less blood loss. Sixteen patients were lost during the follow-up period. All the other fractures were radiographically healed at the last visit. There were no significant differences between the groups in terms of functional outcomes, hospital stay, intra-operative and postoperative complications.
Conclusions: PFNA provides less blood loss and shorter fluoroscopy time but no advantages in functional outcome, intra-operative and postoperative complications when compared with TGN. These two implants were comparable in the treatment of trochanteric fractures.

Introduction

Intramedullary fixation, particularly modern intramedullary osteosynthesis techniques of trochanteric fracture gained rapid acceptance in recent years. However, the complication rates of these techniques such as Gamma nail (GN) and proximal femoral nail (PFN) were still higher[6,15].

Several implant-related complications of GN have been described, such as femoral shaft fracture, failure of fixation and problems of distal locking[1,6]. Some authors have postulated that the causes for these complications were the design and geometry of the nail and inadequate placement of the distal locking screws[4,7]. Because of these, the third generation of Gamma nail was introduced, named Trochanteric Gamma nail (TGN).

The most common complication of PFN reported is the cutting-out of the screw through the femoral head and neck[2,11]. A high rate of intra-operative difficulties and technical and mechanical complications have been reported since the first report of PFN[14]. To solve these problems, a new implant was designed by AO/ASIF, the proximal femoral nail anti-rotation (PFNA), an intramedullary device with a helical blade instead of screw thread suitable for the head and neck fragments.

The purpose of this study was to compare outcomes and complications between TGN and PFNA in the treatment of trochanteric fractures. The hypothesis was that PFNA would have fewer complications and better outcome than TGN.

Patients and methods

Between April 2007 and May 2008, 143 consecutive patients who sustained a trochanteric fracture of the femur were included in this study. The Ethics Committee of the Hospital approved the study. Informed consent was obtained from the patients or from their relatives if the patients were incapable of consent. Patients

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Table 1
Baseline data.

	PFNA	TGN
Patients	55	52
Mean age, years (SD)	76.8 (9.6)	76.6 (8.2)
Sex		
Female	32	37
male	23	15
Mechanism of injury		
Domestic fall	41	36
Vehicle accidents	9	12
Others	5	4
Fracture type		
Stable	19	21
Unstable	36	31
ASA risk score		
1	9	11
2	17	13
3	21	25
4	8	3
Walking ability (SD)	7.2 (2.1)	7.4 (1.8)

who were admitted to our hospital with a trochanteric fracture during the study period were considered eligible for the study. Exclusion criteria were patients younger than 60 years, ASA score V, unable to work before injury, or patients refusal to participate. So finally, 107 patients were eligible for the study.

The patients were randomised for treatment into 2 groups, PFNA ($n = 55$) or TGN ($n = 52$), using consecutive numbered and sealed envelopes based on a computer generated list. Sealed envelopes were opened before the surgeon attempted a closed reduction of the fracture.

The preoperative variables including patient age, gender, fracture classification, walking ability and ASA rating of operative risk were summarised in Table 1. The fracture pattern was classified by the system of Evans as modified by Jensen[5], and then categorised as either stable (types I and II) or unstable (types III, IV and V). Both treatment groups were comparable before operation.

Operation was performed according to standard protocols for either PFNA or TGN, which are recommended by the manufacturer and have been described in earlier studies[10,16,19]. The PFNA used in the study was a solid titanium nail of 170 or 240 mm in length and 10 or 11 mm in diameter, which was inserted without reaming of the medullary canal. The special helical blade was inserted into the femoral neck without drilling. This blade has the advantages of fixation stability, anti-rotation and anti-varus collapse. The PFNA may be distally locked either dynamically or statically. The TGN is a 170 mm cannulated steel nail with a lower mediolateral curvature (4°) and a diameter of 11 mm. The femur was reamed 2 mm larger than the proximal and distal diameters of the nail, and insertion was performed manually without hammering. There is one distal locking screw for anti-rotation. The neck shaft angle of the two devices was 130°. The PFNA and the TGN were inserted using percutaneous technique.

The operating procedures were comparable, the main difference being the type of implant. All operations were performed by surgeons who had experience with at least 5 procedures, with both the PFNA and TGN. All patients received preoperative intravenous antibiotics with 2 g of ceftriaxone. General anaesthesia and spinal anaesthesia were used in both groups. Patients were operated on a traction table in a supine position, and if possible, closed reduction was performed under image-intensifier control.

The operative time, fluoroscopy time, blood loss, and intra-operative complications, if any were recorded. After operation, all patients had suction drains for 2 days and were given prophylactic antibiotics for 3 days. All patients were encouraged to move hip, knee and ankle joints from the first day after operation under the guidance of surgeons. The CPM was used twice a day when the drainage tube was removed. Plain anteroposterior (AP) and lateral radiographs were obtained on the first postoperative day, and analysed for reduction of the fracture and position of the implant. All patients, assisted by surgeons, were encouraged to walk fully weight-bearing after operation as soon as possible.

Follow-up was undertaken at 3, 6, and 12 postoperative months, and yearly thereafter. Plain AP and lateral radiographs were obtained at each visit (Figs. 1 and 2). All changes in the position of the implant, complications, or fixation failures were recorded. At each postoperative control, we recorded the motion range of hip, pain about the hip and the thigh, and walking ability score, which was assessed with the mobility score (0–9 points) of Parker and Palmer[13].

Sample size and statistical analysis

The variable used to determine sample size was fluoroscopy time. The investigators decided that a difference in fluoroscopy time of 0.5 min was an amount that could reliably be estimated. This required a total of 100 patients with 80% power at the 5% significance level

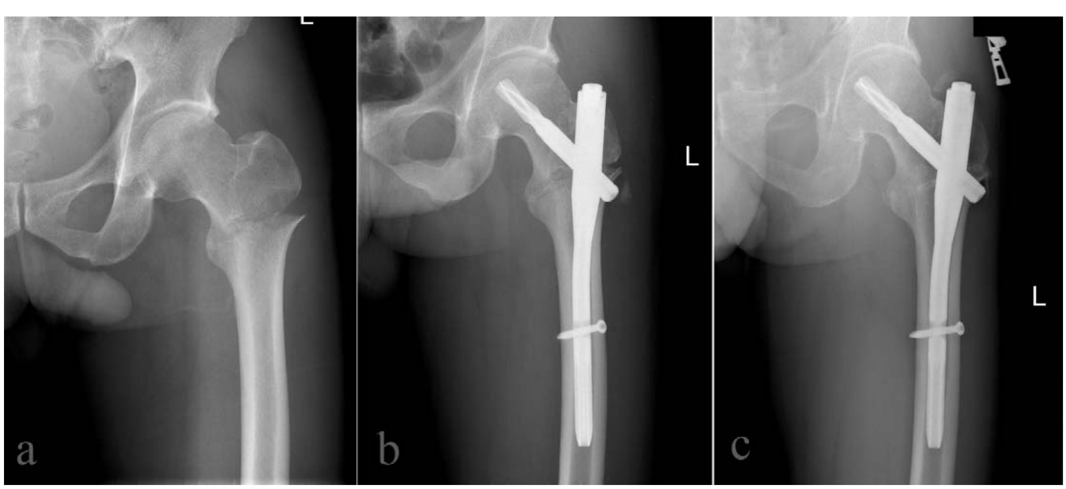

Fig. 1. A 76-year-old man sustained a pertrochanteric fracture of left hip when she fell outside home (a). The fracture was reduced and fixed with a PFNA (b), and X-ray 12 months after the operation (c) while living at home and walking independently. .

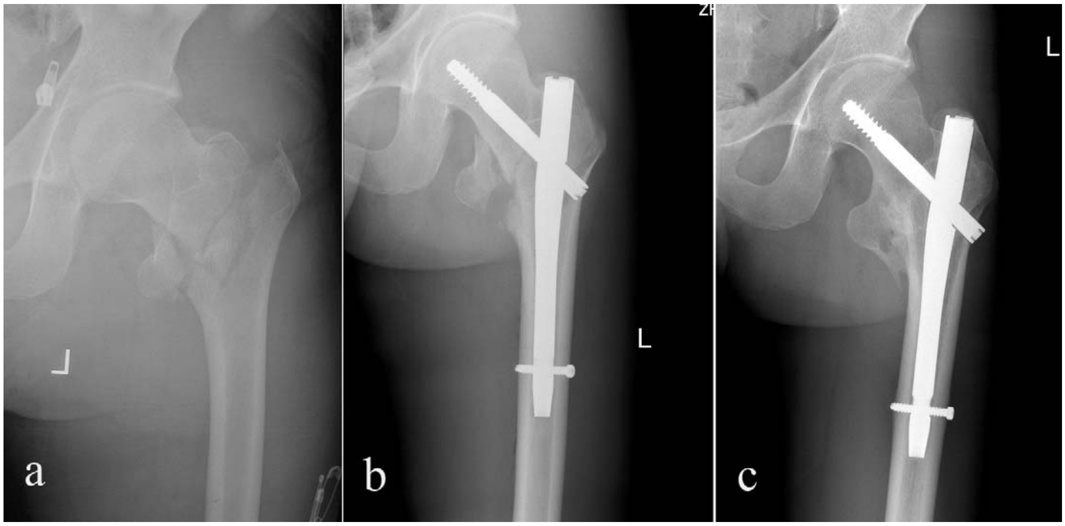

Fig. 2. Anteroposterior radiograph showing an unstable proximal femoral fracture of the left hip in a 63-year-old man who fell from his bicycle (a). A TGN device was placed, with the screw inferior in the femoral head (b). Radiograph made 12 months after operation (c), showing a healed fracture.

Table 2
Perioperative variables.

	PFNA	TGN	Difference of means (95%CI)	p value
Anaesthesia				0.69
General	39	35		
Spinal	16	17		
Open reduction	7	10		0.36
Mean operation time (SD)	66.6 (15.4)	73.1 (20.8)	6.44 (−0.5 to 13.4)	0.07
Blood loss (SD)	219.5 (107.5)	269.0 (123.9)	49.6 (5.2 to 94.0)	0.03
Fluoroscopy time (SD)	2.9 (1.1)	3.4 (1.2)	0.5 (0 to 0.9)	0.04
Hospital stay (SD)	7.09 (1.68)	7.40 (1.72)	0.3 (−0.3 to 1.0)	0.34

The statistical analysis was performed using SPSS 10.0 software (SPSS Inc, Chicago, Illinois). Student *t* test was used for quantitative variables. Data were expressed as mean (standard deviation). Categorical variables were analysed by the chi-square test or Fisher exact test where appropriate. The level of statistic significance was set at a two-sided p value of 0.05.

Results

Treatment groups were comparable with regard to patient age, sexual distribution, mode of injury, fracture type, walking ability and ASA score. According to the Evans and Jensen classification, 67 fractures were unstable and 40 stable (Table 1).

The method of anaesthesia (general or spinal) did not differ between the groups, and surgeons who performed the operation are all experienced. The perioperative data were recorded (Table 2). Open reduction was performed in 17 patients, 7 in the PFNA group and 10 in the TGN group ($p = 0.36$). There was a longer operative time in the TGN group compared to the PFNA group, though the difference was not obvious ($p = 0.07$). The mean intra-operative blood loss differed significantly, 219.5 (107.5) ml in the PFNA group compared with 269.0 (123.9) ml in the TGN group ($p = 0.03$). Fluoroscopy time was significantly lower in the PFNA group with a mean value of 2.9 min compared to the TGN group with a mean value of 3.4 min. Length of hospital stay did not differ statistically between the patients in the different treatment groups ($p = 0.34$).

Table 3
Intra-operative complications.

Complication (n)	PFNA	TGN	p value
Femoral shaft fracture	4	2	0.68
Locking difficulties	2	3	0.67
Inappropriate length of screws	5	7	0.55

There were 23 intra-operative complications, 11 in PFNA and 12 in the TGN groups (Table 3). Distal locking difficulties were noted in 5 patients. In 1 the drill bit of the TGN missed the nail, in 2 the distal interlocking of the TGN was impossible due to malposition of the targeting device. In 2 patients the desired static locking of the PFNA failed, after which dynamic locking was performed. Six femoral shaft fractures were observed intra-operatively, four in the PFNA group and two in the TGN group ($p = 0.68$). This fracture was unilateral, not whole diaphyseal. Moreover, this complication had nothing to do with the type of fracture (stable 2, unstable 4). Those cases with femoral shaft fractures are all short old Chinese women and the new trauma was treated successfully with conservative management of delay full weight-bearing. After 6–8 weeks, these patients were allowed full weight-bearing. After one year, the fractures all healed very well.

At the final follow-up, of the 107 patients in the study, 11 were lost to follow-up (5 in the PFNA group and 6 in the TGN group) and 5 died within the follow-up period, 4 in the PFNA group and 1 in the TGN group. These exclusions left 91 patients for clinical study, 46 in the PFNA group and 45 in the TGN group. The mean follow-up time was 17.5 months, ranging from 12 to 24 months.

Complications occurring in the postoperative period are listed in Table 4. No cases were observed rotation or cutting-out through the femoral head and neck within the follow-up period. Statistical analysis revealed that there was no significant difference between the two patient groups with regard to postoperative complications. In the PFNA group, one patient fell down one month after operation

Table 4
Postoperative complications at the final follow-up.

Complication (*n*)	PFNA	TGN	*p* value
Femoral shaft fracture	1	0	
Lateral blade migration	5	3	0.71
Delayed union	6	9	0.37
Reoperation	1	0	
Superficial wound infection	1	3	0.36
Haematoma	5	7	0.51
Decubital ulcer	3	3	
Pneumonia	3	4	0.71
Urinary tract infection	6	8	0.53
Cerebral infarction	2	1	1.00

and sustained a displaced femoral shaft fracture that was treated with osteosynthesis plate. In one patient, DHS was used instead of PFNA because of poor reduction of the fracture and severe pain one month after operation.

Of the 91 patients eligible for the study, both functional test and radiographs were obtained. Fracture healing occurred in all patients at the last follow-up. There was no difference in the walking ability among the patients treated with two different implants. Walking ability restored to preoperative levels in 51 patients. The postoperative mobility score calculated at the latest follow-up decreased in both groups. Eighty-two patients complained about hip and thigh pain during the follow-up period. However, there was no difference between the two groups with regard to postoperative pain and range of hip flexion (Table 5).

Discussion

The current study was initiated in order to compare PFNA and TGN for differences in outcomes, based on the hypothesis that PFNA would reveal fewer complications than TGN. Pilot studies in different patient groups had shown good outcome with few complications after treatment with PFNA[10,16]. Several trials compared extramedullary fixation devices or PFN with the TGN in trochanteric fracture[12,18,19]. No obvious differences were found among the results of treatments with either TGN or other implants. However, to our knowledge, no comparison was made with PFNA in literature.

PFNA was developed by the AO/ASIF group based on PFN with a special helical blade. This special design was inserted into the femoral neck without drilling. The helical blade avoids bone loss that occurs with the drilling and insertion of the standard sliding hip screw. This device allows for improved purchase in the femoral head, by radial compaction of the cancellous bone around the blade during insertion[20]. The helical neck blade has the advantages of fixation stability, anti-rotation and anti-varus collapse. Similarly, a new Gamma nail was designed by Stryker based on the standard Gamma nail[19]. Biomechanical studies showed that the new generation of Gamma nail appeared to be stronger and to reduce the risk of lag screw cutting-out. Strauss et al. performed a biomechanical evaluation to compare the fixation stability of the conventional lag screw design versus the helical blade for unstable intertrochanteric fractures[17]. The helical blade system showed a significantly increased stability of fracture fixation in regard to inferior femoral head displacement.

Our study showed no significant differences between the results of treatment with either PFNA or TGN. Intra-operative problems were encountered in 11 of the 55 patients with PFNA and 12 of the 52 with TGN. Six patients (PFNA 4, TGN 2) of femoral shaft fracture were encountered in the short elderly patients. As the height of Chinese population on average is less than that of Europeans and Americans, the proximal femoral length and femoral medullary cavity diameter are relatively shorter [8]. When the implant was used in short elderly Chinese patients, the stem did not fit her femur very well. Therefore, after loading, the fractures occurred. Several articles have described this intra-operative complication that may be due to insufficient reaming of the TGN[12,19] or by wedge effect of the PFNA when introduced with a hammer[14]. At present, the PFNA II has been developed for Asian patients. It may go better for the elderly Chinese population.

The mean operative time, fluoroscopy time, and blood loss were higher in the TGN group. These phenomena have not been described before and probably associated with a reamed technique in TGN operation.

Fracture of the femoral shaft at the tip of the nail is a known complication associated with the use of intramedullary nail in the treatment of proximal femoral fractures[1,6,14,15]. The secondary femoral fracture of standard Gamma nail occurred at the tip of the nail, with an incidence between 0% and 17%[1,6,14]. However, we did not observe any typical femoral shaft fracture postoperatively in our TGN group. This modified design of Gamma nail was associated with a lower rate of postoperative complications than with the standard Gamma nail[12,18,19]. Although there were no significant differences, patients treated with PFNA had a slightly higher rate of additional surgery. This may be explained by the preexisting physical conditions and complex fracture type, rather than the implant.

Most reports have shown that the complication such as hip and thigh pain was common when treated with intramedullary fixation[11,19]. 90.1% of patients complained about hip and thigh pain during the follow period in our study without significant impact on postoperative function. These common complications seemed to be associated with intramedullary technique. McConnell et al. reported that damage to the gluteus medius tendon is inevitable during appropriate placement of the intramedullary nail[9], and this should be the potential cause of postoperative hip and thigh pain.

There were no significant differences in the final functional outcome between the two devices. Approximately 56.0% of patients returned to where they had lived before operation, without any correlation to the implant. This finding agrees with the results from retrospective studies who also observed restoration of preoperative mobility in approximately 40–50% of the patients treated with PFNA or TGN[10,12,16,18,19]. These results demonstrated that approximately half of the patients with peritrochanteric fracture return to their preoperative domestic status at the time of healing of the fracture, regardless of the method of treatment used. The key factors of functional outcome were fracture type, general condition and surgeon's experience, not the implant[3].

Table 5
Outcome measurements at the final follow-up.

	PFNA	TGN	Difference of means (95%CI)	*p* value
Walking ability score in points (SD)	6.3 (2.1)	6.7 (1.8)	0.4 (−0.5 to 1.2)	0.38
Hip flexion (SD)	95.7 (14.7)	96.4 (15.5)	0.8 (−5.5 to 7.1)	0.80
Hip pain	17	20		0.47
Thigh pain	21	24		0.46
Recovery of walking ability to the preoperative status				0.61
Yes	27	24		
No	19	21		

The present study had several limitations. First, it did not include a large number of patients. Second, a common problem in this kind of study was that a large number of patients withdrew[14,19], even after a short follow-up. Many patients had concomitant illnesses affecting their general health, making it impossible to participate in follow-up. In our series, the 16 patients who did not attend their final review had either died during the follow-up period, or been too weak to attend, or refused to participate. Third, the follow-up period was relatively short. Potential long-time problems associated with intramedullary implant may yet occur.

Conclusion

PFNA shows some advantages over TGN, namely less blood loss, less fluoroscopy time, and similar intra-operative complication rate. However, there was no significant difference of postoperative complications and functional outcome between the two devices. Our results demonstrated that these two implants were comparable in the treatment of trochanteric fracture. Since the results were just from the comparison of two intramedullary implants, more randomised studies with the "gold standard" using the sliding hip screw are needed in order to decide which one is the ideal implant for the treatment of trochanteric fractures.

References

1. Ahrengart L, Törnkvist H, Fornander P, et al. A randomised study of the compression hip screw and Gamma nail in 426 fractures. Clin Orthop Relat Res 2002;(401):209–22.
2. Ekström W, Karlsson-Thur C, Larsson S, et al. Functional outcome in treatment of unstable trochanteric and subtrochanteric fractures with the proximal femoral nail and the Medoff sliding plate. J Orthop Trauma 2007;21(1):18–25.
3. Handoll HH, Parker MJ. Conservative versus operative treatment for hip fractures in adults. Cochrane Database Syst Rev 2008;16(3). CD000337.
4. Haynes RC, Pöll RG, Miles AW, Weston RB. Failure of femoral head fixation: a cadaveric analysis of lag screw cut-out with the Gamma locking nail and AO dynamic hip screw. Injury 1997;28(5–6):337–41.
5. Jensen JS. Classification of trochanteric fractures. Acta Orthop Scand 1980;51:803–10.
6. Kukla C, Heinz T, Gaebler C, et al. The standard Gamma nail: a critical analysis of 1000 cases. J Trauma 2001;51(1):77–83.
7. Lacroix H, Arwert H, Snijders CJ, Fontijne WP. Prevention of fracture at the distal locking site of the Gamma nail: a biomechanical study. J Bone Joint Surg Br 1995;77(2):274–6.
8. Leung KS, Procter P, Robioneck B, Behrens K. Geometric mismatch of the Gamma nail to the Chinese femur. Clin Orthop Relat Res 1996;323:42–8.
9. McConnell T, Tornetta 3rd P, Benson E, Manuel J. Gluteus medius tendon injury during reaming for gamma nail insertion. Clin Orthop Relat Res 2003;(407): 199–202.
10. Mereddy P, Kamath S, Ramakrishnan M, et al. The AO/ASIF proximal femoral nail anti-rotation (PFNA) A new design for the treatment of unstable proximal femoral fractures. Injury 2009;40(4):428–32.
11. Pajarinen J, Lindahl J, Michelsson O, et al. Pertrochanteric femoral fractures treated with a dynamic hip screw or a proximal femoral nail. A randomised study comparing postoperative rehabilitation. J Bone Joint Surg Br 2005;87(1): 76–81.
12. Papasimos S, Koutsojannis CM, Panagopoulos A, et al. A randomised comparison of AMBI, TGN and PFN for treatment of unstable trochanteric fractures. Arch Orthop Trauma Surg 2005;125(7):462–8.
13. Parker MJ, Palmer CR. A new mobility score for predicting mortality after hip fracture. J Bone Joint Surg Br 1993;75(5):797–8.
14. Schipper IB, Steyerberg EW, Castelein RM, et al. Treatment of unstable trochanteric fractures. Randomised comparison of the gamma nail and the proximal femoral. J Bone Joint Surg Br 2004;86(1):86–94.
15. Simmermacher RK, Bosch AM, van der Werken Chr. The AO/ASIF-proximal femoral nail (PFN) a new device for the treatment of unstable proximal femoral fracture. Injury 1999;30(5):327–32.
16. Simmermacher RK, Ljungqvist J, Bail H, et al. The new proximal femoral nail anti-rotation (PFNA) in daily practice Results of a multicentre clinical study. Injury 2008;39(8):932–9.
17. Strauss E, Frank J, Lee J, et al. Helical blade versus sliding hip screw for treatment of unstable intertrochanteric hip fractures: a biomechanical evaluation. Injury 2006;37(10):984–9.
18. Suckel AA, Dietz K, Wuelker N, Helwig P. Evaluation of complications of three different types of proximal extra-articular femur fractures. Int Orthop 2007; 31(5):689–95.
19. Utrilla AL, Reig JS, Muñoz FM, Tufanisco CB. Trochanteric gamma nail and compression hip screw for trochanteric fractures: a randomised, prospective, comparative study in 210 elderly patients with a new design of the gamma nail. J Orthop Trauma 2005;19(4):229–33.
20. Windolf M, Braunstein V, Dutoit C, Schwieger K. Is a helical shaped implant a superior alternative to the Dynamic Hip Screw for unstable femoral neck fractures? A biomechanical investigation. Clin Biomech (Bristol Avon) 2009; 24(1):59–64.