A Comparison of Two Proximal Femoral Nail Devices For Fixation of Unstable Intertrochanteric Femur Fractures

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Citation

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Abstract

Background: Unstable intertrochanteric femur fractures are common fractures posing a surgical challenge in reduction and fixation. The fixation devices frequently used are based on hip intramedullary nailing with femur head lag screw or blade. The aim of this paper is to compare between two different proximal femoral nail (PFN) with double screw mechanics. Methods: We retrospectively reviewed 386 unstable pertrochanteric femur fractures surgically treated in our hospital from 2000 to 2009. Of these 227 patients had either a complication or completed six months recorded follow-up with fracture resolution. One hundred and forty seven fractures (64.8%) were fixed by the Targon proximal femur (TPF) device (Aesculap, Tuttlingen, Germany) and 80 fractures (35.2%) were fixed using the antirotation trochanteric nailing system (ATN) device (dePuy, Warsaw, IN, USA). We compared the clinical and surgical immediate outcome (e.g., tip apex distance, reduction quality), between the fixation devices. Long term results, i.e., complications, revisions and survival rates, were compared as well. Results: We found higher rates of complications in patients treated by the ATN device (32.5%) as compared to the patients treated by the TPF device (14.9%). This difference was statistically significant (p value= 0.002). In the ATN group 15 patients (18.8%) required revision surgery as compared to 18 patients (13.4%) requiring surgery in the TPF group. This difference was not statistically significant (p value =0.18). Multivariate logistic regression found that ATN fixation device increased the odds ratio for any complication by 2.82 (95% CI 1.29-6.16). One year survival for patients treated by the ATN and Targon PF devices were 84.1% (95% CI = 79.6%-88.6%) and 76.4% (95% CI = 69.1%-83.6%), respectively. This difference was statistically significant (p value = 0.047). Conclusions: Although the two devices compared share similar biomechanical properties, e.g., double screw design, their outcome differed. Better outcome was observed in the Targon PF group. Our results implicate that clinical trials results using a specific fixation device cannot be easily extended to other devices with similar designs.

INTRODUCTION

Intertrochanteric fractures are among the most widely treated orthopedic injuries. Their annual incidence is expected to reach 500,000 by 2040, in the US alone[1]. About half of them are estimated to be unstable factures[2]. According to the AO/OTA classification system[3] the fractures can be divided to stable fractures (AO/OTA: 31.A1-1 to 31.A2-1) and unstable fractures (AO/OTA: 31.A2-2 to 31.A3.3)[4-6]. Unstable intertrochanteric fractures were shown to benefit from intramedullary fixation devices such as the Cefalomedullary nail, Gamma nail and Y nail among others[5,7-20].

Subtrochanteric fractures are fractures within 5 cm distal to the lesser trochanter. These fractures require fixation of the femur head-neck-shaft complex and are often fixed by intramedulary proximal femur fixation devices. As such these factures can be included as part of the unstable inter-subtrochanteric fractures patterns[21.22].

Helwig et al studied the biomechanical properties of four different proximal femur implants[23]. Using finite element analysis they have shown that the TPF nail creates favorable fracture healing conditions when positioned cranially. Other implants examined, ensure favorable outcome when positioned caudally. We are not aware of any work comparing the clinical results of two proximal femoral nails (PFN) for fixation of unstable intertrochanteric fractures.

In this report we compare between the TPF and ATN devices. We compare the epidemiology, reduction achieved, screw placement, failure types, revision rates and survival analysis between the two fixation devices.

PATIENTS & METHODS

Between 2000 and 2009, 386 unstable pertrochanteric fractures were operated in our institute. After receiving IRB approval a retrospective analysis of our hospital clinical files was performed. Inclusion criteria were either failure of any cause or a completion of six months follow-up signs of union on radiography. We excluded patients with a pathologic fracture or impending fracture.

Of the initial 386 patients, 64 (16.6%) had died for reasons unrelated to the surgery. Another 95 patients (24.6%) did not complete six months follow-up and were not included in the study. The study population included 227 patients that met the inclusion criteria. Of these 147 fractures (64.7%) treated between 2000 and 2007 were fixed by the Targon proximal femur (Targon PF) device (Aesculap, Tuttlingen, Germany). During 2007 we have changed our fixation device to the antirotation trochanteric nailing system (ATN) device (dePuy, Warsaw, IN, USA). During 2007-2009, 80 fractures (35.3%) were fixed with the antirotation trochanteric nailing system (ATN) device (dePuy, Warsaw, IN, USA). Both of these devices are double screw intramedullary fixation devices (Figures 1 and 2). All surgeries were performed in accordance to standard surgical technique and manufacturers' recommendations.

The radiology computerized achieve was used for fractures' classification according to the OTA/AO classification system[3]. Patterns were classified by two independent researchers (A.H and Y.L). The senior author (N.S) was consulted whenever consensus was not reached. Radiography measurements were performed including the tip apex distance (TAD) and assessment of fracture translation post-reduction[24]. Acceptable reduction was considered as translation of less than 20 mm in any plane as measured by the medial cortex in anterior-posterior view or anterior cortex on axial view.

Data were extracted by reviewing patients' admission and out-patients clinic charts. Complications, morbidity as recorded by the American society of anesthesiologists score (ASA), usage of walking aids and recovery parameters were extracted from the hospital records. The national mortality registry was consulted for mortality status and date. Patients that were not registered as deceased were considered as censured at the date of the inquiry.

Statistical analysis was performed by an experienced biostatistician (A.H.). Data analysis was conducted using SPSS© 16 (SPSS©, Chicago, IL). Categorical data are presented as frequency count (percent of available data). Comparisons of categorical variables between fracture types were performed using either the chi-square test or the Fisher's exact test. The latter was used when expected count in any cell was less or equal five. Continuous variables are presented as mean (± standard deviation). Comparisons of continuous variables among fracture patterns were performed using the Kruskal-Wallis test. Comparisons of paired data, mainly the increase in mobility aids before and one year after surgery, were performed using the Wilcoxon rank sign test. Multivariate logistic regression was performed using complication of any kind as the outcome variable. Independent covariates included in the model were ASA score, Tip apex distance, reduction achieved and nailing system used.

Survival data were analyzed using the entire dataset (386 fractures). Kaplan-Meier survival estimates were used for one year survival along with 95% confidence interval (95% CI). Comparisons between survival curves were done by the log-rank test.

RESULTS

The study population consisted of 227 unstable pertrochanteric fractures treated by reduction and fixation with PFN, in our department from 2000 to 2009. The study population included 175 women (77.1%) and 52 men (22.9%). Mean patients' age at surgery was 75.6 years (SD 15.6). Mean American society of anesthesiologists (ASA) score was 2.7 (SD 0.6). According to the AO/OTA classification, 45 fractures (19.8%) were classified as 31.A2-2 or 31.A2-3, 151 fractures (66.5%) were classified as 31.A3 (including reverse oblique, transverse or comminuted fractures). Thirty one fractures (13.7%) were subtrochanteric fractures. No statistically significant difference was found in demographic characteristics between the two PFN systems compared (Table 1).

Reduction was not achieved (above 20mm translation in AP + Axial) in 20 (8.8%) patients. No statistically significant difference was found between the two PFN devices (Table 2). Ninety patients (84% of 106 patients with available data) were able to walk with any walking aid one year after surgery. Comparing the walking abilities between the two PFN devices, no statistically significant difference was found (Table 2).

Optimal tip apex distance (TAD) of less than 25 was achieved in 119 (76.8% of 155 available) fractures fixed. More fractures fixed by the TPF nail had TAD of less than 25 in fractures (Table 2). Univariate analysis showed the difference in TAD between PFN types to be statistically significant (p value =0.008). However, TAD above 25mm was not found to be associated with higher rates of cutout. Thirty six patients had a TAD above 25mm, of these only three (8.3%) had cutout of the fixation device. Of the 119 patients with TAD less or equal 25mm, 8 patients (6.7%) had a cutout. This difference was not found to be statistically significant (p value = 0.72). Four patients with cutout did not have an axial X-ray available to measure the TAD. Even if these patients had a TAD above 25mm the association between TAD and cutout in our cohort would not be statistically significant (p value=0.09). Further, multivariate analysis did not find the TAD to be a significant factor in predicting complications (see later discussion).

Complications were observed in 48 (21.1%) patients. More complications were observed in fractures fixed by the ATN device. This difference was found to be statistically significant (p value=0.002). More hardware failure, e.g. screw break, nail break, were observed in fractures fixed by the ATN device. More cases of secondary reduction loss, cutout and fixations in internal rotation were observed in fractures fixed by the ATN device. All the aforementioned differences were not found to be statistically significant, but showed a statistical trend (p value < 0.1, see Table 3).

Thirty three patients (14.5%) had revision surgery. The rate of revision surgery was higher in patients who's fracture was fixed by the ATN vs TPF, 13.4% vs 23.4%, respectively. However, this difference did not reach a statistical significance (p value=0.18). No specific revision type was more prevalent in any fixation device (Table 4).

Multivariete logistic regression has identified the PFN system used as the only statistically significant factor in predicting fixation complication (p value =0.009). The odds ratio for any complication comparing TPF (OR=1) to the ATN device was 2.8 (95% CI = 1.29-6.16). Other covariates in the model were not found to be statistically significant (Table 5).

One year survival for the entire cohort was 81.7% (95% CI 77.6%-85.4%). One year survival for patients treated by the ATN and TPF devices were 84.1% (95% CI = 79.6%-88.6%) and 76.4% (95% CI = 69.1%-83.6%), respectively. This difference was statistically significant (p value = 0.047).

Figure 1

Table 1 : demographic and clinical characteristics (Total = 227 patients)

	Targon PF (N=147)	ATN (N=80)	P value
Gender			
Male	32 (21.8%)	20 (25.0%)	
Female	115 (78.2%)	60 (75.0%)	0.580
Age	75.1 (±15.0)	76.6 (±16.6)	0.066
Side			
Left	77 (52.4%)	39 (48.8%)	
Right	70 (47.6%)	41 (51.2%)	0.601
ASA score	2.64 (±0.63)	2.81 (±0.55)	0.033
Mechanism of injury (N=113)			
Low energy (fall)	48 (85.7%)	67 (85.9%)	
High energy	8 (14.3%)	11 (14.5%)	0.976
OTA fracture type			
31.A2-2 or A2-3	25 (17.0%)	20 (25.0%)	
31.A3-1,A3-2 or A3-3	103 (70.1%)	48 (60.0%)	
Subtrochanteric	19 (12.9%)	12 (15.0%)	0.392

ASA = American Society of Anesthesiologists.

Figure 2

Table 2: Surgery and post operative outcome parameters (Total = 191 patients)

	Targon PF (N=147)	ATN (N=80)	P value
Nail length			
Standard (200-240mm)	117 (79.6%)	59 (73.8%)	
Long (300-340mm)	24 (20.4%)	21 (26.2%)	0.314
Tip Apex distance≤25mm (N=155)	73 of 86 (84.9%)	46 of 69 (66.7%)	0.008
Reduction not achieved (translation≥20 mm)	14 (9.5%)	6 (7.5%)	0.607
Walking 1 year after surgery (with any walking aid) (N=106) 80 – 90.9%	38 of 42 (90.5%)	56 of 64 (87.5%)	0.636

Figure 3

Table 3: Complications

Total N=227 pts	Targon PF (N=147)	ATN (N=80)	P val
Cut out – 15 pts (6.6%)	6 (4.7%)	9 (12.5%)	0.07
Hardware failure – 9 pts (3.9%)	3 (2.1%)	6 (10.9%)	0.07
Nonunion – 3 pts (1.3%)	2 (1.4%)	1 (1.2%)	1
Deep wound infection – 5 pts (2.2%)	4 (2.7%)	1 (1.2%)	0.658
Secondary loss of reduction 5 pts (2.2%)	1 (0.7%)	4 (5.0%)	0.053
Internal rotation – 7 pts (3.1%)	2 (1.4%)	5 (6.2%)	0.099
Other – 4 pts (1.7%)	4 (1.7%)	0 (0%)	0.301
Total complications – 48 pts (21.1%)	22(14.9%)	26 (32.5%)	0.002

Table 3 includes surgical complications and revision surgery. Other complications included two patients with pain that required revision, one patient with fracture distal to the lower end of the fixation device, and one patient with superior placement of the fixation device that required revision.

Figure 4

Table 4: Revisions

Total N=227 pts	Targon PF (N=147)	ATN (N=80)	P value
Total Hip replacement – 4 pts (1.8%)	3 (2.0%)	1 (1.2%)	1
Hemiarthroplasty – 4 pts (1.8%)	1 (0.7%)	3 (3.8%)	0.126
Exchange nail– 4 pts (1.8%)	2 (1.4%)	2 (2.5%)	0.615
Hardware removal – 11 pts (4.8%)	6 (4.1%)	5 (6.2%)	0.524
Nail removal and plating – 3 pts (1.3%)	2 (1.4%)	1 (1.2%)	1
Rotation correction – 5 pts (2.6%)	2 (1.6%)	3 (4.7%)	0.348
Soft tissue revision due to infection 1 pt (0.5%)	1 (0.8%)	0 (0%)	1
Total revisions – 33 pts (14.5%)	18 (13.4%)	15 (18.8%)	0.18

Figure 5

Table 5 : Multivariate Logistic Regression

Variable	Odds Ratio (95% CI)	P value
Baseline (constant)	0.049 (0-0.52)	0.012
ASA score (for each point)	1.018 (0.542-1.914)	0.956
Tip apex distance		
Baseline (below 25 mm)	1	
Above 25mm	1.309 (0.526-3.256)	0.563
Reduction achieved		
Translation lower than 20 mm	1	
Translation ≥20 mm	2.864 (0.887-9.245)	0.079
PFN system used		
Targon PF	1	
ATN	2.819 (1.289-6.160)	0.009

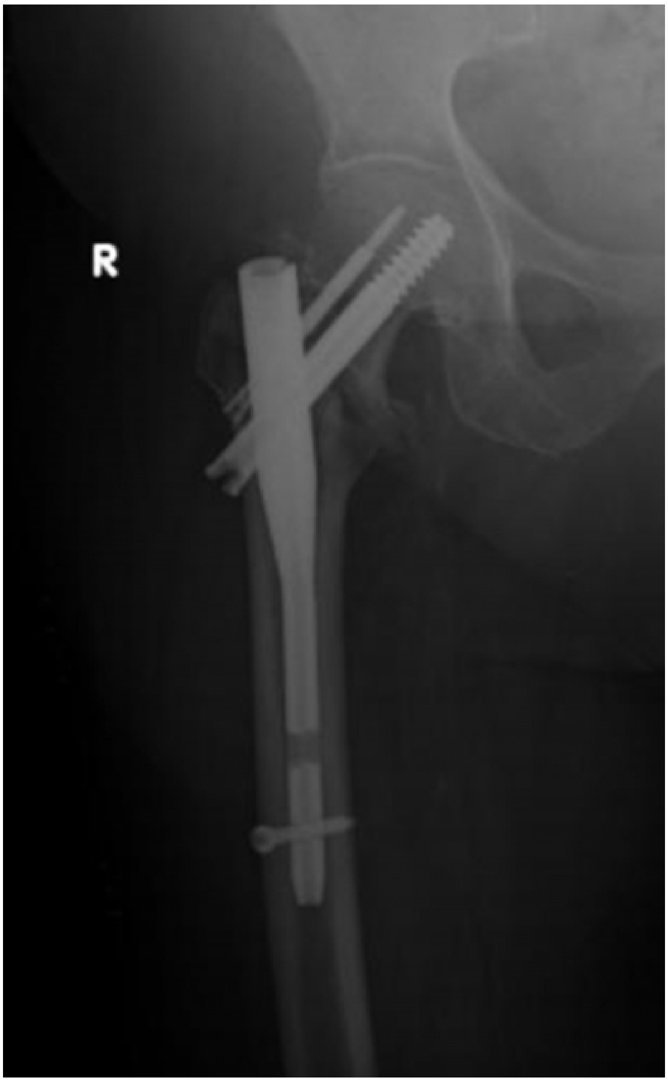
CI – confidence interval; ASA= American Society of Anesthesiologists; Targon PF = Targon proximal femur nail (Aesculap, Tuttlingen, Germany); ATN = antirotation trochanteric nailing system (dePuy, Warsaw, IN, USA).

Figure 6

Figure 1: Targon Proximal Femur nail (TPF)

Figure 7

Figure 2: Antirotational Trochanteric Nailing system (ATN)



DISCUSSION

In this manuscript it was shown that two PFN fixation devices differ in their complication rates. We found higher surgery complication rates in fractures fixed by the ATN device. This was reflected by higher survival rates seen with the TPF nail as compared to the ATN nail. No difference was found in clinical or epidemiology characteristics that could explain the differences found.

The overall high complication rates reported here can be attributed to the high complication rates observed in the ATN fixation device. Our complication rates with the TPF nail (14.9%) are compareable to those reported by other authors. Reported complications of unstable intertrochanteric fractures fixation included cut-outs (4%-20%), femoral shaft fractures (0%-10%) and nonunion (1%-2%)[4]. Subtrochanteric fracture fixation has shown similar results[21]. This further strengthen our conclusions.

Tip apex distance lower than 25 mm was shown, by Baumgarten et al (1995), to be associated with low failure rates[24]. Other works presented similar results[25,26]. We have shown that fixation by the ATN device had higher proportion of patients in which TAD was above 25mm. However, in our cohort this difference was not associated with higher complications or cutout rates.

We note that some failures are surgeon dependent while other (hardware failure) are more device dependent. However, we believe that one cannot be separated from the other. A device hard to handle may make even the most able surgeons have an imperfect result. We believe that the outcome of the surgeries should be judged considering all the complications observed.

Forte et al[27] (2010) and Donegan et al[28] (2010) separately considered factors influencing the mortality of patients after internal fixation of intertrochanteric fractures. Forte et al have shown that patients treated at a low volume versus high volume institutes had ninety days mortality rates of 24.4% and 12.9%, respectively.These survival rates are comparable to the survival presented in this study. Donegan et al (2010) has shown that higher ASA was associated with higher in hospital mortality rates. This was due to higher medical complications in patients with higher ASA scores[28]. In our study no clinically significant difference in ASA score was found between patients treated by the different devices.

The main drawback of our study is that it is a retrospective study. A prospective, randomized trial is necessary in order to reassure our results. However, our study can be viewed as a quasi randomized study. Patients admitted to our hospital with unstable pertrochanteric fracture from 2000-2007 had their fracture fixed by an TPF nail. Those admitted from mid 2007 to 2009 were fixed by the ATN device.

We believe our results are important since they offer surgeons some data for device selection. We also believe that our results carry an even broader implication; two devices even sharing similar devices cannot be expected to have similar results. The results of clinical trials with one device cannot be easily adapted to another, however similar.

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