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ORIGINAL ARTICLE

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A randomised comparison of AMBI, TGN and PFN for treatment of unstable trochanteric fractures

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Abstract *Introduction*: In this study, we initiated a prospective, randomised, clinical trial comparing the AMBI, TGN and PFN operations used for treatment of unstable fractures, for differences in intra-operative use, consolidation, complications and functional outcome. *Materials and methods*: We have compared the pre-, intra- and post-operating variables of AMBI, TGN and PFN operations that were used for treatment of unstable trochanteric fractures, of 120 patients all above 60 years old diagnosed with extracapsular hip fractures classified as AO Type 31-A2 or Type 31-A3. *Results*: According to our results the three methods are comparable in the treatment of unstable trochanteric fractures of patients above 60 years old. *Conclusion*: The AMBI remains the gold standard for the fractures of trochanteric region. TGN has an easier and faster procedure, facilitates early weight bearing and had minor late complications. An improper use of the PFN system was the reason for the most complications and the longer operation time of the device. PFN is also an accepted minimally invasive implant for unstable proximal femoral fractures but future modification of the implant to avoid Z-effect phenomenon, careful surgical technique and selection of the patients should reduce its high complication rate.

Keywords DHS · AMBI · TGN · PFN · Fractures · Trochanteric region

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Introduction

Trochanteric femoral fractures are common in elderly patients. The treatment of unstable fractures, type 31-A2, 31-A3 according to the AO [17] classification, requires a surgeon with considerable experience in these injuries. Implant failure and other complications are relatively common in non-compliant patients particularly.

The most widely used extramedullary implant—the dynamic hip screw (DHS, AMBI hip screw)—seems to have a biomechanical disadvantage when compared with intra-medullary devices because the load bearing in the proximal femur is predominantly shared through the calcar. Intra-medullary devices such as the Gamma Nail (classic GN, TGN) and Proximal Femoral Nail (PFN) are more stable under loading with a shorter lever arm, so the distance between the hip joint and the nail is reduced compared with that for a plate, so diminishing the deforming forces across the implant [14]. For unstable trochanteric and subtrochanteric fractures, the failure rate for a DHS is reported to be as high as 21% [28]. Comparative studies between DHS and GN have shown the highest incidence of complications in the GN group, in particular fracture of the femur below the tip of the implant, collapse of the fracture area and cutting out of the femoral neck screw [7, 8]. The proximal femoral nail (PFN) was designed by AO/ASIF group to overcome the above-mentioned limitations of GN [24]. Comparative studies between DHS and PFN in the treatment of low-energy pertrochanteric fractures (AO, A1/A2) did not show any statistical difference in intra-operative, radiological or clinical parameters [22]. Finally, comparative studies between GN and PFN in the treatment of unstable trochanteric fractures [23] have shown equal results in functional outcome, consolidation and local complications between the two implants. Overall complications were mostly related to the suboptimal reduction of the fracture and/or positioning of the implant. Pitfalls were mainly surgeon- or fracture-related, rather than implant-related. We therefore initiated a prospective, randomised, clinical trial comparing the AMBI, TGN and PFN for differences in intra-operative use, consolidation, complications and functional outcome based on the overall function according to Salvati and Wilson hip scoring system (pain, walking, muscle power-motion and function).

Materials and methods

Enrolment in our study was from January 2000 through December 2002, with follow-up until December 2003 (at least 1 year). Our University Hospital (Level 1 Trauma Centre) has an Orthopaedic Department that first introduces the use of intra-medullary nailing in Greece. During this period 262 patients were admitted to our hospital with the diagnosis of a fracture in the trochanteric region of the femur. One hundred and forty-one of those patients fulfilled the inclusion criteria. There was a good enough experience with each implant in the clinic. Four surgeons from the total stuff were involved in the operations.

Inclusion criteria

We included all extracapsular hip fractures classified as AO Type 31-A2 or Type 31-A3, age above 60 years old and a signed informed consent by the patient (or his/her relatives). We excluded those patients that were unable to walk before injury (resulting low mortality after the operation), those presenting with a pathologic fracture, any patient with previous ipsilateral hip or femur surgery, or any fracture with extension 5 cm distal to the inferior border of the lesser trochanter. Stable trochanteric fractures classified as AO Type 31-A1 were also excluded from the study.

Groups distribution

Pre-operative and later radiographs were reviewed by the consultant surgeon who carried out the operation and independently by another two experienced residents. Those patients who met our entry criteria ($n = 141$) were strictly randomised to one of three treatment groups. Non-survivors prior to first post-operative year (ten patients) and those who lost last follow-up evaluation (11 patients) were excluded leaving a total of 120 patients for the outcome analysis: Patients of group I ($n = 40$) were treated with the Dynamic Hip Screw (AMBI hip screw-Smith and Nephew), those in Group II ($n = 40$) with the Standard Proximal Femoral Nail (PFN-Synthes) and those in Group III ($n = 40$) with the Trochanteric Gamma Nail (TGN-Howmedica).

Pre-operative data

The pre-operative variables (Table 1) included age, sex, mode of injury and type of fracture. Pre-fracture mobility was assessed with the Salvati and Wilson hip function scoring system [21] that considered four specific parameters; pain, walking ability, muscle power-motion and overall function (Table 2). Pre-operative health status was assessed by obtaining a history of any co-morbid diseases and medication, as well as by determining the American Society of Anesthesiologists status of physical health.

Intra-operative variables

Intra-operatively, we recorded the type of anesthesia, the duration of the procedure, the amount of fluoroscopy, and the mean number of blood units transfused to the patients. There was no blood transfused post-operatively. Post-operative reduction of the fracture was assessed and characterised as anatomical, accepted or poor while the consultant surgeon considered the nature of the procedure as easy, moderate of difficult. Intra-operative technical and mechanical complications related to the implant or the surgeon was registered as well (Table 3).

Hospital course and stay

All patients received one dose of a second generation cephalosporin intra-operatively and two doses post-operatively and subcutaneous low molecular heparin starting the day of admission until the sixth post-operative week. The rehabilitation protocol was identical, including withdrawal of drainage and mobilisation out

Table 1 Pre-operative data of the patients

Data	AMBI	TGN	PFN
Mean age (years; 81.2)	81.4	82.8	79.4
Sex			
Male (47)	14	16	17
Female (73)	26	24	23
Mode of injury			
Fall at home	35	36	36
Fall from height	3	3	2
Traffic accident	2	1	2
Mean functional status[a]			
> 30	29 (72.5%)	30 (75%)	31 (77.5%)
20–29	6 (15%)	6 (15%)	5 (12.5%)
< 20	5 (12.5%)	4 (10%)	4 (10%)
ASA classifications[b]			
1	13 (32.5%)	14 (35%)	15 (37.5%)
2	10 (25%)	11 (27.5%)	11 (27.5%)
3	17 (42.5%)	15 (37.5%)	14 (35%)
Fracture			
A2	27	26	24
A3	13	14	16

Table 2 Salvati and Wilson hip function scoring system [10] *(max score = 40)*

Pain	
0 = Constant and unbearable, frequent strong analgesia	
2 = Constant but bearable, occasional strong analgesia	
4 = Nil or little at rest, pain with activities	
6 = Little pain at rest, pain on activity	
8 = Occasional slight pain	
10 = No pain	
Walking	
0 = Bedridden	
2 = Wheelchair	
4 = Walking frame	
6 = One stick,limited distances upto 400 yards	
8 = One stick, long distances	
10 = Unaided and unrestricted	
Muscle power and motion	
0 = Ankylosing and deformity	
2 = Ankylosing with good functional position	
4 = Poor muscle power, flexion < 60, abduction < 10	
6 = Fair muscle power, flexion 60–90, abduction 10–20	
8 = Good muscle power, flexion > 90, abduction > 20	
10 = Normal muscle power, full range of movement	
Function	
0 = Bedridden	
2 = House-bound	
4 = Limited housework	
6 = Most housework, can stop freely	
8 = Very little restriction	
10 = Normal activities	

of bed on the second post-operative day and subsequent ambulation with weight bearing as tolerated from the third or fourth day. We also recorded peri-operative medical complications and overall duration of hospitalisation.

Radiographic parameters

Anteroposterior and lateral views of the affected hip were obtained post-operatively and at each follow-up control. We noted any change in the position of the implants and the progress of fracture union. Non-union, malunion, avascular necrosis, loss of reduction, breakage of screws or implant were recorded and evaluated.

Last follow-up evaluation

Radiological control, overall time of consolidation, the need of reoperation and the overall function according to Salvati and Wilson hip scoring system was evaluated at the last follow-up assessment, at a mean time (1.0.) 1 year after the operation.

Surgical technique

The three- or four-hole Ambi hip system was used in 77% of the cases in group I. The position of the femoral head screw in the femoral head was divided into upper, middle and lower thirds and on the lateral radiographs into anterior, middle and posterior thirds. In 75% of the patients the length of hip screw was 90 mm or 95 mm and almost in all cases the side plate had an angle of 135°. The 135° angled TGN with the standard proximal diameter of 17-mm, distal diameter of 11 mm and lag screw diameter of 12 mm was used in all cases of group II. The common hip screw length was 90–100 mm. Distal locking with a 6.28 mm fully threaded screw was applied to all patients. Both Ambi hip screw and GN have yielded a great acceptance in our Department and there was a lot of experience in their application. During the last 10 years more than 450 Ambi and 250 GN have been implanted. In contrast, the PFN system has been recently introduced and a learning curve cannot be detected. The theoretical advantages of the PFN system to overcome the most common limitations of GN (fracture below the tip of the nail and cut out of the neck screw), can be summarised to: (a) the addition of the 6.5 mm anti-rotation hip pin to reduce the incidence of implant cut-out, (b) the smaller diameter and fluting of the tip of the nail, specially designed to reduce stress forces below the implant and therefore the incidence of low energy fracture at the tip, (c) the greater implant length, less valgus angle and setting of this angle at a higher level (11 cm from the proximal end) and (d) the more proximal positioning of distal locking to avoid abrupt changes in stiffness of the construct. In this respect, it should be born in mind that the neck screw must be adjusted to the calcar, taking into account the need of placement of

Table 3 Prioperative variables

Variables	AMBI	TGN	PFN	*P*
Mean operating time (min)	59.2 (40–100)	51.3 (30–240)	71.2 (60–240)	< 0.05
Mean fluoroscopy time (min)	0.21 (0.1–0.3)	0.26 (0.1–0.5)	0.26 (0.1–0.6)	> 0.05
Kind of reduction				
Anatomical	37 (92.5%)	36 (80%)	34 (85%)	> 0.05
Acceptable	2 (5%)	2 (5%)	4 (10%)	
Poor	1 (2.5%)	2 (5%)	2 (5%)	
Nature of the procedure				
Easy	7 (17.5%)	5 (12.5%)	2 (5%)	> 0.05
Moderate	21 (52.5%)	26 (65.5%)	24 (60%)	
Difficult	12 (40%)	9 (22.5%)	14 (35%)	
Mean blood loss (units)	282.4 ml	250 ml	265 ml	> 0.05
Average hospitalisation (*d*)	9.9	8.6	8.8	> 0.05
Died in hospital	1	2	1	> 0.05

the antirotational hip pin. The surgical technique was according to the manufacture's instructions. The proximal fragment was reamed in all cases, but rarely was any distal reaming carried out. If the surgeon noted excessive resistance to nail insertion as it crossed the fracture, then limited reaming was performed. Nail diameter was 11 or 12 in the majority of the cases and the common length of the hip neck screw 95–100 mm. A standard distal locking procedure was feasible as 37/40 patients were received two distal locking screws. According the side of the fracture there were for right/left the following: 21/19 cases for AMBI, 20/20 cases for TGN and 17/23 cases for PFN.

Statistical analysis

For abnormally distributed variables, the median was used for evaluation whereas the Mann–Whitney U test was used for comparison between groups. For approximately normally distributed variables, the arithmetic mean ± standard deviation and the unpaired Student's test were used. Differences were considered to be significant at a level of $P < 0.05$.

Results

Treatment groups were comparable with regards to all the pre-fracture variables, including age, sex, functional score, mode of injury, type of fracture and American Society of Anesthesiologists score (Table 1). The perioperative variables are seen in Table 3. There were not statistical important differences between the tree groups regarding the mean fluoroscopic time, kind of reduction, nature of operation, mean blood loss and averaged hospitalisation period. There was a statistically important difference only in the mean operative time between the three implants. As DHS and GN implantation have gained popularity in our clinic whereas the operative time for the PFN will be expected to be higher because a standard procedure and learning curve has not be established yet. The reason for the delay was attributed in most of our cases in technical difficulties, especially during the application of hip pin. TGN implantation was proved to be the faster operation with a mean time of 51.3 min. During hospitalisation, the three groups were similar with regards to medical complications, local wound complications, time to begin weight bearing, and hospital discharge (Table. 3, 4). Two patients in the AMBI group and one patient in TGN and PFN groups had scintigraphically verified pulmonary embolism. Superficial wound infections were treated with antibiotics. Intra-operative technical complications were noted mostly with the PFN implantation and had statistically significance. In 6 cases there were locking difficulties concerning mostly the application of hip pin (four cases) and the more distal locking screw (two cases).

Table 4 Systemic and local complications of the patients

Complications	AMBI	TGN	PFN
Systemic (total)	(10)	(8)	(9)
Chest infection	–	–	–
Pulmonary embolism	2	1	1
Respiratory distress	1	1	2
Mental disturbances	2	3	3
Urinary tract infection	2	2	1
Urinary retention	1	–	1
Deep venous thrombosis	2	1	1
Local (total)	(4)	(3)	(4)
Haematoma	3	2	3
Superficial wound infection	1	–	1
Delayed wood healing	1	1	–

The main reason for that was the lack of inappropriate space for the application of hip pin, as the neck screw in these particular cases has been placed quite superiorly. Inappropriate length of proximal screws was noted also in three cases (two shorter hip pins and one longer neck screw). One case of fracture of the great trochanter was noted also. In the AMBI group, there was only one case with a shorter neck screw while in the TGN group there was an extension of a fracture line to inner cortex by overeaming, which had been managed conservatively with decreased mobilisation for a period of 1 month.

Last follow-up radiographic review revealed that there were two cases of cut out in both AMBI and TGN groups and one case in the PFN group. Two of these cases in each group were managed with implant removal as the fracture had already united. A total hip arthroplasty (THA) was implanted to the other AMBI cut out and an exchange osteosynthesis into AMBI was made to the other TGN cut out case. In the PFN group only one cut out case was detected and it revised to THA. Non-union, malrotation and varus or valgus deformity were not statistical significant among the three groups. The AMBI non-union case was managed with conversion to the TGN implant plus autologous bone grafting whereas the TGN non-union was revised to THA as the femoral head had stage III degenerative osteoarthritis. There were not cases of implant breakages, especially fracture below the tip of the nail in both TGN and PFN groups.

Two cases with distal locking difficulties due to malalignment of the targeting device were noted also together with a case of inappropriate length of the neck screw. Finally a fracture of the greater trochanter was happened due to excessive hammering of the insertion device. The fractures of the great trochanter in all groups were treated conservatively.

The Z-effect phenomenon in the PFN group is a special complication referred to a characteristic sliding of the proximal screws to opposite directions during the post-operative weight-bearing period. In some cases, this sliding occurs only to one of the proximal screws while the other remains in its initial position leading to penetration of the femoral head. The term reversed Z-effect occurred with movement of the hip pin towards the lateral side, which required early removal. We had four cases of Z-effect and one case of reverse Z-effect. The latter and three of the cases with the Z-effect were managed with removal of implants, while the other case with Z-effect was treated conservatively because the length of the hip pin was quite short and do not lead to femoral head protrusion. There was no significant difference between the three groups with regards to consolidation period and return to pre-fracture level of ambulation and independence. The mean Salvati and Wilson score was higher in the TGN group (Table 5).

Discussion

The need for internal fixation and early mobilisation of patients with trochanteric fractures of the femur is generally accepted, not only to reduce the morbidity/mortality rates associated with the prolonged immobilisation, but also to improve the functional result in terms of malunion and mobility [25]. The best treatment for unstable trochanteric femoral fractures remains controversial. Intra-medullary devices seem to have mechanical and biological advantages in such fractures [13]. The TGN and PFN were designed to overcome difficulties encountered with extramedullary systems (DHS or AMBI) as breaking or bending of the implant, blood loss, wood complications and the lack of an immediate post-operative weight bearing. The goal of our study is to determine if there is a role for intra-medullary implants such as TGN and PFN in the management of unstable extracapsular hip fractures.

Other investigators have contacted a number of prospective randomised clinical studies comparing a sliding hip screw, most often the DHS, with an intra-

Table 5 Post-operative and follow-up data (1 year)

Variables	AMBI	TGN	PFN
Technical complications			
Intra-operative (total)	(1)	(5)	(10)
Intra-operative fracture	–	1	–
Locking difficulties	–	2	6
Inappropriate length of screws	1	1	3
Screw breakage	–	–	–
Fracture of the great trochanter	–	1	1
Late (total)	(5)	(4)	(10)
Neck screw cut-out	2	2	1
Malrotation	2	1	2
Varus/valgus deformity	2	1	2
Z-effect[b]/reverse Z-effect[a]	[a]	[a]	5 (4[b] + 1[a])
Implant breakage	–	–	–
Non-union	1	1	–
Reoperation			
Implant removal	1	1	4
Other method offixation	1	–	–
Total hip arthroplasty	1	2	1
Salvati and Wilson score (mean)	27	33	30
Consolidation (months)	3.4	3.1	3.2

[a]Salvati and Wilson Score [9]
[b]American Society of Anaesthesiologists scale [10]

medullary nail, usually the Gamma nail. The majority of the studies do not find a significant difference regarding the incidence of complications and patient outcome [3–5, 7, 8, 18–20, 22], and several note the common complication of femoral shaft fracture with the Gamma nail and recommend against its use [7–9, 20, 27]. On the other hand there are a limited number of reports that specifically favour the Gamma nail over the DHS [12, 16]. There have already been several large studies analysing the use of PFN, and few comparative studies. Simmermacher et al [24] in 1999 reported an overall technical failure rate of only (4.6%) in five cases out of 191 fractures. A high rate of intra-operative difficulties and technical and mechanical complications have been reported since this first report of PFN [1, 2, 6, 10, 26]. Werner et al. [26], was the first that introduced the term Z-effect, detected in five (7.1%) over 70 cases. The incidence of cut-out of the neck screw in this study was 8.6%. The term reversed Z-effect introduced by Boldin et al. [6] occurred with movement of the hip pin towards the lateral side. In his prospective study of 55 patients with unstable intertrochanteric or subtrochanteric fractures he had three cases with Z-effect and two with reverse Z-effect. Saudan et al. [22] compared a population of 206 patients the DHS with the PFN in the treatment of low energy trochanteric fractures and he found no advantages of PFN considering the patient outcome and the overall complications rate. Herera et al. [11] in a comparative study of 250 pertrochanteric fractures treated with the simple GN or the PFN system (125 fractures in each group) reported a statistical significant difference in the incidence of neck screw cut-out (4%) and fracture below the nail (3.2%) in the GN group, whereas in the PFN group, there were a higher incidence of secondary varus (7.2%) and collapse at the fracture site due to screw migration (8%). Finally, Schipper et al. [23] in a multicentric prospective clinical study compared 211 patients with unstable trochanteric fractures treated with the PFN with 213 patients treated with the GN. They found more cases (7.6%) with "lateral protrusion" of the hip screws in the PFN group compared with the GN group (1.6%). Most local complications were related to suboptimal reduction of the fracture and/or positioning of the implant. Functional outcome and consolidation were equal for both implants.

From our review of the literature, we did not find any other report that compares three different implants for the treatment of unstable trochanteric fractures. In the current study almost 90% of the fractures were healed in all groups by 3.5 months. In this respect, all the proposed fixation methods worked quite well. The differences in blood loss, infection rate, hospitalisation, systemic and local complications, consolidation time, non-union and overall functional outcome were not statistically important. Most technical complications were seen with the PFN implant and this can be explained by our immature learning curve. A slight but not statistically important difference was seen also between the AMBI and TGN group in respect to intra-operative difficulties and technical complications.

The nature and aetiology of Z-effect phenomenon has not yet be clarified. Normally a vertical force passing from the centre of the femoral head trends to move the affected hip into varus as soon as the patient is mobilised. This leads to normal sliding of both proximal screws achieving the expected compression at the fracture site. In some cases, this sliding occurs only to one of the proximal screws while the other remains in its initial position leading to penetration of the femoral head. Analysing our four Z-effect cases, we noted that all these patients had unstable trochanteric fractures with comminution of the medial cortex. The post-operative reduction of the fracture was not anatomic and the proximal screws had been placed higher from the level of the end cup of the nail. A possible explanation for the Z-effect phenomenon is the impaction of the hip pin into the proximal hole of the nail while the neck screw is normally sliding back during the weight-bearing period. The proximal fragment and the femoral head are moved back normally, whereas, the impacted hip pin protrudes through the head. The reverse Z-effect phenomenon has the same principles but here the hip pin is sliding back, whereas the neck screw remains impacted to the hole of the nail. Boldin et al. [6] suggest the use of a "ring" in the lateral side of hip pin in an effort to prevent this complication.

Conclusions

The three methods are comparable in the treatment of unstable trochanteric fractures. The AMBI remains the gold standard for the fractures of trochanteric region. TGN has an easier and faster procedure, facilitates early weight bearing and had minor late complications. An improper use of the PFN system was the reason for the most complications and the longer operation time of the device. At present, we consider that the PFN is an highly accepted minimally invasive implant for unstable proximal femoral fractures but future modification of the implant to avoid Z-effect phenomenon, careful surgical technique and selection of the patients should reduce its high complication rate.

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