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Intramedullary fixation of intertrochanteric hip fractures: a comparison of two implant designs

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Abstract We report a randomised prospective study comparing two implants, the Gamma trochanteric nail and the ACE trochanteric nail, in the treatment of intertrochanteric femoral fractures in the elderly. One hundred and twelve patients were randomised on admission into two treatment groups. Fifty-six patients were treated with Gamma nail implants, and 56 were treated with ACE trochanteric nail. The average age of these patients was 78 years. Twenty fractures were stable and 92 unstable. The mean follow-up time was 8 months (6–12). Regular clinical and radiological review was done 1, 3 and 6 months postoperatively. Operation time, fluoroscopy time, blood transfusion and complications were recorded. The mobility score was used to assess the pre-injury and postoperative mobility status. All the patients were treated within 36 h of their accident. There were no complications during surgery. All the patients were mobilised in the first 24 h postoperatively, regardless of the fracture type, and weight bearing was permitted as tolerated. Union of the fracture was achieved in all patients. There was no statistically significant difference between the two groups with regard to the studied parameters. There was no mechanical failure of the implants despite the early patient mobilisation. Early operation and early mobilisation resulted in a good functional outcome in all patients. Both the trochanteric gamma nail and ACE trochanteric nail provide effective methods of treatment for intertrochanteric fractures in elderly patients.

Résumé nous rapportons une étude randomisée prospective comparant deux implants : le clou gamma et le clou ACE dans le traitement des fractures inter trochantériennes fémorales chez les sujets âgés. Cent douze patients ont été randomisés à l'admission avec deux groupes de traitement;

56 patients ont été traités avec le clou gamma et 56 avec le clou ACE. L'âge moyen de ces patients est de 78 ans. Vingt fractures étaient stables, 92 instables. Le suivi moyen était de 8 mois (6 à 12 mois). Une surveillance clinique et radiographique a été réalisée à 1, 3 et 6 mois post-opératoire. Le temps opératoire, le temps d'amplificateur de brillance, la transfusion sanguine, le taux de transfusion sanguine et les complications ont été rapportés. La mobilité pré traumatique des patients et le statut d'indépendance post-opératoire ont été rapportés. Tous les patients ont été opérés dans les 36h00 après l'accident. Il n'y a aucune complication durant la chirurgie. Tous les patients ont été mobilisés à 24h00 post-opératoire quels que soient le type de fractures et l'appui a été autorisé. La consolidation de la fracture a été obtenue chez tous les patients. Il n'y a pas de différence significative entre les deux groupes. Il n'y a pas eu de problèmes mécaniques sur les implants, malgré la mobilisation précoce des patients. Une opération précoce et une mobilisation précoce entraînent un bon résultat et un bon devenir chez ces patients. Les deux clous, gamma ou ACE représentent une méthode effective du traitement des fractures inter-trochantérienne chez les sujets âgés.

Introduction

The sliding hip screw and side plate have for decades been the implant of choice in the management of intertrochanteric (IT) hip fractures [1]. Several studies have shown the satisfactory results achieved with the use of this implant design [2, 3]. Nonetheless, mechanical and technical failures have been reported in as many as 6 to 18% of cases, especially in the treatment of unstable IT hip fractures [4, 5, 21]. Intramedullary sliding hip screw devices were introduced to address these problems. The Zickel nail was introduced in the late 1960s for fixation of unstable pertrochanteric and subtrochanteric fractures of the femur [20]. This nail combined intramedullary and intracephalic fixation, but it was soon criticised because it usually demanded extensive exposure and failed to provide rotational and axial stability. The Gamma nail (Howmed-

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ca) was introduced in the late 1980s to overcome the problems associated with the Zickel implant. This implant was designed to combine the advantages of locking intramedullary nailing and of lag screw fixation. Unfortunately, early and late complications have been reported with the use of the 1st generation Gamma nail implant design that reduced the initial enthusiasm [8, 9]. The second generation Gamma nail and other newer improved implant designs have been introduced aiming for better results [10, 11, 16]. The purpose of this study was to compare the outcome and complications of the second generation Gamma nail (Trochanteric Gamma Nail-Stryker) and the ACE Trochanteric Nail System (DEPUY) in the treatment of intertrochanteric femoral fractures in elderly patients. The trochanteric Gamma nail was first introduced in 1997. It has a 17-mm proximal diameter, 180-mm length, and 4° valgus curvature, with only one transverse distal locking screw, and a 12-mm diameter lag screw. It is made of a nitrogen-containing stainless steel alloy (Orthinox®). The ACE trochanteric nail was introduced 4 years later and is manufactured from titanium alloy (TIMAX®). It has a 16-mm proximal diameter, 180- or 200-mm length, 5° valgus curvature and 10.5-mm diameter lag-screw. Additionally, an optional anti-rotation lag-screw is available, and two distal holes for static or dynamic locking can be used. To our knowledge, this is the first study comparing these two implant designs in the English literature.

Patients and methods

After approval by the ethics committee of the hospital, 112 consecutive patients with 112 intertrochanteric femoral fractures were randomised upon their admission to the hospital using a sealed envelope method. Fifty-six of them were treated with the trochanteric Gamma nail (Gamma nail) and 56 with the ACE trochanteric nail (ACE TN). The average age of the 32 male and 80 female patients was 78 years (69–89 years). Two patients had fallen from a height, and four patients had been involved in a motor vehicle accident; the rest of the injuries resulted from low energy falls. Exclusion criteria were patients younger than 65 years, pathological fractures (i.e., secondary to metastasis), non-ambulatory patients and American Society of Anesthesiologists (ASA) score V. Patients with previous ipsilateral or contralateral hip fractures were also excluded from the study. The fracture pattern was classified by the system of Evans as modified by Jensen [12], and then categorised as either stable (types I and II) or unstable (types III or IV). The preoperative variables studied included patient age, mobility status, fracture classification and the American Society of Anesthesiologists rating of operative risk [13]. The preoperative information of the two groups is summarised in Table 1. The operations were performed by two experienced surgeons, usually outside the regular working hours. All the patients were treated within the first 36 h of their injury. Sixty-six patients were treated within the first 6 h. The intraoperative variables

studied included operation time, blood transfusion, fluoroscopy time and complications (Table 2). The type of anaesthesia was spinal in most patients. Operations were performed in a standardised fashion under image intensification on a traction table with the patients in the supine position. Every effort was made to achieve the optimum reduction. The desired position of the implant was a central position in the femoral neck on both AP and lateral views, and the tip within 5–10 mm from the subchondral bone. A description of the operative technique and the implant characteristics is not within the scope of this paper. Briefly, the trochanteric Gamma locking nail is 18 cm long and is only available in a single distal diameter (11 mm). The cervico-diaphyseal angles available are 125°, 130° and 135°. A single distal locking screw is used to prevent rotation. The ACE trochanteric nail is 18 or 20 cm long and is available in distal diameters of 9, 11 and 13 mm. The cervicodiaphyseal angles available are 125°, 130°, 135° and 140°. Two distal locking holes are available for static or dynamic distal locking.

In all patients an 11-mm distal diameter ACE trochanteric nail was used. In all patients distal locking was performed with one locking bolt (always the proximal bolt for the ACE TN patient group). Thus, in no case was distal reaming necessary. Two typical examples of the osteosynthesis with the Gamma nail and the ACE TN are shown in Figs. 1 and 2, respectively.

Postoperatively, all patients were given prophylactic antibiotics for 24 to 48 h and deep venous thrombosis prophylaxis (low molecular weight heparin) for 6 weeks. Patients were mobilised on the first postoperative day, regardless of the fracture pattern, and full weight bearing was permitted as tolerated.

Regular radiological and clinical examinations were performed in all patients 1, 3 and 6 months postoperatively. The mobility status and the postoperative complications were recorded at the latest follow-up. For the patients with unstable fractures, the mobility status was calculated separately in addition (Table 4).

Statistical analysis was performed with the use of Student's *t*-test for continuous data, the chi-square test and the Wilcoxon run sum test. The statistical calculations were performed with the GraphPad InStat software, version

Table 1 Background parameters of the patients (n=112)

	Gamma nail	ACE TN	P value
Patients (n)	56	56	NS
Sex (males/females)	19/37	13/43	
Mean age (years)	79.5	78.1	NS
Fracture unstable/stable	44/12	48/8	NS
Side left/right	38/18	24/32	
ASA score			
1	8		NS
2	16		NS
3	23		NS
4	9		NS

NS= no significant difference

Table 2 Intraoperative and early postoperative data (within the 1st week postoperatively)

	Gamma nail (n=56)	ACE TN (n=56)	P value
Anaesthesia general/regional	7/49	10/46	
Operative time (skin to skin)	51 min (SD 11)	54 (SD 15)	NS
Fluoroscopy time	2.2 (SD 1.8)	2.5 (SD 1.7)	NS
Blood transfused (units)	2.3 (SD 1.6)	2 (SD 1.7)	NS
Patient transfused	42	49	NS
Hospital stay	7 days (4–14)	7.2 days (4–15)	NS
Major/minor complications	0/6	0/9	NS
Deaths	2	2	NS

NS=no significant difference

3.00. Differences were considered to be significant at a level of $P<0.05$.

Results

Randomisation provided similar groups with regard to patient age, gender distribution, fracture pattern and American Society of Anesthesiologists rating of operative risk. According to the Evans classification, 92 fractures were unstable and 20 stable (Table 1). The preoperative mobility score, as proposed by Parker and Palmer (14), was calculated to be 7.7 ± 1.8 for the Gamma nail group and 7.4 ± 1.9 for the ACE TN group (Fig. 3) (Table 4). In 95% of the Gamma nail group and 92% of the ACE TN group, a 130° cervico-diaphyseal angle nail was used. There were no intraoperative complications in either patient group. The mean fluoroscopy time (reduction manipulations not included) was 2.2 ± 1.8 for the Gamma nail group and 2.5 ± 1.7 for the ACE TN group (Fig. 4). The mean operation time (skin to skin) was 51 ± 11 min for the Gamma nail group and 54 ± 15 min for the ACE TN group. In summary, 91 patients were transfused in both groups with 2.1 ± 1.1 blood units. Forty-two patients of the Gamma nail group were transfused with 2.4 ± 1.6 blood units, and 49 patients of the ACE TN group were transfused with 2.0 ± 1.7 blood units (Fig. 5).

Fig. 2 Intramedullary nailing of an unstable intertrochanteric fracture with the ACE trochanteric nail, preoperatively and 3 months after surgery

Of the patients 5 were lost to follow-up and 19 died within the study period. This left us with 88 patients for clinical study. Forty-one of these patients were treated with the Gamma nail and 47 with the ACE TN. The mean follow-up time was 8 months, ranging from 6 to 12 months. We saw no mechanical failure of either implant during the study period. Fracture healing occurred in all patients within the first 5 months. The postoperative mobility score

Fig. 1 Intramedullary nailing of an unstable intertrochanteric fracture with the Gamma nail, preoperatively, 1 month and 6 months after surgery

Fig. 3 Pre-injury mobility score

Fig. 4 Fluoroscopy time (reduction manipulations not included)

Fig. 5 Blood transfused (units)

as calculated at the latest follow-up, decreased in both groups (Table 4) (Fig. 6).

One case of deep vein thrombosis in the Gamma nail group was treated with long-term anticoagulation therapy. Other complications, including cardiopulmonary compli-

Fig. 6 Postoperative mobility score

cations, urinary tract infections and superficial wound infections are listed in Table 3.

In summary, statistical analysis revealed that there was no significant difference between the two patient groups with regard to the operation time, the mean fluoroscopy time, the amount of blood transfused and the latest functional outcome. The mobility status for stable and unstable intertrochanteric fractures is summarised (Table 4).

Discussion

The discussion about the ideal implant for the treatment of IT fractures continues. For decades the implant of choice for the treatment of most intertrochanteric fractures was a sliding hip screw and side plate [15]. Reports of high failure rates especially in the treatment of unstable IT fractures and complications due to the greater surgical trauma [7] have led to the introduction of the Gamma nail (Howmedica). This implant was designed to combine the advantages of locking intramedullary nailing and of the lag screw fixation. Additionally, the use of an intramedullary device should decrease the bending level arm and the torsion force, resulting in less implant stress [6, 7]. Despite these theoretical advantages, high complication rates were reported with the Gamma nail, such as intraoperative and postoperative femoral shaft fracture at the nail tip and at the insertion sites of the locking bolts [3, 17]. Other studies comparing the Gamma nail with a sliding hip screw have found no differences or only minor differences regarding the operating time, duration of hospital stay, infection rate, wound complications, implant failure, or screw cut out [18, 19].

Several authors have suggested that the high failure rates of the first generation Gamma nail resulted from the design and the geometry of the nail [3]. Biomechanical studies have shown that in the Gamma nail, the compression loads are concentrated at the implant's distal point of fixation [22], resulting in the high rates of femoral shaft fractures at the tip of the implant, particularly in the early years following its introduction. The non-anatomical 10° valgus bend of the Gamma nails was partly responsible for this [23]. New implant devices have been introduced to address these problems [10, 18, 19].

Table 3 Postoperative complications (recorded at the latest follow-up)

	Gamma nail (n=41)	ACE TN (n=47)	P value
Implant failures	0	0	
Deep vein thrombosis	1	0	
Superficial wound infection	3	4	NS
General complications	12	17	NS

NS= no significant difference

Table 4 Preinjury and postoperative mobility score

Mobility score	Gamma nail	ACE TN	P value
Pre-injury	7.7±1.8 (n=56)	7.4±1.9 (n=56)	NS
Postoperatively	7.0±2.1 (n=41)	7.1±2.5 (n=47)	NS
Postoperatively for the patients with unstable IT fracture	5.4±2.5 (n=32)	5±1.9 (n=39)	NS

NS= no significant difference

The purpose of this study was to compare two second-generation intramedullary implants, the Gamma trochanteric nail with the ACE trochanteric nail, in the treatment of intertrochanteric hip fractures. To our knowledge, this is the first study comparing these two intramedullary implants.

The second generation Gamma nail is shorter than the standard Gamma nail and has only one distal locking screw and one distal diameter of 11 mm. Additionally, the valgus offset angle is decreased to 4° and the nail's length is decreased to 18 cm. Similarly, the ACE trochanteric nail has a valgus offset angle of 5° and implant length of 18 and 20 cm. Additionally, the surgeon can make a decision between proximal (dynamic) and distal (static) locking, and an extra option is available for a second anti-rotation lag screw.

In this series we treated all the patients of the ACE TN group with 11-mm distal diameter nails, and we always locked the nails with a single proximal locking bolt. Moreover, we did not use an anti-rotation lag screw in any patients, regardless of the fracture pattern. By using small diameter nails, distal reaming was not necessary in any patient of either group, thus reducing both the possibility of femoral shaft fracture and the operation time.

The operation time and the fluoroscopy time were higher in the ACE TN group. The cannulated awl of the Gamma nail tool set helps the initial placement of the guide wire leading to a reduction in the operation time. Nevertheless, statistical analysis revealed that the difference between the two groups was not statistically significant.

In the ACE TN group, we always used the proximal locking bolt. This provided adequate torsional stability of the fixation whilst decreasing the stress riser at the tip of the nail. In this series no intraoperative or postoperative femoral shaft fracture occurred at the tip of the implants, despite the early patient mobilisation, with full weight bearing regardless of the fracture's pattern.

We believe that early operation was crucial for the good functional outcome and for the absence of serious postoperative complications. All patients were operated on within 36 h of their injury, and 59% of the patients were operated on within the first 6 h. At the latest follow-up, 65% of the patients of the Gamma nail group and 63% of the patients of the ACE TN group had reached the preoperative mobility status. Additionally, there was no significant

difference between the two groups as far as the final mobility scores were concerned. We calculated the mobility score for the unstable IT fractures separately, but found no significant difference between the two groups.

In a recent study, Siegmeth et al. [24] have shown that a delay of more than 48 h before operation significantly prolonged the hospital stay in patients with hip fractures. Other studies suggest that early operation and early patient mobilisation reduces the risk of fatal pulmonary embolism and the risk of deep vein thrombosis, whereas prolonged bed rest may increase the risk of medical complications such as deep venous thrombosis, pulmonary complications, urinary tract infection and skin breakdown [25].

Conclusions

The goal of the operative treatment of the intertrochanteric hip fractures is the stabilisation of the fracture and early patient mobilisation, restoring the function of the limb. This was achieved satisfactorily with the use of the two implant designs studied. Despite the fact that ACE TN is a newer implant design and even though there are differences in the manufacturing material and the design of the nails, we found no statistically significant differences with regard to the studied parameters. Early operation and early mobilisation resulted in a good functional outcome, without serious complications for the implant or the patient.

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