



## Intramedullary fixation of intertrochanteric hip fractures A comparison of two implant designs *A prospective randomised clinical trial*

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We report the results of a prospective randomized clinical trial comparing the Gamma 3 nail with the ACE trochanteric nail for the treatment of pertrochanteric femoral fractures. One hundred and twelve consecutive patients were enrolled in the study: 61 patients were treated with the Gamma 3 nail, 51 with the ACE trochanteric nail.

The two groups were matched for age, fracture type and preoperative Merle d'Aubigné hip score. All patients were followed up clinically and radiographically on a regular basis between 6 weeks and one year postoperatively. Twenty-six patients (23%) died within the first postoperative year. Six patients were lost to follow-up. In each group, two patients were revised due to mechanical failure. Nonunion did not occur. The mean postoperative hip scores in the Gamma 3 and the ACE group were 14.19 and 14.12 respectively, with no significant difference ( $p = 0.92$ ). Walking ability was adequately restored in approximately 80% of the patients. Both implants appeared as safe and effective methods of treatment for intertrochanteric hip fractures.

**Keywords** : intertrochanteric fractures ; internal fixation ; Gamma 3 nail ; ACE nail.

### INTRODUCTION

An increase in the elderly population has resulted in a higher incidence of pertrochanteric fractures of the femur. The annual global number of hip frac-

tures is expected to exceed 7 million in the next 40 to 50 years (16). These fractures therefore constitute an important part of an orthopaedic practice.

To prevent the complications of prolonged immobilisation, timely management using methods that provide sound fracture stabilisation and allow early patient mobilisation, becomes increasingly important (8,15,19).

Over the years, various techniques and implants have been introduced to achieve stable fracture fixation.

The first highly successful device was the sliding hip screw and side plate (5,14), but because of some

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mechanical and technical failures, especially in the treatment of unstable pertrochanteric fractures (10,23), intramedullary devices were introduced. The shortcomings of the Zickel nail and the experience with the first-generation intramedullary hip designs (4,26), led to the development of a successful intramedullary hip nail in the 1990s (9,20). Currently, several intramedullary hip devices are available. The purpose of this study was to compare the outcome of the Gamma 3 nail (Stryker, Kiel, Germany) and the ACE trochanteric nail (DePuy, Warsaw, USA) in the treatment of intertrochanteric femoral fractures in elderly patients.

The third-generation trochanteric Gamma nail, which was redesigned from the 1988 and 1997 versions, was introduced in 2004. It has a 17-mm proximal diameter, 180-mm length and 4° valgus curvature, with a single transverse distal locking screw and a 10.5-mm diameter lag screw. It is made of a nitrogen-containing stainless steel alloy (Orthinox®) or titanium alloy.

The ACE trochanteric nail was introduced in 2001. 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 antirotation lag-screw is available. Two distal holes for static or dynamic locking can be used. The nail is manufactured from titanium alloy (TiMAX®). To our knowledge, this is the first study comparing these two implant designs.

## PATIENTS AND METHODS

After approval of the study plan by the hospital ethics committee, 112 consecutive patients with pertrochanteric femoral fractures resulting from a low-energy fall, were on admission randomised into treatment with either a Gamma 3 nail or an ACE nail between August 2006 and July 2009. Exclusion criteria were pathological fractures, multiple injuries and a high likelihood of loss to follow-up.

The preoperative variables studied were patient age, Merle d'Aubigné score, fracture classification (Evans and AO classification), and the American Society of Anesthesiologists (ASA) rating of operative risk.

There were no significant differences between the Gamma 3 and the ACE group with regard to these variables.

All patients were treated within 24 hours of admission. A senior orthopaedic resident performed the operations in a standard fashion on a traction table with use of an image intensifier. Every effort was made to achieve an optimal reduction. Preferential positioning of the lag screw was inferior to central in the femoral neck on the AP view and central on the lateral view, with the tip within 5-10 mm from the subchondral bone. With the Gamma 3 nail (11-mm distal diameter, 180-mm length, 4° valgus curvature, 120°, 125° or 130° neck angle), the set screw (antirotation) and one distal locking screw were used in all cases. With the ACE nail (11-mm distal diameter, 200-mm length, 5° valgus curvature, 125° or 130° neck angle), only one distal locking screw was used. The additional antirotation screw was used when rotational instability was expected. All patients were given one dose of cefuroxime before the operation and low-molecular-weight heparin for 4 weeks postsurgery. They were mobilised with full weight-bearing as tolerated. Regular radiographic (AP and lateral views) and clinical examinations (with Merle d'Aubigné score) were performed in all patients between 6 weeks and 1 year postoperatively. Technical failures were defined as penetration of the lag screw, excessive displacement, e.g. medialisation of the femoral shaft, breakage or loosening of the implant, intraoperative or postoperative fracture of the femoral shaft, or nonunion. The fracture was considered healed if there was visible callus across the fracture line. Nonunion was defined as the absence of radiographic callus across the fracture line, including early redisplacement or progressive displacement. Complications such as superficial or deep wound infections, avascular necrosis, deep vein thrombosis, and severe general complications (cardiac, pulmonary, thromboembolic, cerebro-vascular or death) were recorded.

Statistical analysis was performed with SPSS Statistics 19.0, with use of the Student's t-test, the chi-square test, the Wilcoxon rank-sum test and the Fischer exact-test.

## RESULTS

One hundred and twelve patients with a mean age at surgery of 74.9 years (SD 13.2) were randomized into two groups treated with either the Gamma 3 nail or the ACE trochanteric nail. The two treatment groups were comparable with respect to sex distribution, age, side and fracture pattern (Table I).

Table I. — Preoperative characteristics of the Gamma 3 group and the ACE group

	Gamma 3	ACE	p value
Patients	61	51	NS
Sex (male/female)	35/26	32/19	NS
Mean age (years)	73 SD 12.5	77 SD 14	NS
Fracture stable/unstable	18/43	20/31	NS
Right/left side	29/32	21/30	NS
Merle d'Aubigné score (/18)	16.42 SD 2.06	16.06 SD 2.49	NS (0.47)

Table II. — Postoperative complications

	Gamma 3 (61)	ACE (51)
Non-union	0	0
Deep vein thrombosis	0	0
Peripheral nerve injury	1 (1.6%)	0
Failure of internal fixation	2 (3.2%)	2 (3.9%)
Wound infection	0	0
Implant failure	0	0
Death (non surgery-related)	14 (22.9%)	12 (23.5%)



Fig. 1. — Gamma 3-Nail

The preoperative Merle d'Aubigné hip score was 16.42 (SD 2.061) for the Gamma 3 group and 16.06 (SD 2.495) for the ACE group. The mean skin-to-skin operative time was 41 min and 51 min, respectively. No intraoperative technical errors occurred in either group. Six patients were lost to follow-up.

Five complications were observed (Table II). One peripheral nerve injury (foot drop) due to preoperative traction was noted postoperatively. Two failures occurred in both the Gamma 3 group (3.2%)

and the ACE group (3.9%), due to screw cut-out or secondary displacement of the fracture components (Table III). Deep vein thrombosis or superficial and/or deep wound infections were not encountered. No implant failure was recorded. Twenty-six patients died during the follow-up period, none from a cause directly related to the operative procedure.

The postoperative Merle d'Aubigné hip score at consolidation was 14.19 (SD 2.86) in the Gamma3 group and 14.12 (SD 2.95) in the ACE group (Table IV & Figure 3). Analysis revealed no

Table III. — Failure of internal fixation

Sex	Age	Fracture	Hip score	Implant	Time to failure	Screw cut-out	Revision
Female	59	A1.2	18	ACE	4 weeks	No (rotation)	THA
Male	79	A1.1	18	Gamma 3	10 weeks	No	THA
Female	86	A2.2	17	ACE	11 weeks	Yes	BHA
Female	82	A2.3	17	Gamma 3	7 weeks	Yes	THA



Fig. 2. — ACE Trochanteric Nail

statistically significant difference between the two groups. The same applied to the Merle d'Aubigné subgroup scores.

However, compared to the preinjury level, a significant deterioration of the mean hip scores at consolidation was seen in both groups (Table V).

Walking ability (with or without a walking aid) was restored in 80% of the Gamma3 group and in 83 % of the ACE group. The mean walking score diminished from a mean of 5.05 preoperatively to 4.20 postoperatively in both groups.

## DISCUSSION

After its introduction in the 1950s, the sliding hip screw with its side plate became the gold standard for the treatment of intertrochanteric femoral fractures. However, because of reports of mechanical failures (10,23), especially in unstable fractures, newer devices became available with theoretically superior biomechanics. The nails of the 1980s performed less well because of their design with a large valgus curvature, large diameter and long length. This resulted in a three-point fixation of the non-elastic implant within the proximal femur, causing stress concentration at the distal part of the implant, with

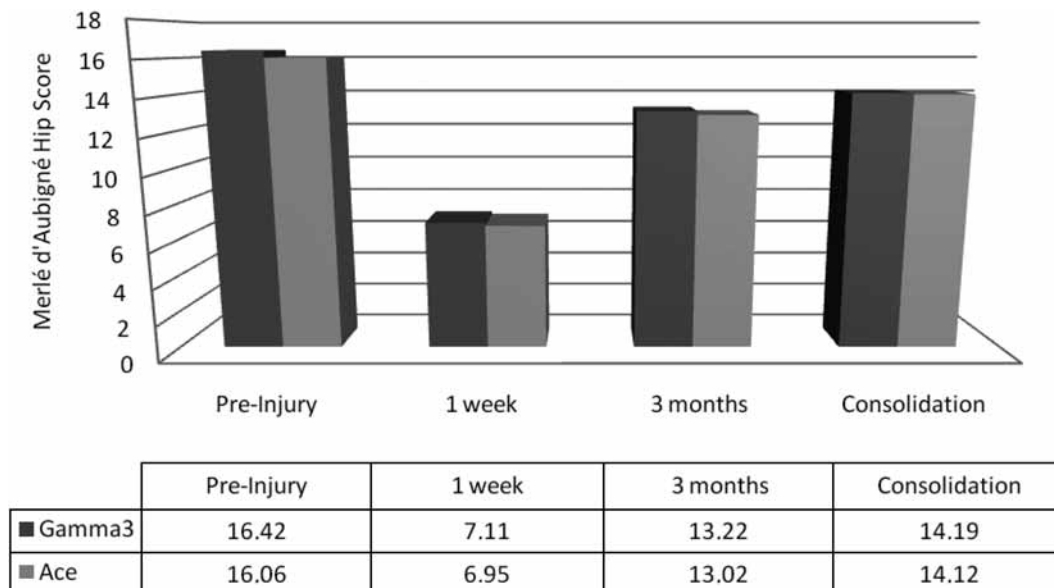


Fig. 3. — Evolution of the mean Merle d'Aubigné hip score in the two groups

Table IV. — Merle d'Aubigné hip score at consolidation

Merle d'Aubigné	Gamma 3	ACE	p value
Pain (/6)	5.40 SD 0.88	5.09 SD 1.10	NS (0.13)
Mobility (/6)	4.88 SD 0.97	5.03 SD 0.68	NS (0.16)
Walking (/6)	4.10 SD 1.70	4.40 SD 1.45	NS (0.68)
Total (/18)	14.19 SD 2.86	14.12 SD 2.95	NS (0.92)

Table V. — Merle d'Aubigné hip score preinjury and at consolidation

	Preinjury	Consolidation	p value
Gamma 3	16.42 SD 2.06	14.19 SD 2.86	0.001
ACE	16.06 SD 2.49	14.12 SD 2.95	0.15

femoral shaft fractures as a result (1,3,18). In the last 15 years, since the introduction of the second- and third-generation nails with a more anatomic and slimmer design, only few femoral fractures have been encountered. In the literature, the reported incidence ranges between 0% (13) and 1.4% (12), which is consistent with our series. No femoral fractures were seen. Because of these favourable results, the intramedullary nail has become a powerful, minimally invasive and safe implant for the treatment of intertrochanteric femoral fractures (9,11,20). This has led to an exponential increase in the use of the nail, at the expense of the sliding hip screw and side plate. The American Board of Orthopaedic Surgery noted a major change in practice since 1999 (2). In their study cohort, 3% of intertrochanteric fractures were treated with intramedullary fixation in 1999, increasing to 67% in 2006. This trend occurred especially among young orthopaedic surgeons.

The present study was designed to compare two proximal femoral nails, the Gamma 3 nail and the ACE trochanteric nail, for the treatment of intertrochanteric hip fractures.

Good results were achieved with both the Gamma 3 nail and the ACE nail. The postoperative hip scores were comparable in both groups (Table IV). The complication rate was very low and did not differ between the groups (Table II). The theoretical advantages of intramedullary nailing,

being low invasiveness, short operative time and good safety profile, could be confirmed.

To our knowledge, no similar trials have been reported in the literature. An Athens study group compared the use of the second-generation Gamma nail with the ACE nail and reported a Palmer and Parker mobility score of 7.0/10 and 7.1/10, respectively, with no statistically significant difference (17). The complications and technical failures were not significantly different either. Our results are highly consistent with their findings.

We believe that early surgery is essential to reduce the postoperative complication risk. All patients were treated within 24 hours of admission. The earlier a patient is operated on, the better the outcome and the lesser the complications (22). Early surgery was found to be associated with a 19% reduction in mortality risk (25). Also, a short anaesthesia time and a minimally invasive procedure are important advantages in an elderly population and make intramedullary nailing a valuable treatment option.

In our series, 4 failures occurred (Table III), but early diagnosis and early revision surgery led to a good outcome in all 4 patients. Mechanical failure in intramedullary nailing is mostly due to the lag screw cutting out from the femoral head, and in our opinion, necessitates early revision to a hip prosthesis (dual mobility hemiarthroplasty or total hip arthroplasty). Repeat internal fixation is rarely successful in elderly osteoporotic patients. Failures with the use of a sliding hip screw and sideplate are more frequently caused by a medialisation of the femoral shaft, especially in unstable fractures. In these cases, conversion to intramedullary nailing with reduction of the femoral shaft is worth trying.

A weakness of our study is the number of different surgeons (n = 9) who operated on the patients. Therefore, the surgical procedure was always meticulously followed with both types of nails. The postoperative scoring was performed by one single investigator.

Another weakness is the small patient group, with a relatively large number of patients lost to follow-up. Unfortunately, this is inherent to dealing with an elderly population and has a negative effect on the power of statistical analysis. Almost 1 out of

Table VI. — Literature data on mortality rate after proximal femoral fracture

Study	Country	Year	Population	Follow-up	Mortality rate
Zuckerman <i>et al.</i> (27)	USA	1995	367	1 year	26.9%
Elliot <i>et al.</i> (7)	Ireland	2003	1780	1 year	21.9%
Scheerlinck <i>et al.</i> (21)	Belgium	2003	201	4 months	15.9%
Smetkala <i>et al.</i> (25)	Germany	2008	2325	1 year	13.4%

4 patients died within the first postoperative year, which is consistent with the 1-year mortality ratio after proximal femoral fractures reported in the literature (Table VI).

In conclusion, the results of the present study show that both the Gamma 3 nail and the ACE nail provide effective methods of treatment for pertrochanteric hip fractures. No significant differences were found in functional outcome, or complication – and failure – rate. However, further follow-up is mandatory to confirm these findings. Early surgery is essential to prevent complications and to maximize patient outcome. Nevertheless, a hip fracture is always associated with severe temporary and sometimes permanent impairment of independence and quality of life. It continues to be an important predictive factor of the 1-year mortality rate in elderly patients.

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