ORIGINAL PAPER

A Clinical Comparison between the Gamma® and the Claufitt® Nails in Unstable Proximal Femoral Fractures

R. Sanjuan-Cerveró[a], M. Morales Suárez-Varela[b], J.R. Sanchis-Sanegre[a] and J. Fenollosa-Gómez[a]
[a]Department of Orthopedic and Trauma Surgery. Doctor Peset University Hospital. [b]Department of Clinical Research and Epidemiology. Doctor Peset University Hospital. Department of Preventive Medicine and Public Health. University of Valencia. Valencia

Purpose. To assess the differences that exist between two intramedullary osteosynthesis systems for the treatment of unstable proximal femoral fractures in an attempt to find out whether the use of an antirotation screw improves the final result.
Materials and methods. A retrospective study was carried out to analyze the plcement and clinical evolution of both intramedullary nailing systems (Gamma® y Claufitt®). The patients' medium-term functional status was evaluated and benchmarked against the characteristics of the population served by our University Hospital. A final database was obtained made up of 43 cases of Claufitt® that met the criteria of our study. A functional assessment system was custom designed for each patient.
Results. Although the results are not statistically significant, the results obtained with Claufitt® proved to be 10% better than those for the Gamma®, nail. The Real Functional Assessment is a straightforward, reproducible and useful evaluation method to perform an detailed individualized follow-up of our patients that can be applied to any type of procedure or follow-up protocol.
Conclusions. The data obtained are in line with that published in the literature. The differences between the two intramedullary osteosynthesis systems cannot be quantified technically or clinically. Each patient's functional status and clinical evolution can be determined easily through the Real Functional Assessment.

Key words: *intramedullary nail, antirotation screw, Claufitt®.*

Comparación clínica entre clavo Gamma® y clavo Claufitt® en fracturas inestables de fémur proximal

Objetivo. Evaluar las diferencias entre dos sistemas de osteosíntesis intramedular en fracturas de extremo proximal de fémur inestables, observando si la presencia de un tornillo antirrotación mejora el resultado final.
Material y método. Se diseña un sistema de valoración funcional individualizada por enfermo. Aplicando este sistema se realiza un estudio retrospectivo valorando la colocación y evolución clínica de dos sistemas de enclavado endomedular (Gamma® y Claufitt®). Se valora la situación funcional del paciente a medio plazo en el área de población de un hospital universitario. Se obtiene una base final de datos con 43 casos de Claufitt® aptos para el estudio.
Resultados. La valoración funcional real es un método de evaluación sencillo, reproducible y útil para el seguimiento pormenorizado de los enfermos de modo individual y del mismo modo aplicable a cualquier tipo de intervenciones o protocolos de seguimiento. Aunque los resultados no son estadísticamente significativos, el Claufitt® presenta, respecto al clavo Gamma®, un 10% de mejores resultados.
Conclusiones. La valoración funcional y la evolución de cada enfermo en particular pueden ser evaluadas de un modo sencillo mediante la valoración funcional real. Las diferencias entre los dos tipos de sistemas de osteosíntesis intramedular no son objetivables ni técnica ni clínicamente. Los datos obtenidos son acordes con la bibliografía publicada.

Palabras clave: *clavo intramedular, tornillo antirrotación, Claufitt®.*

Corresponding author:
R. Sanjuan Cerveró.
C/ del Vall, 42, 1.º, 1.ª.
46400 Cullera. Valencia.
E-mail: sanjuan_rafcer@gva.es

Received: August 2006
Accepted: March 2007

Femoral fractures are the most serious complication of osteoporosis in the elderly. The incidence of femoral fractures in the US is estimated at around 250,000 a year (about 80 per 100,000 inhabitants/year)[1], and is expected to reach 500,000 by 2040[2,3]. In Spain this incidence is estimated at around 520 fractures per 100,000 inhabitants/year in the population over 69 years of age[4].

If we consider that this type of lesion is one of the injuries that most frequently requires hospitalization[5], that the direct cost of every proximal femoral fracture is about 4,000 euros[4], and that the indirect costs (from the financial point of view, as well as to the family and to the patient) are of a significance that is difficult to ascertain, we may grasp the importance of the problem in terms of public health.

Within the group of proximal femoral fractures, pertrochanteric fractures are the most frequent, and are growing considerably in number in developed countries[6]. Subtrochanteric fractures, in spite of belonging to the group of less frequent lesions[7], are also experiencing a significant increase[8] that is directly proportional to age and osteoporosis.

These fractures are still addressed today using the surgical treatment that began with the nail and plate systems made popular by Jewett in the 1930s[3], which have currently been expanded to include a wide variety of implants[3,5,6,9]. No correlation exists between the type of fracture and the form of osteosynthesis applied. The Gamma® Nail represented a true revolution in terms of the implants that were used for the treatment of proximal femoral fractures. Since 1985, when it was introduced, it has undergone many modifications[10] and variations in the hands of different authors[11-15]. The Proximal Femoral Nail (PFN®) was introduced by the AO/ASIF in 1996[29]. In our department, we are now beginning to use the Clauffit® Nail, a model whose basic aim is to combine the advantages of both the above mentioned systems.

The aims of the present study were: firstly, to compare the Claufitt® and Gamma® Nails from the point of view of short-term surgical evolution and medium-term functional results in a retrospective study; and secondly, to compare the results obtained at our center with those reported in the current literature for hip fractures treated with the Gamma® Nail and the PFN®.

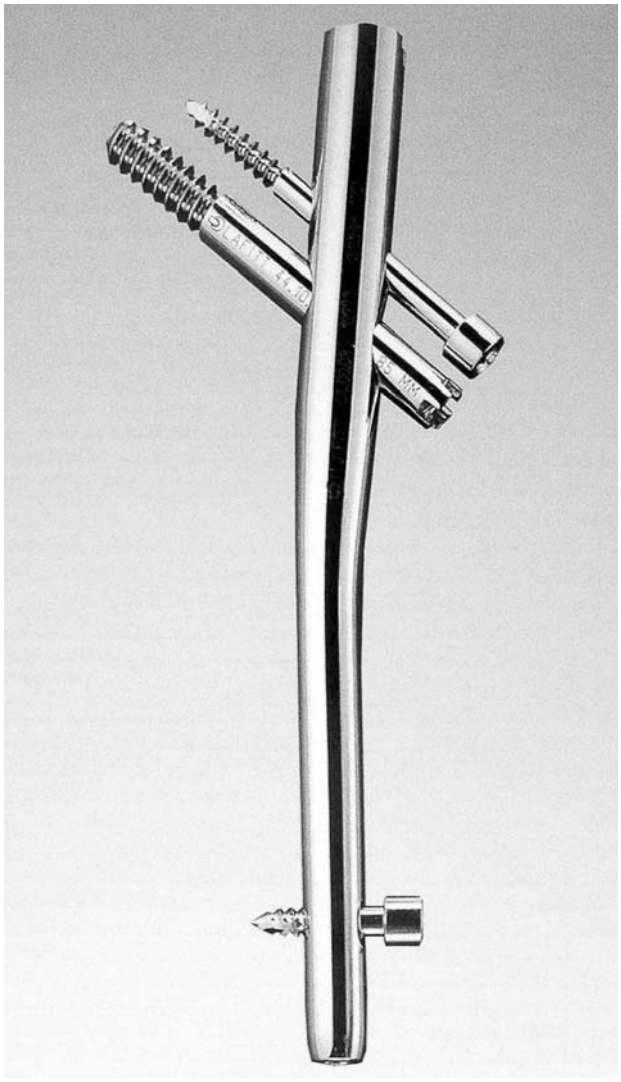

Figure 1. *The Claufitt® Nail. Its design consists basically of a trochanteric nail that is similar to the Gamma® Nail (although of a smaller proximal diameter) and a lag screw combined with an antirotational screw, or hip-pin, resembling the PFN® (Proximal Femoral Nail) system.*

MATERIALS AND METHODS

A two stage retrospective study is presented: the first stage consists of an evaluation of the type of fracture, the length of surgery and the immediate postoperative period. The second stage includes a functional assessment of medium- to long-term results of implants in each individual.

The study encompasses the population of a university hospital catchment area. It includes all the patients entered into an internal data base of the Department of Orthopedic and Trauma Surgery using Access software after being implanted with an endomedullary Clauffit® Nail. Additional inclusion criteria were that lesions must have resulted from low-energy trauma, in patients over 60 years of age. A group of 53 patients was defined. Similarly, a control group of 129 patients treated with the Gamma® Nail was defined, based on a ratio of 2:1 in order to obtain statistically significant results. The type of osteosynthesis used at the time of surgery depended solely on each surgeon's choice.

The Claufitt® Nail (Fig. 1) is a second generation intramedullary nail equipped with a lag screw and a superior, smaller diameter antirotational screw. The nail has a lateral diameter of 16 mm (somewhat smaller than the Gamma® Nail) and a medial diameter of 11 mm. It has a valgus angle of 6°, a total length of 200 mm, and a locking screw diameter of 10 mm. Trochanteric and diaphyseal nails are available; they are all made of stainless steel, and may be used statically or dynamically. As shown in Table 1, the design of the system is halfway between the Gamma® Nail and the PFN®.

Follow-up lasted from December 2000 to May 2005. Thirteen patients (3 Claufitt® and 10 Gamma®) were exclu-

Table 1. Comparison of the design and material of the three nails included in the study

	Comparison of nail design		
	Claufitt®	Gamma®	PFN®
Lateral diameter (mm)	16	17	17
Medial diameter (mm)	11-12	11	11-12
Valgus angle	6º	4º	6º
Length (mm)	200	180	240
Material	Steel	Steel	Steel/titanium
Diameter of locking screw (mm)	10	12	11

PFN: proximal femoral nail.

Table 2. Basic demographic data and surgical characteristics of the population included in the study

General characteristics of the patient group	
Age	78 ± 14.1 years
Sex (male:female)	1:4
Involved side (right:left)	1:1
Average follow-up	30 months
Average hospital stay	16 ± 8
Overall mortality	27%
Early mortality	5%
Delay before surgery	1.6 (1-9) days
Regional anesthesia	105 (65%)
Duration of surgery	1.42 ± 0.55 hours
Nonweightbearing required	46 (32.5%)
Senior surgeon	100 (63%)

Table 3. AO/ASIF fracture classification in the studied group: A2 and A3 (unstable)

AO/ASIF classification results			
	Gamma®	Claufitt®	Total
A21	10 (9.4%)	1 (9.1%)	11 (7.4%)
A22	27 (25.5%)	8 (18.6%)	35 (23.5%)
A23	14 (13.2%)	7 (16.3%)	21 (14.1%)
A31	30 (28.3%)	13 (30.2%)	43 (28.9%)
A32	4 (3.8%)	3 (7%)	7 (4.7%)
A33	21 (19.8%)	11 (25.6%)	32 (21.5%)

ded for being under 60 years of age; 17 (5 Claufitt® and 11 Gamma®) because of missing details in their clinical histories; and 3 (1 Claufitt® and 2 Gamma®) due to a data base error.

A final study group of 43 Claufitt® patients and 106 Gamma® patients (a total of 149 subjects) was obtained. All data were collected using a protocol that had been specifically designed for the purpose, based on a previous protocol used in the department for all hip fracture patients.

Statistical analysis was based on Pearson's chi-square test, with 'p' values of 0.05 or less-depending on each case-taken as valid. The number of individuals selected was determined by means of a power analysis of the test, which revealed that in order for results to be statistically significant a ratio of 2:1 must exist between the two groups. The analysis was performed using an SPSS software package for Windows. The study was approved by our center's Ethical Committee.

RESULTS

The average age of the selected population (Table 2) was 78 ± 14.1 years. The male to female ratio was 1:4. The ratio of left to right femur involvement was 1:1. Average follow-up time was 30 ± 20.4 months. Hospital stay averaged 16 days, and was slightly shorter for the Claufitt® group, although the difference did not reach statistical significance. The overall rate of mortality during follow-up was 27% (44/161). By groups, the mortality rate was 13% (6/45) in the Clauffit® patients, and 32% (38/116) in the Gamma® patients.

No intraoperative deaths occurred. Early mortality during post-surgical hospitalization was 5% (9/161). Eight (7%) of these deaths occurred in the Gamma® group, and only 1 (2%) in the Claufitt® group. These differences were not associated with other parameters.

Only patients with fractures classified as unstable were selected (Table 3). Prevalence according to the AO/ASIF classification was 29% for group 31 A31 fractures, and 23.5% for group 31 A22 fractures. The Clauffit® Nail was used more frequently for the treatment of highly unstable fractures: 60% of Clauffit® patients were in the AO 31 A3 1 and 3 groups. Twenty per cent of patients (33/161) had only one associated medical condition; 64% had multiple pathologies (2-5 organic diseases). Seven per cent of patients (13 cases) had sustained associated lesions, most of which were mild.

Delay before surgery averaged 1.6 days (range 1-9). Spinal anesthesia was used in two thirds of the cases (65%), and general anesthesia in the rest. All patients were given prophylaxis with low molecular weight heparin beginning on the day of admission, and antibiotic prophylaxis (cephazolin 2 g iv or clindamycin 600 mg in cases of allergy to betalactamics) at the time of anesthetic induction. Sixty-three per cent of the procedures (60% in the Gamma® group and 70% in the Clauffit® group) were performed by senior surgeons. The rest (37%, accounting for 40% and 30% of each respective group) were carried out by fourth or fifth year residents ($p < 0.005$). Ninety-eight per cent of patients registered a postsurgical hemoglobin (Hb) decrease of 3.6 ± 1.85 mg/ml (3.55 ± 1.97 in the Gamma® group and 3.8 ± 1.5 in the Claufitt® group). In 78% of cases (80% in the Gamma® group and 72% in the Claufitt® group) a blood transfusion was needed; the criterion for transfusion was an Hb level of less than 8.5 mg/dl.

Average surgery time was 1 h 42 ± 55 min. (1 h 43 ± 55 min. in the Gamma® group and 1 h 38 ± 55 min. in the Claufitt® group; $p < 0.005$). These times include total anesthesia time, and do not reflect the actual duration of surgery itself. The most frequently used nail was the 130° version, which was employed in 86% (128/149) of cases (91/106 in the Gamma® group and 37/43 in the Claufitt® group). Nail thickness was 11 mm in 58% (87/149) of cases (58.5%-62/106-in the Gamma® group and 58%-25/43-in the Clauffit® group). The 90 mm lag screw was the most frequently used (24%) both in the Gamma® group (23%, 27 cases) and the Clauffit® group (24%, 11 cases). In 117 cases (73%) trochanteric nails were used (81/116 in the Gamma® group and 36/45 in the Clauffit® group); in the remaining 44, long nails or diaphyseal nails were used (35-80% –in the Gamma® group and 9-20% –in the Clauffit® group). No antirotational screw was placed in 10 cases (21%) in the Clauffit® group.

Fracture reduction was considered anatomical when fragment diastasis was less than 3 mm and the cervicodiaphyseal angle was in the physiological position. This was observed in 50% of cases (74/149) (49% [52/106] in the Gamma® group and 52% [22/43] in the Clauffit® group). Reduction was considered to be fair or acceptable in the presence of a slight diastasis of less than 1 cm, which was found in 36% [53/149] of cases (37% [39/106] in the Gamma® group and 33% [14/43] in the Clauffit® group). Poor or unacceptable reductions were detected in 14% (21/149) of cases (14% [15/106] in the Gamma® group and 14% [6/43] in the Clauffit® group; $p < 0.005$). Nonweightbearing on the involved limb was advised in 32.5% [46/141] of cases due to instability or lack of reduction of the fracture (35.5% [35/99] in the Gamma® group and 26% [11/43] in the Clauffit® group, excluding cases of early mortality; $p < 0.005$).

Among immediate complications (Table 4) the most frequent was bursting of the greater trochanter, which happened in 9 cases (5.6%) (8 in the Gamma® group and 1 in the Clauffit® group). Five cases (3.1%; all of them in the Gamma® group) of lateralized screw penetration occurred. In 4 cases (2.5%; all of them in the Gamma® group) open reduction was necessary. Antirotational screw insertion difficulties were encountered in 4 cases (2.5%); all of them occurred in the Clauffit® patients, and accounted for 9.5% of that group. In 2 cases (1.3%; both of them in the Clauffit® group) distal locking difficulties were encountered. There were 2 varus reductions (both in the Clauffit® group), 2 reduction diastases (both in the Gamma® group), and isolated cases of reaming of the external cortex and excessive antirotational screw length (all of them in the Claufitt® group).

Early complications were defined as those occurring during the hospital admission period. Local complications occurred in 28 cases (Table 4). These included: 11 (6.8%) superficial infections (9 in the Gamma® group and 2 in the Claufitt® group), 9 (5.5%) limb rotations (5 in the Gamma® group and 4 in the Claufitt® group), 8 (5%) wound seromas (6 in the Gamma® group and 2 in the Claufitt® group), 4 (2.5%) hematomas (2 for each type of nail), 2 (1.1%) deep infections (one for each type of nail), and 2 (1.1%) antirotational screw alterations (both in the Claufitt® group) ($p < 0.005$). General or systemic complications affected 63 patients. The most frequent of these was the acute confusional syndrome, which was suffered by 42 patients (26%) (30 in the Gamma® group and 12 in the Claufitt® group). Fourteen patients (9%) developed pneumonia or respiratory problems (11 in the Gamma® group and 3 in the Claufitt® group), 12 (7.5%) experienced decompensations in their basic endocrine condition (mainly diabetes mellitus) (11 in the Gamma® group and 1 in the Claufitt® group), 12 (7.5%) developed urinary infections (9 and 3, respectively), 9 (5.6%) suffered

Table 4. Intraoperative or immediate postoperative complications, early complications during hospitalization and complications following hospital discharge

	Gamma®	Claufitt®
Immediate postoperative complications		
Bursting of the greater trochanter	8 (7.5%)	1 (2.4%)
Distal locking difficulties	0	2 (4.8%)
Varus reduction	0	2 (4.8%)
Reduction diastasis	2 (1.9%)	0
Open reduction	4 (3.8%)	0
Antirotational screw placement difficulties	0	4 (9.5%)
Reaming of external cortex	0	1 (2.4%)
Lateralized screw penetration	5 (4.7%)	0
Plug placement difficulties	1 (0.9%)	0
Rupture of the medial cortex	1 (0.9%)	0
Rupture of the external cortex	1 (0.9%)	0
Antirotational screw too long	0	1 (2.4%)
Drainage tube pullout	1 (0.9%)	0
Combination (see text)	5 (4.7%)	4 (9.5%)
Early complications		
Superficial infection	10 (9%)	1 (2%)
Limb rotation	5 (5%)	4 (9%)
Wound seroma	6 (5.5%)	2 (5%)
Deep infection	1 (1%)	1 (2%)
Wound hematoma	2 (4%)	2 (9%)
Late complications		
Severe secondary varus migration	3 (2.9%)	2 (4.9%)
Three point loading, zone 2	3 (2.9%)	2 (4.9%)
Delayed healing	1 (1%)	0
Pseudoarthrosis	1 (1%)	0
Late diaphyseal fracture	1 (1%)	0
Cut-out	3 (2.9%)	0
Proximal migration of the nail	4 (3.9%)	3 (7.3%)
Lag screw backout	1 (1%)	0
Protrusion «Z» effect	0	3 (7.3%)
Extrusion «Z» effect	0	1 (2.4%)
Screw breakage	1 (1%)	0
Limb length discrepancy of over 3 cm	2 (1.9%)	0
Plug loss	0	1 (2.4%)
Distal progression of the nail	1 (1%)	0
Trochanteric calcifications	5 (5%)	0
Distal hyperostosis, zone 0	1 (1%)	0
Proximal hyperostosis	0	1 (2.4%)

from decubitus ulcers (6 and 3, respectively), and 6 (3.7%) had acute kidney failure (all cases in the Gamma® group). There were also 5 patients (3.1%) with upper digestive tract bleeding (3 in the Gamma® group and 2 in the Claufitt® group), 3 (1.8%) with severe cardiac decompensation or acute myocardial infarction (2 in the Gamma® group and 1 in the Claufitt® group), 2 (1.25%) pulmonary thromboembolisms (1 for each type of nail), 2 (1.25%) patients with lower limb phlebitis (both in the Gamma® group), and 2 (1.25%) strokes or transient cerebral ischemic attacks (one for each type of nail) ($p < 0.005$).

As regards late complications (Table 4), none were present in 81% of patients. The most frequent late complication, proximal nail migration, occurred in 7 cases (5%) (4 in the Gamma® group and 3 in the Claufitt® group). There were 5 cases (3.5%) of severe secondary varus migration (3 in the Gamma® group and 2 in the Claufitt® group), 5 (3.5%) trochanteric calcifications (all of them in the Gamma® group), 5 cases (3.5%) of the so-called 'three point loading' effect (3 in the Gamma® group and 2 in the Claufitt® group), 3 instances (2%) of cut-out (all in the Gamma® group), 1 (0,7%) excessive backout of the lag screw (also in the Gamma® group), and 2 cases of limb-length discrepancy of more than 3 cm (in the Gamma® group). In the Gamma® group there was 1 (0.7%) pseudoarthrosis, 1 (0.7%) delayed healing, 1 (0.7%) late diaphyseal fracture, 1 (0.7%) nail breakage, and 1 case (0.7%) of distal progression of a long nail. In the Claufitt® group, in relation with antirotational screw phenomena, there were 4 instances (2.8%) of the so-called 'Z' effect, of which 3 (7.3%) were due to protrusion and 1 (2,4%) to extrusion. In 18% of cases (27/149), problems associated with intramedullary nail placement made it necessary to perform an additional surgical procedure.

The most frequent reason for additional surgery was the need for distal unlocking of the nail, which was required in 6 cases (4%) (4 in the Gamma® group and 2 in the Claufitt® group). In 7 cases (5%), extraction with or without complete nail replacement was necessary (2 deep infections, 2 screw breakages, 1 diaphyseal fracture and 1 pseudoarthrosis in the Gamma® group, and 1 cut-out in the Claufitt® group). In 3 of the Gamma® group cases (2%), cleaning and surgical debridement of the wound had to be performed. The antirotational screw was removed in 3 cases (2%) (2 protrusions and 1 extrusion). The fracture had to be reduced again, and distal locking applied, in 2 cases (1.5%) (1 for each type of nail). In 1 of the Gamma® group cases (0.7%) cerclage wires were placed instead of distal locking. One case (0.7%) of cut-out, in the Clauffit® group, required surgery. In the Gamma® group, 1 nail (0.7%) had to be replaced because of a diaphyseal fracture, 1 nail (0.7%) broke, 1 long nail (0.7%) was replaced due to knee protrusion, and 1 case (0.7%) of poor fracture reduction and healing required exostectomy of the greater trochanter due to patient discomfort ($p < 0.005$).

Of the 80 patients who were contacted by phone for evolution control purposes, 71% considered that their functional status before the lesion was excellent; 25% considered it was good; and 3.7% considered it was fair. Functional assessment was performed using a modification of the method described by Kyle *et al.*[16] Each patient's progress is reflected by the ratio between functional status before and after surgery, the functional prognosis being determined individually. Functional results, assessed on the basis of this method, were shown to be excellent in 14% of cases, good in 46%, fair in 15%, and poor in 15%. In the Gamma® group, results were excellent in 11.5% of cases, good in 47%, fair in 21%, and poor in 21%. In the Clauffit® group, results were considered excellent in 18.5% of cases, good in 44.5%, fair in 33%, and bad in 4%. This kind of ratio-based assessment allows a comparison of the patient's condition before and after the fracture, permitting final assessment of the process using a single parameter. Assessment outcomes are the result of a simple ratio calculation that may be applied to any kind of functional appraisal; the only indispensable prerequisite is a knowledge of the patient's data before and after treatment. In our case, results were considered excellent when the ratio equaled or exceeded 0.8; good, when the ratio was between 0.8 and 0.6; fair, when the ratio was between 0.6 and 0.4; and poor, when the ratio equaled or was lower than 0.4. Based on these parameters, and on each patient's individual assessment of functional status before the procedure, surgical outcome was considered poor in only 2 patients (3%); fair in 20%, good in 43%, and excellent in 32%. Using these outcomes, which are considered actual results, surgical assessment based on the patient's initial status is much better than an assessment that only considers functional outcomes after surgery.

DISCUSSION

Fractures of the proximal femur in patients of over 60 or 65 years of age are one of the most serious social and health-care problems associated with orthopedic and trauma surgery. Whatever the choice of therapy, the basic aim of treatment is to allow patients to return to the same functional status they enjoyed before the lesion. In most cases, this is achieved using surgery, followed as early as possible by mobilization[1].

Rosemblum *et al.*[17] report that the Gamma® Nail transmits loads to the femur in a similar way to a hip prosthesis: a reversed physiological load is transmitted, with a value of zero at the calcar and a maximum value at the tip. The authors prove this fact using four-fragment fractures.

The force resulting from loads applied at the head and neck of the femur passes through the center of rotation of the hip in the center of the femoral head. If the edge of the implant remains frontally and horizontally in the exact cen-

ter or rotation, no rotation takes place[19]; however, if the implant is not placed precisely in that position, rotation of the femoral head will occur. This is avoided by means of a locking nail, which is the principle behind the hip-pin or smaller screw of the Claufitt® o PFN® systems. Another basic principle consists in spreading out the vacuum created by the lag screws at two points of the nail stem, in such a way that the area of the nail that bears the highest stress does so much more evenly, thereby decreasing the rupture rate. The second lag screw also increases the bone-implant contact surface area, reducing fracture displacement and creating greater stability for both the angulation and the coaptation of the fracture measured in terms of nail retraction.

Correct nail placement was performed using the method described by Kyle *et al.*[16]: the radiological image of the femoral head is divided between two lines running parallel to the longitudinal axis of the neck into three equal sectors both on the AP view and the lateral view, creating nine zones. Based on this division, correct placement is achieved when the screw is centered either on the lower zone (AP) and/or the posterior (lateral) zone. Eccentric placement of the nail produces a higher degree of migration, especially in more superior placement sites; central lag screw positioning is therefore imperative. No consensus currently exists as to which implant is best for the treatment of per-subtrochanteric hip fractures. We advocate the use of nail and plate systems for stable fractures and intramedullary nails for unstable fractures, depending on criteria that include stress-bearing characteristics of the fracture, early weight-bearing in the standing position, and other purely financial and managerial aspects. Follow-up time was 30 ± 20.4 months.

Mortality rates in hip fractures, according to Zuckerman[1], range from 14% to 36% in the first year. These data fully coincide with ours (27%). Surgery-related mortality (5% in our series) is indicative of the aggressive nature of the surgical procedure and the basal status of patients, although it is unfortunately not often assessed in studies.

The AO/ASIF[20] system is the most widely accepted of the published classifications. The debate over inter- and intraobserver reproducibility raises doubts about the convenience of subgroups in fracture classifications, since other systems like the classic Jensen classification (which only distinguishes between stable and unstable fractures) greatly simplify the procedure. Furthermore, it is difficult to draw conclusions from the literature, considering the lack of consistency between the groups selected in the different reported studies. In our series, there were no statistically significant differences between procedures performed by senior surgeons and 4th or 5th year residents.

Our most frequent implant was the 130°, 11 mm nail, with a 90 or 100 mm lag screw. The most frequent diaphyseal screw length was 360 mm. Many of the nails in the Claufitt® group were placed without an antirotational screw, due to the required learning curve and to lag screw asymmetry, which in the event of insertion difficulties, incorrect placement of the larger screw or comminution of the lateral cortex of the greater trochanter, allows the surgeon to choose between placing this hip-pin or not, as the lag screw is thick enough to bear all the weight by itself.

As regards fracture reduction, the criteria of Honkonen *et al*[21] were followed. These authors achieve anatomically reduced results in 61% of cases, acceptable results in 5% of cases, and unacceptable results in 32% of cases. Such results are comparable to those of our series and the series of Edwards *et al.*[22] The lack in many cases of axial radiographs prevented us from strict application of the model presented by Kyle *et al.*[16] Lag screw height variations did not exhibit statistically significant differences, although the positioning of lag screws in the Claufitt® group was generally better, due to strict placement in the mid third or lower third (since hip-pins had to be placed, and a specially adapted implantation guide was available for that purpose). Screw placement in almost subchondral bone, or failing that in an inferior or posterior position, helps to avoid cut-out.

When complications are taken to include all nail-associated problems, both in terms of placement and alignment, the total rate of immediate (27%), early (17%) and late (29%) complications is alarming (73%). Since complications, properly speaking, may be defined as problems that make it necessary to reoperate, the rate in our series is 18%, a slightly higher value than those reported in other publications, which range between 7% and 11.5% for the Gamma® Nail. Some published data, however, are quite comparable to ours, with complication rates of 16% to 24% for the Gamma® Nail or 21% for the PFN® device. In the Claufitt® group, taken alone, our complication rate was 20% (slightly higher than in the Gamma® group, although the difference is not statistically significant). In spite of this fact, if we exclude reoperations due to nail dynamization (6 cases), the complication rate would be 14%, which comes within normal values for this type of implant (Table 5).

Bursting of the greater trochanter upon nail insertion occurred in 8% of cases in the Gamma® group and in only 2.5% of cases in the Claufitt® group. This difference might be due to the fact that the proximal diameter of the Claufitt® Nail is 1 mm smaller. Rupture of the greater trochanter was already reported in the first Gamma® Nail studies, published in 1992[10,32], as the most frequent complication, although it did not affect healing or long-term fracture stability. An excessively lateral insertion can lead to reaming of the external cortex or even cortical rupture due to nail misplacement, although the latter may also be caused by eccentric reaming or valgus placement of the nail[55], as evidenced by the two cases of rupture of the greater trochanter in connection with an excessively lateralized insertion in our series. The rate of open reductions, which normally ranges from 1% to 18%, is intermediate when using the PFN®, and more frequent in

Tabl3 5. Comparison of complications reported for the Gamma® Nail and the PFN® in the different published series

	Valverde et al.[23]	Bertrand et al.[24]	Panisello et al.[25]	Aune et al.[26]	Habernek et al.[27]	O'Brien et al.[28]	Pervez y Parker.[29]	Edwards et al.[22]	Marques et al.[30]	Al-Yassari et al.[11]	Simmermacher et al.[14]	Boldin et al.[12]	Bertrand et al.[24]	Pérez-Albela et al.[25]	Banan et al.[31]
Nail type	Gm	Gm	Gm Lg	Gm	Gm	Gm	Gm Lg	Gm Lg	Gm	PFN	PFN	PFN	PFN	PFN	PFN
Intra-op femoral fracture	7/224	2%			2/105	2/53	1/35			1/76			4%	1/120	2/60
Post-op femoral fracture	4/224	6%		6%	1/105		1/35						2%		
Cut-out	9/224	4%		3/177					2/43	4/76	1/191	2/55	2%	7,5%	4/60
Pseudoarthrosis	1/224		3/36			2/53								1%	
Delayed healing			1/36				2/35			1/76					1/60
Difficult distal screw insertion	8/224	4%								3/76			6%		
Deep infection	2/224				3/105									1/120	
Nail breakage	1/224	2%					2/35							2/120	1/60
Z-effect												5/55	8%	8/120	
Variación grave		4%	3/36			5/53									
Severe varus migration			1/36												
Distal locking breakage Thigh pain	5/224	8%		4/36											
Fracture of greater trochanter	1/224														
Severe shortening	2/224		1/36												
Proximal migration	7/224							9/51							
Subcapital fracture		2%							3/43						

Gm: Gamma®; Gm Lg: gamma largo; PFN: *Proximal Femoral Nail®* .

subtrochanteric fractures treated with long nails. We did not use open reduction in any of the cases in the Claufitt® group. Our local complication rates, at 7% for superficial wound infection, 6% for decubitus ulcers and 5% for seromas, were totally consistent with the literature. Deep infection, which occurred in 1.1% of cases (with no differences between the groups[25]), was also consistent with published reports. Proximal migration of the nail and cut-out (Fig. 2) are processes involving many different factors that are determined by bone resistance, fracture patterns, reduction quality, and implant placement and design[43].

Intramedullary nails with double lag screws, such as the Clauffit® Nail and the PFN®, exhibit a peculiar phenomenon known as the 'knife effect'. According to Schipper *et al.*[19], this occurs when the lag screws converge or diverge due to misplacement or as a result of weight-bearing. Since the upper screw has to bear more weight, sliding motion is restricted, and the active forces become vertical and induce the cut-out effect. Load causes the hip-pin, with its smaller diameter, to cut through the cancellous bone like a knife, creating a hole for the larger lag screw and facilitating increased varus and cut-out. The rate of proximal migration ranges from 3% to 17% for the Gamma® Nail and from 1.5% to 2.5% for other nails; for Claufitt® Nails, the rate is 7%. Considering that in a high percentage of such cases migration itself has no clinical consequences, the only real problem is ensuring rigorous patient control, in order to avoid subsequent complications. As regards varus displacement of the fracture, the stiffness of the Gamma® Nail and its large lag screw diameter favor such an effect in that device. Double screw systems reduce varus displacement for several reasons: increased contact area, smaller diameter of screws,

Figure 2. *Axial hip radiograph showing the cut-out phenomenon in a Clauffit® Nail. We see how the antirotational screw has paved the way for the lag screw to produce this phenomenon, known as the «knife effect».*

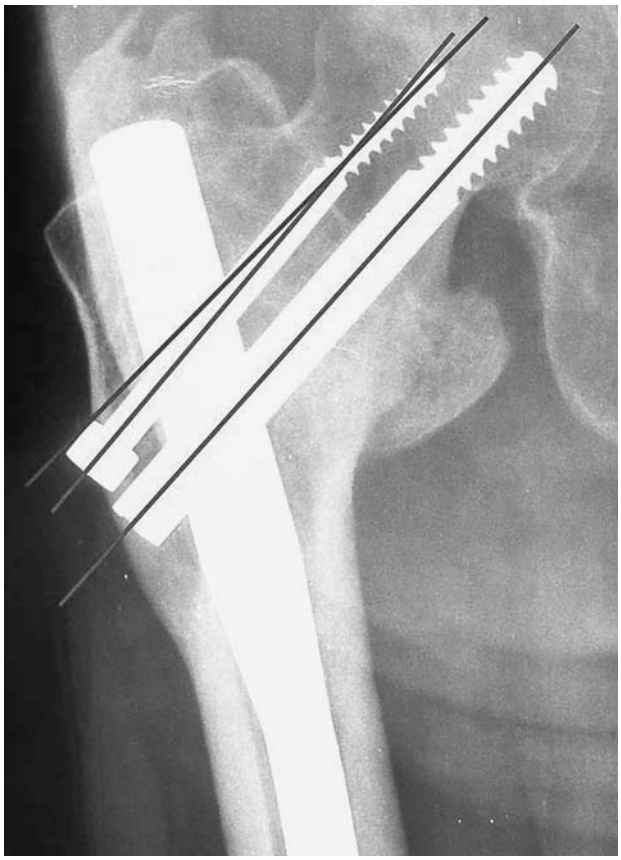

Figure 3. *Antirotational screw breakage in a Claufitt® device, detected upon routine control in a healed fracture.The patient was symptom-free, and had suffered no associated alterations. No isolated cases of this complication have been found in the literature.*

and rotation stabilization. The effect is estimated to appear in 4% to 9%[25] of cases with the Gamma® Nail; in our series, it was only recorded in 5% of cases in the Claufitt® group. Cut-out is one of the major parameters in studies of intramedullary nails, and is a key reference datum as regards nailing results. The different published series report cut-out rates of 1% to 4% for the Gamma® Nail, and 0.05% to 8.7% for the PFN®. No instances of cut-out have been reported in the Claufitt® Nail to date.

The effect known as 'three point loading' is associated with nail stiffness and with the appearance of femoral fractures. It occurs in about 2% of cases with the Gamma® Nail, and 3% of cases with the Claufitt® Nail, although it is not frequently assessed in studies. Diaphyseal fractures are caused by technical errors during surgery, or develop during long-term evolution due to malpositioning of the nail, and are therefore not related to implant design. In our series, we had no cases of diaphyseal fractures associated with nail placement in the Claufitt® group, and only one case in the Gamma® group. The literature reports rates of 0% to 6% in Gama® Nails, in which incidence is higher when using long nails, and of 0% to 4% in PFN® devices. As regards pseudoarthrosis and delayed healing in our study, we had no cases in the Claufitt® group, and only one in the Gamma® group. Reported rates for these complications are 0.5% to 8% in Gamma® Nails[25] and 1% in the PFN®.

Implant breakage occurs in two areas of critical overload in the nail: at the cephalic locking hole, where Gamma® nail thickness decreases by 73%[33], and at the distal locking sites[34]. The PFN® and the Claufitt® Nail have lag screws of a smaller diameter, and nail thickness does not therefore decrease so sharply in one single point. Breakages are more frequent in cases of non-healing[35,36] and in long nails[33,35]. Rates of fatigue-related breakage range from 0.5% to 2% with the Gamma® Nail and 1.6% to 2% with the PFN®. No nail breakages occurred in our series in the Claufitt® group. One nail broke in the Gamma® group.

One antirotational screw breakage occurred (Fig. 3) in a patient with complete fracture healing. The patient had not exhibited any alterations and was completely free from symptoms. The literature reports no isolated antirotational screw breakages in double lag screw nails. The so-called 'Z effect' (Fig. 4) only occurs in double lag screw nails, and involves the antirotational screw. It has to do with the 'knife effect' described above, and results from isolated medial or lateral displacement of the hip-pin within the head, leading to cartilage destruction in the first case or protrusion through the skin in the second case. The 'Z effect' occurs in the presence of alterations in the alignment, fixation or length of the upper screw, and its extent is still a matter of debate. At 10%, the incidence of the 'Z effect' in our series was slightly higher than published values, probably due t o the learning curve associated with this device in our hands.

The modified Kyle *et al.*[16] functional scale is easy to apply, and elderly patients do not find it difficult to understand. Functional assessment at the time of the study was performed by means of telephone consultations aimed at evaluating the patient's status and maintaining consistency throughout the series. Our greatest problem was the large amount of patients who were not available for consultation, which limited the sample to only 80 individuals. This loss was probably due to the fact that interviews were conducted by telephone.

Based on admission hip fracture protocols (which include each patient's main functional activity data), functional status before and after surgery was analyzed in order to arrive at an exact assessment of surgical outcome in all the individuals included in the study. It is not the same to operate on a patient with associated dementia who is practically prostrate in bed as it is to do so on an active patient with no underlying organic pathologies. After adapting our study's results in terms of what we called 'actual functional assessment', evaluation was satisfactory (good or excellent outcomes) in 76.8% of cases: 73% in the Gamma® group, and 85.7% in the Claufitt® group (Fig. 5). Although the diffe-

rence is not statistically significant, a trend towards better functional results in the Claufitt® group was evidenced by the fact that its clinical results were superior to those of the Gamma® group in almost 10% of cases. The Kyle *et al.*[16] assessment method was used as an evaluation protocol because it was easy to apply upon admission of patients, and to reproduce in telephone interviews in the case of elderly patients. The use of these precise models adjusts perfectly to actual functional assessments, and offers the same kind of results and the same evaluation potential.

In conclusion, it may be said that the Clauffit® Nail, with regard to which there is an almost total lack of information in the literature, is an intermediate design that may be placed between the two systems that are currently in widest use: the Gamma® Nail and the PFN®. The complication rate of the Claufitt® Nail is similar to that of other devices reported in the literature, but its design is biomechanically safer. Our clinical results agree with those of studies carried out in other centers on similar population samples.

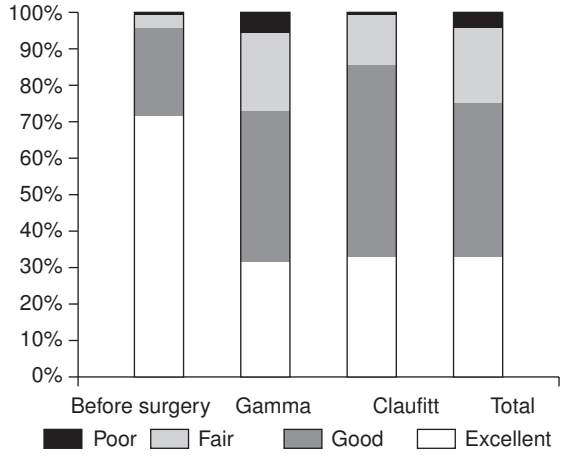

Figure 5. *Graph comparing the results for each type of nail and population, based on patient status before surgery. Basal patient status was determined using the functional scale of Kyle et al., to which the actual functional assessment was subsequently applied.*

Figure 4. *AP radiograph of the hip revealing isolated antirotational screw extrusion due to the «Z effect». The lag screw and the nail remain in good position. The problem was solved by simply removing the hip-pin from the trochanteric device.*

Clinical results with the Gamma® and Claufitt® nails are essentially interchangeable, with similar complication rates and placement difficulties, except for specific aspects such as rupture or bursting of the greater trochanter (which was less frequent in the Claufitt® group, probably due to the nail's smaller proximal diameter). Actual functional assessment is a simple evaluation method, which has proved to be reproducible and very useful for the detailed, individual follow-up of patients, and applicable to all types of procedure or follow-up protocol.

ACKNOWLEDGEMENTS

In memory of Dr. Sanchís, a dear friend and colleague, and a teacher to those of us at the Doctor Peset University Hospital whose wish it was to learn a little more about the art of orthopedic and trauma surgery.

REFERENCES

1. Zuckerman JD. Hip fracture. New Engl J Med. 1996;334: 1519-25.
2. Willing R, Keinänen-Kiukaaniemi S, Jalovaara P. Mortality and quality of life after trochanteric hip fracture. Public Health. 2001;115:323-7.
3. Lorich DG, Geller DS, Nielson JH. Osteoporotic pertrochanteric hip fractures. Management and current controversies. J Bone Joint Surg Am. 2004;86-A:398-410.
4. Pérez-Ochagavia F, de Pedro JA, de Cabo A, Blanco J, Borrego D, Zan J. Estudio epidemiológico de las fracturas proximales del fémur en una población mayor de 69 años durante los años 2000-2001. Rev Ortop Traumatol. 2003;47:113-21.

5. Evans PJ, McGrory BJ. Fractures of the proximal femur. Hospital Physician. 2002;38:30-8.
6. Curto JM, Ramos LR, Santos JA. Fracturas pertrocantéreas. Métodos e indicaciones terapéuticas. Rev Ortop Traumatol. 2003;47:146-55.
7. LaVelle DG. Fracturas de la cadera. En: Canale ST, editor. Cirugía ortopédica. Tomo III. Madrid: Elsevier España S.L.; 2004. p. 2873-938.
8. Cuenca J, Martínez AA, Herrera A, Herrero L, Sola A, Panisello JJ. Cambios epidemiológicos de las fracturas del tercio proximal del fémur en un período de 10 años. Rev S And Traum y Ort. 2002;22:140-7.
9. Gillespie WJ. Hip Fracture. Br Med J. 2001;322:968-75.
10. Halder SC. The Gamma® Nail for pertrochanteric fractures. J Bone Joint Surg Br. 1992;74-B:340-4.
11. Al-Yassari G, Langstaff RJ, Jones JWM, Al-Lami M. The AO/ASIF Proximal Femoral Nail (PFN®) for the treatment of unstable trochanteric femoral fracture. Injury. 2002;33:395-9.
12. Boldin C, Seibert FJ, Frankhauser F, Peicha G, Grechenig W, Szyszkowitz R. The Proximal Femoral Nail (PFN®)-a minimal invasive treatment of unstable proximal femoral fractures. A prospective study of 55 patients with a follow-up of 15 months. Acta Orthop Scand. 2003;74:53-8.
13. Sadowski C, Lubbeke A, Saudan M, Riand N, Stern R, Hoffmeyer P. Treatment or reverse oblique and transverse intertrochanteric fractures use of an intramedullary nail or a 95º screw-plate. J Bone Joint Surg Am. 2002;84-A:372-81.
14. Simmermacher RKJ, Bosch AM, Van der Werken C. The AO/ASIF-proximal femoral nail (PFN®): a new device for the treatment of unstable proximal femoral fractures. Injury. 1999;30:327-32.
15. Pérez-Albela AL, Álvarez R, Godoy N, Martínez JL, Capilla JA, Delgado M. Clavo femoral proximal de AO/ASIF (PFN®) en el tratamiento de las fracturas de la región trocantérea y subtrocantérea del fémur. Rev Ortop Traumatol. 2002;46: 47-63.
16. Kyle RF, Gustilo RB, Premer RF. Analysis of six hundred and twenty-two intertrochanteric hip fractures. J Bone Joint Surg Am. 1979;61-A:216-21.
17. Rosemblum SF, Zuckerman JD, Kummer FJ, Tam BS. A biomechanical evaluation of the Gamma® Nail. J Bone Joint Surg Br. 1992;74-B:352-7.
18. Galanakis IA, Steriopoulos KA, Dretakis EK. Correct placement of the screw or nail in trochanteric fractures: Effect of the initial placement in the migration. Clin Orthop Rel Res. 1995;313:206-13.
19. Schipper IB, Bresina S, Wahl D, Linke B, van Vugt AB, Schneider E. Biomechanical evaluation of the proximal femoral nail. Clin Orthop Rel Res. 2002;405:277-86.
20. Orozco R, Sales JM, Videla M. Atlas de osteosínteis. Barcelona: Masson S.A.; 1998.
21. Honkonen SE, Vihtonen K, Järvinen MJ. Second-generation cephalomedullary nails in the treatment or reverse obliquity intertrochanteric fractures of the proximal femur. Injury. 2004;35:179-83.
22. Edwards SA, Pandit HG, Clarke HJ. The Long Gamma® Nail: a DGH experience. Injury. 2000;31:701-9.
23. Valverde JA, Alonso MG, Porro JG, Rueda D, Larrauri PM, Soler JJ. Use of the Gamma® nail in the treatment of fractures of the proximal femur. Clin Orthop Rel Res. 1998;350:56-61.
24. Bertrand D, González-Busto I, Solís A, Paz-Aparicio J, Núñez-Batalla D, Paz-Jiménez J. Fracturas pertrocantéreas de fémur en el anciano: clavo Gamma® y clavo PFN®. Estudio comparativo. Rev Ortop Traumatol. 2004;48:22-30.
25. Panisello JJ, Cuenca J, Herrera H, Martínez A, Canales V. Uso clínico y complicaciones con el clavo Gamma® largo. Rev Ortop Traumatol. 2001;45:368-73.
26. Aune AK, Ekeland A, Odegaard B, Grogaard B, Alho A. Gamma® Nail vs. Compression Screw for trochanteric femoral fractures. 15 reoperations in a prospective, randomized study of 378 patients. Acta Orthop Scand. 1994;65:127-30.
27. Habernek H, Schmidt L, Frauenschuh E. Sport-related proximal femoral fractures: a retrospective review of 31 cases treated in an eight year period. Br J Sports Med. 2000;34:54-8.
28. O'Brien PJ, Meek RN, Blachut PA, Broekhuyse HM, Sabharwal S. Fixation of intertrochanteric hip fractures: Gamma® nail versus Dynamic hip screw. A randomized, prospective study. Can J Surg. 1995;38:516-20.
29. Pervez H, Parker MJ. Results of the long Gamma® nail for complex proximal femoral fractures. Injury. 2001;32:704-7.
30. Marques F, Pelfort X, Garcías-Casas O, Ramírez M, Aeon A, Ballester J. Estudio prospectivo aleatorio comparativo del tornillo deslizante y el clavo Gamma® en el tratamiento de las fracturas pertrocantéreas. Rev Ortop Traumatol. 2002;46: 505-9.
31. Banan H, Al-Sabti A, Jimulia T, Hart AJ. The treatment of unstable, extracapsular hip fractures with the AO/ASIF Proximal Femoral Nail (PFN®)-our first 60 cases. Injury. 2002;33: 401-5.
32. Calvert PT. The Gamma® Nail-a significant advance or a passing fashion? J Bone Joint Surg Br. 1992;74-B:329-31.
33. Wozasek GE, Radler C, Vecsei V. Case report: Multiple Gamma® nail failure. Orthopaedics. 2002;25:183-4.
34. Sitthiseripratip K, Van Oosterwyck H, Vander Sloten J, Mahaisavariya B, Bohez ELJ, Suwanprateeb J, et al. Finite element study of trochanteric Gamma® nail for trochanteric fracture. Med Eng Phys. 2003;25:99-106.
35. Ruiz-Ibán MA, Crespo-Hernández P, de Frías-González M, Castrillo-Amores MA. Estudio de ocho casos de rotura de clavo Gamma® en 1478 implantes. Rev Ortop Traumatol. 2004;48: 435-42.
36. Randle JA, Meisami-Fard B, McKee MD. Mechanical failure of a Gamma® Nail in a patient with an impending pathologic subtrochanteric fracture. Can J Surg. 1999;42:384-6.

Conflict of interests

The authors have declared that they have no competing interests.