



Does the implant make the difference ? – Prospective comparison of two different proximal femur nails

Sascha HOPP, Reiner WIRBEL, Ishaq OJODU, Antonius PIZANIS, Tim POHLEMANN, Joerg FLEISCHER

From the Department of Trauma, Hand and Reconstructive Surgery University of the Saarland

The aim of this study was to compare two proximal femur nails with regard to the complication rate and midterm clinical outcome : the InterTAN nail (ITN) versus the third generation gamma nail (GN).

78 patients older than 60 years with an unstable intertrochanteric femoral fracture (AO/OTA 31 A2/A3) were randomised over a 20 month period into either ITN (n = 39) or GN (n = 39). The outcomes of interest were the perioperative implant-related complications and the functional status (Harris Hip Score) at 6 months postoperatively.

In 14 of the ITN and in two of the GN procedures the surgeons rated the implant as cumbersome (p = 0.002). Functional outcome and complication rate did not differ between both groups. The mechanical failure correlated with the positioning of the lag screw independent on the used implant.

The surgeon's technique (closed reduction, positioning of lag screw) and not implant configuration, is of crucial importance in achieving successful outcome.

Keywords : intertrochanteric fracture ; InterTAN ; Gamma nail ; outcome ; mechanical failure.

INTRODUCTION

Due to the rapidly growing of ageing population, with increasing incidence of osteoporotic fractures of the proximal femur, great challenges lie ahead for orthopaedic surgeons. On account of the high morbidity and mortality rate associated with this

fracture type (22), early operative treatment of these elderly patients should be advocated (11). The aspired immediate postoperative mobilisation may help not only to restore the function of the injured limb but also to reduce the risk of early postoperative complications like thromboembolism, pulmonary or cardiac failure, urinary tract infection or decubital ulcers (5).

Because of the often reduced bone quality, intertrochanteric fractures are a special issue in geriatric traumatology. Generally, a higher degree of instability of a proximal femur fracture requires a more stable fixation. The demands for such a stabilisation

- Sascha Hopp¹.
- Reiner Wirbel².
- Ishaq Ojodu^{1,3}.
- Antonius Pizanis¹.
- Tim Pohlemann¹.
- Joerg Fleischer⁴.

¹Department of Trauma, Hand and Reconstructive Surgery, University of Saarland, 66421 Homburg, Germany.

²Department of Trauma-, Hand- and Reconstructive Surgery, St. Elisabeth Hospital, 54516 Wittlich, Germany.

³Division of Orthopaedics and Trauma, Cedarcrest Hospital, Abuja, Nigeria.

⁴Department of Trauma and Orthopedics, Marien Hospital, 66606 St. Wendel, Germany.

Correspondence : Sascha J. Hopp, Department of Trauma, Hand and Reconstructive Surgery University of the Saarland Kirrbergerstrasse 66421 Homburg, Saar Germany.

E-mail : sascha.hopp@uks.eu

© 2016, Acta Orthopædica Belgica.

No benefits or funds were received in support of this study. The authors report no conflict of interests.

Acta Orthopædica Belgica, Vol. 82 - 2 - 2016

device must include the possibility of a minimally invasive procedure to decrease perioperative blood loss and wound complications, the faculty to guarantee immediate full weight bearing, and a low complication rate, especially concerning mechanical failures (5).

While stable intertrochanteric fractures (AO/OTA 31A1) can sufficiently be stabilised by extramedullary devices like the sliding hip screw, fractures of higher instability (AO/OTA 31A2 and A3), i.e. fractures with additional loss of the lesser trochanter or reverse type fractures, are suggested to have to be fixed by an intramedullary implant due to its biomechanical advantages (17,21). The gamma nail (Stryker Howmedica, Stryker Trauma GmbH, Schönkirchen, Germany) introduced in 1988, is widely used in the treatment of unstable intertrochanteric fractures (23). With the use of the first generation gamma nail, several authors have reported serious implant-related complication rates ranging from 6% to 20% (8,14,16). These complications include femoral shaft fractures (1,4,5,27), failures of fixation (1,14), cutting-out of the proximal screw (14), and difficulty in distal locking of the implant (27). Consequently, modifications in the design of the gamma nail have led to the introduction of the second and recently third generation gamma nail. These design modifications included reduction in the diameter of the nail and of the valgus angle, improvement of the lag screw and possibility of dynamic distal locking option (7). A recent study has reported significant decrease of the implant-related complications with the use of the third generation gamma nail from the initial complication rate of 20% to as low as 1% (12).

Various other implant designs have flooded the market with the same objective of reducing these implant-related shortcomings. Amongst these new designs, the Trigen InterTAN Nail (Smith & Nephew, Memphis, Tennessee) has two integrated cephalo-cervical screws which permit linear compression as well as rotational stability of the head/neck fragment (19). According to the information of the manufacturer, the design would offer stability and greater resistance to implant cut-out (15,25).

Ruecker *et al* (22) reported good results with a very low complication rate in the first one hundred

of implanted nails. However, Erez *et al* (12) and Matre *et al* (19), who prospectively compared the InterTAN with the sliding hip screw in 684 consecutive patients with intertrochanteric fractures, found similar complication rates as reported by historical studies about other devices.

Since the interest in intramedullary devices is growing, we are not aware of any study comparing the InterTAN nail and the often used third generation trochanteric gamma nail, and hence it remains unclear which device provides better clinical and radiographic outcomes.

A recent biomechanical study reported advantages of the InterTAN nail compared to the gamma nail being able to withstand higher loads (29).

Bojan *et al* (3) demonstrated in their large series of more than 3000 cases of gamma nails, that the screw position and the quality of fracture reduction are the two essential factors regarding mechanical failure rate. Furthermore, surgical learning curve still is an important factor when introducing a new implant design. If surgeons are unfamiliar with new implant a number of complications or a conversion to an open procedure may occur.

Therefore, the objective of our study was to investigate the perioperative clinical and radiographic outcome of two intramedullary devices in the treatment of unstable intertrochanteric fractures in elderly patients, with regard to implant-related complications and functional results over a six-month period. We hypothesised that intramedullary fixation with InterTAN nail yields lower complication rates and better functional results than the standard gamma nail.

MATERIALS AND METHODS

We conducted a prospective randomised trial involving a total of 87 patients above 60 years of age admitted to our hospital, a University Level 1 Trauma Center, between October 2007 and May 2009 (20 months), with unstable intertrochanteric femur fractures as a result of low impact trauma.

Each fracture was classified according to the AO/OTA classification. Exclusion criteria were inability to walk prior to the fracture, pathological fracture, associated severe osteoarthritis of the affected hip, co-morbidities

that preclude surgical intervention, and refusal to give informed consent for the study. After rigorous selection, a total of 78 consecutive patients with an isolated unstable intertrochanteric fracture (AO/OTA 31-A2/A3), who met the inclusion criteria and had given informed consent to the study, were enrolled in the study. Randomised allocation of the patients to receive either one of the two implants was performed with sealed, opaque and consecutively numbered envelopes. Altogether 5 patients were not operated upon according to the randomisation code (all stable A1 fractures, exclusion criteria) and further 4 patients received an incorrect implant after allocation in error. Finally, 39 patients were treated with the third generation gamma nail (GN) (Stryker Trauma GmbH, Schönkirchen, Germany) and 39 with the Inter-TAN (ITN) (Smith-Nephew, Memphis, TN, USA). Our institutional ethics committee approved the study (IRM no. 121/07). All patients gave their informed consent to the study.

Preoperative health status of the patients was assessed by obtaining history of any co-morbid diseases and medication and categorisation in risk groups proceeded with the use of the system of the American Society of Anaesthesiology. Preoperative demographic data including patient age, gender, time to surgery, fracture side, ASA categorization in risk groups, mode of accident, fracture classification according to the AO/OTA classification and the Singh index as an indicator for osteoporotic changes of the femoral neck/head region of the non-fractured side, recorded at the preoperative AP radiograph of the pelvis, were collected. Additionally, functional data about the preoperative mobility of the patients as well as the Harris Hip Score (13) (preoperative range of motion was adjusted with the un-fractured side) were documented. Both treatment groups were comparable before the index procedure. All surgeries were performed by 5 consultants with experience of at least five procedures with both GN and ITN nails, or the resident doctors under supervision inclusive.

The procedures were done under general anaesthesia and both groups received a standard dose of single-shot cefuroxime as routine prophylaxis. All procedures were performed using a traction table and by insertion of the nail via a percutaneous approach. The surgery proceeded under image-intensifier control with the patient in the supine position. The nails were inserted in the medullary canal without reaming, the lag screw of the GN and the cephalo-cervical twin-screws of the ITN were inserted after pre-drilling of the head/neck fragment. The position of the lag / cephalocervical screw was assessed under fluoroscopic control.

The quality of reduction achieved intra-operatively was assessed on the basis of the alignment and displacement of the fracture. According to the categorisation of Baumgaertner *et al* (2), we graded quality of the reduction into three categories, 'good', 'acceptable' and 'poor'. "Good" reduction was considered when the alignment was normal or in slight valgus on the AP view and less than 20° angulated on the lateral view; "acceptable" reduction was stated when either of the 'good' criteria is present, and "poor" reduction was noted if neither criteria were met. In those cases, where adequate closed reduction of the fracture could not be achieved, open reduction was done and consequently documented as an intraoperative complication.

The position of the lag / cephalo-cervical screw in the femoral head was determined according to the criteria of Cleveland *et al* (9). The femoral head is divided into three columns in the antero-posterior and in the lateral views to create nine zones. Fixation was deemed to be adequate if the lag screw was placed in the central or inferior zone in the AP view and centrally in the lateral view. We did not measure the tip apex distance according to Baumgaertner *et al* (2) due to lack of magnification raster in the OR and, on lateral postoperative x-rays, but we aimed to seat the lag / cephalo-cervical screw as far as possible in the subchondral area of the femoral head in both planes.

The nail length was 180 mm in both groups. The nail diameters of both implants were 10, 11 and 11.5 mm, depending on surgeons' preference concerning the expected extent of the medullary canal. The CCD angle of the GN was 125° and of the ITN 130°. All nails in both groups were distally locked.

Perioperative data collection included operating time, image intensifier time, intraoperative blood loss and hemoglobin decrease, as well as subjective data of the surgeons' opinion about: (1) the difficulty of the surgery (easy, not so easy or difficult), (2) the adequacy of the fracture fixation (good, acceptable or poor), and (3) the handling aspects with the different nails (easy to use or cumbersome).

Postoperative rehabilitation program included muscle strengthening, coordination and walking gait exercises for both groups, full weight bearing in all patients was encouraged.

The following postoperative data were documented: occurrence of general complications (thromboembolism, pneumonia, early postoperative death), wound haematoma of infection, requirement for blood transfusion in the perioperative period, the initial postoperative pain level using the VAS score, the duration of stay in the intensive care unit, and the time to discharge.

Radiologic evaluation consisted of intra- and postoperative radiographs as well as radiographs at each follow-up visit in antero-posterior and lateral view of the hip joint. The heterotopic ossification according to Brooker grading system (6) recorded at the latest follow-up, the amount of lateral sliding of the lag / cephalo-cervical screw and the reduction loss were evaluated. Reduction loss was defined as a progression of varus malalignment of the neck shaft angle $> 10^\circ$ from the time of fracture reduction to union. Fracture healing was stated when evidence of bridging callus formation became obvious or when the trabeculae had continued across the fracture site ; non-union was defined as lack of fracture healing 6 months after surgery.

Mechanical failure of the implant was ascertained when cutout of the lag / cephalo-cervical screw has to be noted. Secondary varus malalignment was also recorded ; but without cutout and consecutive healing of the fracture it was not valued as mechanical failure.

Follow-up's were done at 6 weeks, 12 weeks and 6 months or until union or failure of the fracture. At each follow up visit, radiological evaluation as well as functional parameters were done. The functional parameters were assessed by the Harris Hip Score (13) with regard to pain, mobility, daily activities and range of motion. Furthermore, data about leg-length discrepancy, abnormal walking gait, ability to full weight bearing, return to prior ambulation as well as the overall mortality were also collected. At the last follow-up the patients were examined if they had regained or even improved their prefracture activity level or not.

Statistical analysis was done by SPSS 18.0 software package. Mann-Whitney-T test was used for quantitative variables. Data were expressed as mean (standard deviation). Categorical variables were analysed by the chi-square test or Fisher's exact test where appropriate. and logistic regression analysis was performed within the groups between different variables. Differences were considered significant when the p value was < 0.05 .

RESULTS

Demographic patient data

The population consisted of 58 female and 20 male patients with an average age of 81.7 (± 7.78) years. The demographical preconditions for both groups were comparable with regard to BMI, time to surgery, fracture side, ASA score, mode of injury, functional preconditions and osteoporosis de-

gree of the femoral neck area. According to the AO/OTA classification system of intertrochanteric fractures, there were 54 fractures of type A2 and 24 fractures of type A3 (Table I).

Perioperative data

The list of the perioperative data and the surgeon's subjective evaluations of the implant and of the procedure are summarised in Table II.

Between the two groups there were no statistical significant differences with regard to intraoperative complications ($p = 0.767$). Altogether 9 open reductions, 5 in GN group and 4 in the ITN group, with or without femoral cerclage wiring had to be performed and one femoral shaft fracture at the tip of the GN during nail insertion occurred, necessitating cerclage wiring and insertion of a long nail (Fig. 1).

In general, open reductions significantly produced longer fracture reduction times ($p = 0.027$) and increased blood loss ($p = 0.005$). The occurrence of an intraoperative complication significantly increased image intensifier times ($p = 0.03$), operative times ($p = 0.001$) and blood loss ($p = 0.027$).

Fracture reduction time was similar in both groups, the mean operating time in the GN group was 14 minutes shorter than in the ITN group (64,6 versus 78 minutes ; $p = 0.044$). The image intensifier time during surgery (average 4.8 minutes), the intraoperative blood loss (average 171.9 ml), or the requirement for blood transfusion were not significantly influenced. The postoperative hemoglobin value was significantly decreased in the ITN group ($p = 0.021$) and most likely was in consequence of prolonged operative times in this group.

Neither subjective rating of the difficulty of the surgery ($p = 0.875$) nor rating of the adequacy of the fracture fixation ($p = 0.864$) differed significantly between the two groups. However, the difficulty of surgery significantly correlated with the over-all blood loss ($p = 0.005$). There was significant statistical difference in the subjective rating of the implants by the surgeons. For instance, 36% in the ITN group compared to 5% in the GN group rated the implant cumbersome ($p = 0.002$). Frequently mentioned reasons were the additional intermediate

Table I. — Demographic data

	GN (n = 39)	ITN (n = 39)	p Value
Age (years)*	80.73 ± 8.44	82.70 ± 7.06	0.307
Gender (female)	26	32	0.125
BMI*	26.32 ± 3.87	24.57 ± 4.76	0.255
Time to surgery (days)			0.532
< 24 h	29	32	
> 24 h	10	7	
Fracture on right side	19	17	0.796
ASA score*	2.83 ± 0.46	2.77 ± 0.66	0.708
Mode of accident			0.754
Domestic fall	35	33	
Accident	4	6	
Preoperative mobility (n = 75)			0.285
Independent from aids	27	30	
Crutches/cane	5	1	
Walking frame	4	1	
Wheel chair (some steps indoor)	3	0	
Preoperative HHS*	71.85 ± 21.54		0.085
Fracture Classification (AO/OTA 31)			0.779
A2 (2.1-2.3)	26	28	
A3 (3.1-3.3)	13	11	
Singh Index*	4.10 ± 1.03	4.37 ± 0.93	0.366

*Data are described as mean values and standard deviation. P values calculated by Fisher's exact test. GN : gamma nail ; INT : InterTAN nail ; BMI : body mass index ; ASA : American Association of Anaesthesiology ; HHS : Harris Hip Score : motion was adapted to the non-fractured side.

steps in the assembly of the implant with many parts looking similar, a locking of the two-screw construct and a frequently observed divergence of both cephalo-cervical screws in the femoral head during compression.

There were no significant differences between the groups concerning postoperative time in ICU (mean 1.8 days), initial postoperative pain (mean VAS 4.4), and time to discharge from hospital (mean 17 days) (Table II).

Lag / cephalo-cervical screw position

The screw positions for both implants in the femoral head are illustrated in Figure 2. According to antero-posterior radiographs, 7 out of the 8 screws in the superior zones belonged to the ITN. In contrast, 23 GN and only 7 ITN screws were placed in the caudal third of the femoral head ($p = 0.001$).

Although in the lateral view, most screws were positioned in the central third, distribution in the anterior and posterior thirds differed almost significantly ($p = 0.062$) with more screws in the anterior third in the GN group (17 versus 6 screws in ITN group), while there were more posterior screws in the ITN group (8 versus 3 screws in GN group).

Postoperative data

Eighteen patients, 9 in each treatment group were lost during the mean follow-up time of 25.5 weeks (± 16.75). Sixteen patients, 8 in each group, died within the follow-up period with a mean survival time of 18 weeks. Two patients were lost for follow-up due to moving out of province. As a consequence, only 30 patients (76.9%) in each treatment group (ITN and GN) were available for radiographic and functional evaluation.

Table II. — Perioperative data

	GN (n = 39)	ITN (n = 39)	p Value
fracture reduction time (minutes)*	11.63 ± 7.6	12.47 ± 8.57	0.812
operating time (minutes)*	64.6 ± 29.22	78.03 ± 34.07	0.044
image intensifier time (seconds)*	268.11 ± 148.72	307.73 ± 162.82	0.367
intraoperative Blood loss (ml)*	175.7 ± 189.26	168.1 ± 151.25	0.915
hemoglobin decrease (g/dl)*	2.24 ± 1.65	2.84 ± 1.35	0.076
preoperative hemoglobin*	12.33 ± 1.73	11.82 ± 1.55	0.332
postoperative hemoglobin*	9.89 ± 1.56	8.87 ± 1.58	0.021
requirement for blood transfusion (red cell units)*	2.07 ± 2.15	1.9 ± 1.4	0.731
postoperative time on ICU (days)*	1.73 ± 1.66	1.93 ± 2.84	0.327
initial postoperative pain (VAS 1-10)*	4.88 ± 2.46	4.07 ± 1.62	0.169
time to discharge (days)*	17.83 ± 7.15	16.47 ± 5.28	0.640
difficulty of surgery (subjective)			0.875
- easy	14	10	
- medium	24	23	
- difficult	5	6	
adequacy of osteosynthesis (subjective)			0.864
- good	16	18	
- acceptable	20	17	
- poor	3	4	
rating of the implant (subjective)			0.002
- easy to use	37	25	
- cumbersome	2	14	

*Data are described as mean values and standard deviation. Significant p value is in bold (Fisher's exact test). GN : gamma nail ; ITN : InterTAN nail ; : intensive care unit ; VAS : visual analogue scale.

Radiological outcome

Except of three cases of non-union ($p = 0.473$), fracture union in both groups was seen radiographically in all surviving patients at the latest follow-up visit.

There were no differences in the subjective rating of the fracture reduction (garden alignment index) ($p = 0.077$), in the CCD angle at the fracture side ($p = 0.536$) as well as in the adequate positioning of the lag / cephalo-cervical screw in the Cleveland zones ($p = 0.483$) (Fig. 2) obtained from the postoperative radiograph.

Furthermore, there were also no differences in the degree and frequency of heterotopic ossification according to the Brooker grading system ($p = 0.816$), in the lateral sliding of the lag screws ($p = 0.163$), and in the loss of reduction with a varus malalign-

ment of more than 10° ($p = 0.362$) recorded from the radiograph at the latest follow-up (Table III).

Postoperative complications

The complications, operative as well as non-operative, did not significantly differ between the groups ($p = 0.466$). Three patients died postoperatively within 48 hours due to complications of pre-existing cardiac and pulmonal diseases, two in the GN- and one in the ITN-group ($p = 0.557$). The rate of general complications was high in both treatment groups (48.7%). There were mostly pulmonary and urinary tract infections, 20 in the GN- and 18 in the ITN-group ($p = 0.797$).

The incidence of the local complication (10.2%) seen as haematomas or seromas was also not different in the two groups, five in the GN- and three in

Table III. — Radiological outcomes and mechanical complications

	GN	ITN	p Value
obtained postoperatively	(n = 39)	(n = 39)	
quality of reduction (GAI)			0.855
good	13	11	
acceptable	23	24	
poor	3	4	
lateral sliding of the lag screw (mm)*	26.36 ± 8.33	29.1 ± 1.64	0.163
CCD angle (°)*	122 ± 7.63	122 ± 12.01	0.536
reduction loss (varus dislocation > 10°) (n)	2	3	0.362
obtained at the last follow-up			
heterotopic ossification (Brooker grade)			0.816
0	21	22	
I	6	5	
II	3	2	
III	0	1	
IV	0	0	
secondary dislocation +/- cut-out (requiring surgical revision)	1	2	0.466
secondary varus collaps (all healed)	2	3	

*Data are described as mean values and standard deviation. P values calculated by Fisher's exact test. GN : gamma nail ; ITN : InterTAN nail ; GAI : Garden alignment index ; CCD : caput collum diaphyseal.

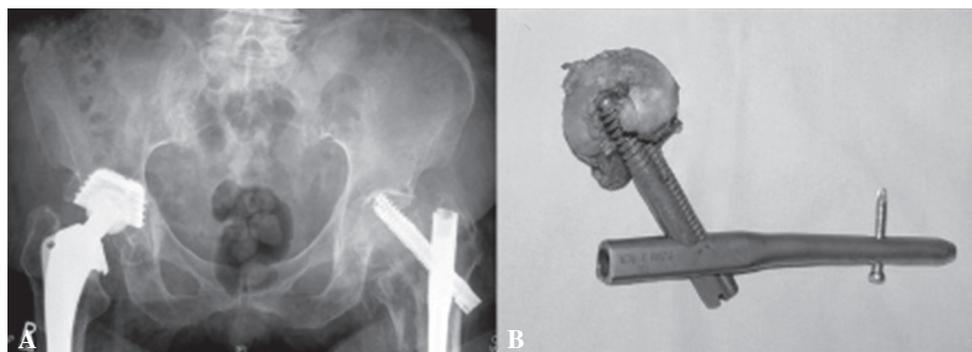


Fig. 3. — A. postoperative radiograph (AP view) 6 weeks postoperatively shows cut-out with arrosion of the acetabular dome, B. intraoperative ex-situ setting of cut-out after resection of femoral head.

zone (GN), no significantly increased risk of mechanical complication could be deduced ($p = 0.277$ and $p = 0.702$). There was only one varus collapse without cut-out and normal healing of fracture out of 26 adequately positioned screws in the centre-centre sector ($p = 0.524$).

Further statistical analysis with logistic regression revealed, that two additional variables influenced significantly the mechanical complication rate : the fracture classification (fracture of type A2

versus type A3, $p = 0.024$) and an increased lateral sliding of the lag screws in both groups ($p = 0.003$). Neither the adequacy of reduction as judged by the garden alignment index ($p = 0.154$) nor the postoperative CCD angle (0.187), although reduced in the group with complications (111.17° vs. 124.03°), were significantly associated with the occurrence of an implant-related complication.

Concerning the analysis of the subjective assessment of the surgeons, neither rating of the surgical

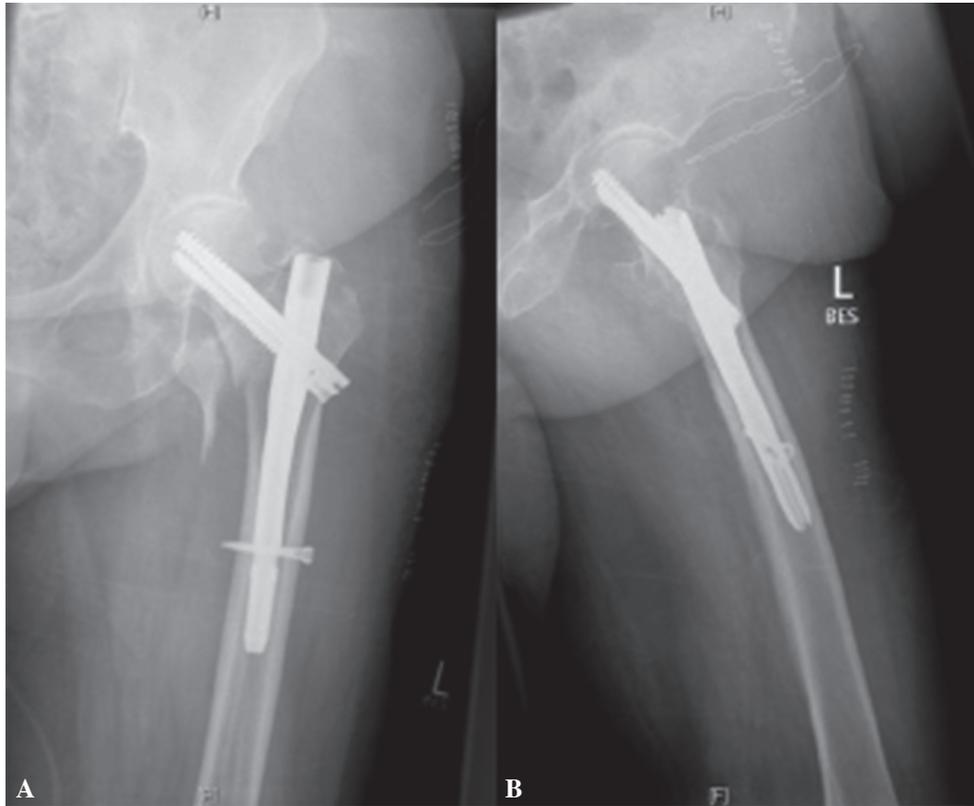


Fig. 4. — Initial postoperative radiographs after stabilisation of an intertrochanteric femoral fracture with the ITN device. AP (A) and axial (B) views. Despite adequate reduction of the fracture, axial cephalo-cervical screw position in the anterior third was considered as “suboptimal”.

difficulty ($p = 0.374$) nor the valuation of the quality of their fracture reduction ($p = 0.853$) were associated with the occurrence of specific complications.

Functional outcome

There were no significant differences between the two groups in terms of functional outcome concerning the postoperative mobility and the Harris Hip Score (HHS) at the latest follow-up examination ($p = 0.437$ and $p = 0.298$) (Table IV).

In comparison to the preoperative HHS, the values had significantly decreased in the GN group ($p = 0.021$) as well as in the ITN group ($p = 0.015$). Overall, only 19 of the patients (24.4%) regained their pre-ambulatory mobility ($p = 0.604$), 54 patients (69.2%) were able to gain full weight bearing

($p = 0.842$). Altogether 25 patients (32%) showed an insecure walking gait ($p = 0.316$). The mean leg length discrepancy was similar and ranged between 11.5 mm in the GN group and 12.5 mm in the ITN group ($p = 0.608$).

Interestingly, the preoperative general health status of the patients valued by the ASA classification correlated with the achieved HHS at 6 months postoperatively ($p = 0.002$, Fisher's exact test), implicating that impaired general health status undoubtedly influences functional outcome measures.

DISCUSSION

Intertrochanteric femoral fractures have been regarded as a common occurrence in the elderly. Early surgical fixation is recommended to prevent the complications associated with prolonged

Table IV. — Functional outcome (at last follow-up)

	GN (n = 30)	ITN (n = 30)	p Value
Harris Hip Score*	35.33 ± 14.15	42.77 ± 12.24	0.298
postoperative mobility (n)			0.437
independent from aids	9	6	
crutches/cane	14	16	
walking frame	0	1	
mostly wheel chair (some steps indoor)	7	7	
insecure walking gait	10	15	0.316
return to prior ambulation (or better) (n)	10	9	0.604
ability to full weight bearing (n)	27	27	0.842
leg-length discrepancy (mm)*	11.50 ± 8.45	12.50 ± 10.61	0.608

*Data are described as mean values and standard deviation. P values calculated by Fisher's exact test. GN : gamma nail ; INT : InterTAN nail.

immobility (29). There are still controversies about the ideal implant system to stabilise unstable intertrochanteric femoral fractures, especially in the elderly patients with often reduced or osteoporotic bone quality. The biomechanical advantages of the third generation gamma nail system have been variously described with an implant-related complication rate ranging from 8% to 15% (1,3,4,7,8,14,16,21,27). Various other implant designs have been developed to reduce these shortcomings of the traditional Gamma nail system.

The Trigen InterTAN nail system, introduced in 2005, has been reported to offer good clinical outcome and low complication rate (19). We are not aware of any previous study comparing the use of the third generation Gamma nail (GN) with the InterTAN (ITN) implant system. Therefore, we intended to evaluate if there are any significant advantages of the ITN over the GN in the treatment of unstable intertrochanteric femoral fractures in the elderly, especially in the perioperative period.

Screw positioning

Our results showed that the positioning of the tip of the screw in the femoral head was of great importance in the prediction of fixation failure. In both groups, positioning of the screw into the superior and the posterior zone of the femoral head was associated with mechanical implant failure. In our se-

ries 6 out of 16 screws positioned in these special zones led to a cut-out. Surprisingly, one additional cut-out occurred in a supposed „correct“ centre/centre position. Retrospectively, there was an inadequate reduction of the fracture prior to screw placement in this case.

Concerning the incidence of mechanical implant failure (cut-out) there was no statistical difference in the two implant groups (ITN versus GN).

Our findings therefore confirm earlier studies, which reported incidence of cut-out rates between 3% to 10% (1,4). Some studies proved screw placement into the central or inferior position of the femoral head to be the best screw position to prevent cut-outs (10,29). Davis *et al* (10) concluded in their series of 230 intertrochanteric femoral fractures that the probability of screw cut-out is mostly determined by the positioning of the device into the femoral head.

Practically, we recommend targeting the tip of the screw in the AP view as inferior as possible to assure, that the tip comes to lie at least in the central zone or even as expected in the inferior third close to the femoral calcar. In the lateral view, no risk should be taken and the screw should be placed centrally as possible in the femoral head. In that combination, one can be sure, that only the central/central or the central/inferior zone of the femoral head are seated by the screw and the critical areas avoided. In this regard as an interacting cause, the neck shaft

angle of the used implant must also be taken into account. Numerous companies offer a variety of different implants with variable neck shaft angle for the fixation of trochanteric fractures. It seems logical, that with increasing angle of the device, the likelihood of a supposed too high aimed screw in the femoral head will rise, consequently be associated with an increased risk of a cut-out. Unfortunately, to our knowledge no current investigation focussing on this issue is available.

The tip apex distance (TAD) according to Baumgaertner *et al* (2), a well recognised measure for the position of the tip of the lag screw and describes a lower complication rate for implant tips placed close to the subchondral bone of the femoral head. In our study, we could not measure TAD for two reasons: first, surgeons did not routinely perform strict standardized radiographic protocol during final x-rays of the hip in the OR, especially for the lateral projection. Second, magnification of the radiographs in the OR as well as for the post-operative lateral controls could not be reliably calculated due to missing magnification raster. Apart from that, every surgeon aimed to seat the lag/cephalo-cervical screw as far as possible in the subchondral area of the femoral head.

Reduction of fracture

The implant-related complications are also related to the quality of fracture reduction before implant fixation. Previous studies confirmed that meticulous reduction of intertrochanteric fractures before fixation will minimise the mechanical failure rate associated with the intramedullary implant device (3,14, 18,21). Although our results show that the majority of the participating surgeons described the fracture reduction as good or acceptable, the implant-related complication rate is still high in both treatment groups. Although there was no statistically significant correlation between the quality of fracture reduction and the complication rate in our presented case series, the correct screw position is decisively associated with the previous adequate fracture reduction.

The review of 87 trochanteric fractures by Thomas (26) came to the conclusion that a good

screw placement is undoubtedly dependent on a perfectly reduced fracture.

Functional results

Considering, that the study lacks power when it comes to demonstrating similar functional results, we found no significant statistical difference between the two implant groups, based on the functional outcome at 6 months postoperatively. However, there was a reduction of the Harris Hip Score postoperatively in both groups. Although 90% of the patients (27/30) in each treatment group attained full weight bearing, more than 40% of the patients (25/60) demonstrated an unsecure walking gait. Only 15 patients (25%) were able to walk without supports. Less than one third of the patients (19/60) regained their prefracture ambulatory status.

These findings are confirmed by the study of Zhang *et al* (28). They compared the InterTAN nail with the PFNA nail in a series of 132 consecutive patients with intertrochanteric femoral fractures and found no significant difference in the functional outcome after a mean follow-up of 18 months between the two groups. One possible explanation for the less satisfactory functional results in both groups may be the violation of the abductor muscles, inherent to the introduction of the nail proximally. However, there was no clinical evidence of Trendelenburg gait in our patients.

Femoral shaft fracture during insertion of the nail

Our study recorded only one femoral shaft fracture during the insertion of a GN, which confirmed an earlier study of Schipper *et al* (23), who reported one femoral shaft fracture out of 213 patients treated with GN. But this is in contrast to earlier reports with higher incidences, as high as 17% of femoral shaft fractures in fixation intertrochanteric fractures by intramedullary devices (1,18). This discrepancy in the incidence of femoral shaft fractures might be due to improved surgical technique of implant fixation and due to modifications of implant design (smaller diameter) (23).

Limitations of the study

This study had several limitations. First, there was a small sample size for each treatment group, thus limiting the external validity of the results. Nonetheless, this randomized study rigorously selected only patients over 60 years with exclusively unstable fracture pattern (AO OTA 31 A2.1 – A3.3). An error rate of 10 percent (9 patients) in the randomisation of our patients is a quiet large number, but we had to rigorously exclude those patients for risk of reducing the quality of our study. Second, a common problem and a major drawback in this kind of study was that a large number of patients withdrew, even after a relatively short follow-up. Many patients had increased comorbidity affecting their general health, making it impossible participating in follow-up. In our study, 16 patients, 9 in each group (23.1%), had either died in the follow-up period, or moved out of province.

We chose a limited postoperative follow-up of 6 months, because most of the mechanical complications associated with this type of stabilisation occur on average in the first 90 days and is probably due to weak implant-bone interface associated with inherent osteoporosis.

CONCLUSION

Despite the various attempts made to overcome the poor postoperative outcomes of unstable intertrochanteric femoral fractures in the elderly, with introduction of new implant designs, the ideal implant configuration is yet to be found. The results of our prospective cohort study have clearly shown that the InterTAN femoral nail system is comparable to the gamma Nail system in terms of functional outcome and implant-related complication rate.

The two critical factors to consider are optimal fracture reduction and proper positioning of the implant in the femoral head, and should be strive for in all cases. Therefore, the outcome of treatment for unstable intertrochanteric femoral fractures in the elderly, is the sole responsibility of the surgeon and not of the configuration of the implant used.

REFERENCES

1. **Albareda J, Laderiga A, Palanca D et al.** Complications and technical problems with the gamma nail. *Int Orthop* 1996 ; 20 : 47-50.
2. **Baumgaertner MR, Curtin SL, Lindsag DM et al.** The value of the tip-apex distance in predicting failure of fixation of peritrochanteric fractures of the hip. *J Bone Joint Surg* 1995 ; 77-A : 1058-1064.
3. **Bojan AJ, Beimel C, Taglay G et al.** Cut-out complication after Gamma nail treatment of proximal femoral fractures. *BMC Musculoskeletal Disorders* 2013 ; 14 : 1. doi : 10.1186/1471-2474-14-1
4. **Boriani S, Bettelli G, Zmerly H et al.** Results of the multicentric Italian experience on the Gamma nail : a report on 648 cases. *Orthop* 1991 ; 14 : 1307-1314.
5. **Bridle SH, Patel AD, Bircher M et al.** Fixation of intertrochanteric fractures of the femur. A randomised prospective comparison of the gamma nail and the dynamic hip screw. *J Bone Joint Surg* 1991 ; 73-B : 330-334.
6. **Brooker AF, Bowerman JW, Robinson RA et al.** Ectopic ossification following total hip replacement : incidence and a method of classification. *J Bone J Surg* 1973 ; 55-A : 1629-1632.
7. **Buecking B, Bliemel C, Struwer J et al.** Use of the gamma 3 nail in a teaching hospital for trochanteric fractures : mechanical complications, functional outcomes, and quality of life. *BMC Research Notes* 2012 ; 5 : 651 doi : 10/1186/1756-0500-5-651.
8. **Chevale F, Gamba D.** Gamma nailing of peritrochanteric and subtrochanteric fractures : clinical results of a series of 63 consecutive cases. *J Orthop Trauma* 1997 ; 11 : 412-415.
9. **Cleveland M, Bosworth DM, Thompson FR et al.** A ten-year analysis of intertrochanteric fractures of the femur. *J Bone Joint Surg* 1995 ; 41-A : 1399-1408.
10. **Davis TRC, Sher JL, Horsman A et al.** Intertrochanteric femoral fractures : mechanical failure after internal fixation. *J Bone Joint Surg* 1990 ; 72-B : 26-31.
11. **Efstathopoulos NE, Nikolam VS, La Zaretos JT.** Intramedullary fixation of two implant designs. *Int Orthop* 2007 ; 31 : 71-76.
12. **Erez O, Dougherty PJ.** Early complications associated with cephalomedullary nail for intertrochanteric hip fractures. *J Trauma Acute Care Surg* 2012 ; 72 : 101-105.
13. **Harris HW.** Traumatic arthritis of the hip after dislocation and acetabular fractures : treatment by mold arthroplasty. An end-result study using a new method of result evaluation. *J Bone Joint Surg* 1969 ; 51-A : 737-755.
14. **Hesse B, Lampert C, Remiger A et al.** Treatment of trochanteric fractures with the gamma nail. *Unfallchirurg* 2003 ; 106 : 281-286.
15. **Huang Y, Zhang C, Luo Y.** A comparative biomechanical study of proximal femoral nail (InterTAN) and proximal

- femoral nail antirotation for intertrochanteric fractures. *Int Orthop* 2013 ; 37 : 2465-2473.
16. **Leung KS, Chen CM, So WS et al.** Multicentre trial of modified gamma nail in East Asia. *Clin Orthop* 1996 ; 323 : 141-154.
 17. **Lindsey RW, Teal P, Probe RA et al.** Early experience with the Gamma interlocking nail for peritrochanteric fractures of the proximal femur. *J Trauma* 1991 ; 31 : 1649-1658.
 18. **Mainds CC, Newman RJ.** Implant failures in patients with proximal fractures of the femur treated with a sliding screw device. *Injury* 1989 ; 20 : 98-100.
 19. **Matre K, Vinje T, Havelin LI et al.** TRIGEN INTERTAN Intramedullary Nail Versus Sliding Hip Screw : A prospective randomised multicentre study on pain, function, and complications in 684 patients with an intertrochanteric or subtrochanteric fracture and one year of follow up. *J Bone Joint Surg* 2013 ; 95-A : 200-208.
 20. **Nüchtern JV, Ruecker AH, Sellenschloh K et al.** Malpositioning of the lag screws by 1- or 2-screw nailing systems for pertrochanteric femoral fractures : a biomechanical comparison of gamma 3 and intertan. *J Orthop Trauma* 2014 ; 28 : 276-282.
 21. **Rosenblum SF, Zuckerman JD, Kummer FJ et al.** Biomechanical evaluation of the gamma nail. *J Bone Joint Surg* 1992 ; 74-B : 352-357.
 22. **Ruecker A, Rupprecht M, Gruber M et al.** The Treatment of Intertrochanteric Fractures : Results Using an Intra-medullary Nail With Integrated Cephalocervical Screws and Linear Compression. *J Orthop Trauma* 2009 ; 23 : 22-30.
 23. **Schipper IB, Steyerberg W, Castelein RM et al.** Treatment of unstable trochanteric fractures : Randomised comparison of the Gamma nail and the proximal femoral nail. *J Bone Joint Surg* 2004 ; 86-B : 86-94.
 24. **Singh M, Nagrath AR, Minni PS.** Changes in trabecular pattern of the upper end of the femur as an index of osteoporosis. *J Bone Joint Surg* 1970 ; 52-A : 457-467.
 25. **Smith & Nephew.** TRIGEN INTERTAN Intertrochanteric Antegrade Nail, Surgical Technique brochure. Rucker A, Russell TA, Sanders RW, Tornetta P. [http:// global.smith-nephew.com/is/TRIGEN_INTRAMEDULLARY_NAIL_3849_679](http://global.smith-nephew.com/is/TRIGEN_INTRAMEDULLARY_NAIL_3849_679).
 26. **Thomas AP.** Dynamic hip crews that fail. *Injury* 1991 ; 22 : 45-46.
 27. **Valverde JA, Alonso MG, Porro JG et al.** Use of gamma nail in the treatment of fractures of the proximal femur. *Clin Orthop Relat Res* 1998 ; 350 : 56-61.
 28. **Zhang S, Zhang K, Jia Y et al.** InterTAN Nail versus proximal femoral nail antirotation - Asia in the treatment of unstable trochanteric fractures. *Orthop* 2013 ; 36 : 288-294.
 29. **Zuckerman JD, Skovron ML, Koval KJ et al.** Post-operative complications and mortality associated with operative delay in older patients who have a fracture of the hip. *J Bone Joint Surg* 1995 ; 77-A : 1551-1556.