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ORIGINAL STUDY

Comparable clinical and radiographical outcomes between second and third generation of gamma nails

Lode Holsters, Simon van Laarhoven, Rik J.M. Bruls, Bob Jong, Martijn G. M. Schotanus, Pieter B.J. Tilman

From the Dept. of Orthopaedic Surgery and Traumatology, Zuyderland Medical Centre, Sittard-Geleen and Heerlen, The Netherlands

The aim of the study is to compare the overall complication rate and in particular lag screw cut-out between the Trochanteric Gamma Nail and the Gamma 3 Nail.

A total of 294 implants (Trochanteric Gamma Nail= 132 and Gamma 3 Nail=163) in 291 patients were analysed. All clinical data was obtained from the patients medical records. Subsequently radiographs were evaluated for fracture type according to the AO classification and lag screw position by determining the tip-apex distance, the Parker's ratio and the neck-shaft-angle.

No significant differences in complication rates were found. The Parker's ratio was associated with lag screw cut-out : patients with medial cut-out had more a posteriorly placement (n=9, 3.1%), while patients with cranial cut-out had a more cranial placement of the lag screw (n=10, 3.4%). The tip-apex-distance and neck-shaft-angle were not associated with cut-out.

The complication rate of the Gamma 3 Nail does not differ from the Trochanteric Gamma Nail. A lag screw positioning central or slightly inferior on the anteroposterior view and central on the lateral view is recommended.

Keywords : hip fracture ; osteosynthesis ; intramedullary nail ; trochanteric fracture ; gamma nail ; gamma 3 ; complication ; lag screw ; cut-out.

Conflict of Interest : L. Holsters, S. van Laarhoven, R.J.M. Bruls, B. Jong, P.B.J. Tilman and M.G.M. Schotanus declare that they have no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted manuscript.

INTRODUCTION

Trochanteric fractures are frequent amongst the western population, and are generally associated with bone fragility and age. An increase in these fractures is to be expected in the near future *(1,2)*.

Most intertrochanteric fractures are managed by intramedullary fixation or a sliding hip screw fixation *(3,4)*. However early intramedullary nails

■ L. Holsters[1], MD, Orthopaedic resident
■ S. van Laarhoven[2], MD, orthopaedic surgeon
■ R.J.M. Bruls[3] MD, Radiology resident
■ B. Jong[3], MD, Radiologist
■ P.B.J. Tilman[3] MD, Orthopaedic surgeon
■ M.G.M. Schotanus[1,4], PhD, MSc, BEng, Research & Scientific Director

[1]Dept. of Orthopaedic Surgery and Traumatology, Zuyderland Medical Centre, Sittard-Geleen and Heerlen, The Netherlands.
[2]Dept. of Orthopaedic Surgery, Sint Maartenskliniek, Nijmegen, The Netherlands.
[3]Dept. of Radiology, Zuyderland Medical Centre, Sittard-Geleen and Heerlen, The Netherlands.
[4]Dept. of Orthopaedic Surgery and Traumatology, School of Care and Public Health Research Institute, Faculty of Health, Medicine and Life Science, Maastricht University, The Netherlands.

Correspondence: Mr Lode Holsters, Dept. of Orthopaedic Surgery and Traumatology, Zuyderland Medical Centre, Sittard-Geleen and Heerlen, the Netherlands. Phone : +32497/29.48.54.
E-mail : lodeholsters@live.be

Level of evidence III: Case Controlled Study

showed high rates of various complications, e.g. femoral fractures and lateral migration of the lag screw *(5-8)*.

Several options have been developed by different firms, such as the Trochanteric Fixation Nail by DepuySynthes and the gamma nail by Stryker in 1988. Over time several modifications of the original Gamma Nail have been introduced. These modifications resulted in the development of the second generation Gamma Nails, called Trochanteric Gamma Nail (TGN), in 1997. This nail was shortened and its mediolateral curve was lowered *(9)*. In 2004 the Gamma 3 Nail (G3N) was introduced and with it a downsizing of the proximal diameter of the nail (17mm to 15.5mm), the lag screw (12mm to 10.5mm) and the distal locking screw (6.25mm to 5mm). In addition the option of dynamic locking was added and the shape of the lag screw was changed (removal of the abrupt taper).

In our centre the switch from the TGN to the G3N was made in August 2008. We perceived an increase in lag screw cut-out. Case reports regarding cut-out of the lag screw after use of the TGN and of the G3N have been published, including two studies directly comparing the TGN with the G3N *(4,10-15)*.

Georgiannos et al. concluded a higher rate of lag screw cut-out in the TGN group (6.77%) compared to the G3N (2.28%), whereas Mingo-Robinet et al. reported 3.27% and 15.38% respectively.

The tip-apex distance (TAD) has been well established as a measurement to predict lag screw cut-out in intertrochanteric femoral fractures. A TAD greater than 25 mm is considered a strong positive predictor of screw cut-out *(16-18)*. Another predictor of lag screw cut-out is the Parker's ratio. Parker found that superiorly and/or posteriorly placed lag screws had a higher rate of cut-out than the ones that were placed centrally *(19)*.

The aim of this study is to evaluate whether or not the G3N has a higher cut-out rate than the TGN, in relation to the TAD, Parker's ratio and neck-shaft-angle. Both standard and long versions were included.

PATIENTS AND METHODS

This study was approved by the institutional review board (METC Z, Heerlen, the Netherlands ; IRB-nr.13N153) and was registered online at the Dutch Trial Register (NTR4771).

We included 2 groups of patients in this analysis. Group A received a TGN in the period between January 2005 and July 2008 (n=132), and group B received a G3N in the period between February 2009 and July 2012 (n=162). Patients between July 2008 and February 2009 were not included to prevent bias caused by the learning curve. Both standard G3N and TGN and longer alternatives, Gamma3 long nail and long gamma locking nail respectively were included in the analysis.

Clinical data was obtained from the medical records : date of birth, gender, date of surgery, type of implant material, American Society of Anaesthesiologists (ASA) classification, body mass index (BMI), surgery duration, amount of blood loss, anaesthetic technique, medical history, occurrence of complications and date of death.

Exclusion criteria were : (impending) pathological fractures, previous surgery, and (a history of) stress fractures. Surgery was performed by orthopaedic surgeons and residents at Zuyderland Medical Centre in Sittard-Geleen, The Netherlands.

The analysis of complications was limited to medial and cranial lag screw cut-out, irritation by lag screw, femoral fracture, pseudarthrosis, infection or miscellaneous. Systemic and wound related complications have not been taken into account. The patient mortality and the implant survival rate after one year were calculated for both the TGN and the G3N groups.

All pre-operative radiographs were categorized according to the AO/OTA classification of fractures *(20)*. The post-operative radiographs were analysed using 3 parameters : tip-apex distance (TAD), Parker's ratio and neck-shaft angle difference (ΔNSA). The TAD was calculated as proposed by Baumgaertner et al. : the sum of the distance (in mm) of the tip of the lag screw to the apex of the femoral head as measured on a standard anteroposterior and lateral hip x-ray (after correction for magnification) *(21)*. Measurements of the TAD on a digital picture archiving and communication system have proven to be accurate and reproducible *(22)*. The ΔNSA was calculated as the difference in neck-shaft angle (NSA) between both hips on a standard anteroposterior pelvic x-ray, with a positive ΔNSA indicating an increase in valgus angle, and a negative ΔNSA an decrease in valgus angle. We also measured the Parker's ratio as proposed by Parker and used a cut-off value of 40 *(19,23)*.

To find out whether lag screw placement is associated with the occurrence of lag screw cut-out, we compared the radiological outcomes of a group with lag screw cut-out to those of a group without lag screw cut-out. This was done for medial and cranial lag screw cut-out separately.

The assessor of the radiographs was blinded for the occurrence of any complications. Fifty patients were randomly selected from the whole group to be measured a second time by the same assessor to calculate the intra-observer agreement. All measurements were carried out using AGFA IMPAX 6, the x-ray archiving and communication system used in our hospital.

Statistical analysis was performed using IBM SPSS Statistics Version 22. Independent samples t-test and Mann-Whitney U test were used for calculating statistically significant differences of quantitative variables. Pearson's chi-squared test and Fisher's exact test were used for categorical variables. Differences were considered to be statistically significant when the P-value was 0.05 or less. Intraclass correlation coefficients (ICC) were calculated to check for intra-observer agreement. An ICC ≥ 0.7 was considered as a good correlation.

RESULTS

Demographic data and perioperative variables

A total of 337 patients with 352 implants were retrieved from patient records. Fifty-eight procedures or 46 patients were excluded with a remainder of 291 patients or 294 implants (n=294). In group A 131 patients were included with a total of 132 procedures (n=132). For further analysis this group was subdivided in a short (n=108) and long (n=24) subgroup. In group B a total of 160 patients were included for a total of 162 procedures (n=162). This group was also subdivided in a short (n=140) and long (n=22) subgroup.

Patients in both in the short and long subgroups did not differ statistically significant in regard to preoperative patient characteristics (see tables I and II). In the short nail subgroup we did see a statistically longer duration of surgery : 37.9 min. in group A versus 32.7 min. in group B (P <0.001). There was less blood loss in group B in both short and long subgroups (117.9 and 219.1 mL respectively) compared to group A (143.3 and 423.6 mL).

In group A one-year survival was 95.5% and one-year mortality rate was 28% (37 patients). In group B this was 93.2% and 21.0% respectively. This difference was not statistically significant.

Table I. — Patient characteristics and perioperative variables in the short subgroups

	Short gr. A (n=108)	**Short gr. B (n=140)**	**p-value**
Age, years (SD)	80.4 (9.4)	81.2 (11.1)	0.184
Female, n (%)	82 (75.9)	114 (81.4)	0.291
Right side, n (%)	54 (50.0)	59 (42.1)	0.218
BMI (SD)	23.8 (3.2)	23.8 (4.9)	0.642
ASA			0.383
I, n (%)	21 (19.4)	15 (10.7)	
II, n (%)	65 (60.2)	78 (55.7)	
III+IV, n (%)	20 (18.5)	21 (15.0)	
General anaesthesia, n (%)	38 (35.2)	67 (47.9)	0.052
Surgery time, min. (SD)	37.9 (13.3)	32.7 (14.2)	**<0.001**
Blood loss, ml (SD)	143.3 (105.2)	117.9 (103.9)	**0.040**

In case of numerical variables mean values are shown with corresponding standard deviations. Values in bold are statistically significant. gr. = group.

Table II. — Patient characteristics and perioperative variables in the long subgroups

	Long gr. A (n=24)	Long gr. B (n=22)	p-value
Age, years (SD)	75.3 (12.5)	77.0 (14.2)	0.317
Female, n (%)	15 (62.5)	18 (81.8)	0.197
Right side, n (%)	9 (37.5)	7 (31.8)	0.763
BMI (SD)	26.1 (3.9)	24.8 (4.1)	0.356
ASA			0.158
I, n (%)	7 (29.2)	4 (18.2)	
II, n (%)	12 (50.0)	10 (45.5)	
III+IV, n (%)	2 (8.3)	7 (31.8)	
General anaesthesia, n (%)	7 (29.2)	13 (59.1)	0.073
Surgery time, min. (SD)	70.9 (30.8)	58.9 (24.0)	0.101
Blood loss, ml (SD)	423.6 (293.3)	219.1 (210.0)	**0.004**

In case of numerical variables mean values are shown with corresponding standard deviations. Values in bold are statistically significant. gr. = group.

Short group

The distribution of complications are shown in table III. In group A (n=108) there were 13 (12.0%) complications in total, compared to 19 (13.6%) complications in group B (n=140). The difference in complication rate was not statistically significant (p=0.849). No significant differences were found in further subgroup analysis.

In general medial (see figure 1) and cranial (see figure 2) cut-out of the lag screw was the most common complications. Nine patients (3.6%) had a cranial lag screw cut-out requiring a reoperation in 8 patients (3.2%). In 6 cases there was a medial migration of the lag-screw (2.4%), four patients requiring a reoperation (1.6%). Further distribution of complications are shown in table III.

Long group

The distribution of complications are shown in table IV. In group A (n=24) there were 4 (17%) complications compared to 2 (9.1%) complications in group B (n=22). The difference was not statistically significant (p=0.667). Subgroup analysis showed no further statistically significant differences. In group A 2 patients had a medial lag screw cut-out compared to 1 patient in group B. Only 1 patient had a medial lag screw cut-out in group B.

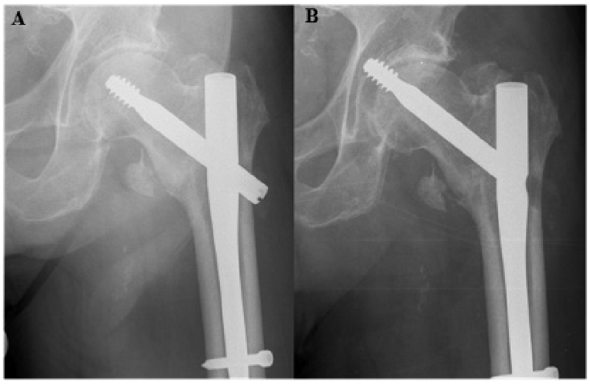

Figure 1. — Medial cut-out of a short TGN. (A) day one postoperatively (B) 2 months postoperatively.

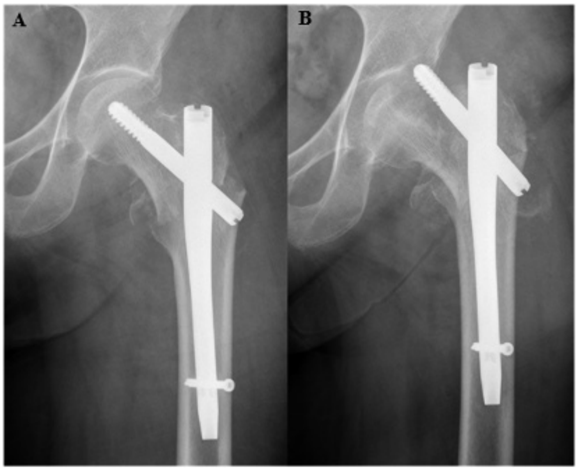

Figure 2. — Cranial cut-out of a short G3N. (A) day one postoperatively (B) 6 weeks postoperatively.

Table III. — Overall complications in the short subgroups

	Short gr. A (n=108)	**Short gr. B (n=140)**	**p-value**
Medial lag screw cut-out, n (%)	3 (2.8)	3 (2.1)	>0.900
Cranial lag screw cut-out, n (%)	4 (3.7)	5 (3.6)	>0.900
Irritating lag screw, n (%)	3 (2.8)	2 (1.4)	>0.900
Femoral fracture, n (%)	2 (1.9)	1 (0.7)	0.583
Pseudarthrosis, n (%)	0	2 (1.4)	0.506
Infection, n (%)	0	2 (1.4)	0.506
Miscellaneous, n (%)	1 (0.9)	4 (2.9)	0.400
Total complications, n (%)	13 (12.0)	19 (13.6)	0.849

gr.= group.

Table IV. — Overall complications in the long subgroups

	Long gr. A (n=24)	**Long gr. B (n=22)**	**p-value**
Medial lag screw cut-out, n (%)	2 (8.3%)	1 (4.5%)	>0.900
Cranial lag screw cut-out, n (%)	0	1 (4.5%)	0.478
Irritating lag screw, n (%)	1 (4.2%)	0	>0.900
Miscellaneous, n (%)	1 (4.2%)	0	>0.900
Total complications, n (%)	4 (17%)	2 (9.1%)	0.667

gr.= group.

Table V. — Complication rates in each fracture type for both group A and B.

	Complication rate		**p-value**
	Gr. A (n=132)	**Gr. B (n=162)**	
31-A1, n	4/31	2/45	0.218
31-A2, n	7/59	14/85	0.482
31-A3, n	4/28	4/20	0.703
32-A1, n	0/7	0/7	
32-A2, n	1/4	0/2	>0.900
32-A3, n	1/2	1/1	>0.900
32-B1, n	0/1	0/1	
32-B3, n	-	0/1	

The numerator of the fraction displays the amount of complications, the denominator displays the total amount of implants in that fracture type. gr.= group.

The results here were pooled together for both long and short implants.

The distribution of fracture types and their respective complication rates are shown in table V. Pertrochanteric fractures (31-A1 and 31-A2) were the most common type, and intertrochanteric fractures (31-A3) the second most common type.

Table VI. — The four radiological outcomes of a group with and without medial cut-out of the lag screw

	No medial cut-out (n=285)	**Medial cut-out (n=9)**	**p-value**
TAD (mm)	23.7 (7.5)	26.1 (12.7)	0.584
NSA-difference (°)	1.0 (10.3)	1.9 (7.8)	0.786
Parker's ratio AP (%)	45.9 (9.1)	45.1 (15.4)	0.867
Parker's ratio lateral (%)	44.6 (9.4)	36.2 (8.6)	**0.020**

The table shows the mean values and corresponding standard deviations. Results in bold are statistically significant.

No statistically significant differences were found in fracture distribution between both groups (p-value 0.305). Fisher's exact test also revealed no significant differences in complication rates between the implants.

Results shown here were pooled for both group A and B and analysed according to the type of complication.

The group with medial cut-out of the lag screw had a significantly lower lateral Parker's ratio, i.e. a more posteriorly placed lag screw (see table VI). The group with cranial cut-out of the lag screw had

Table VII. — The four radiological outcomes of a group with and without cranial cut-out of the lag screw

	No cranial cut-out (n=284)	Cranial cut-out (n=10)	p-value
TAD (mm)	23.7 (7.8)	24.2 (3.0)	0.463
NSA-difference (°)	0.9 (10.3)	1.9 (7.3)	0.771
Parker's ratio AP (%)	45.6 (9.4)	53.9 (4.5)	**<0.001**
Parker's ratio lateral (%)	44.6 (9.4)	39.5 (10.6)	0.092

The table shows the mean values and corresponding standard deviations. Results in bold are statistically significant.

a significantly higher anteroposterior Parker's ratio, i.e. a more superiorly placed lag screw (see table VII).

The TAD and ΔNSA were not statistically different both for medial and cranial cut-out.

The intraclass correlation coefficients (ICC) were calculated for TAD, ΔNSA, anteroposterior Parker's ratio and lateral Parker's ratio : 0.93, 0.81, 0.98 and 0.96 respectively.

DISCUSSION

The hypothesis was that the Gamma3 Nail (G3N ; group B) suffered more overall complications than the Gamma Trochanteric Nail (TGN ; group A), and more specifically more lag screw cut-out. The data in this study does not support the hypothesis : no statistically significant differences in complications between both groups were found. We combined the complication rates of medial and cranial cut-out : 5.7% versus 6.5% in the short subgroup and 9.0% versus 8.3% in the long subgroup for the G3N and TGN respectively. Mingo-robinet et al. supported the hypothesis : in their results the G3N had a relative risk of cut-out of 4.71 and even 8.78 in unstable fractures compared to the TGN *(13)*. On the contrary Georgiannos et al. reported a cut-out rate of 2.28% in the G3N group and 6.77% in the TGN group *(4)*. The difference in results can partially be explained by the fact that Georgiannos et al. did not do a separate analysis for cranial and medial cut-out, and Mingo-robinet et al. only reported cranial cut-out.

The higher complication rate seen with Mingo-robinet et al. might be partially explained by the smaller amount of G3N implants used, and without a prior timeframe to build up expertise with the new implant.

The G3N had two advantages over the TGN in the perioperative outcomes : shorter surgery duration and less blood loss. These can be explained by the improved targeting device of the G3N, making the procedure easier and faster. The blood loss however is never an exact measurement but is a mere indication for the real amount, however we assume the relative difference in blood loss to be sufficiently reliable and useful to compare the difference in surgical procedure between implants.

This study showed an association between the Parker's ratio and lag screw cut-out. Medial cut-out of the lag screw was associated with a significantly lower lateral Parker's ratio (36.2 vs. 44.6), i.e. a more posteriorly placed lag screw. At the same time cranial cut-out of the lag screw was associated with a significantly higher anteroposterior Parker's ratio (53.9 vs. 45.6), i.e. a more superiorly placed lag screw. A study that used micro-CT data showed that the centre of the femoral head has the highest ratio of bone volume to total volume and the highest trabecular thickness, especially compared to the superior and the posterior part of the femoral head *(24)*. This could be an explanation for our finding that more posteriorly as well as more superiorly placed lag screws are associated with cut-out.

When Baumgaertner et al. introduced the TAD, they found a direct relationship between a TAD above 25 mm and an increased risk of lag screw cut-out *(21)*. Subsequent studies confirmed this correlation *(23,25-26)*. The quality of the fracture reduction has also been assessed, but was only moderately reliable in predicting lag screw cut-out *(25)*. However, we were unable to confirm an association between TAD and lag screw cut-out in this study. The same result was also reproduced by Mingo-robinet et al. *(13)*. The neck-shaft-angle did not show to influence cut-out rates.

The limitations of this study are the retrospective character and, as a consequence, the lack of randomization of treatment options and a loss to follow-up. Furthermore, a number of variables we examined are not fully reliable ; among these are ASA classification and BMI. The presence of osteoporosis was not examined with bone densitometry in most of the hip fracture patients and medication usage was insufficiently documented, therefore it is impossible to draw any conclusions concerning these variables and therefore not included.

Based on our findings we recommend placing the lag screw slightly inferiorly of the centre on the anteroposterior view and in the centre on the lateral view to minimize lag screw cut-out. In the current study an association between TAD and lag screw cut-out could not be confirmed.

We believe that, in addition to the lag screw placement, bone quality is another major factor that determines the success rate of the osteosynthesis. More research is required on this subject to be able to minimize complications of osteosynthesis in the future.

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