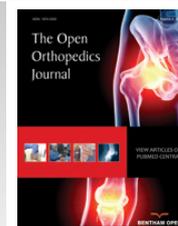




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RESEARCH ARTICLE

Complications in Treatment of 31-A Fractures with Trochanteric Gamma Nail (TGN) Versus Gamma3 Nail (G3N) - A Review of 217 Cases

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Abstract:

Introduction:

The aim of this study was to clinically evaluate two generations of intramedullary gamma-nail used in the treatment of 31-A femur fractures.

Materials and Methods:

In two consecutive series, 117 trochanteric gamma nails (TGN) and 100 Gamma3 nails (G3N) were implanted for the treatment of inter- and subtrochanteric fractures between 2009 and 2011. Clinical and radiological follow-up examinations were assessed. An analysis of surgical time, hemoglobin drop and complications were performed.

Results:

Average surgical time, fluoroscopy time, haemoglobin drop and length-of-stay (LOS) were similar in both groups. No significant differences were found in surgery-related complications like wound hematomas ($p=0,59$), abscesses ($p=0,38$), wound infections ($p=0,69$) and Cut-outs ($p=0,69$) between the two groups. The cumulative surgery-related complication rate was higher in the TGN group compared to the G3N group (13,68% vs. 8%) but this did not reach statistical significance ($p=0,2$).

Conclusion:

Our findings suggest that both TGN and G3N allow adequate treatment of trochanteric fractures with an acceptable complication rate.

Keywords: 31-A fracture, Complications, Elderly gamma3 nail, Intertrochanteric fracture, Trochanteric gamma nail.

INTRODUCTION

The incidence of proximal femoral fractures is constantly increasing. Demographic changes and higher lifespan lead to a considerable group of high-risk patients [1 - 3]. As a result, these fractures became one of the most serious health care problems in elderly people, comprising immobilization and spontaneous helplessness and potentially provoking life-threatening situations [1, 3, 4]. In the future, the growing number of proximal femoral fractures will lead to an increase in health care costs. In 2014, approximately 2 billion euros were invested for implantation devices in Germany,

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and an estimated sum of 4 billion euros per year is prognosed for the next years [5].

Inter- and subtrochanteric fractures represent half of all proximal femoral fractures [6]. Consequently, a demand for improvement in medical devices, operative technique and hospitalization arises in order to optimize patient outcome and decrease treatment costs.

In 1988, the gamma nail was introduced as a treatment option for proximal femoral fractures. The biomechanical advantages in combination with minimal invasive technique lead to a widespread use of the gamma nail system.

There is a smaller incision in comparison to the dynamic hip screw (DHS). As a consequence, local infection rate as well as tissue trauma were reduced. However, intraoperative and technical complications increased (*e.g.* additional fractures, perforation, dislocation) [7, 8].

These complications could be reduced by process modifications, development of standardized operative procedures and greater experience of surgeons [8, 9], resulting in the improvement of clinical outcome [7, 9].

The aim of this study was to compare the performance of the trochanteric gamma nail (TGN) to the next generation Gamma3 nail (G3N) in treatment of intertrochanteric and subtrochanteric fractures. Primary research question was to evaluate possible benefits of the new system.

Patients and Method of Study

In this study, we analyzed two consecutive series of patients who have been treated for 31-A fractures according to the AO/OTA classification with the trochanteric gamma nail (TGN) or the Gamma3 nail (G3N) retrospectively. According to the classification of evidence from the Journal of Bone and Joint Surgery the study has a level III of evidence. The TGN cohort consisted of 117 patients treated for trochanteric fractures from March 2009 to April 2010. The G3N cohort was treated between April 2010 and April 2011. All operations were performed by the same three well skilled orthopedic surgeons with large expertise concerning the principles of intramedullary nailing and experience in the use of gamma nails. Patients were followed up one year after the surgical procedure. After 12+/-1 months, study data was evaluated.

The following variables were analyzed: patients' age and gender, pre-existing cardiac diseases, ASA physical status [10], mechanism of injury, fracture side and type classified according to AO/OTA classification, time until operation, operation time, fluoroscopy time, length-of-stay (LOS), intra- and postoperative complications and mortality rate.

Preoperative Management

Patients were usually admitted to our hospital as emergency admission. A clinical examination and a CR in two planes were performed and an initial diagnosis provided. Following this, an operative treatment was planned.

Classification of Trochanteric Fractures

According to the AO/OTA classification we defined 31-A1.1, 31-A1.2, 31-A1.3 and 31-A2.1 types as stable fractures. Unstable fractures were defined as 31-A2.2, 31-A2.3, all 31-A3 types and all subtrochanteric fractures.

Surgical Procedure

The method of treatment was standardized in both groups. Low-molecular heparin (heparin 5000 IU) as thromboembolic prophylaxis was used in all cases. The osteosynthesis was performed under general anaesthesia as previously described [11]. Patients were positioned supine on a traction table. All patients underwent closed reduction of fracture under fluoroscopic control. The final diagnosis was confirmed and the fracture was graded according to the AO/OTA classification and recorded. All short nails were locked distally with one locking screw using the targeting device. Every patient obtained postoperative fluoroscopic control and was mobilized full weight-bearing as tolerated by the first postoperative day.

Postoperative Management

While in-patient stay physiotherapy was performed daily. Elderly (>70 years) were mobilized with walker and younger patients with forearm crutch. Just very few patients underwent partial weight-bearing for mobilization. Low-molecular heparin as thromboembolic prophylaxis was given once a day until full mobilisation or discharge of hospital.

A recommendation of physiotherapy was administered once to twice weekly. Re-appointment after three and twelve

months in consultation-hour was arranged.

Inclusion Criteria

All patients older than 18 years treated with TGN and G3N for inter- or subtrochanteric fracture from March 2009 to 4th April 2011, were eligible for inclusion.

Exclusion Criteria

Pregnant women with intertrochanteric and subtrochanteric fractures and fractures from malignant diseases were excluded from this study.

Statistical Analysis

Results from the clinical investigations were collected in Excel 2011 and statistical analysis was performed using SPSS (IBM Corporation, Armonk, New York, United States Version 22). Categorical data was analyzed by contingency tables and compared with Chi-square or *t*-test. For all tests, a statistical significance level of $p < 0,05$ was defined.

RESULTS

In the TGN group, 96 (82,1%) patients presented with an intertrochanteric fracture, whereas 21 (17,9%) patients had a subtrochanteric fracture. In the group of 100 patients treated with the gamma3 nail, 85 (85%) had an intertrochanteric fracture and 15 (15%) had a subtrochanteric fracture. Patients' characteristics and preoperative parameters are shown in Table 1. The median age in the TGN group was 84 (range 40-99) years and 82 (range 47-98) years in the G3N group. No significant differences were found between the two groups regarding gender, age, sex, side of fracture, type of fracture, ASA score and pre-existing cardiac conditions.

Table 1. Patient characteristics.

Parameter	TGN-cohort	G3N-cohort	<i>p</i> -value
Number of patients	117	100	
Sex:			
Female	85 (72,6%)	78 (78%)	0,43†
Male	32 (27,4%)	22 (22%)	
Age in years:			
Median (range)	84 (40-99)	82 (47-98)	0,41‡
Fracture side			
Right	52 (44,4%)	45 (45%)	0,52†
Left	65 (55,6%)	55 (55%)	
Fracture typ			
31-A1	28 (24%)	36 (36%)	
31-A2	75 (64,1%)	52 (52%)	
31-A3	11 (9,4%)	10 (10%)	
Unspecified type	3 (2,6%)	2 (2%)	
Stable fracture	41 (35%)	39 (39%)	0,31†
Unstable fracture	76 (65%)	61 (61%)	
ASA physical status			
Median ASA	3	3	
ASA 1	4	0	
ASA 2	21	25	
ASA 3	78	63	
ASA 4	11	8	
ASA 5	0	3	
Pre-existing cardiac conditions	32 (27,4%)	31 (31%)	0,65†

† *p*-value according to Chi-square test

‡ *p*-value according to *t*-test

Operation was performed in 60% in G3N and 70% in TGN-group at the same day of hospital admission and in both groups surgery was achieved in 88% within two days.

Intraoperative and hospitalisation data are shown in Table 2. Average surgical time, fluoroscopy time, hemoglobin drop and length-of-stay (LOS) were similar in both groups.

Table 2. Operative and hospitalisation data

Parameter	TGN-cohort	G3N-cohort	p-value
Average time to operation (in days ±SD)	1,7 (+4,5)	1,3 (+3,8)	
Average surgical time (in min ±SD)	51,6 (±24,8)	49,5 (±17,9)	0,43‡
Average fluoroscopic time (in min ±SD)	3,8 (±3,8)	3,3 (±2,7)	0,20‡
Average haemoglobin drop (in mg/dl ±SD)	3,6 (±1,4)	3,8 (±1,4)	0,89‡
Length-of-stay (LOS) (in days ±SD)	18,3 (±9,8)	17 (±12)	0,95‡

‡ p-value according to *t*-test

Postoperative data are shown in Table 3. No significant differences were found in surgery-related complications such as wound hematomas ($p=0,59$), abscesses ($p=0,38$), wound infections ($p=0,69$) and Cut-outs ($p=0,69$) between the two groups. The cumulative surgery-related complication rate was higher in the TGN group compared to the G3N group (13,68% vs. 8%), although the difference did not reach statistical significance ($p=0,2$). The general complications of surgery and hospitalization were similar in both groups (cardiovascular failure ($p=0,58$), pneumonia ($p=0,63$), pulmonary edema ($p=0,38$) and embolism (0,71). The mortality rate was comparable ($p=0,52$).

Table 3. postoperative complications

Parameter	TGN-cohort	G3N-cohort	p-value
Wound hematomas	4 (3,4%)	3 (3%)	0,59†
Abscess	4 (3,4%)	1 (1%)	0,38†
Deep infection	4 (3,4%)	2 (2%)	0,69†
Femoral shaft fracture	0 (0%)	0 (0%)	
Cut-out	4 (3,4%)	2 (2%)	0,69†
Cumulative surgical-related complication rate	13,68%	8%	0,2†
Cardiovascular complications	3 (2,6%)	3 (3%)	0,58†
Pneumonia	3 (2,6%)	1 (1%)	0,63†
Pulmonary oedema	1 (0,9%)	3 (3%)	0,38†
Pulmonary embolism	1 (0,9%)	1 (1%)	0,71†
Death	8 (6,8)	6 (6%)	0,52†

† p-value according to Chi-square test

DISCUSSION

In 2006, Stryker Corporation introduced the Gamma3 Nail-System as a completely re-designed system for the treatment of inter- and subtrochanteric fractures [12]. These new nails have a proximal diameter of 15.5mm compared to the previous 17mm. The idea was to help shorten the incision length for minimally invasive surgery, while offering the biomechanical strength and cut-out resistance of the established Trochanteric and Long Gamma Nails [13].

The new nail model was designed from Titanium alloy with Type II anodization (Ti-6Al-4v) instead of the previously used medical steel. It was recommended as an option for the younger or smaller patient where bone removal is a concern [12]. Furthermore it includes new aiming devices and tools.

It was forecasted that the new system might reduce trauma to patients through closed operative technique and that the limited incision at the tip of greater trochanter may result in minimal blood loss and potentially less operative time [12].

In our institution, the Gamma3 Nail system was introduced with delay to the general market entry, which enabled us to sample data from two consecutive cohorts, receiving either the old or the new system with an otherwise fully standardized and equal treatment regimen. In the present study, we therefore compared TGN to G3N in terms of operation time, haemoglobin drop and complication rates. We found no significant differences in terms of operative and hospitalisation data as well as postoperative complications between these two types of gamma nail.

Since the introduction of the first generation of gamma nail, specific implant-related complications were reported. In this context, especially femoral fractures as a result of the implantation procedure are regarded as severe complications leading to adverse effects in patient outcome [14]. For the first generation of gamma nail, high complication rates were

reported as compared to data available for consecutive generations of gamma nail. Postoperative morbidity was mainly attributable to extensive length and diameter as well as valgus curvature of the implant [15].

In 1997, the trochanteric gamma nail (TGN) was introduced as the second generation of gamma nail. Evaluating implant safety, Valverde *et al.* described a reduction of intra- and postoperative complications and acceptable rates of Cut-outs of the lag screw [16].

In 2003, Gamma3 nail (G3N) was developed as the next generation product. Technical improvements comprise reduced loss of bone substance, an extended operation set and minimal invasive operation procedure. However, data regarding complication rates and postoperative outcome is rarely available for G3N. Georgiannos *et al.* reported femoral fracture rates of 4,68% for TGN vs. 0% for G3N. The authors attributed these results mainly to the improvement of implant design, decreased proximal diameter and reduced three-point-loading at the femoral shaft [17, 18]. Nonetheless, expertise of the surgeon might also minimize femoral fracture rates, possibly explaining very low rates of this complication in our study.

The most frequent complication reported in literature remains the Cut-out of the lag screw through the femoral head. In this regard, our results found no significant difference between TGN and G3N. In contrast to our findings, other studies describe a lower incidence rate up to 4% for G3N [18] as compared to a rate up to 9,72% for TGN [15].

A total of 217 patients were included in this study. However, the number of patients could be insufficient regarding statistical power to show a difference in complications between both treatments.

Several studies have indicated median hospitalization periods of 12 to 37 days for Gamma nail implantation [19 - 21]. In our study, length-of-stay (LOS) ranged from 3 to 70 days for TGN and from 4 to 105 days for G3N. These findings may be related to high risk comorbidity profiles of included patients (median age of 83 years and median ASA score 3) and resulting postoperative complications eventually leading to prolonged LOS. Average LOS was 18,3 days in the TGN group as compared to 17 days in G3N group. Thus, the effect of treatment was not statistically significant. However, a prospective study is necessary to finally address the issue of hospitalization time.

In literature, 12-month-mortality rate of G3N ranges from 15,4% to 23,2% [13, 22, 23]. We reported lower rates possibly explained by improved anesthetic techniques and faster rehabilitation schemes as determinants of reduced mortality [23]. The death of patients was unrelated to surgery, but could be explained by high comorbidity index of the patients (median ASA score 3).

When considering the findings of this study, the limitations of this study should be taken into account. First, the amount of patients is moderate and could be insufficient regarding statistical power. Second, we recorded very few postoperative complications. This could be explained as follows: We recorded these events only if there was clinical evidence. The possibility of unreported events should be taken into account. Third, the transfusion rate after surgical treatment was not available in contrast to the hemoglobin drop. Fourth, the retrospective nature of this study bears a risk of hidden selection bias and suffering due to non-standardized follow-up. These limitations might be eliminated by a prospective randomized-controlled trial.

We are convinced that both the TGN and the G3N groups were well-balanced, thus partially compensating the limitations of this study.

CONCLUSION

Our findings suggest that TGN and G3N are both adequate treatments with an acceptable complication rate. According to our results the use of G3N shows less postoperative complications, but was not significant compared to TGN treatment.

LIST OF ABBREVIATIONS

AO/OTA	=	Classification system of the Orthopaedic Trauma Association Committee for Coding and Classification
ASA	=	American Society of Anesthesiologists
CR	=	Computed radiography
DHS	=	Dynamic hip screw
G3N	=	Gamma3 nail
IU	=	International units

LOS = Length-of-stay
 TGN = Trochanteric gamma nail

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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