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CLINICAL AND RADIOLOGICAL OUTCOMES OF PATIENTS TREATED WITH THE ORTHOFIX CHIMAERA LONG NAILING SYSTEM FOR PROXIMAL AND DIAPHYSEAL FEMORAL FRACTURE

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ABSTRACT – *Objective*: The long intramedullary nailing system is a widely used method for treating femoral shaft and subtrochanteric fractures. However, it can lead to complications such as intraoperative anterior cortical perforation of the distal femoral shaft and postoperative lateral thigh pain. To address these issues, a new intramedullary nailing system, the Chimaera (Orthofix®), was developed. This study evaluates the clinical and radiological outcomes following antegrade intramedullary nailing of traumatic femoral shaft and inter-/subtrochanteric fractures using this system.

***Patients and Methods*:** A prospective cohort study was conducted on 20 consecutive patients with AO/OTA (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association) type 31A2.3-A3.3 and type 32A-C fractures treated with the Chimaera long nailing system between December 2017 and January 2021 at our level 1 trauma center. Clinical outcomes were measured using Parker and Palmer and Jensen scores at three months post-surgery and compared to preoperative scores. The radiological assessment included evaluating the position of the cephalic screw using the tip-apex distance (TAD) and Cleveland zone. The mean follow-up period was 12.5 months (range 1-33 months).

***Results*:** Parker and Palmer's scores returned to pre-fracture levels for four patients (31%), with minor changes observed in 6 patients (46%). Jensen scores were equivalent to pre-surgery or improved by up to 1 point in 11 patients (87%) at three months post-surgery. No major intraoperative complications were recorded. The median TAD was 16.4 mm [interquartile range (IQR) 14.0-20.2], and 85% of patients had the lag screw positioned in the Cleveland central zone. Two patients required revision surgery. All patients achieved fracture union.

***Conclusions*:** The Chimaera long nailing device demonstrated good functional and radiological outcomes, proving to be an effective treatment option for the femoral shaft and inter-/subtrochanteric fractures.

KEYWORDS: Proximal femoral fracture, Diaphyseal femoral fracture, Surgical treatment, Intramedullary nailing, New nail, Orthofix® Chimaera, Intertrochanteric fracture, Subtrochanteric fracture.

INTRODUCTION

Intramedullary nailing is one possible surgical treatment option for intertrochanteric and subtrochanteric, as well as diaphyseal femoral fractures[1]. A Swedish national data study[2] showed the annual incidence of femoral shaft fractures (6,409 fractures identified in a period of 7 years) to be 1 per 10,000 people per year. A bimodal age distribution is usually found, with high-velocity trauma responsible for fractures in young men and mainly low-energy fractures in the female geriatric population[2].

Küntscher[3] introduced the concept of intramedullary nailing for the stabilization of long bone fractures in the 1940s. During the last two decades, nail designs and materials have evolved, but the increase in indications for intramedullary nailing was the major factor popularising the technique[4].

The long nail design can be responsible for major perioperative complications[5]. Due to an insufficient anteroposterior curve of the long nail, intraoperative anterior cortical fractures of the distal femoral shaft have been reported[1]. Additionally, the postoperative lateralization of the lag screw after the dynamization of the fracture can cause post-surgical lateral thigh pain due to fascia lata friction. In order to counteract these two complications, the Chimaera (Orthofix®, Lewisville, TX, USA) long nail (CLN) has a bending curve of 1,500 mm and a self-retaining and sliding lag screw. Other complications of anterograde nailing are nonunion and malunion (around 1%)[6].

Mobility and social function outcomes after management of femoral fractures are described in only few studies[1], which mainly focus on muscle testing[7]. Short-term results after the fixation of intertrochanteric fractures and diaphyseal femoral shaft fractures using the CLN have not been reported to any meaningful extent until now.

This prospective study aimed to evaluate the CLN for treating AO/OTA (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association) fracture types 31A2/3 and 32A/C using the mobility scores of Parker and Palmer[8] and social function scores of Jensen[9]. We also evaluated the radiological outcomes and complication rate specific to this new device.

PATIENTS AND METHODS

Patients

We conducted a prospective cohort study between December 2017 and January 2021 in our level-1 Trauma Center after obtaining local Ethical Committee approval in accordance with the Declaration of Helsinki. All patients included in the study were informed and provided consent. Inclusion criteria were the patients with AO/OTA type 31A2/3 and 32A/C fractures caused by high or low-energy trauma treated with Chimaera long nail (Figure 1). Exclusion criteria were patients not able to walk before the trauma, open fracture, bilateral fractures, major concomitant trauma, severe hip osteoarthritis, preexisting hip surgery, or pathological fracture. Of the 20 patients (Table 1), 12 females and 8 males were included in the study. The mean age was 80.2 years (range: 25-95 years old). According to the AO/OTA fracture classification, 14 patients had type 31A2.3-A3.3/per-subtrochanteric (six 31A2.3 and eight 31A3.3); 6 patients had type 32A-C/diaphyseal (three 32A1a, one 32A1b, one 32A3a and one 32C3i) fractures. High-energy trauma was found in 2 patients (one fall from a 2-meter wall and one fall during winter skiing). All other patients had low-energy trauma (fall from the patient's height). At six months, seven patients were lost to follow-up (5 had passed away). All patients alive were followed at a minimum of one year after the surgery. The median follow-up was 12.5 months (IQR 3-28). All included patients were classified as ASA 1 to 4 on the ASA scale.

Chimaera Nail Characteristics

The Chimaera nail (Figure 2) is made of titanium alloy with anodized type II surface treatment. It is cannulated for guide-wire controlled insertion. Different lengths are available, from 280 mm to 460 mm, in 20 mm increments. The proximal diameter of the nail is 15.5 mm; the distal diameter is 10 mm and 11 mm. There are two proximal nail caput-collum-diaphyseal angles available: 125° or 130°. Angulations of the nail are a mediolateral bend for valgus curvature of 5° and an anterior bend with a radius of 1,500 mm. The lag screw locks itself into the nail. The dynamic distal locking hole can be used to allow fracture compression up to 6 mm in the diaphysis direction.

Figure 1. A, Pre-operative anteroposterior (AP) X-ray of the pelvis in a 70-year-old patient with AO 31A2.3 type fracture treated with Chimaera long nail. **B**, Pre-operative axial X-ray of the left hip in a 70-year-old patient with AO 31A2.3 type fracture treated with Chimaera long nail. **C**, Three months post-operative weight-bearing long axis X-ray of the pelvis in a 70-year-old patient with AO 31A2.3 type fracture treated with Chimaera long nail.

Table 1. Patients' demographics.

Number of patients	**20**
Mean age (years)	80.2 (25-95)
Sex	
Women	8 (40%)
Men	12 (60%)
Side	
Right	9 (45%)
Left	11 (55%)
AO classification	
31A2.3 / A3.3	6 / 8
32A1a / A1b / A3a / C3i	3 / 1 / 1 / 1
Velocity	
Low	18 (90%)
High	2 (10%)

For sex, side, and velocity, the values are given as numbers with percentages between brackets.

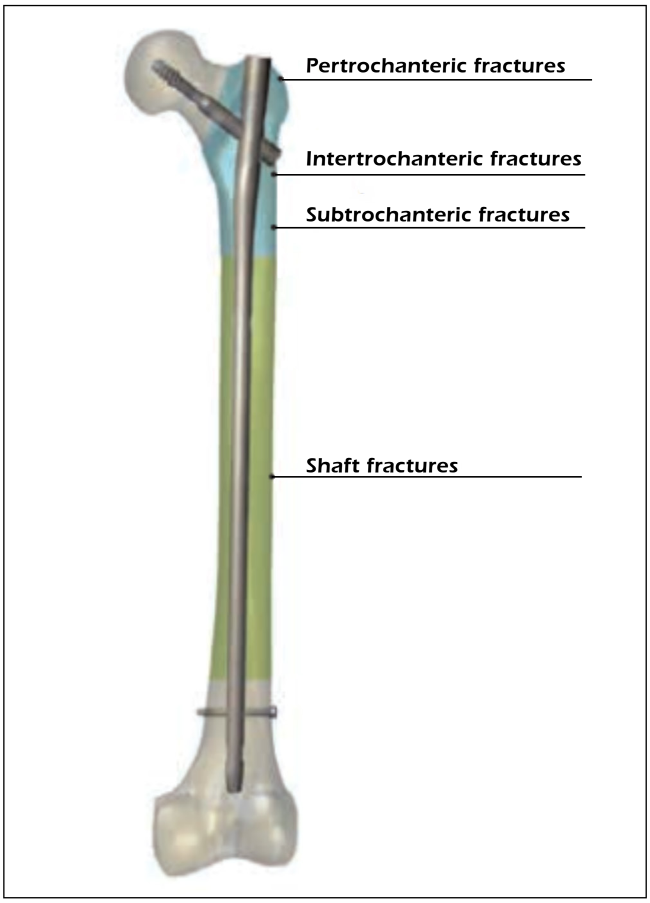

Figure 2. The Chimaera long nail.

Surgical Technique

The patient is placed in a supine position on a fracture table, and the fracture is reduced under fluoroscopic guidance. A single-shot prophylactic antibiotic therapy is given 45 minutes before surgery. The CLN is inserted through the tip of the greater trochanter[10]. A supplementary lag screw can be used for rotational stability (none of our patients benefited from it because the operator considered it unnecessary in our cases). Open reduction before nailing was needed in 75% (n=15) of patients; 60% of those patients (n=12) had one or two cerclages to help achieve and/or maintain the reduction. The length of the implanted nail varied from 340 mm to 440 mm and the length of the cervical screws ranged from 90 to 120 mm. Distal locking consisted of two distal screws for 10 patients (50%), locked in static and dynamic or both in static mode. For 10 patients (50%), only one distal screw was placed: the screw was locked in dynamic or static mode depending on the operator's own preference and fracture type. For transverse fractures, a dynamic distal locking method was chosen; for spiroid or communitive fractures, a distal static locking method was chosen; for oblique fractures, the operator chose which distal locking method was the most appropriate (depending on whether compression was needed or not). A board-certified orthopedic surgeon supervised all surgeries.

Post-Operative Follow-Up

On day 1, early mobilization was initiated with weight-bearing as tolerated and without limitation of the hip motion. All patients had the same reeducation protocol. Post-operative X-ray and red blood cell count were performed the day after the surgery.

Postoperative Assessment

The primary outcome was mobility and a return to social life. We used the mobility score of Parker and Palmer[8] and the social function score of Jensen[9] assessed at three months. Secondary outcomes were intraoperative fluoroscopy time and complications, adverse events, postoperative pain [evaluated during the medical exam with interrogation (sleep on the affected side) and palpation], surgical time, perioperative blood loss, fluoroscopy time, tip-apex distance (TAD)[11], Cleveland zone[12], material breakage, wound problems, length of hospital stay and readmission rate. The TAD and the Cleveland zone were analyzed on the first post-operative anteroposterior pelvis X-ray and sagittal hip X-ray. Mal- and non-union were analyzed respectively at 3, 6 and 12 months.

Statistical Analysis

Descriptive statistics were used to characterize the population. Continuous variables were expressed as the median and interquartile range (IQR) (25^{th}-75^{th} percentiles). Categorical variables were summarized as a percentage. All statistical analyses were performed with Stata 15.0 (StataCorp, College Station, TX, USA).

RESULTS

Clinical Results

Median operative time was 124 min (IQR 89-149). The median blood loss was 500 ml (IQR 260-1213). Median blood loss was 300 ml in closed reduction and 500 ml in open reduction. The median fluoroscopy time was 114 seconds (IQR 95-172) (Table 2).

We did not encounter any intraoperative fracture, cortical scraping, or adverse event due to nail bending. We had one minor intra-operative complication, which was the breakage of a cervical screw thread because the screw was turned too tight in the nail.

The Parker and Palmer[8] mobility score was good to excellent at three months for most of the patients. It was equivalent or slightly modified compared to before the fall in respectively 54% of patients (maximum loss of 1 point of 9) with a median change of 3 points [median=9 (IQR 5.5-9)] preoperatively to a median of 6 (IQR 5.5-9) postoperatively. Jensen's social score[9] at three months was good to excellent for 87% of patients (maximum gain of 1 point) with no median change of the score (median score preoperative and postoperative unchanged at 2) (Table 3).

Complications

There were neither wound healing problems nor infections nor lateral pain of the thigh due to lag screw irritation nor bony malunion/nonunion during post-operative follow-up.

There were two postoperative complications: the first one was a cut-out of the lag screw after six weeks (the TAD[11] was 19.6 mm and according to Cleveland zone[12] the cephalic screw was in position 3), treated by revision total hip arthroplasty. The second complication was the breakage of a single distal locking screw (screw deficiency) seven weeks post-operatively (Figure 3), treated by revision of the screw and an additional screw.

Table 2. Patients' perioperative data.

Number of patients	20
Operative time (minutes)	124 (89-149)
Blood loss (ml)	500 (260-1,213)
Fluoroscopy time (s)	114 (95-172)
Reduction	
Open	15 (75%)
Close	5 (25%)
Cerclage	
Yes	12 (60%)
No	8 (40%)

For operative time, blood loss and fluoroscopy time, the values are given as the median with interquartile range (IQR) between brackets.

Table 3. Patients' postoperative data.

Number of patients	**13**
Mobility score of Parker and Palmer[8]	
0-1 Point change	54%
0-2 Points change	77%
0-3 Points change	92%
Social function score of Jensen[9]	
0-1 Point change	87.5%
0-2 Points change	100%
Tip-apex distance[11]	
10.0-24.9 mm	19 (95%)
>25.0 mm	1 (5%)
Cleveland Zone[12]	
3	1 (5%)
4	1 (5%)
5	17 (85%)
6	1 (5%)
Complications	
Cephalic screw cut-out	1 (5%)
Distal screw breakage	4 (20%)
Revision surgery	2 (10%)

Figure 3. A, Post-operative anteroposterior (AP) X-ray of an AO: 31A3.3 fracture with a distal broken screw. **B**, AP X-ray 6 months post-operative of the same patient.

Radiological Results

The median TAD[11] was 16.4 mm (IQR 14.0-20.2); only one TAD was superior to 25 mm. The lag screw position was center-center in 85% of patients, according to the Cleveland zone[12].

Recovery

All patients, except two, were able to walk weight-bearing as tolerated within seven days after the surgery. One patient did not walk because of dementia; the other patient because of a generally poor condition.

DISCUSSION

Primary Outcome

Intramedullary nailing has become the standard treatment for diaphyseal and extra-capsular proximal femoral fracture due to the decreased risk of non-union and the low rate of complications[6]. Ricci et al[10] found that the hip range of motion was similar to the unaffected side when using a femoral nail specially designed for trochanteric insertion, which is the case for the CLN. Our study provides new data regarding the use of CLN in proximal and diaphyseal femoral fracture treatment. Post-operative functional scores analysis showed that the CLN provides good to excellent mid-term functional and social outcomes at three months post-operation, with most patients maintaining or slightly declining their preoperative scores.

Secondary Outcome

A well-known complication of long intramedullary nailing is iatrogenic distal femoral shaft fracture. For example, an 8% incidence rate has been reported[13] for the long trochanteric Gamma nail (Stryker®, Portage, MI, USA). Femoral bowing and stress risers created by the implant's rigidity, along with compressive loads at the nail tip, are major contributors to these fractures[14]. A key advantage of the CLN is its radius curve. The radius curve of the femur has been shown to be 110-120 cm[15]. The radius of the CLN is 1,500 mm, which is more anatomical than other nails like the original long Gamma Nail with a bowing of 2,000 mm. The femoral bow increases with age[16] and undergoes a morphological change: because of the increasing bow, the anterior tensile cortex becomes thinner, and the posterior cortex becomes relatively thicker[16]. Hence, it is easy to perforate the anterior cortex either while reaming or during nail insertion of a "straight" nail in a curved femur. The use of a hammer increases the risk of this complication[17]. No fracture of the distal femur occurred in our group, which is lower than the results from other studies[17], with a reported incidence of 1%. In our study, we attributed the lower rate of femoral shaft fractures and incidence of distal anterior cortical penetration to the design of the new CLN and its mechanical characteristics, with the distally positioned apex of the curvature of the nail, which reduces the three-point loading at the femoral shaft[14]. Furthermore, Shetty et al[18] concluded that a cephalomedullary nail with a 1,500 mm radius allowed the positioning of its distal tip more centrally in the femoral canal, reducing the risk of anterior femoral cortex penetration.

Another significant advantage of the CLN is the self-retaining locking mechanism of the cephalic screw, which prevents screw back-out and irritation of the fascia lata. This design feature eliminates the complications of screw impingement, as reported by Soucanye de Landevoisin et al[19], where 15.7% of patients experienced pain and 2% required reoperation. The CLN's self-telescoping effect also allows for fracture compression without the risk of screw migration.

Surgical Time

A review of the surgical time indicates that the CLN is slightly longer to insert [average 119 minutes, median 124 minutes (IQR 89-149)] than the Grosse-Kempf nail, the Synthes nails, the Russell Taylor nail[20] and then the expandable (Fixion) or locked intramedullary nail of Sipahioglu et al[21] with an average of 60.9 min but slightly inferior to Köseoğlu et al[22], in which the mean duration of operation was 122 minutes. These results may be influenced by the technical novelty of the implant, and it may require a little adaptation time to progress.

Bleeding

The average blood loss during the procedure was 670 ml, similar to Cameron et al's[20] 610 ml for femoral shaft fractures treated with intramedullary nailing. The median blood loss was 500 ml (IQR 260-1213), with open reductions resulting in an additional 200 ml of blood loss compared to closed reductions.

Fluoroscopy

Fluoroscopy times in our study were consistent with other studies[22,23] on femoral shaft intramedullary nailing. Our median time was 114 s (IQR 95-172 s) with an average time of 139 s. Georgiannos et al's[23] average time for a similar procedure was 45 seconds and Köseoğlu et al's[22] average time was 283 seconds.

Screw Positioning

All TAD but one (TAD=31 mm) were less than 25 mm, according to Baumgaertner et al[11] for optimal lag screw positioning. The single recorded cut-out was not due to an excessive TAD (TAD=19.6 mm). According to Cleveland et al[12], 3 lag screws were improperly positioned. It was the case for the only cut-out recorded where the lag screw was in position 3, which can explain the failure of the fixation in line with the bone quality of a 95-year-old woman.

We did not report any nail breakage, in comparison with Georgiannos et al[23], who found an incidence of nail breakage at the level of the cephalic screw of 2.4% for the long trochanteric gamma nail.

Complication

Georgiannos et al[23] have shown that the re-operation rate with the Long Gamma 3 nail was 10.6% and increased up to 20.5% with the long trochanteric gamma nail. Non-statistical results with the CLN showed a lower rate of re-operation in our study. Only one patient required implant-related re-operation: the distal broken screw, which caused the failure of the nail fixation, was changed and replaced by two distal screws with no further complication recorded after the second surgery.

No wound complications or bony nonunion/malunion were noted.

Study Limitations

The primary limitation of our study is the small sample size, which limits the generalizability of our findings. Additionally, several patients withdrew before the recording of functional and social scores due to concurrent illnesses, affecting the overall health outcomes and mortality rates. Another limitation is the lack of a control group, as this was an uncontrolled study. However, the study's strength lies in providing the first clinical evaluation of a new nail design, contributing valuable insights into its efficacy.

CONCLUSIONS

The new Chimaera proximal long nail is a valid implant for nailing diaphyseal and trochanteric fractures of the femur within the limit of this study. Good to excellent functional outcomes were reported, with few per- and postoperative complications. The CLN is slightly longer to insert than other nails, but the results may have been influenced by our limited experience with this nail. The CLN can be easily inserted and provides stable fixation, which allows early full-weight bearing of the patient and good social and functional outcomes.

Informed Consent

Informed consent was obtained from all subjects involved in the study.

Ethics Approval

Ethical approval for this study was granted by the CER-VD under protocol number 2018-00148 (date of approval: March 1, 2018). This research followed the ethical standards set by the 1964 Declaration of Helsinki and its later amendments.

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O. Borens: final manuscript approval and critical review.
S. Cherix: writing, validation.
K. Moerenhout: writing-review and editing, and final approval of the manuscript.
All authors have read and approved the final version of the manuscript.

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Availability of Data and Materials

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

AI Disclosure

The authors declare that no generative artificial intelligence (AI) tools were used in the creation of this manuscript. All writing and editorial work was performed by the authors.

Conflict of Interest

The authors declare they have no conflict of interest with the present work.

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