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Clinical and radiological outcome of the Chimaera short nailing system in inter- and subtrochanteric fractures

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ABSTRACT

Background: cephalomedullary devices are popular treatment for femoral intertrochanteric or subtrochanteric fractures. Various complications include post-surgical lateral thigh pain and cut-out. To prevent those complications, a new concept cephalomedullary device system was designed (Chimaera, Orthofix®). This study aimed to evaluate the clinical and radiological outcomes in patients with femoral intertrochanteric or subtrochanteric fractures treated with the proximal femoral cephalomedullary device system.

Methods: A prospective cohort study involved consecutive patients with Arbeitsgemeinschaft für Osteosynthesefragen/ Orthopaedic Trauma Association type 31-A1, 2, 3 fractures treated with the Chimaera short cephalomedullary device system from October 2016 to September 2017 at our level 1 trauma center. The Parker and Palmer mobility score and Jensen social function scores and post-surgical lateral thigh pain were assessed at 3 months post-operatively and compared to before surgery. Radiologic assessment consisted of controlling the position of the cephalic screw by using the tip-apex distance (TAD) and Cleveland zone as well as union and cut-out rates.

Results: We included 99 patients (79 women; 100 hips; one bilateral fracture 3 months after a first trochanteric fracture) with a mean follow-up of 2 years. The Parker and Palmer mobility score decreased by 22% at 3 months post-operatively as compared with the pre-fracture score (42/99 patients showed a return to their pre-injury level). The Jensen social function score increased by 16.5% at 3 months post-operatively as compared with the pre-fracture score (68/99 patients showed a return to their pre-injury level). No major intra-operative complication was recorded. Nine TAD scores were $>$ 25 mm. The mean TAD was 16.5 mm (range 5–36), and the lag screw position was well positioned in most (95%) hips according to Cleveland zones. Three patients required revision surgery (one for cut-out of the lag screw, one for hip osteoarthritis and one for gluteus medius insufficiency). All patients but the one with the cut-out showed fracture union.

Conclusion: The Chimaera short cephalomedullary device exhibited good mid-term functional and radiological outcomes.

Introduction

Cephalomedullary devices are a possible surgical treatment option for intertrochanteric and subtrochanteric femoral fractures and became the gold standard in recent years [1]. The age distribution of patients is usually bimodal, with high-velocity trauma responsible for fractures in young men and most of the fracture are mainly low energy fractures in the female geriatric population with osteoporotic bone [2]. During the last 2 decades, nail designs and materials have evolved, but the increase in indications for cephalomedullary devices was the major factor popularizing the technique [3]. Compared with other stabilization methods, cephalomedullary devices advantages include minimal disturbance to the fracture site, early patient ambulation, decrease blood loss, small operative scars and low infection rate [1].

The post-operative lateralization of the lag screw after dynamization of the fracture can be a cause of post-surgical lateral thigh pain due to fascia lata friction and this makes it mandatory to remove or change the screw [1]. Femoral head rotation is a major risk factor for cut-out of the lag screw [1]. To counteract these complications, the Chimaera (Orthofix®, Lewisville, Texas,

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USA) short nail (CSN) has a self-retaining and sliding lag screw, and its design allows for inserting a second lag screw. Other complications of anterograde cephalomedullary device are non-union and mal-union (about 1%) and femoral shaft fracture [4,5]. Only a few studies have described mobility and social function outcomes after femoral fractures treatment [1,6-9] and mainly focused on muscle testing. Mid-term clinical and radiological results after fixation of intertrochanteric and subtrochanteric femoral fractures using the CSN have not been reported to any meaningful extent.

The aim of this prospective study was to evaluate the clinical outcomes of the CSN for treating Arbeitsgemeinschaft für Osteosynthesefragen/ Orthopaedic Trauma Association (AO/OTA) fracture types 31-A1,2,3 by using the Parker and Palmer mobility score [10] and the Jensen social function score [11]. We also evaluated the radiological outcomes and complication rates specific to this new device.

Materials and methods

Patients

This was a prospective cohort study performed between October 2016 and September 2017 in our level-1 trauma center after local ethics committee approval (CER-VD 2016–02,228) in accordance with the Declaration of Helsinki. All patients were informed and agreed to participate. Inclusion criteria were AO/OTA type 31-A1, 2, 3 fractures caused by high- or low-energy trauma and treated with CSN. Exclusion criteria were inability to walk before the trauma, open fractures, bilateral fractures, major concomitant trauma, severe hip arthrosis, preexisting hip surgery or pathological fractures.

Chimaera cephalomedullary device characteristics

The Chimaera short nail is made of titanium alloy with anodized type II surface treatment. It is cannulated for guide-wire controlled insertion. The CSN length is 180 mm. The proximal diameter of the nail is 15.5 mm; distal diameter is 11 mm. There are two proximal cephalomedullary device angles available: 125° or 130° The lag screw is self-locking into the nail by the extension of the wings into the cephalomedullary device once it is fully tightened. Tts length goes from 70 mm to 130 mm with 5 mm increments. The screw is locked The supplementary lag screw is also self-locking and its length goes from 60 mm to 120 mm with 5 mm increments. The sliding mechanism of the two screws allows their telescoping. The dynamic distal locking hole can be used to allow fracture compression up to 6 mm in the diaphysis direction. All details are given according to the reference guide available online.

Surgical technique

All of the operations were performed by a senior surgeon or by a trained-resident under supervision of a senior surgeon. The patient is placed in a supine position on a fracture table and the fracture is reduced under fluoroscopic guidance (open reduction was performed if the surgeon deemed it useful). A single-shot prophylactic antibiotic therapy is given 30 min before surgery. The CSN is inserted through the tip of the greater trochanter [9]. The lag screw positioning can be similar to that of other commonly used cephalomedullary device or can be preceded by insertion of a second wire through the supplementary lag screw hall to prevent head rotation. The supplementary lag screw can be inserted using the wire placed or the pin can be removed if the use of a single cervical screw is decided. Screws should be inserted till it locks itself into the nail. The distal locking screw is inserted similarly to that of other commonly used cephalomedullary device.

Post-operative follow-up

Early mobilization was initiated with full weight-bearing as tolerated and without limitation of the hip motion on the first post-operative day. All patients had the same rehabilitation protocol. Post-operative antero-posterior and lateral X-rays (Fig. 1) were performed three day after the surgery. Patients were followed up at 2

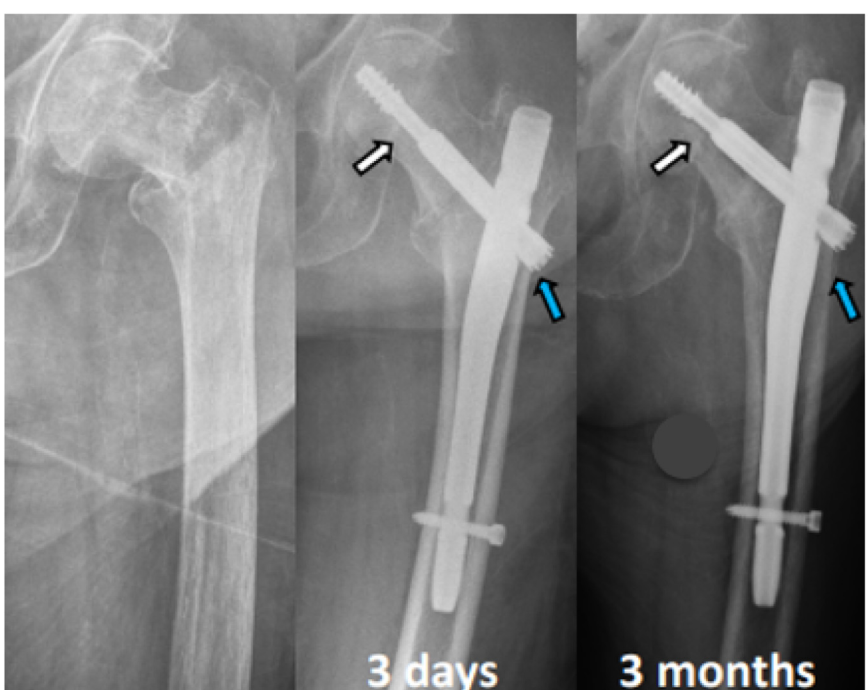

Fig. 1. Pre- and post-operative (3 days and 3 months) radiographs with AO/OTA type 31A2.2 type fracture treated with Chimaera short nail showing telescoping sliding movement of the lag screw (white arrows) without protrusion from the lateral cortex (blue arrows) AO/OTA, Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association.

Table 1
Patient demographics (n = 99 patients; n = 100hips).

Mean age (years)	83 (37–99)
Gender	
Women	79 (80%)
Men	20 (20%)
Hip side	
Right	60 (60%)
Left	40 (40%)
AO/OTA classification	
31 – A1	14 (14%)
31 – A2	73 (73%)
31 – A3	13 (13%)
Velocity	
Low	96 (96%)
High	4 (4%)

AO/OTA, Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association.
Data are median (interquartile range) unless otherwise indicated.

weeks, 6 weeks, 3 months, 6 months and 1 years after the surgery and then annually.

Per- and postoperative assessment

Per-operative data, such as surgical time and fluoroscopy time were recorded. The TAD [12] and the Cleveland zone [13] were analyzed on the first post-operative AP pelvis X-ray and lateral hip X-ray. The primary outcome was the patients' mobility and return to social life at 3 months. We used the mobility score of Parker and Palmer, a score from 0 to 9 based on the ability to mobilise inside the house, outside the home and tasks outside the home (0 = poor mobility; 9 = hightly mobile) [10] and the social function score of Jensen, classification into one of 4 groups based on independence (1 = independent; 4 = totally dependent) [11] assessed at 3 months to evaluate early recovery. We stated that an excellent outcome was a same score before the trauma and after the surgery. A good outcome was the loss of one point maximum. Secondary outcomes were post-surgical lateral thigh pain, intraoperative complications, surgical time, fluoroscopy time, adverse events, material breakage, wound problems, length of hospital stay and readmission rate. Mal-union 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) [25th–75th percentiles]. Categorical variables were summarized as a percentage. All statistical analyses were performed with Miniwebtool.

Results

We included 99 patients, 79 females, (100 hips: one patient had a contralateral fracture 3 months after the first trochanteric fracture) (Table 1), the mean age was 83 years (range: 37–99). According to the AO/OTA fracture classification, 14 fractures were type 31-A1; 73 were type 31-A2 and 13 were type 31-A3. Four patients experienced high-energy trauma. All other patients experienced low-energy trauma (fall from the patient's height). The mean follow-up was 24 months (median 12 months [IQR 5–58]). Twenty one patients died before the 1-year follow-up. All remaining patients were followed at a minimum of 1 year after the surgery.

Table 2
Patients' postoperative functional status at 3 months (n = 86 for mobility score and n = 57 for social score).

Mobility score of Parker and Palmer10		
0–1	Point change	**57%**
≤ 2	Point change	**79%**
≤ 3	Point change	**91%**
Social function score of Jensen11		
1-%2	Point change	86% 94%
≤ 2	Points change	

Table 3
Patients' peri–operative data (n = 99 patients).

Operation time (minutes)	**52 (40.5–60)**
Fluoroscopy time (s)	57 (42.5–82)
Secondary lag screw	3 (3%)
Tip apex distance, mm[12]	
≤ 24.9	91 (91%)
≥ 25.0	9 (9%)
Cleveland zone[13]	
3	1 (1%)
4	2 (2%)
5	87 (87%)
6	2 (2%)
8	8 (8%)

Data are median (interquartile range) unless otherwise indicated.

Table 4
Complications (n = 99 patients).

Per-operative (breakage of a	1
cervical screw thread)	(1%)
Post-operative	1
Cephalic screw cut out	(1%)
Distal screw breakage	0
Revision surgery	(0%)
	3
	(3%)

Clinical outcomes

The Parker and Palmer [10] mobility score was good to excellent at 3 months. It was equivalent or slightly modified in 57/99 patients (maximum loss of 1 in 9 points) with a median change of 1 point [IQR: 0–2] from pre- to post-operatively (Table 2). The Jensen social score [11] at 3 months was good to excellent for 86/99 patients (maximum gain of 1 point) with no median change in score [IQR: 0–1] (Table 2).

Median operative time was 52 min [IQR 40.5–60] (mean operative time was 54 min). The median fluoroscopy time was 57 s [IQR 42.5–82]. A second lag screw was inserted in 3 cases (3%) to increase rotational stability (Table 3).

Radiologic outcomes

The median TAD was 16.78 mm (range 5–36); 9 TAD measurements were > 25 mm (Table 3). The lag screw position was center-center or inferior-center in 95% of patients according to the Cleveland zone [13] (Cleveland zone 5 and 8) (Table 3). Other positions (5%) were zone 3 (1 patient), zone 4 (2 patients) and zone 6 (2 patients) (Table 3).

Complications

We did not find any perioperative fracture, cortical scraping or adverse events of the cephalomedullary device. We noted one minor intra-operative complication: The breakage of a cervical screw thread because the screw was turned too tight in the nail (Table 4).

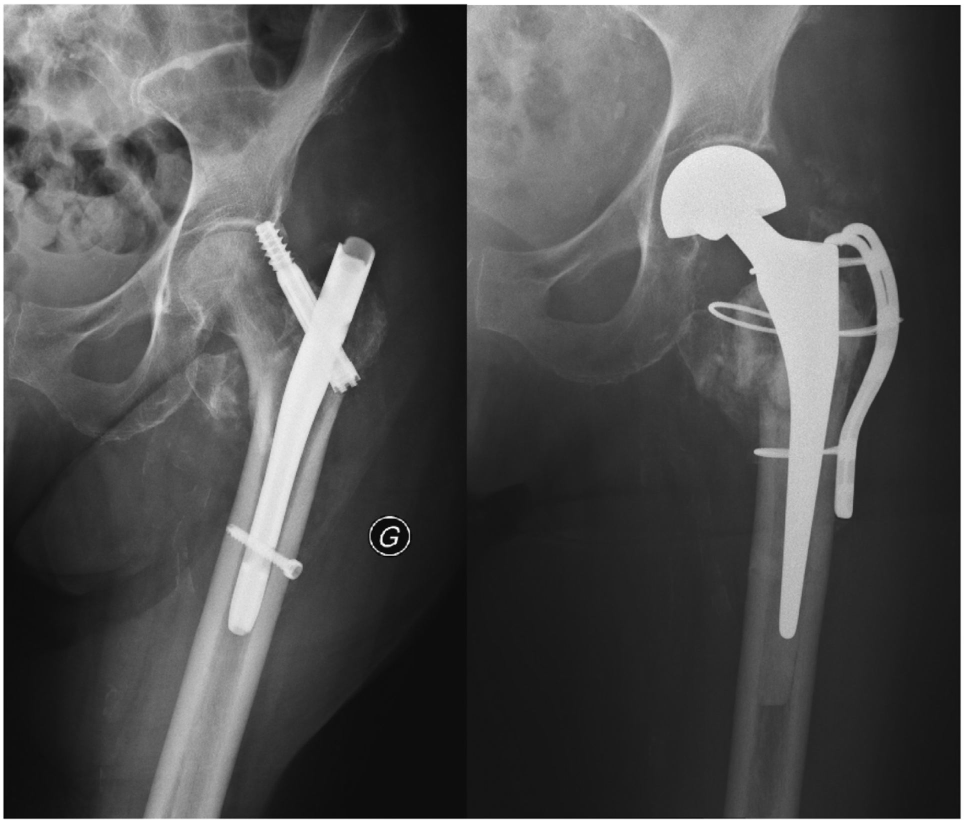

Fig. 2. Cut-out of the lag screw and revision with open reduction with internal fixation and cemented hemi-arthrop lasty.

The damaged cervical screw was removed and a new screw was inserted, with no complications.

We found no wound healing problems or infections, lateral pain of the thigh due to lag screw irritation, or bony mal-union/non-union during post-operative follow-up. One patient presenting a cut-out of the lag screw after 3 weeks (the TAD was > 25 mm, and according to the Cleveland zone, the cephalic screw was in position 3). This fixation failure was treated by revision cephalic hip arthroplasty and hook plate insertion (Fig. 2). A second patient had revision surgery for osteoarthritis (total hip arthroplasty) at 8 months after the initial surgery. A third patient had revision surgery for gluteus medius insufficiency (muscle shortening due to fracture dynamization) (total hip arthroplasty). Therefore, the re-operation rate was 3%.

Recovery

In total, 92/99 patients were able to weight bear as tolerated within 7 days after the surgery. One patient died during the first post-operative week due to very poor general health. Those who did not walk at 1 week (8%) had dementia or general poor condition. The mean length of hospital stay was 11 days (range 3–32).

Discussion

Cephalomedullary device has become a standard treatment for intertrochanteric and subtrochanteric femoral fractures because of decreased risk of non-union and low rate of complications as compared will all other possible treatments [5]. Ricci et al. [14] found that hip range of motion was similar to that on the unaffected side when using a femoral nail specifically designed for trochanteric insertion, which is the case for the CSN.

Our study provides new data regarding the use of CSN in treating intertrochanteric and subtrochanteric femoral fractures. Post-operative analysis and direct comparison of absolute figures within a margin of error show the results bellow. Analysis of the Parker and Palmer mobility score [10] showed that the CSN provides good to excellent mid-term functional results at 3 months post-operatively with the same or slightly modified score for most patients as compared with the pre-operative score (Table 2). Sharma et al. [6] showed that 8/23 (35%) of their proximal femoral nail (PFN) group and 8/25 (32%) of their proximal femoral nail autorotation (PFNA) group were able to return to their pre-injury Parker and Palmer score. Our study showed better results, with 42% (28/68) of patients who were able to return to their pre-injury Parker and Palmer score. Post-operative analysis of the Jensen score [11] showed that the CSN provided good to excellent mid-term social results at 3 months post-operatively, with the same or slightly modified score for most patients as compared with the preoperative score (Table 2). Huang et al. [8] reported that the 1.3 mean pre-operative Jensen social score [11] increased to 1.8 post-operatively (increase of 38.5%), which is more than double than in our study, with a pre-operative mean score of 2.29 that increased to 2.67 (increase of 16.5%).

One major advantage of the CSN is the self-retaining locking mechanism of the cephalic screw, which can slide on itself. In Soucanye de Landevoisin et al. [15], 15.7% of patients had pain due to screw impingement on the fascia lata; 2% underwent re-operation. For the Talon Distalfix Proximal Femoral Nail, Yapici et al. [16] reported 3.6% of lateral migration of the cephalic screw. In our study, no cephalic screw back-out occurred because of intranail fixation of the screw, thus preventing irritation of the fascia lata. Compression of the fracture is still permitted by the self-telescoping effect of the screw. However one screw breakage occur during surgery. The screw has been tightened too much and one wing has broken. The screw and the wing was removed and a new screw has been inserted.

Overall, 91 of our patients had a TAD < 25 mm according to the Baumgartner et al. [12] principle of the lag screw positioning. Our mean TAD of 16.78 mm was less than that in Sharma et al. [6] 19.08 mm for the PFN group (range 8.42–27.37 mm) and 21.13 mm for the PFNA group. The cut-out recorded was probably due to excessive TAD (TAD 25 to 30). Our study showed a lower cut-out rate than with the Talon distalfix proximal femoral nail (3.6%) [16], the PFNA nail (8.3%) [17] and the Dyna Locking Trochanteric nail (25%) [18] (Table 4).

According to Cleveland et al. [13], 5 lag screws (5%) were not positioned properly. Center-center or inferior-center placement of the lag screw in the femoral neck is recommended to prevent migration and cut-out because of the intersection of the compression and tensile trabeculae of the proximal femur leading to strong architecture at the inferior part of the neck [16]. These results show a lower rate of malposition of the femoral lag screw than Sharma et al. [6] who found a malposition of the lag screw in 4 of 23 (17%) patients in the PFN group and 8 of 25 patients (32%) in the PFNA group, and Yapici et al. [16], who found 15.5% malpositioning with their talon distalfix proximal femoral nail. The risk of cut-out of various proximal femoral intertrochanteric nails ranges from 4% to 20% [16] fracture type, reduction quality and position of the lag screw have a direct influence on the risk of cut-out [16]. In our study, the lag screw was in position 3 for the only cut-out recorded (no supplementary lag screw was added), which can explain the failure of the fixation in addition to the poor bone quality. This complication lead to nail removal and hemi-arthroplasty combined with open reduction and internal fixation of the trochanteric area (Fig. 2).

Our surgical time indicates that insertion of the CSN is within the average of insertion of other proximal femoral nails (mean Talon distalfix proximal femoral nail insertion: 34.9 min; PFNA nail insertion: 44.4 min; InterTran nail insertion: 55.4 min) [16,17]. These results may be influenced by the technical novelty of the implant and hence its learning curve (Table 3). Our fluoroscopy time was lower than that in other studies for cephalomedullary device of intertrochanteric and subtrochanteric fractures. In Zehir et al. [17], the average time for a similar procedure of 100 s for the Talon distalfix proximal femoral nail, 110 s for the PFNA nail and 120 s for the InterTran nail (Table 3) which is longer than our average time.

In comparison with other studies, our reoperation rate (3%) was lower than in Yapici et al. [16] for the Talon distalfix proximal femoral nail (5.5%) and Zehir et al. [17] for the Talon distalfix proximal femoral nail (3.8%), the PFNA nail (9.4%) and the InterTran nail (4.9%).

The mean hospital stay was 11 days in our study which is longer than for Hoffmann et al. [19] in their review of cephalomedullary device treatment for intertrochanteric femoral. This long stay is probably due to different health systems and their functioning.

The complication rate of treating intertrochanteric fracture with proximal cephalomedullary device ranges from 4% to 53%[16]. We did not find any wound complications. Our local complication rate was lower than Yapici et al. [16] for the Talon distalfix proximal femoral nail (1.8% superficial infection and 1.8% hematoma). It was also lower than Zehir et al. [17] for the Talon distalfix proximal femoral nail (3.8%), the PFNA nail (9.4%) and the InterTran nail (4.9%). We did not find any nail breakage. Our in-hospital mortality rate was 4% ($n = 4$), which is lower than that for Zehir et al. [17] for the InterTran nail (4.9%) but higher than the same authors for the Talon distalfix proximal femoral nail (2.6%) and PFNA nail (2.1%).

Study limitations and strengths

The first limitation of the study is the lack of a randomized control group, which implies lack of a control group and could lead to interpretation bias. Second, a number of patients withdrew before functional and social score recording due to concomitant illnesses affecting their general health and mortality rate, which could also lead to interpretation bias, although the follow-up of geriatric patients often implies a high loss of follow-up. Third, although our study is the first to analyze the CSN functional and radiological outcome, future studies should include a larger population for more formal conclusions. The major strength of our study is its design, as it is the first prospective cohort study analyzing the clinical and radiological outcomes of a new proximal femoral nail.

Conclusions

The new Chimaera short nail is a valid implant for nailing intertrochanteric and subtrochanteric fractures of the femur within the limitations of this study. The CSN can be easily inserted, it provides stable fixation and good to excellent functional outcomes, with few preoperative, postoperative and radiological complications.

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Competing interests

The authors have nothing to disclose

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