Clinical outcome of using a third-generation short gamma nail in the treatment of extracapsular proximal femoral fractures Ihab I. El-Dessokey, Molham M. Mohammed

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Introduction

A sliding hip screw is still considered the gold-standard method for fixation of extracapsular hip fractures; however, failures are still encountered with some subtypes. A short gamma nail is considered to allow better fixation for unstable subtypes, with the additional advantages of intramedullary fixation.

Aim

The aim of the study was to prospectively evaluate the clinical outcome of traumatic proximal femoral fractures fixed with a short gamma nail (third-generation design), with a particular focus on our experience of surgical techniques.

Patients and methods

We prospectively reviewed the results of 20 patients who had undergone intramedullary fixation with a short gamma nail for traumatic extracapsular proximal femoral fractures in Kasr Al-Ainy hospitals during an 18-month period from September 2009 to March 2011. The average age of the patients was 55 years (range 31–69 years), with seven male patients and 13 female patients. The average operative time was 75 min (range 50–110 min). Clinical and radiographic assessments were performed during follow-up visits at 6 weeks, 12 weeks, 6 months, 1 year, and $1\frac{1}{2}$ years using the Kyle scoring system.

Results

Nineteen of the 20 traumatic fractures healed uneventfully. One patient required reoperation after a period of 6 months for screw cutout, although this patient was healed completely. Walking and squatting ability was restored in all patients by 6 months postoperatively.

Conclusion

This study suggests that a short gamma nail is a reliable implant for proximal femoral fractures, leading to a high rate of bone union and minimal soft tissue damage. Intramedullary fixation has biological and biomechanical advantages, but the operation is technically demanding, with some restrictions.

Keywords:

third-generation short gamma nail, gamma nail, extracapsular proximal femoral fractures

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Introduction

Hip fractures are considered one of the major health problems in aging societies [1]. These fractures are correlated with increased disability and mortality and a decreased quality of life [2,3]. Early mobilization of patients with these fractures is essential to improve fracture healing, minimize immediate postsurgical morbidity, and reduce care costs. One essential prerequisite for early mobilization is mechanically stable fracture fixation [4]. Nowadays, most hip fractures are treated by extramedullary or intramedullary implants, which allow a stable fixation in the majority of cases [5].

A dynamic hip screw (DHS) is the most commonly used implant for intertrochanteric fractures [6,7]. Load bearing in the proximal femur is predominantly through the intact calcar femoral; the lever arm of the laterally placed plate is increased, thus, there is a risk of implant cutout if the calcar is not intact [8,9]. Biomechanically, compared with a laterally fixed side plate, an intramedullary device decreases the bending force of the hip joint on the implant by 25–30%. This has advantages especially in elderly patients, in whom the primary treatment goal is immediate full weight-bearing mobilization [10].

It has been postulated that cephalomedullary nails have an advantage over DHS fixation because of the load-bearing axis being closer to the hip joint fulcrum, and also less blood loss, minimal tissue dissection, shorter operation time, and faster ambulation after surgery [11–13]. However, other studies have reported that fixation with DHS is better [6,14,15]. One of the major drawbacks discovered with the use of the short gamma nail is a higher reoperation rate as a result of new fracture around the implant [14,16]. The reoperation rate varies from 3 to 12%, which has led to the recommendation that the gamma nail should not be used routinely for trochanteric fractures [13,17]. In this study, we present our results for the treatment of extracapsular femoral fractures using a short gamma nail in terms of the outcome, drawbacks, and possible complications.

Patients and methods Patient selection

Twenty patients with recent traumatic extracapsular proximal femoral fractures were treated using a short gamma nail of third-generation assembly. There were seven men and 13 women; the mean age of the patients was 55 years (range 31–69 years) (Table 1). Two other patients were planned to be treated with a gamma nail. They were morbidly obese women with overhanging torso flanks; breaching of the greater trochanter occurred with initial reaming and the procedure was aborted and switched to DHS. These patients were not included in the study and mentioned for avoidance of this complication.

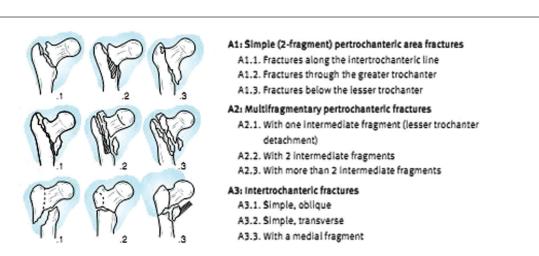
Modes of trauma

Four patients had high-energy trauma (motor car accidents and fall from a height) and 16 patients had had other minor falls on the ground among elderly patients.

The inclusion criteria were as follows: traumatic, extracapsular fractures of the proximal femur (till 5 cm below the lesser trochanter), intertrochanteric

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30-40 years	2 cases
40-50 years	2 cases
50-60 years	7 cases
Above 60 years	9 cases

Figure 1



AO-ASIF classification. A1, simple two-part pertrochanteric fractures; A2, multifragmentary pertrochanteric; A3, intertrochanteric fractures.

and pertrochanteric fractures with or without subtrochanteric extension, isolated subtrochanteric fractures not extending to the shaft, and surgically fit patients.

Anteroposterior (AP) radiographs of the pelvis and AP and lateral radiographs of the affected hip were taken at admission.

Classification of the fractures was carried out using the AO-ASIF system as shown in Fig. 1 [8] and extracapsular fractures were assigned number 31–A.

Three patients were found to be A1, 13 patients to be A2, and four patients to be A3.

Associated injuries: two of the polytrauma patients had associated injuries: one had an ipsilateral undisplaced calcaneus fracture and the other had a contralateral un displaced fracture of the acetabulum; all associated injuries were managed nonoperatively.

Low-molecular-weight heparin was administered to all patients preoperatively at a prophylactic dose, with proper preoperative assessment and correction of general medical problems; consent was obtained from all the patients.

The nail used (Fig. 2) was a short gamma nail with the following third-generation specifications:

- (1) Length: 240 mm.
- (2) Proximal part diameter: 13 mm.
- (3) Distal diameter (below the lag screw): 11 and 12 mm.
- (4) Valgus angle (mediolateral angle of the nail): 4°.
- (5) Flanged distal 7 cm to reduce stresses around the nail.
- (6) Lag screw diameter: 10.5 mm.
- (7) Lag screw-nail angle: fixed angle of 135°.
- (8) Flanged lateral end was fitted with a set screw to prevent lag screw migration, but allow controlled impaction.





Gamma nail used in the study.

- (9) Distal locking screws' position: 10 and 8 cm from the distal tip of the nail with a relatively long segment inferior to the distal hole to decrease stress and the incidence of femoral fracture at the tip of the nail.
- (10) Fully threaded self-tapping screws were 5 mm in diameter. Screw holes: the upper one was static and the lower one was dynamic, to be inserted first to allow some dynamization in cases of subtrochanteric fractures.
- (11) End caps could be used to occlude the nail after application of the set screw (optional).

Surgical technique

The surgical operations were performed under general anesthesia (four patients) and spinal anesthesia (16 patients) with the patients in the supine position on a fracture table. One gram of third-generation cephalosporin was administered at the time of induction. The upper part of the body was curved to the opposite side, with the injured lower extremity adducted as much as possible for ease of nail insertion. The opposite lower limb was flexed and abducted to make room for the image intensifier. Fractures were reduced under traction and C-arm fluoroscopy. A lateral longitudinal incision of about 3 cm was made superior to the greater trochanter after the top of the greater trochanter was palpated by the surgeon's index finger. The entry hole on the top of the greater trochanter, usually at the junction of the anterior third and posterior two-thirds, was made with an awl under fluoroscopic monitoring. A guide rod was inserted through this hole into the distal femoral canal, followed by reaming of the femoral isthmus and the proximal fragment. The guide rod sometimes abuts against the iliac crest and causes the impingement so that it goes toward the varus position. Therefore, it is recommended that the torso of the patient should be pushed toward the opposite side.

Reaming was performed distally to a size of 12 mm and proximally to a size of 13 mm; for all patients, had 11 mm nails were used. The short gamma nail was placed over the guide wire. We used gentle manual

reaming of the proximal fragment and not power reaming to avoid breaching of the greater trochanter encountered in two patients in our early experience (these two patients were not included in the study). The nail was not hammered into the femur; it was pushed gently by hand. Then, the proximal aiming device was used to plan a short incision over the proximal hole and a guide wire was advanced into the femoral neck and head with fluoroscopic guidance aiming for the center of the neck on lateral view and inferior in AP view to avoid impingement of the nail tip with the trochanter area using a proximal aiming device. The lag screw was placed after reaming within 5-10 mm from the subchondral bone, and the screw was locked to the nail with a set screw and one or two distal locking screws were placed using a distal aiming jig through stab wounds. Correct placement of the distal locking screw should always be confirmed by fluoroscopy. The deep wound layers were irrigated and closed in layers with absorbable sutures with closed suction drainage, and the skin was closed with clips.

Estimated blood loss and operative time were documented.

Postoperative care

Third-generation cephalosporin was administered for 5 days postoperatively; removal of the suction drain was performed after 48 h or with less than 50 ml discharge over 24 h. Low-molecular-weight heparin was used for a total of 3 weeks until full nonassisted ambulation was possible. Assisted ambulation was allowed after 5 days according to the general condition of the patient irrespective of the fracture configuration using a walker to allow toe-touch; partial weight bearing was enforced at 6 weeks and full weight bearing at 3 months.

After beginning ambulation, AP and lateral radiographs of the operated hip were taken to evaluate the position of the implant, distance from the screw tip to the subchondral bone (tip — apex distance), and reduction in the fracture and the neck — shaft angle. At follow-up, the presence of pain, need for ambulatory aids, and hip range of motion were reported. Follow-up AP and lateral radiographs of the hip were taken to evaluate the neck — shaft angle, changes in the position of the screw, cutout of the implant, and fracture union.

A fracture is considered to be healed when fracture lines are filled with callus in radiograph films and when there is no pain at the fracture site on full ambulation.

Follow-up radiographs were taken at 6 weeks, 12 weeks, 6 months, 1 year, and 1½ years. Functional outcome was estimated according to the Kyle scale (Table 2) [18].

Results

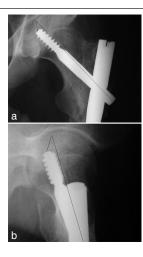
A total of 20 patients had their fractures reduced and fixed with short gamma nails within the period under review. The interval from trauma to operation varied from 3 to 8 days according to the patient's general condition. Intraoperative blood loss was less than 100 ml in 16 patients; one patient required blood transfusion and was a case of polytrauma. The operative time ranged from 55 to 110 min in early cases, with a mean of 75 min.

The tip-apex distance was less than 25 mm in 19 patients and more than 25 mm in one patient who required reoperation after 6 months (Fig. 3).

No intraoperative complication or mortality was encountered. Perioperative complications such as acute respiratory distress syndrome and deep vein thrombosis were not encountered in our cases. No early or late infection was reported. There was no intraoperative or postoperative femoral fracture around the nail tip during the entire period of follow-up.

There was one patient who required reoperation because of cutout of the hip screw that appeared after 6 months (the patient was taking steroids for the management of idiopathic thrombocytopenia purpura), with full healing of the trochanteric fracture

Figure 3



Tip-apex distance in anteroposterior and lateral view of less than 25 mm.

Excellent	Good
No or minimal limp	Mild limp
No pain hip joint	Mild occasional pain
Full ROM hip joint	Full ROM
Fair	Poor
Limp up to moderate	Wheelchair bound
Moderate pain (using two sticks)	Pain in any position
Limited ROM	Nonambulatory

ROM, range of motion.

and removal of the lag screw while the nail was still in place, with nonassisted full weight bearing after the removal of the lag; this patient was 41 years old and had a combined trochanteric subtrochanteric fracture AO/ASIF: 31–A3 type.

All patients showed healing within a mean period of 4 months (2.8-5.2 months). There were no femoral shaft fractures (Fig. 4a-c).

One case of screw cutout appeared after 6 months and was removed, with complete healing (Fig. 5a and b).

According to the Kyle score, 18 patients achieved excellent results, two patients achieved good results, and one patient with polytrauma developed a mild limp with associated fracture of the acetabulum (Fig. 6a and b).

Another patient developed a screw cutout.

No shortening was encountered. Removal of the distal locking bolt was not performed to dynamize the nails to improve bone union as it was considered unnecessary. No varus angulation was detected during the follow-up.

Discussion

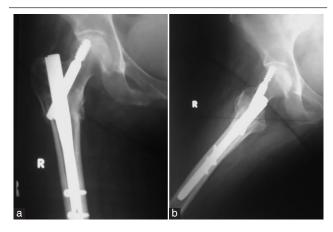
Hip fracture is the general term for fracture of the proximal (upper) femur. These fractures can be subdivided into intracapsular fractures (those occurring within or proximal to the attachment of the hip joint capsule to the femur) and extracapsular (those occurring outside or distal to the hip joint capsule). Extracapsular hip fractures are defined as those fractures of the

Figure 4



(a) Preoperative unstable fracture 31-A3. (b) Immediate postoperative and (c) after 4 months with healed fracture.

Figure 5



Radigraph of the case after healing of the 31-A3 pattern. (a) Anteroposterior view and (b) lateral view.

proximal femur within the part of the bone from the attachment of the hip joint capsule to a level of five centimeters below the distal (lower) border of the lesser trochanter. Other terms used to describe these fractures include trochanteric, subtrochanteric, pertrochanteric, and intertrochanteric fractures. The extracapsular groups of fractures are assigned the code 31–A in numerical classifications of the AO/ASIF categories and include three subgrades of A1, A2, and A3 (Fig. 1) [5].

Hip fractures remain a significant source of morbidity and mortality in the elderly and their incidence is increasing as the population ages. Ninety percent of hip fractures occur in patients older than 65 years, and about 75% of these occur in women. Approximately half of these fractures involve the intertrochanteric region. Despite this frequent occurrence, the method of optimum stabilization and subsequent mobilization for these fractures still remains a matter of debate. DHS has yielded satisfactory results in the treatment of pertrochanteric fractures; nonetheless, they have been associated with up to a 20% failure rate and this is particularly important in unstable trochanteric and subtrochanteric fractures [19].

Traditionally, it was the posteromedial comminution that was considered the most important factor in determining the severity and stability of fracture. The importance of the integrity of the lateral femoral wall has been documented recently [20–22]. This lateral wall is very thin in unstable 31–A2-type fractures [20,21]. In 31–A1, with an intact lateral wall, treatment with DHS provides a lateral buttress for controlled fracture impaction and to prevent collapse. Palm *et al.* [20] found that there was an eight fold higher risk of reoperation because of technical failure with the goldstandard technique of DHS in patients with a fracture

Figure 6



(a) High subtrochanteric fracture with a compromised lateral wall fitting 31-A3 with contralateral fracture acetabulum. (b) Fixation by a gamma nail.

of the lateral femoral wall in 31–A2 and A3. This has been attributed to the fact that when the lateral femoral wall is fractured, the fracture line is parallel to the sliding vector of the sliding hip screw, which, as in the reverse oblique intertrochanteric fracture, allows the trochanteric and femoral head and neck fragments to slide laterally and the shaft to slide medially. The fracture complex subsequently disintegrates, with a high risk of failure, including cutout of the screw into the hip joint [20] as shown in Fig. 7.

Another fact is that most of the fractures of the lateral femoral wall occur intra-operatively with the goldstandard technique when a large-diameter hole is drilled into the lateral femoral wall, thereby converting a 31-A2 type into a 31-A3 type. Gotfried [21] in a retrospective analysis of 24 patients with documented postoperative fracture collapse, showed unequivocally that in all patients, this complication followed fracture of the lateral wall and resulted in a protracted period of disability until fracture healing. The importance of the integrity of the lateral wall for event-free fracture healing is clearly indicated, and fracture of the lateral wall should be avoided in any fixation procedure. Palm et al. [16] have recommended dividing the fractures into two categories, A1-A2.1 and A2.2-A3, and not just into A1, A2, and A3 fracture types as has been reported in most studies taking into account the integrity of the lateral femoral wall. This has implications for treatment guidelines; the DHS is not a good implant option in patients falling into the second category. In the series by Gotfried [20], lateral wall fracture occurred in one-third of the hips with the most vulnerable lateral femoral wall, that is, in those with an AO/OTA A2.2 or A2.3 fracture, which lacks buttress support of the greater trochanter.

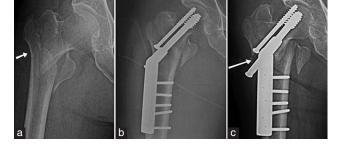
In our study, 17 patients had the 31–A2 and A3 fractures. Only two patients had 31–A2.1 fractures and the remaining 15 patients had unstable fractures.

Intramedullary nails are associated with less shortening and less sliding of the lag screw. This is because of the fact that an intramedullary nail prevents the telescoping displacement of the proximal aspect of the femur. In fact, the proximal part of the nail blocks the head and neck fragment, preventing its complete impaction into controlled impaction; thus, its mass may act as an internal block against neck translation and prevent medial displacement of the shaft. Hardy *et al.* [23], in a randomized study of 100 patients with an intertrochanteric fracture, found less limb shortening in the group treated with an intramedullary hip screw than in those treated with a DHS, especially in unstable intertrochanteric fractures.

Biomechanical studies have shown intramedullary devices to be superior to plating systems in the treatment of unstable extracapsular fractures of the hip; an intramedullary device decreases the bending force of the hip joint on implant by 25–30% because of load bearing being closer to the hip joint fulcrum (Fig. 8) [10,11].

The Zickel nail was introduced in the late 1960s for fixation of unstable pertrochanteric and subtrochanteric fractures of the femur. It combined intramedullary and intracephalic fixation but usually required extensive exposure and did not allow postoperative impaction caused by early ambulation. The Zickel nail was subsequently criticized for its lack of rotational and axial stability. The gamma nail, sharing the same cephalomedullary fixation principle, was introduced in the late 1980s. It offered the biomechanical benefits of intramedullary nailing and

Figure 7



(a) Initial radiograph shows a 31-A2.1 fracture with an intact lateral femoral wall (arrow) initially. (b) Postoperative radiograph shows good reduction and fixation. (c) Follow-up radiograph taken 1 month after the operation shows fracture of the lateral femoral wall (arrow) with excessive sliding. The lateral wall fracture that developed after the operation turned the initial A2 fracture into an A3 fracture pattern.

was designed to overcome the problems associated with the Zickel implant [24].

The gamma nail was named as such because it resembles the Greek letter gamma (γ) [25].

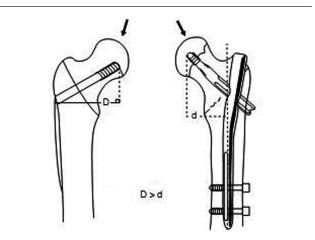
In 1988, the first-generation nail was designed with a mediolateral angle of 10° and two locking holes. Historically, the first reports of use of the gamma nail were encouraging [11,12], but recently, several studies have focused on the relatively high complication rate associated with its use [6,14,26–28].

The most serious complication in the literature related to the use of the standard gamma nail has been the high incidence of a secondary femoral fracture (rate between 0 and 17%). Gamma nail implants have been reported to cause three-point loading in the femoral trochanter and diaphyseal cortices because of a large valgus angle of 10°, thus exposing the femur to a high frequency of intraoperative and postoperative refractures. In addition to the nail shape, the recommended technique of distal locking screw insertion may have contributed toward the incidence of shaft fractures. Some of the reported complications may have been technical errors during surgery, such as inadequate reaming of the medullary canal or forceful nail insertion [29].

Thus, several authors did not recommend the use of the standard gamma nail in trochanteric fractures until resolution of the problem of femoral shaft fractures [7,15].

Intraoperative shaft fracture is usually localized along the nail and could be because of forceful nail insertion, often by a hammer, or inadequate reaming of the femoral medullary canal [30].

Figure 8



Increased lever arm with the dynamic hip screw (D) implant in comparison with the gamma nail (d).

Delayed shaft fractures typically occurred at the tip of the nail, with an incidence rate between 1 and 5% of all cases; these delayed complications occurred between 10 days and 6 months after surgery. Biomechanical studies have shown that the standard gamma nail produces a low compressive load on the proximal medial cortex and an excessive load at the tip of the nail, resulting in weakness at that level of the femur; this may be because of the excessive mediolateral curvature of the standard nail, which causes impingement of the tip of the nail against the external femoral cortex. Moreover, difficulty with distal locking screw insertion when inserted free hand and the drilling of additional holes into the cortex may also lead to an increase in stress around the nail tip, predisposing to failure [31].

Subsequently, the next generation of intramedullary hip screws was developed in order to improve clinical results and minimize complications [9,23,32].

In 1997, the second-generation nail had a mediolateral angle of 4° and one locking hole, whereas the advent of gamma three in 2003 included further modifications such as a thinner proximal diameter of 15.5 mm instead of 17 mm, a smaller lag screw diameter of 10.5 mm instead of 12 mm with a different pitch pattern of the threading, and the locking screw, now 5.0 mm, could fit into a dynamic and static locking slot instead of a thicker 6.28 mm locking screw in a static distal locking slot (Fig. 9) [33].

Many modifications have been made during the subsequent years to enhance the results; these modifications were made to the nail and to the operative technique.

The older generation cephalomedullary nails were made of stainless steel and had a very large distal locking screw,

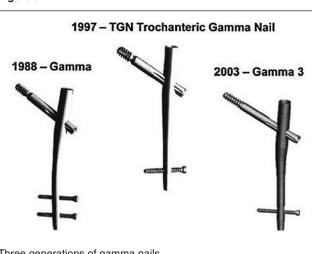


Figure 9

Three generations of gamma nails.

increasing the risk of an increase in stress at the tip of the nail. Newer generation nails are made of titanium and are tapered distally, with the locking screw being located more proximally on the nail in an attempt to decrease the increase in stress. An advantage of the short gamma nail in selected fracture patterns is that it requires less reaming of the distal femur for proper placement. This may lead to decreased postoperative incidences of fat and pulmonary emboli. In addition, the short gamma nail allows for shorter operative and fluoroscopy time, and necessitates less blood transfusion [31].

Specific techniques of nail insertion were recommended. The prevention of intraoperative femur fracture starts with proper positioning of the patient, with the ipsilateral gluteus leaning slightly out of the operating table and the contralateral leg abducted far enough to make room for the image intensifier. The nail entry is in the greater trochanter, but if it is in a highly lateral position, it may cause the nail to enter into the medial cortex, thereby imposing a stress on it. It is advisable to regularly verify the position of the tip of the implant with the image intensifier during insertion. No excessive use of the hammer should be made during insertion of the implant, as over-reaming of the canal by at least 2 mm allows manual insertion of the nail. The possible stress-increasing effect produced by the tip of the nail can be controlled with the use of distal interlocking screws [33,34].

Revised recent reports indicated the following: Menezes *et al.* [35] studied of a total of 129 patients available for follow-up and found that failure of fixation occurred in three (2.0%) patients and a femoral shaft fracture occurred in one (0.7%) patient.

Leung *et al.* [12], in an early study, used a modified nail for Asian anthropometry that had a length of 180 mm, a mediolateral curvature of 4°, a proximal diameter of 16 mm, and distal diameters of 11 and 12 mm; they reported four out of 349 intraoperative fractures of the greater trochanter but no cases of postoperative femoral shaft fractures. This modified design of the gamma nail was associated with a lower rate of postoperative complications than with the standard gamma nail [5].

Using the same specificity, Utrilla *et al.* [31], in a much more recent study, found no postoperative femoral shaft fractures in 104 cases; yet, other complications (lag cutout, trochanteric fracture, DVT) were comparable with the use of DHS as a method of fixation.

Similar results were obtained by Bernard *et al.* [33]; after 71 patients were fixed with a short gamma nail, there were no cases of femoral shaft fractures, but two cases of screw cutout (3%) were found.

However, the complication rate of lag cutting out in the third generation was lower (2.5-7%) than that in the second generation (14%). This proved that the third-generation nails are safe and reliable implants. Compared with second-generation devices, fewer complications are observed [36].

In addition, intramedullary fixation has superiority over surface fixation in the management of fractures of osteoporotic and pathological bone [10]

In this study, no cases of intraoperative or postoperative femoral shaft fractures were encountered during the follow-up period. One patient developed lag screw cutout (5%), which is within the reported percent of this complication. Breaching of the greater trochanter was observed in two cases intraoperatively (not included in the study) during early cases done; therefore, we adopted some parameters to obtain better results.

- (1) Manual reaming of the proximal part was performed cautiously to avoid breakage of the trochanter.
- (2) The procedure was not performed in morbidly obese patients because of difficult insertion of the awl and reamers, which resulted in breaching of the greater trochanter and conversion to sliding hip screws (two cases, not included in the study).

Reoperation was performed in 5% of our patients, which is similar to the results documented (2.5-7%) in other studies reporting on the use of a third-generation gamma nail [36].

In terms of functional outcome, a recent similar study [37] found an excellent outcome using the Kyle system in 87% of cases, which is similar to our result (18 of 20 outcomes were excellent, which equals 90%).

There were some limitations in our prospective longitudinal study. First, there was no control group that included patients in whom a DHS or other types of internal fixation method were used to serve as a comparison with the surgical technique being investigated. Second, we did not use an accepted outcome measurement instrument such as the Harris hip score or SF-36 to present our results. Evaluation of patients' ability to squat and walk with no limp for assessment of outcome was also performed using a crude method. However, assessment of bony union with serial radiographs in our study was acceptable. Third, a small group of cases was included as we are in our early experience in using this type of implants. Fourth, we did not compare our study with the DHS method of fixation because most of our cases were unstable (15 cases of the 20 fell into 31-A2.2 to 31-A3).

Conclusion

Data from this case series show that third-generation short trochanteric nails are a safe alternative for stabilization of complex proximal femur fractures. Postoperative complications included one screw cutout requiring removal of the lag only. Management of unstable intertrochanteric and subtrochanteric fractures with a short third-generation femur cephalomedullary device seems to be a reliable technique, with a low incidence of complications. Newer designs of the implants resulted in no periprosthetic fractures commonly encountered with older devices and we believe that third-generation cephalomedullary nails can be used effectively for the treatment of these fractures. Weaknesses of this study include a short follow-up period and the inclusion of a small study group; however, we expect to report our long-term results in the near future.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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