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Original Research Article

Management and Treatment of Trochanteric Fracture -A Novel Factor of Intramedulary Nail Failure

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Abstract

Trochanteric fractures usually occur in elderly patients with associated comorbidities or in case of low energy trauma. The trochanteric fractures represent a challenging pathology with many possible complications. The usual treatment issurgical with either intramedullary nail or dynamic hip screw (DHS).Most of the complications are due to the severe osteoporosis or implant malpositioning. Due to the complications encountered during practice, we decided to make an adequate assessment of our complicated cases and a study of the intramedullary nails used in our surgical treatment of the trochanteric fractures. In the study were included twenty-three patients, of which thirteen followed a fast recovery program with early walking (FWB group). The other ten patients were not allowed full weight bearing up to 6 weeks (NFWB group). All the patients were diagnosed with osteoporosis pre-operative. The T-score was determined post-operativefor all the cases. The T-score on your bone density report shows how much your bone mass differs from the bone mass of an average healthy adult. A bone density test is like any other medical test or measurement. The results for the entire population will be distributed around an average score (the mean). The stress testing of the implant was done in another centre and we measured the tolerances of the material. The average T-score was 2.5 for the patients that followed the fast recovery program and 2.7 for the patients from non-full weight bearing. The average age of patients was 70 years old with a Body mass index (BMI) between 26-31 and no septic post-operative complications were recorded. Four patients, one from the NFWB group and three from FWB group, presented a screw cut-out. We also presented three particular cases with very serious post-operative complications. One of the cases is a patient with a failed dynamic hip screw implant fixed in another hospital centre, where we decided to remove and use an intramedullary nail. Even though the screw position was optimal, the nail broke in the proximal part after 6 months due to the insufficient bone healing and high stress shielding forces. The patient underwent revision surgery for the implant and the broken nail was sent for metallurgic testing and electronic microscopic examination. We found that the errors of the guiding instruments may create dents or scratches on the coating or on the inside proximal hole that may lead to a reduced resistance to the high number of cycles of stress forces. Even though such an event is not frequent, it must be avoided, especially in patients with osteoporosis, which have an increased risk of implant failure.. Despite the reported postoperative complications, the gamma nail remains one of the main solutions for the treatment of pertrochanteric fractures.

Keywords: Arthroplasty surgical technique, Internal fixation, Nail ruptures, Trochanteric fractures

INTRODUCTION

Adult trochanteric fractures represents a challenging orthopaedic pathology Most of these patients are elderly, with associated comorbidities and sometimes with fractures resulting from high intensity trauma. Mechanical complications are generallly less common than systemic ones. Elderly patients or ones with various lytic lesions present at the emergency room with per-trochanteric fractures resulting from low-level trauma. Most of the complications occur due to severe osteoporosis or implant's malpositioning. Although rheumatological research is still in progress, osteoporosis' treatment has not yet succeeded in reducing the complications of trochanteric fractures, which are increasing in elderly patients (White and Griffiths, 2011). Low compliance of patients undergoing rheumatological treatments may be one of the causes determining pertrochanteric fractures (Gillespie et al., 2010; Cameron et al., 2011). Increasing life expectancy in Romania (75.31 years, data from The World Bank) may also be a factor for this frequent pathology.

For elderly patients non-surgical treatment is not an option due to increased complications and poor clinical results. Literature research show a higher mortality rate and poor functional results after conservative treatment.

The usual surgical treatment is represented by osteosynthesis with intramedullary nails or extra-medullary osteosynthesis with dynamic hip screw (DHS) (Bjorgul et al., 2011; Biber et al., 2012).

Our method of choice, in treating this pathology is reduction and internal fixation with a titanium made gamma-nail system. Due to the complications encountered during practice, we decided to make an extensive literature review, an adequate assessment of our complicated cases and a study of the intramedullary nails used in our surgical treatment of the trochanteric fractures.

The fractures that occur in the proximal third of the femur, which extend from the base of the femoral neck up to 5 cm below the small trochanter, are called trochanteric fractures (Loizou et al., 2010).

Throchanteric fractures classifications are based on various factors, the most frequently being the fracture's line (Ramadier et al., 1956; Decoulx and Lavarde, 1969) and the degree of comminution. In our study we used Evans classification (Evans, 1949) which is divided into five types, starting with the first one (non-displaced with 2 fragments) and ending with the fifth type where comminution is high. The classifications of pertrochanteric fractures, like all classifications, have their limitations regarding reproducibility. The main challenge is achieving a satisfactory reduction, before surgery, under C-Arm X-rays. Figure 1

The cases of pertrochanteric fractures in elderly have an increasing incidence in hospitals across Romania. Risk factors for trochanteric fractures are represented by increased bone fragility, falls from the same level or in some patients either cardiac either psychiatric pathology (Grigorie et al., 2019). Figure 2

The clinical diagnosis of trochanteric fracture is supported by the shortened limb, which is adducted and in external rotation. Although the diagnosis is clinical in most cases, type 1 trochanteric fractures in the Evans classification do not display an external rotation and the diagnosis cannot be complete without a radiography in the anteroposterior and lateral incidence, since imaging is crucial in determining the classification. The imaging can be completed with a computer tomography (CT) when a fracture is suspected because of the medical history.

Trochanteric fractures occur frequently in patients over 70 years old with associated comorbidities as malnutrition and severe osteoporosis (Mizrahi et al., 2008).

In patients over 70 years old, the immediate post-operative complications are the loss of the ability to walk and the failure of psychiatric and emotional coping. Rehabilitation has a crucial role and it is sometimes hard to exert.

The treatment of this pathology must be quick, with limited blood loss and a fast recovery of walking. Theoretically the patient should be encouraged to walk immediately after the surgery, even at the risk of full weight bearing on the fractured limb. Regardless of the chosen treatment, the complications that may occur pre- or postoperatively, the treatment of pain, the prevention of pulmonary thromboembolism and the maintenance of an adequate musculature must be taken into account.

From the analysis of cases with failed mechanical device stability, the purpose of the study is to identify all the causes that lead to immediate or late complications, even the serious one such as revision or exitus.

MATERIALS AND METHODS

23 patients with previous osteoporosis were included in the study, 10 were not allowed for full weight bearing until 6 weeks after surgery, and 12 were following a fast recovery program, with early walking. Osteoporosis was diagnosed for all before surgery, and all patients were under treatment for this pathology. None of these patients had major comorbidities. All patients were over 70 years old. No septic complications were recorded. Body Mass Index was between (Dangles and Altstetter, 2010; Lakstein et al., 2011; Magnissalis et al., 2003; Patel et al., 2009; Sotereanos et al., 2012; Sul et al., 2002). T-score was recorded for all patients.

One patient, operated in another clinic, was admitted in our hospital, in the emergency room, with severe sepsis. A failed and displaced implant was identified on x-rays. CT scan was necessary to examine any secondary septic determinations.

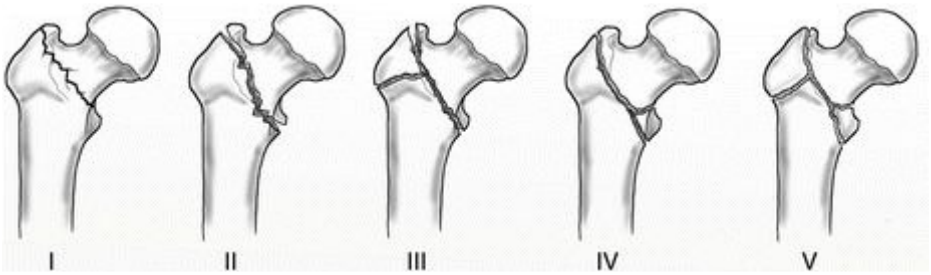

Figure 1. Evans classification

Figure 2. Radiography showing left pertrochanteric fracture

One patient operated in another emergency clinic with a DCS system for a right hip fracture, needed second surgery. The gamma nail that we used failed after one year. Full set of blood tests were performed on all patients.

During the surgery, we follow the international guidelines and the manufacture`s implanting technique. In all cases we struggle to achieve a close to perfect preoperative fracture reduction. The positioning of the patient it is important. The orthopaedic table is used and the fracture is reduced, a manoeuvre that will help us later when implanting the nail in the ideal position. The manoeuvre of reduction on the orthopaedic table is performed under radiological control.

Small incisions are performed and the nail is implanted intramedullary and stabilised. X-rays are used on all patients to verify the correct position. The ideal position for the lag screw is inferior and posterior in the femoral head (Kuzyk et al., 2012). We used, for all our patients, gamma nail implants made of titanium, from same manufacturer. The implant had cervical-diaphyseal angle of 125°, a distal diameter of 10 mm, a U-lag screw, and a distal static screw. Since we encountered one case with a broken implant, we decided to analyse in laboratory conditions and identify what are the factors that influenced it`s durability. Patients with severe osteoporosis were included in this study to verify the efficiency of fast rehabilitation program with immediate full weight bearing. Patients with non-consolidation were included and also one patient with implant failure, due to septic complications.

Stress testing on the implant was done in a different centre. Extremely interesting findings lead us to a close check on the nail`s surgical tray for accuracy and measurement tolerances. Results will be discussed later in the article.

RESULTS

Titanium and titanium alloys, which have been used widely as biomedical implant materials since the 1970s and possess desired properties or biomedical applications, such as excellent biocompatibility, good corrosion resistance, and high ratio strength (Niinomi, 2008; Elias et al., 2008; Black, 1994). We only used in

Figure 3. Before right hip surgery

this study titanium nails, from the same brand.

23 patients with osteoporosis were included in the study. Follow-up was 6 month, until fracture healing. Average T-score was 2.6 for the whole group. Randomly assigned, by means of the operating surgeon, 10 patients were not allowed for full weight bearing rehabilitation (NFWB group). Their average T-score was 2.7. the other 13 patients had an average T-score of 2.5(FWB group). None of these patients had major comorbidities. All patients were over 70 years old. No septic complications were recorded. Body Mass Index was between 26-31. No significant influence was identified, so the topic was not addressed.

Average T-score is not statistically important, small differences in T-score did not change the postoperative results. The only difference in in the rehabilitation program, between the two groups, was the full weight bearing indication. NFWB group had 1 case of screw cut-out, that needed reintervention. Lag screw was malpositioned. Weight bearing was possible, but with moderate pain. The patient had a reintervention, with total hip arthroplasty with revision stem. 10% of this group had cut -out complications.

In the FWB group, 3 patient had cut-out screws, with gradual moderate pain. One patient had a small screw displacement, but without cut-out. 23% of these patients encountered mechanical complications during the first 3 months. Statistically, early weight bearing does not benefit to the postoperative results, increasing the number of osteoporotic patients with mechanical failures. ($p<0.05$). Taking to consideration that one of these cases had the lag screw positioned in a not ideal location, statistically, it seems that faster rehabilitation does not increase the chance of screw cut-out with a big percent, but in fact, the screw position is the most important.

The second aspect of this study is a patient, with bilateral hip fractures (aprox. 2 years distance between fractures), operated in another emergency clinic with a DCS system. We changed the implant with an intramedullary nail. The right hip is of interest for this research. We applied the same method, but this time the nail broke after 6 months. Screw position was optimal. The insufficient restore of lateral femoral cortical bone was identified as the cause. The stress shielding forces were high and the bone healing was incomplete. The nail broke in the proximal part. A good solution was bone grafting and a longer nail. The same screw position was used, second time. Pain levels were low and the patient was able to walk. No follow-up was possible. (Figure 3,4)

No signs of infection were identified. No skin complications and bacterial cultures were negative.

Third part of this article is an 83 years patient, female, with diabetes. She presented at the emergency room with pain. weight bearing was impossible. It had a pertrochanteric fracture operated a year ago in another service. The implant was compromised with no signs of callus. Blood sugar levels were uncontrolled and at the clinical exam we identified multiple sacral sores. Clinical signs of shoulder arthritis were present. The affected thigh was 12 cm larger in diameter, hot and associated with redness. We decided to perform surgery and drainage. Next day, the patient was in a semicomatose state. During surgery, an extremely large quantity of

Figure 4. Aprox. 6 months after right hip second surgery

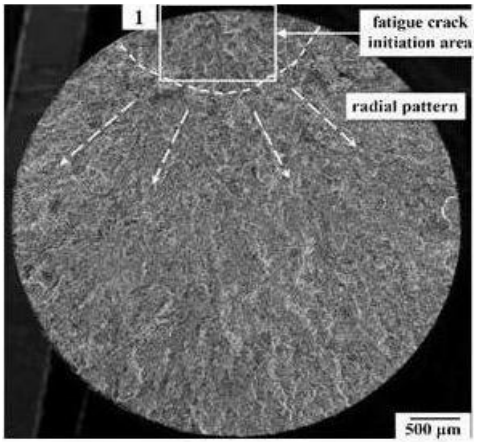

Figure 5. Fatigue crack (modified)

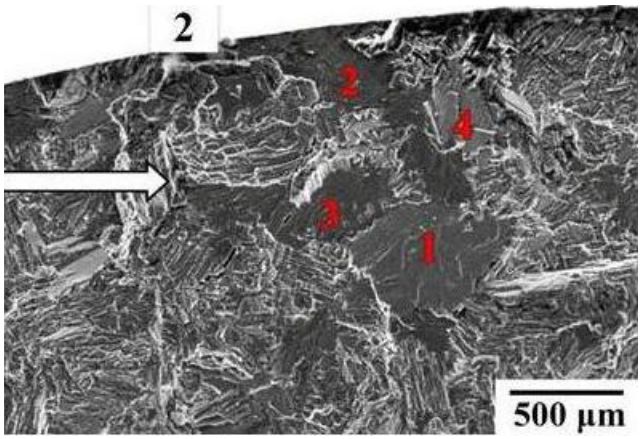

Figure 6. Fatigue cracks initiation area (modified)-low stress

Figure 7. 83y patient, operated in another hospital, presented at our emergency room with local sepsis signs and major misplacement of the implant.

pus was extracted. See pictures:

In the same night the patient went into septic shock with high potassium levels and anuria. She was unresponsive to norepinephrine and epinephrine. Death was recorded in the same night. Slow evolving sepsis, associated with comorbidities and a failed implant, all collaborated to the appearance of septic shock.

The proximal part of the broken nail was sent for analysis. Metallurgic tests and scanning with an electronic microscope were performed. Fatigue zones were identified at the contact between the nail and the screw. It is well-known that most of the fatigue cracks initiate at free surface. This phenomenon occurs only in special cases when a very high cycles fatigue test is performed (Zuo et al., 2008). Figure 5,6

This type of changes in the structure were not confirmed at low-cycle or high-cycle fatigue tests for TIAl6V4 (Wagner and Lütjering, 1987). We suspected that nonunion of the fracture was not the only cause of breakage. High tolerances of the lag screw guide (from multiple uses) leaded to small errors in the screw placement. Small dents were seen under microscope at the beginning of the primary fissure. The rigidity of the implant (titanium alloy) may eliminate micromotions in the axial plane at the fracture site (causing delayed healing), causing extra load relative to the femur, causing stress shielding. Our theory is confirmed also by other articles. The time until the nail broke was over 6 months. We found an average duration until failure of over 10 months on most studies (Willeumier et al., 018) Iwakura et al., 2013; Johnson et al., 2017).

Checking the guide for the for the lag screw, we identified an average of 1.4mm error, from 10 tests. The cause for this error was the locking hex screw that locks the guide to the nail and also the threaded kirschner wire, used as a guide. That allows for small errors at the passing of the lag-screw through the nail. Small scratches on the coating and inside the nail`s hole were observed.

The last case, was an extremely misplaced implant with associated severe sepsis and non-union. Figure 7,8: In this particular case, there was a drastic error in the reduction of the fracture, associated with life threatening comorbidities.

Figure 8: 3D CT reconstruction of the 83y patient

Figure 9. Nail guiding system

Figure 10. High quantity of pus in the hip region.

DISCUSSION

The number of patients with peritrochanteric fractures is increasing, most likely due to the increase of average life span. Given to the gravity of this traumatic event, it is important to determine factors which contribute and are associated with the failure of implant fixation. We tried to approach this subject from a different point of view. We were focused on some particular cases that could lead us to some new presumption of why these systems sometimes fail. The numbers of publications on this topic is low and sometimes data is incomplete.

Peritrochanteric fractures represent a major issue of public health as they are responsible for morbidity, increased mortality and high costs. Usually, after this type of surgery, the rehabilitation period is very long.

There is a constant debate about fast rehabilitation associated with weight bearing and also non-weight bearing protocols. Could this be the primary factor of gamma nail system fail? Osteoporosis has a prevalence of around 10% in US. This number is considered very high, in an age were physical activity is decreasing and people`s average life span is increasing (Wright et al., 2014). Most patients that were hospitalized with hip fractures are suffering also from osteoporosis or at least osteopenia. We included in our study 23 patients with pre diagnosed osteoporosis and associated perithrocanteric fractures, resulted from falls from ground level. We excluded lytic bone lesions as cause of these fractures. The two groups were divided randomly only by means of the surgeon that performed the operations. In one group there was a preference of very fast rehabilitation with weight bearing (FWB). We noticed a very high cut-out rate for these small group (23%). On the non-weight bearing group, only one case had a cut-out, but this incident was caused by lag screw misplacement.

Regarding body mass index, there was no statistical correlation between these groups. T-score was also not relevant. What we did noticed was that the weight bearing indication plays a crucial role in the outcome of the surgery. On osteoporotic patients, full weight bearing should be restricted for at least 6 weeks after surgery. Partial weight bearing can be allowed, but no more than 15% of body weight. It is important to mention that this finding is relevant only to patients diagnosed with osteoporosis (Sharma et al., 2008; Halder, 1992; Kempf et al., 1993).

From our clinical experience, fast rehabilitation protocols associated with weight bearing decrease the recovery period after surgery, increase patient satisfaction, decrease the cost of the medical act and also augment the personal independence. From our findings, this approach should be restricted to patients that have acceptable bone stock and accompanied by an adequate surgical technique. Screw placement plays a crucial role in the outcome of this type of surgery (Sharma et al., 2008).

One patient that we identified was 61y woman, with a body mass index of 29. She was operated before in our clinic after a failed DCS system (performed in another regional hospital), used for a peritrochanteric left hip fracture. The situation on the right leg was identical. We performed the second surgery, using a gamma nail fixation. After 6 months the implant broke. We took in consideration inadequate reduction and insufficient restore of the lateral femoral wall, as primary causes of

fail. Consulting data from literature, we noticed an average duration of over 10 months after nail breakage (Willeumier et al., 2018 Iwakura et al., 2013; Johnson et al., 2017).

This finding leads us to further investigate the broken implant, after extraction. On a microscopic view, we noticed small cracks and dents produced by the lag screw in the nail`s hole. Titanium is an extremely stiff material, resilient to bending. Since its proprieties, it tends to increase stress shielding at the level of the fracture. Small scratches in the weakest point of the nail can determine a decrease in resistance. In this particular case, this was the second surgery, so bone healing was slower. Could small errors in the guiding system cause a decrease of the nail resistance? We identified up to 1.4mm of error in the system guiding instruments tray, caused by multiple use and maybe also inadequate. Figure 9

There are several cases in literature that reported failed titanium or titanium alloy implants, specially gamma nails (Iwakura et al., 2013). Still, the overall long-term results for this type of material are still extremely good (Busch et al., 2005; Dangles and Altstetter, 2010; Lakstein et al., 2011; Magnissalis et al., 2003; Patel et al., 2009; Sotereanos et al., 2012).

Most frequently, failure takes place as a result of high tensile stresses around notches, holes or small indentations. Exceeding the stress forces within the very thin 1.8-17nm of protective coating (titanium oxide TiO2) can produce small/micro cracks followed by repassivation (Sul et al., 2002).

This effect is constant and is augmented by the corrosive environment (oxidative wear). Physiological loading induces unexpected, high cyclic stress during daily activity, weight bearing until fracture healing is complete. It is clear that none of these forces do not exceed the material`s critical breaking point on one exposure, but it is a relevant issue after a high number of cycles. Microcracks in the material grow at a slow per-cycle velocity and can propagate to implant breakage until bone heals (Ritchie et al., 1999). The same principle of titanium allow implants breakage was noticed in the modular systems. Due to small micromotions, the protective titanium oxide coating was destroyed and the implant failed due to increased fretting corrosion at the modular interface (Iwakura et al., 2013). In our case, the disruption of the titanium protective coating was iatrogenic. The lag screw, due to small errors in the guiding system, produces small scratches in the protective coating. Fracture site had a slow healing rate with high stress forces at this level. All leaded to a very fast implant breakage. It seems that this error severely decreased the implant`s lifetime.

The next case that we analysed was a failed gamma nail due to multiple causes. When including this case in the study we wanted to advocate the fast reintervention for this type of patients. An 83y diabetic patient presented in our emergency room with clinical sepsis, with a malpositioned nail, without fracture reduction, after 8 months surgery in another hospital. She did not address another hospital service and no follow-up info was available during this period of time. Septic signs appeared one month before presenting in our clinic (family anamnesis, patient was semicomatose). At the clinical exam we identified a right shoulder arthritis. Since the patient`s status was rapidly declining, we decided to perform extraction of the implant and debridement. Unfortunately, during surgery, the patient went into septic shock. Figure 10

Failed gamma nails should be addressed fast. Peritrochanteric fractures increase morbidity and in conjunction with comorbidities can have a very high mortality rate. Septic complications can lead to sepsis or even shock. We analysed this extreme case only to underline the fact that care must be exercised in fracture preoperative reduction and adequate nail and screw placement, since implant failing can lead sometimes to death.

CONCLUSION

Failure of gamma nail implants is not frequent, but still it must be avoided as much as possible. Such events lead to additional surgical procedures. In the literature the rate of breakage is reported in variable proportions but, in general below 5.6% (Abram et al., 2013; Eberle et al., 2010; Liu et al., 2010). There are many causes that may determine this complication. The aim of this paper is to identify lesser known facts that can lead to surgical reintervention. From our data, some patients have pre existent osteoporosis. This comorbidity increases the percentage of implant failure. It is safe to say that full weight bearing should be allowed after 6 weeks or to patients that have good bone stock. Faster mobilisation after surgery cannot always lead to good results, especially in old people with fragile bone. Lag screw placement and preoperative adequate fracture reduction are critical aspects that greatly influence the surgical outcome. A displaced implant associated with fractured delayed healing or cut-out should be addressed rapidly, since it can increase morbidity and sometimes lead to fatal complication. In our study we identify a novel factor of gamma nail failure. Breakage of the nail at the lag-screw level can be determined by errors in the guiding instruments. These high tolerances can cause dents or scratches in the protective titanium coating. This can lead to early implant breakage due to stress forces in a high-cycles environment. Extra care should be promoted to fracture reduction and adequate use of the gamma instruments tray. It is obvious that the forces that exert at this level do not meet the critical level of implant breaking point, but after a high number of cycles with a lower stress level, the lifetime and resistance of titanium alloy

component are greatly reduced. This theory was observed also in other modular systems, used in the orthopaedic field. Even sometimes associated with postoperative complications, the gamma nail remains one of the best solution in the treatment of peritrochanteric fractures (Klestil et al., 2018).

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