



Failure of the titanium trochanteric Gamma nail in ununited metastatic fractures

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Metastatic lesions often occur in the trochanteric region of the femur with a risk for pathologic fractures, requiring aggressive surgical treatment. We present two cases of mechanical failure of the Titanium Gamma 3 Nail 180 used for treatment of impending pertrochanteric pathologic fractures. Metallurgic and low power optical examination findings are presented. Treatment with intramedullary nailing devices has proven its efficacy. However in cases of delayed union or non-union, a fatigue fracture due to dynamic overload should be expected sooner or later. If there is no evidence of healing within six months postoperatively a hardware exchange or another therapeutic option should be considered.

Keywords: pathologic fracture ; pertrochanteric fracture ; intramedullary nailing ; non-union.

INTRODUCTION

The femur is one of the most common sites for osseous metastatic carcinoma. Stabilisation of impending pathologic fractures is often necessary in order to quickly restore the function of the affected limb. This site is commonly affected by an actual or impending pathologic fracture requiring surgical treatment. The femur is affected with a particular frequency in patients with known breast and renal cell carcinoma and in those patients with solitary skeletal metastatic disease (6). Treatment of actual or impending pathological fractures by means of an IM nailing device has proven its

efficiency (8,13,17). Despite often short follow-up due to patient death there is a clear improvement in quality of life and pain reduction (2). Load-sharing capabilities of IM nails allow for early weight bearing and mobilization.

The Gamma nail has been used for treatment of pathologic trochanteric fractures since its development in 1985. Reports on mechanical failure have appeared in literature (4,5,7,10,11,12,15-18,20).

The trochanteric Gamma nail for stabilisation of impending pathologic intertrochanteric fractures has been used with success for several years in our institution. Recently however, we experienced mechanical implant failure in two patients at the aperture of the lag screw, in both of them with Gamma 3 Nail 180 implants made of Titanium alloy (TGN, Stryker-Howmedica-Osteonics). These implants were retrieved and were submitted to metallurgic and low-power optical examination. The two implants were examined by specialists of

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Stryker Osteosynthesis, Kiel. The surfaces of the implants were studied in order to define signs indicating fatigue failure or deficiency of the device related to non-union of the patient's bone contributed by possible intra operative pre-damage of the implant.

CASE REPORTS

Case Report 1

An 82-year-old male patient was first treated in September 2009 for a TxN0M1 renal cell carcinoma of the right kidney with bone, subcutaneous and suprasternal lymph node metastasis. Due to the extent and progression of the metastatic disease, a first cycle of zoledronate chemotherapy in combination with sorafenib was started in September 2009. One month later, a non-displaced fracture of the right trochanteric region was noted on plain radiographs. A Gamma 3 Trochanteric Nail 180 (diameter 11 mm), with a neck shaft angle of 125° and a 105 mm lag screw was used for operative stabilisation. The nail was locked distally with one distal 40 mm screw. There were no intra-operative complications.

Postoperative mobilization began on the third postoperative day without problems. Weight bearing was increased gradually over the next days within pain limits.

Clinical follow-up at 6 and 12 weeks postoperatively revealed pain in the right hip region during weight bearing, suggesting delayed union. Eight and a half months postoperatively the patient was admitted to the emergency department. Weight bearing and passive manipulation of the right hip were impossible. Radiographs showed mechanical failure at the level of the aperture for the lag screw (Fig. 1).

The broken Gamma-nail was removed and replaced by an Intertan® IM-nailing device (Smith & Nephew, Memphis, USA). Despite this procedure a painful pseudarthrosis developed. Deteriorating general condition and progression of metastatic disease made further revision surgery impossible.

In this case the nail broke after an implantation period of approximately eight and a half months



Fig. 1. — AP radiograph of the right hip showing mechanical failure at the level of the aperture for the lag screw in an unstable intertrochanteric fracture with clearly visible cortical defect laterally.

due to overload. The radiograph shows the broken titanium nail and an unstable intertrochanteric fracture with a clearly visible cortical defect laterally (Fig. 1).

More detailed examination demonstrated significant chamfer-like and sharp edged damage on the lateral edge of the anterior bridge in the proximal and distal fragments of the nail. The lateral edge of the anterior bridge had become damaged due to contact with the step drill. The lateral edge of the posterior bridge of the proximal fragment of the nail on the other hand appears nearly undamaged (Fig. 2a). The fracture surfaces of both bridges of the nail have a smooth topography over the whole cross section. Both surfaces of the bridges have features of a fatigue fracture (semi-circled lines, “rubby shiny areas) (Fig. 2b). These lines of rest

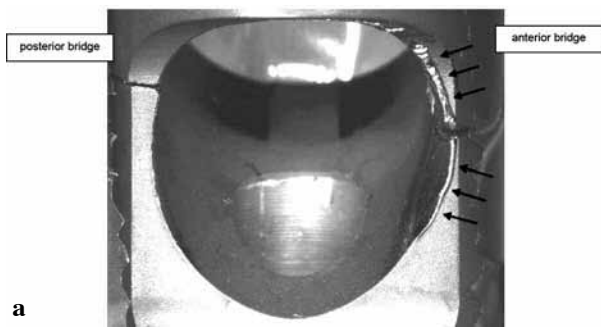


Fig. 2a. — Sharp edged drill damage to the proximal and distal lateral edge of the anterior bridge (arrows). The lateral edge of the posterior bridge of the proximal fragment of the nail on the other hand is almost undamaged.

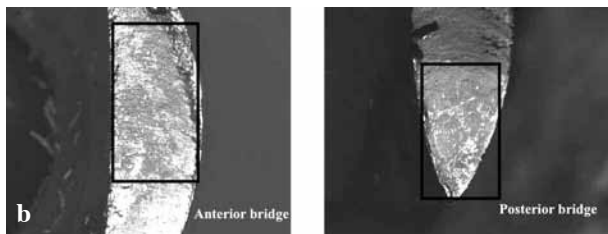


Fig. 2b. — *Left* : Semi-circled lines as a feature of a fatigue fracture. *Right* : Smooth surface over cross-section without deformation indicate a fatigue fracture.

and the missing deformation indicate a fatigue fracture. A hardness test according to Rockwell and translation revealed the tensile strength of the material (titanium) being within specified values.

Considering the orientation of the lines of rest (running from lateral towards medial), the main fatigue crack originated laterally, progressed through the cross-section and ended medially with signs of friction and material deformation towards the outside. An additional sharp edge – caused intra-operatively – contributed to the origin of a crack in the anterior bridge laterally followed by the delayed breakage of the posterior bridge. Additionally an angled breakage line – running from lateral to medial – was defined. This is usually caused by high torsional load application.

Case Report 2

A 52-year-old female patient was treated in 2003 for a T2N3M0 ductal adenocarcinoma of the left

breast with a modified radical mastectomy and adjuvant chemotherapy. Soon afterwards, she was started on tamoxifen. In April 2004 she received locoregional radiotherapy. In 2008 progression of the metastatic disease in her thoracic, lumbar spine and hilus of the right lung was diagnosed. Supplementary radiotherapy was given to the T4-T6 region and the hilus of the right lung. Despite this treatment further progression was noted in October 2009 with several new bone metastases. In November the patient presented with an impending pathologic intertrochanteric fracture of the left femur (Fig. 3a). A Gamma 3 Trochanteric Nail 180 (diameter 11 mm), with a neck shaft angle of 130° and a 90 mm lag screw was used to restore the function of the affected limb as quickly as possible. The nail was locked distally with one 35 mm screw. There were no intra-operative complications. Partial weight bearing was allowed within pain limits from day 2 postoperatively. Five months postoperatively, the patient suddenly experienced pain in the left hip region and walking became impossible. Radiographs showed failure of the titanium trochanteric Gamma nail on the level of the aperture for the lag screw (Fig. 3b).

The broken Gamma nail was removed and replaced by an Intertan® IM nailing device. At follow-up the patient was ambulant but presented with a new pathologic lesion in the head of the right femur. The left side showed no radiological consolidation with lag screw cut-out of the femoral head. Due to collapse on the right side with the failing Intertan® device on the left, the patient received a one-stage bilateral hemiarthroplasty.

In this case the nail broke in a fatigue fracture after an implantation period of approximately five and a half months due to overload. The radiographs showed the broken titanium nail in an unstable inter-trochanteric fracture with clearly visible cortical defects (Fig. 3b).

Low power optical examination revealed complete breakage of the nail in the bridges of the proximal drill hole for the lag screw, nearly perpendicular in all directions.

The breakage surface showed several signs of fatigue failure with lines of rest running semi-circled through the cross-section from lateral to



Fig. 3a. — Undisplaced intertrochanteric fracture of the left hip.



Fig. 3b. — Failure of the titanium trochanteric Gamma nail on the level of the aperture for the lag screw.

medial. The medial tips of both bridges were bent in outward direction. Examination also showed some traces of drill contact on the lateral rim of the lag screw hole of the proximal part of the nail. The shaft of the lag screw showed clear areas of extreme material abrasion.

The fatigue crack initiated in the lateral posterior bridge (drill marks were located here), followed by the anterior bridge and advanced nearly simultaneously completely through the bridges. These findings are similar for implant number 1. Medially bent outside tips in the material suggest that the residual forced fracture was located in a very limited area at the medial tips of both bridges. The friction marks in the lag screw hole with significant material abrasion were caused by high load bearing

with the lag screw during the period of implantation.

DISCUSSION

Breakage of a Gamma nail is a very rare complication. Including the 2 cases presented in this report, we found a total of 14 Gamma nail failures in English language literature. The reported incidence of this complication ranges from 0.2% to 5.7% (1,3-5,7,11,12).

The commonest cause is metal fatigue secondary to delayed union or malunion of the fracture, particularly at the point of insertion of the lag screw. The intertrochanteric and subtrochanteric area of the femur is most frequently involved by metastatic disease and due to the high stresses in this area, this often results in effective or impending pathologic fractures (3,11,19). Prophylactic nailing is therefore often required. Operative treatment of metastatic fractures does not prolong the patient's life but improves its quality (2).

The Gamma nail proved to be an adequate implant to stabilize stable and unstable inter- and subtrochanteric fractures (5). Intramedullary nails allow load sharing by the medial and lateral cortex, and decrease the moment arm at the sliding screw. As with any implant these nails have complications, and once implanted, they are subjected to the usual race between fracture union and implant failure (11).

The Gamma nail is able to withstand long-term cyclic loading. This is especially important in patients with pathological fractures where healing of the fractures is not expected.

Examination of the implants' history and fracture surface in our two patients showed both surgeon-related and implant-related problems. In both cases the nail broke in a fatigue fracture after an implantation period of eight and five and a half months respectively due to overload. Overload was most likely caused by increased bending stresses initiated by high load application because load bearing of the nail was not reduced by bony consolidation. This certainly is linked to progression of the metastatic disease. An additional sharp edge caused intra-operatively may have contributed to the origin of an incipient crack. For this reason, we suggest

immediate intra-operative removal of the implant in cases of obvious abrasion, and insertion of an undamaged Gamma nail.

The traces we found on the implants and on the breakage surfaces of the nails suggest that the breakage of the nails was induced by minor damage during insertion and by progression of the local metastasis. Any deficiency of the Gamma-nailing device however cannot be ruled out.

The region of the lag screw and the distal locking screw hole are both critical zones with high von Mises stresses and are thus vulnerable to fatigue fracture. The von Mises stress is used to predict yielding of materials under any loading condition from results of simple uniaxial tensile tests (9). It has also been proven that a titanium alloy implant exhibits von Mises stresses that are 30-50% lower than a similar stainless steel implant. Nail damage by step drill contact reduces the fatigue strength of titanium alloy nails by 50% while it reduces the fatigue strength of stainless steel nails by 30% (14).

Our results showed no obvious signs of manufacturing weakness, but typical fatigue fractures of the titanium Gamma nail implants. Malreduction of the fracture, metastatic disease and metabolic bone disease are important risk factors for non-union and failure of the implant. In presence of any of these factors the surgeon should be alert of the possibility of impending failure of the implant, often within a period of 6 months after implantation. Reduction of the bone strength of the proximal femur due to stress shielding in which the majority of the stress is transferred through the nail instead of the bone is obviously higher for a stainless steel nail than for a titanium alloy implant. Sithiseripratip *et al* showed that the calculated von Mises stress values in both types of implants entail a substantial risk of fatigue failure (14).

We recommend follow-up with radiographic and physical examination at 6, 12 and 24 weeks post-operatively. This is necessary to evaluate the process of fracture healing in peritrochanteric pathologic fractures treated with the Gamma nail as well as to look for new sites of metastatic bone invasion. If there is no evidence of healing within 6 months postoperatively a nail exchange or other therapeutic options should be considered.

The Gamma nail is an appropriate implant to stabilize actual or impending pathologic inter- and subtrochanteric fractures. In cases of delayed union and nonunion, a fatigue fracture due to dynamic overload stress is expected sooner or later.

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