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Subtrochanteric fracture non-unions with implant failure managed with the "Diamond" concept

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ABSTRACT

Background: Subtrochanteric femoral non-unions in the setting of failed metalwork pose a challenging clinical problem. This study assessed the clinical outcome of patients treated according to the principles of the "Diamond" concept.

Methods: Between 2007 and 2011 all patients presented with a subtrochanteric atrophic aseptic non-union in the setting of metalwork failure (broken cephalomedullary reconstruction nail), and treated in a single tertiary referral unit were included to this study. The hypertrophic and the non-unions of pathologic fractures were excluded. The revision strategy was based on the "Diamond concept"; optimisation of the mechanical and the biological environment (implantation of growth factor (rhBMP-7),scaffold (RIA bone graft from contralateral femur) and concentrated mesenchymal stem cells (MSCs) harvested from the iliac crest). The minimum follow up was 26 months (16–48).

Results: Fourteen patients met the inclusion criteria. A specific sequence of metalwork failure was noted with initial breakage of the distal locking screws followed by nail breakage at the lag screw level. The intraoperative examination of the removed nails revealed no gross structural damage indicative of inappropriate drilling at the time of the initial intramedullary nailing. Varus mal-alignment was present in the majority of the cases, with an average of 5.2 degrees (0–11). The average time to distal locking screw failure was 4.4 months (2–8.5) and nail failure was 6.5 months (4–10). The time to union after the revision surgery was 6.8 months (5–12). Complications included two deaths in elderly patients (due to unrelated causes), one pulmonary embolism, one myocardial infarction, one below the knee deep vein thrombosis and one blade plate failure that required further revision with double plating and grafting.

Conclusion: Varus mal-alignment must be avoided in the initial stabilisation of subtrochanteric fractures. Distal locking screw failure is predictive of future fracture non-union and nail breakage. In the absence of sepsis, a single stage procedure based on the "Diamond concept" that simultaneously optimizes the mechanical and biological environment is a successful method for managing complex subtrochanteric atrophic non-unions with failed metalwork.

Introduction

Subtrochanteric fractures account for 10–34% of all hip fractures.[1,2] The incidence of subtrochanteric femoral shaft fractures has a bimodal age distribution, affecting young patients following high-energy trauma (resulting in significant fracture comminution) and older patients after low velocity trauma secondary to osteoporosis or metastatic pathological lesions.[3,4]

The subtrochanteric region extends distally from the lesser trochanter for a distance of 5 cm[2]. It is an area with predominantly cortical bone with poor vascularity that accounts for longer healing time after a fracture. Biomechanical features are also unique to the subtrochanteric region. The concentration of stresses, has been estimated to be up to 1200 lb/sq inch, the highest of the human skeleton.[5,6] The medial side is subject to high compressive stresses, whilst high tensile stresses are exerted on the lateral side.[7,8] The region of the proximal femur 3–10 cm below the lesser trochanter is eccentrically loaded and the compressive medial forces are considerably greater than the lateral tensile forces.[9] Thus, any internal fixation device is subject to significant concentrated bending stresses, leading to implant fatigue and fixation failure if the fracture does not unite on a timely manner.

In addition, the anatomical features of the subtrochanteric region, with the deforming forces of flexion and external rotation

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from the iliopsoas, abduction from the gluteal medius, adduction and shortening of the shaft from the hamstrings and adductors, as well as the degree of the comminution of the medial cortical buttress at the level of the fracture constitute a surgical challenge for the orthopaedic surgeon.[8,10,11] Intramedullary fixation devices are favoured over the extra-medullary fixation, due to the shorter lever arm of the fixation, the better load sharing and less bending movement across the fracture site and implant.[4,12,13] The overall incidence of non-union or delayed union of subtrochanteric fractures, and subsequent failure for any type of fixation varies from 7% to 20%.[11,14,15]

Over the last years a specific framework of preoperative assessment and subsequently management strategy of non-unions in general has been introduced under the name "Diamond concept".[16–18] The optimisation of the mechanical environment (revision of fixation) along with the enhancement of the multidimensional biological pathways of bone healing has been proposed as the framework of a single stage surgical revision for the recalcitrant or atrophic non-unions with implant failure.

The aim of this study was to evaluate the characteristics and the outcome of a cohort of patients with subtrochanteric non-unions and metalwork failure that were treated according to the diamond concept after an index procedure of a trochanteric entry point locked cephalomedullary nailing.

Patients and methods

Between June 2007 and June 2011, a retrospective cohort study (institutional board approval was obtained) conducted at our institution investigated a series of skeletally mature patients, with subtrochanteric femoral non-unions and failed metalwork following initial locked intramedullary nailing (Gamma 3 IM nailing system; Stryker Biotech). Institutional departmental board approval was obtained for the study.

Non-union was defined as the absence of radiographic progression of healing 6 months post-surgery or hardware failure more than 5 months post-surgery. All the atrophic aseptic subtrochanteric non-unions with failure of metalwork presented to our institution were included in this study. The exclusion criteria were hypertrophic non-unions, pathologic fractures, and non-unions stabilised with implants other than intramedullary nails.

The collected data included demographics, initial fracture pattern, method of stabilisation, quality of fracture reduction at index surgical procedure, mode and pattern of failure of the intramedullary nail, time to revision of fixation, details of revision procedure, complications, and time to final union.

The preoperative evaluation after history taking, clinical examination and blood inflammatory markers excluded the presence of infection in all cases. Imaging studies included plain radiographs of the pelvis, hip and femur, and a CT scan of the affected hip. The revision procedure in all cases was based on the "Diamond concept"[16–18] (revision of the failed implant together with the application of an osteoinductive factor [recombinant human bone morphogenetic protein-7 (Osigraft® Olympus)], of an osteoconductive scaffold [autologous reaming debris obtained via the Reamer-Irrigator-Aspirator from the contralateral femur (RIA, DePuy Synthes, North America, Inc., West Chester, PA, USA)], and osteoprogenitor cells (MSCs) s [nucleated cell concentrate harvested from the iliac crest (MarrowStim Concentration System, Biomet Biologics Inc., Warsaw, IN)].

The single stage revision surgery consisted of the following standardized surgical steps in each case:

1. The patient was positioned supine on a fracture table.
2. Harvesting from the contralateral femur using the RIA system and collection of the filtered reaming aspirate as previously described.[19]
3. Aspiration of 60 ml of bone marrow from the iliac crests, which was then concentrated to 7mls of nucleated cells using the MarrowStim system.
4. Removal of the broken hardware from the non-union site (use of the conical extraction rod and extraction hook from the Implant Extraction Set – Stryker®).
5. Debridement of the non-union site, removal of fibrous tissue, and collection of deep samples that were sent for microbiology analysis to definitely exclude the presence of low grade infection.
6. Prophylactic antibiotics (single dose flucloxacillin and gentamicin) was administered after collection of the samples as per our institutional protocol.
7. The proximal femur was fixed with an appropriately sized 95 degree blade plate (DePuy-Synthes) or the Affixus® Hip Fracture nail (Biomet). Standard operative techniques for both types of implant were utilised.
8. Implantation of the composite graft at the debrided non-union site.
9. Watertight closure was performed in layers without the use of drains for the containment of the graft material.

The post-operative mobilisation scheme included toe-touch weight bearing using two crutches or a zimmer frame for 4–6 weeks, followed by progressive increase to full weight bearing at 3 months. Thromboprophylaxis (low molecular weight heparin subcutaneously (Tinzaparin 4.500 IU)) was administered for the six weeks of the postoperative period of the restricted weight bearing. Outpatient follow-up with clinical and radiographic assessment was carried out at 6 weeks, 3, 4, 5, 6, 8, 12 and 18 months or until radiographic union (Figs. 1–3).

Results

During the pre-specified time frame, 50 femoral non-unions were managed at our institution (tertiary referral centre). Fourteen 14/50 (28%) cases met the inclusion criteria. The mean patient age was 65 years (range 33–92). There were 8 males and 6 females (Table 1).

A specific pattern of metalwork failure was observed; initial breakage of the distal locking screws, was followed by fracture of the nail at the level of the lag screw insertion area through the metaphyseal part of the nail (Figs. 1a,b, 2a–c and 3a–d). At this critical region of the neck of the nail, where the forces are transmitted from the femoral neck to the diaphysis, the cross sectional area of the nail is reduced by approximately 70%. Analysis of the nails intra-operatively after extraction revealed no structural damage to the nail from previous passage of the drill bit or the lag screw itself into the femoral head during the index operation. An analysis of three of the broken nails under an electron microscope was also performed and did not reveal any structural deficiencies.

Varus mal-reduction was present in 11/14 cases, with an average of 5.2 degrees (range 0–11). The average time to distal locking screw failure was 4.4 months (2–8.5 months) and nail failure at the critical region was 6.4 months (5–10) post the index surgery.

Eleven of the 14 cases were revised to a 95 degree angle blade plate and three to an Affixus® Hip Fracture nail. The average time to final clinical and radiological union was 6.8 months (range 5–12). All patients returned to the their pre-injury mobility status. During an average follow-up period of 26 months (range 16–48 months) the observed complications included two deaths (both of them due to unrelated causes), one pulmonary embolism, one below the knee deep vein thrombosis, and one blade plate failure 4 months after the first revision surgery. This case had further revision surgery with a double-plate construct (95 degree blade plate and an anterior femoral plate) and graft (BMP-7, MSCs and RIA Graft) and before progressing to union after 6 months (Fig. 2).