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

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ARTICLE INFO

Keywords: Subtrochanteric non-union Diamond concept BMP-7 RIA graft

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.

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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 cm². 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).



Fig. 1. a) AP radiograph of right hip demonstrating a subtrochanteric fracture non-union with a broken nail in situ 5 months after fixation. b) AP radiograph of right distal femur illustrating the presence of broken distal locking screws. c), d) AP and lateral radiographs of the right proximal femur showing the union of the fracture following the application of the diamond concept (revision of fixation to a blade plate and implantation of composite graft).

Table 1

The basic characteristics of the presented cohort of patients.

Pt	Age/Gender	Type of trauma	Fracture classification		Varus mal- reduction	Time to metalwork failure (months)		Union (months)	Complications
			Description	AO	(degrees)	Screw	Nail		
1	75/Male	Low	Subtroch #	32-A2-1	7	4	5	5*	Died after 6/12 – unrelated
2	75/Female	Low	Subtroch #	32-A2-1	5	3	5	8 *	Pulmonary embolism
3	90/Female	Low	Subtroch #	32-A2-1	5	6	8	12 *	N/A
4	33/Male	High	Comminuted Subtroch #	32-B3-1	5	6	10	10 ^a	N/A
5	39/Male	High	Reverse oblique + subtroch. extension	31-A2-3	5	6	10	6 ^a	N/A
6	92/Male	High	Subtroch #	32-A2-1	11	3	5	5*	Died after 9/12 – unrelated
7	76/Female	Low	Subtroch #	32-A2-1	10	6	8.5	6.5 *	Below knee deep vein thrombosis
8	83/Male	Low	Subtroch #	32-A2-1	9	3	5	6*	N/A
9	63/Female	Low	Subtroch #	32-A2-1	9	4	6	7*	Breakage of blade plate – second revision to double plate construct
10	38/Male	High	Subtroch #	32-B3-1	5	6	8	8 ^a	N/A
11	70/Male	Low	Subtroch #	32-B3-1	0	4	6	6*	N/A
12	81/Female	Low	Subtroch #	32-A2-1	0	3	5.5	5*	N/A
13	67/Male	Low	Subtroch #	31-A2-3	3	4	6	6*	N/A
14	76/Female	Low	Subtroch #	32-A2-1	0	4.5	5	7*	Post-op MI fully recovered

N/A, Not applicable.

* Denotes that nail was revised to blade plate.

^a Denotes that nail was revised to nail again.

Discussion

The treatment of subtrochanteric fractures is a challenging and a technically demanding endeavour for surgeons. The fracture displacement and comminution, the high concentration of stresses in this area, the poor bone quality in the elderly and the slow pace of bone healing of some of the affected patients result to high numbers of non-union and implant failures.¹¹ The management of these cases of subtrochanteric non-union in the context of metalwork failure constitutes a difficult clinical scenario even for the experienced trauma surgeon. This study represents a cohort analysis of such cases treated in a single referral centre over a period of 4 years.

This is retrospective study and its inherent limitations should be taken into account. No comparative analysis could be performed due to absence of a control group of patients managed with a different protocol, or in between the subgroups of this cohort due to its relatively small numbers. Over a period of 4 years this cohort consists of only 14 cases, a fact that can be explained by the rarity



Fig. 2. a) AP radiograph of the right hip demonstrating a subtrochanteric non-union with a broken nail in situ 6 months following the original fixation of the fracture. b) Lateral radiograph of the right hip illustrating subtrochanteric non-union with a broken nail in situ. c) AP radiograph distal femur showing the broken distal locking screws. d) Intraoperative picture illustrating stabilisation of the non-union following removal of the broken nail with a blade plate and the composite graft to be implanted (BMP-7, concentrated bone marrow aspirate and RIA graft). e) Intra-operative picture demonstrating the application of a second plate anteriorly following the implantation of the graft at the non-union site. f), g) AP and lateral radiographs illustrating union of the fracture.

of these complex cases with simultaneous mechanical failure and atrophic non-union, even in a large tertiary referral centre covering a population of more than 3 million people. This fact could also be an indication of a high-level surgical management of acute subtrochanteric fractures provided in a regional level. However, the true incidence of this serious complication could not be determined accurately since the precise number of subtrochanteric fractures that have been treated remains unknown.

One of the most consistent findings in this cohort of patients was the varus mal-alignment of the fixed acute fractures. This is a well-recognised risk factor for failure and non-union of these fractures.^{20–22} The unique biomechanical features of the subtrochanteric region, the great bending stresses developing at the medial cortex along with the deficiency/comminution of the medial buttress can explain the mode of failure especially in the presence of varus mal-reduction.^{3,4,23} The importance of optimal fracture reduction in this anatomic region is highlighted in this series and is emphasized by the findings of other clinical and biomechanical studies.^{3,7,11,23–26}

The second consistent finding in this study was the mode of the implant failure. The "self-dynamisation" of the initial reconstruction nail, as defined by the breakage of the distal locking screws indicates the instability of the overall mechanical construct. Over a period of a few weeks this was followed by the breakage of the nail itself at its junction with the lag screw. This has also been previous described and represents the standard mode of failure of cephalomedullary nails.^{24,27–29} The metalwork failure should be considered the consequence rather than the cause of the non-union.

The early identification of the breakage of the distal locking screws in a patient who is still symptomatic at the fracture level should be utilised as a predictor of a pending failure, and should initiate action by the treating surgeon towards either restriction of weight bearing or revision surgery performed in an institution with experience in the management of these non-unions.

Until recently, the approach to impaired fracture healing and non-union was based on the triangular concept, which placed more emphasis on bone regeneration, utilisation of growth factors, scaffolds and mesenchymal stem cells.¹⁸ The addition of mechanical stability to these three dimensions of biological enhancement of bone healing, transformed the above traditional approach into the "Diamond" concept and highlighted the important role of stability in fracture healing.

The gold standard augmentation in the treatment of fracture non-unions has been autologous bone graft harvested from the iliac crest.³⁰ Iliac crest bone harvesting is associated with significant donor site morbidity and can also result in limited graft availability.³¹ More over in the elderly population the underlying osteopenia and the replacement of red marrow to yellow marrow precludes the harvesting of autologous graft from the pelvis. Contemporary autologous bone harvesting has evolved lately with the introduction of the RIA system. The high volume of the harvested bone graft along with the limited associated morbidity has made the RIA harvesting the method of choice in our unit.^{32,33} The filtered reaming debris possess proven osteogenic properties, whilst at the same time offers a large volume of morselised scaffold covering the bony defect/non-union area.^{34,35}



Fig. 3. a) AP radiograph of the right hip 3 months after stabilisation of the sub trochanteric fracture with a cephalomedullary nail. b) AP pelvic radiograph illustrating broken metal work at 6 months follow up. c) Lateral radiograph illustrating broken metal work at 6 months follow up. d) AP radiograph of distal femur illustrating the broken distal locking screws. e), f) AP and lateral radiograph of the right hip illustrating union of the sub-trochanteric fracture which was stabilised with a lag screw and a blade plate and implantation of the composite bone graft.

The utilisation of composite bone grafts in recalcitrant nonunions, with the combination of potent osteoinductive proteins (in the form of rhBMP-7³⁶) and cells with osteogenic potential (in the form of concentrated osteoprogenitor cells³⁷) has been also advocated with excellent results.³⁸ The complexity of these cases, the proven limited healing potential of atrophic non-union sites, and the high risk of implant failure due to the biomechanical characteristics of the subtrochanteric region, provide the grounds for using the full spectrum of fracture healing optimization options.

Additionally, a comprehensive cost/efficacy analysis, including direct and indirect medical costs as previously defined,³⁹ further strengthens the argument of performing this type of complex single stage surgery, optimising the rates of eventual healing, avoiding prolonged follow up and most importantly the need for additional revisions.

The number of studies commenting on the outcomes of subtrochanteric fracture non-unions is limited.^{15,40–45} The present cohort reflects the practice of a large referral centre in the treatment of subtrochanteric non-unions, according to the principles of the "Diamond" concept. Preoperative evaluation on a case-bycase basis, exclusion of infection and planning according to this conceptual framework, results in a safe and efficient management in a single stage revision surgery. The use of a full spectrum of biological and mechanical enhancement is proposed as a successful, time and cost-saving approach for the management of the atrophic subtrochanteric non-unions with implant failure.

Conflict of interest

All authors declare that they have not received anything of value relating to the preparation of this manuscript.

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