

## ■ TRAUMA

# Post-operative outcomes of atypical femoral subtrochanteric fracture in patients on bisphosphonate therapy

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**Management of bisphosphonate-associated subtrochanteric fractures remains opinion- or consensus-based. There are limited data regarding the outcomes of this fracture.**

We retrospectively reviewed 33 consecutive female patients with a mean age of 67.5 years (47 to 91) who were treated surgically between May 2004 and October 2009. The mean follow-up was 21.7 months (0 to 53). Medical records and radiographs were reviewed to determine the post-operative ambulatory status, time to clinical and radiological union and post-fixation complications such as implant failure and need for second surgery.

The predominant fixation method was with an extramedullary device in 23 patients. 25 (75%) patients were placed on wheelchair mobilisation or no weight-bearing initially. The mean time to full weight-bearing was 7.1 months (2.2 to 29.7). The mean time for fracture site pain to cease was 6.2 months (1.2 to 17.1). The mean time to radiological union was 10.0 months (2.2 to 27.5). Implant failure was seen in seven patients (23%, 95 confidence interval (CI) 11.8 to 40.9). Revision surgery was required in ten patients (33%, 95 CI 19.2 to 51.2).

A large proportion of the patients required revision surgery and suffered implant failure. This fracture is associated with slow healing and prolonged post-operative immobility.

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Bisphosphonates are potent anti-resorptive agents used in the prevention of osteoporotic fractures. Alendronate is a typical bisphosphonate and has been shown to reduce the incidence of vertebral and hip fractures in postmenopausal osteoporotic women.<sup>1-3</sup>

Recent reports suggest that prolonged use of bisphosphonates may be associated with severe suppression of bone turnover, resulting in atypical insufficiency fractures in unusual locations.<sup>4-11</sup> The majority of these reports have described fractures at the subtrochanteric region of the femur.<sup>11,12</sup> The number of atypical subtrochanteric fractures thought to be associated with bisphosphonates is estimated as one per 1000 fractures per year.<sup>12</sup> It is postulated that several contributory mechanisms are involved, including increased advanced glycosylated end-products,<sup>5,6,8</sup> increased mineralisation<sup>6,7,13</sup> and the accumulation of microfractures<sup>5-8,10</sup> in the region of maximal tensile loading.<sup>14</sup> Radiological features of such fractures include a simple transverse pattern<sup>4,9,11,15</sup> with a unicortical beak<sup>6-9,15</sup> in an area of cortical hypertrophy.<sup>5-9,15</sup>

Against this background, the American Society for Bone and Mineral Research (ASBMR) appointed a task force to address key questions related to this problem. The first report<sup>16</sup> identified the absence of studies eval-

uating surgical treatment strategies and outcomes for atypical subtrochanteric fractures. It identified that most management strategies currently are opinion- or consensus-based.<sup>16</sup> Subtrochanteric fractures are debilitating. In a prospective cohort study of 87 patients, Ekström et al<sup>17</sup> reported that more than half (52%) of their patients did not regain their pre-fracture level of activities of daily living and mortality was 25% at 24 months follow-up.

Therefore, in order to better understand the outcomes, and manage subtrochanteric fractures in patients on bisphosphonate therapy, we performed an observational cohort study to determine clinical and functional outcomes using the post-operative ambulatory status, and time to clinical and radiological union. We also assessed post-fixation complications such as implant failure and need for second surgery.

## Patients and Methods

Patient data for this study was retrieved from a database of patients at the Singapore General Hospital, Republic of Singapore. In the study period between May 2004 and October 2009, we identified 33 consecutive patients, all of whom were female, treated surgically after presenting with atypical subtrochanteric fractures whilst on bisphosphonate therapy. Some of

**Table I.** Patient demographics and post-operative outcomes

Categories		Range
Mean age (yrs)	67.5	47 to 91
Mean duration of bisphosphonate therapy (yrs)	4.9	2 to 10
Mean duration of follow-up (mths)	21.7	0 to 53
<b>Fixation device</b>		-
Intramedullary	10	-
Proximal femoral	4	-
Intramedullary nail	6	-
Extramedullary	23	-
Dynamic condylar screw	10	-
Dynamic hip screw	8	-
Plate and screws	5	-
<b>Post-operative weight-bearing status</b>		
Wheelchair mobilisation	12 (36%)	-
Non-weight-bearing	13 (39%)	-
Partial weight-bearing	8 (24%)	-
Mean time to full weight-bear (mths)	7.1	2.2 to 29.7
Mean time for fracture site pain to cease (mths)	6.2	1.2 to 17.1
Mean time to radiological union (mths)	10.0	2.2 to 27.5
Proportion prescribed teriparatide	10 (33%)	-
Mean duration of use (mths)	4.4	1.0 to 15.2

\* CI, confidence interval

these patients have previously been reported on.<sup>11</sup> The sub-trochanteric region is defined anatomically as the region of the femur between the inferior border of the lesser trochanter and the junction of the proximal and middle third of the femoral shaft, usually taken to be the zone extending from the lesser trochanter to 5 cm distal to the lesser trochanter.<sup>5,12,18</sup>

The mean age of patients was 67.5 years (47 to 91). The mean duration of bisphosphonate therapy was 4.9 years (2 to 10), with 22 (66.7%) of them on five or fewer years of therapy. In all 23 (69.7%) patients were fixed with an extramedullary device. The remainder were fixed with an intramedullary implant. Teriparatide, a recombinant form of parathyroid hormone, was prescribed in ten (30.3%) patients with a mean duration of 4.4 months (1.0 to 15.2) (Table I).

We used the revised criteria of the ASBMR task force (2013) in our definition of an atypical fracture.<sup>19</sup> We included patients who fulfil at least four of the five major features, namely (1) non-comminuted or minimally-comminuted fractures, (2) sustained with minimal or no trauma, (3) the fracture line originates at the lateral cortex and is substantially transverse in its orientation, although it may become oblique as it progresses medially across the femur, (4) complete fractures extend through both cortices and may be associated with a medial spike; incomplete fractures involve only the lateral cortex and (5) localised periosteal or endosteal thickening of the lateral cortex is present at the fracture site.<sup>19</sup> We excluded those due to road traffic accidents, high-energy trauma, fall from height or underlying malignancy. The three patients lost to follow-up for more than six months were also excluded from analysis.

Past medical and drug history were obtained to ascertain the duration of bisphosphonates use and the mechanism of injury. All patients had radiographs of the pelvis and affected hip taken at presentation. Surgical fixation was performed according to surgeon's preference at the earliest available date. Immediate post-operative radiographs of the affected femur were taken in two views (anteroposterior (AP) and lateral). The pre-operative and immediate post-operative ambulatory status was recorded.

The patients were tracked from presentation and followed until the last recorded outpatient visit. Use of bisphosphonates was discontinued upon the occurrence of the fracture. At each follow-up, radiographs were repeated and patients were assessed for weight-bearing status and presence of fracture site pain upon manual palpation. We also recorded the need for revision surgery due to delayed union or implant failure. Clinically, union was assessed by the absence of tenderness upon manual palpation of the fracture site and the capacity to fully weight bear. A fracture was considered radiologically united when three of four cortices demonstrated cortical bridging. Based on this definition, two senior practitioners (one orthopaedic surgeon (DTC), and one musculoskeletal radiologist (MAP)) reviewed the radiographs independently to determine union.

Ethical approval was obtained from the Institutional Review Board before commencement of the study.

**Statistical analysis.** This was performed using the Statistical Package for the Social Sciences (SPSS 17.0, SPSS Inc., Chicago, Illinois). Differences in proportions were tested using chi-squared test and means were compared using Student's *t*-test. All analyses were defined as statistically significant when the *p*-value was less than 0.05. Inter-observer

**Table II.** Revision surgery and implant failure

Categories	Range	
Number of patients (n)	30	
Proportion requiring revision operation	10 (33%)	95% CI (19.2 to 51.2)
Bone grafting	4 (13%)	95% CI (5.3 to 29.7)
Implant failure	6 (20%)	95% CI (9.5 to 37.3)
Mean time to revision operation (mths)	6.2	2.4 to 25.0
Mean time to implant failure (mths)	7.9	2.4 to 25.0

**Table III.** Clinical and radiological outcomes stratified by fixation device

Categories	Extramedullary (Range)	Intramedullary (Range)
<b>Post-operative weight-bearing status (n = 33)</b>		
Wheelchair mobilised	11 (48%)	1 (10%)
Ambulation with aid (NWB/PWB)	12 (52%)	9 (90%)
Number of patients excluding lost to follow-up (n = 30)	21	9
Mean time to full weight-bearing (mths)	6.7 (2.2 to 29.7)	8.2 (3.1 to 14.6)
Mean time for fracture site pain to cease (mths)	5.2 (2.2 to 17.1)	8.8 (2.4 to 14.1)
Mean time to radiological union (mths)	10.9 (3.4 to 29.7)	7.7 (2.2 to 14.7)
Proportion requiring revision surgery	8 (38%) 95% CI (20.8 to 59.1%)	2 (22%) 95% CI (6.0 to 54.7%)
Number of implant failures	6 (29%) 95% CI (13.8 to 50.0%)	1 (11%) 95% CI (2.0 to 43.5%)

\* CI, confidence intervals; NWB, non-weight-bearing; PWB, partial weight-bearing

correlation between the two senior practitioners was compared using the Intraclass Correlation Coefficient on a two-way mixed model with single measures.

## Results

Of the 33 patients who fulfilled the revised ASBMR criteria, three patients were lost to follow-up at zero (patient did not return to the clinic at all), one and seven months. They were treated with a dynamic hip screw, a proximal femoral nail and a dynamic condylar screw, respectively. The mean follow-up for the remaining 30 patients from the time of surgery for the fracture was 21.7 months (0 to 53). There was one patient (patient 4) with nonunion at 20 months follow-up. She was fixed with a proximal femoral nail. She refused a secondary procedure due to comorbidity and high operative risk and was managed conservatively.

Post-operatively, 13 out of 33 patients (39%) were placed on non-weight-bearing, 12 (36%) were mobilised in a wheelchair and eight (24%) partial weight-bearing, based on the treating surgeon's management preference and their intra-operative judgment of implant stability. The mean time to full weight-bearing for the 30 patients followed up was 7.1 months (2.2 to 29.7). The mean time for fracture site pain to cease was 6.2 months (1.2 to 17.1). The mean time to radiological union was 10.0 months (2.2 to 27.5) with an Intraclass Correlation Coefficient (ICC) of 0.9 (95% CI 0.91 to 0.98) between the assessment by the two senior practitioners.

**Revision surgery and implant failure (Table II).** Implant failure was seen in seven of the 30 patients (23%, 95% CI 11.8 to 40.9) after a mean duration of 7.9 months (2.4 to 25.0). Revision surgery was required in ten (33%, 95% CI 19.2 to 51.2) patients after a mean duration of 6.2 months

(2.4 to 25). Of the ten patients, four patients required revision surgery for bone grafting due to lack of fracture healing while the other six patients (including patient 4) required revision surgery for implant failure. We found that surgeons generally performed bone grafting at four months if no evidence of bone healing was seen. There was one exception which was performed at three months as the surgeon felt that the fixation had shifted and was not maintaining optimal reduction.

**Extramedullary device (Table III).** Of the 23 patients, ten were treated with a dynamic condylar screw, eight with a dynamic hip screw and the remaining five with plates and screws. Eleven (48%) patients required wheelchair mobilisation post-operatively. Two patients mentioned above were lost to follow-up. With respect to clinical parameters, the mean time to full weight-bearing was 6.7 months (2.2 to 29.7) and for cessation of fracture site pain was 5.2 months (2.2 to 17.1) in the remaining 21 patients. The mean time to radiological union was 10.9 months (3.4 to 29.7). Revision surgery was required in eight patients (38%) after a mean duration of 6.3 months (2.4 to 25.0). Implant failure was seen in 6 (29%) patients after a mean duration of 7.3 months (2.4 to 25.0).

**Intramedullary device (Table III).** Of the ten patients, four were treated with a proximal femoral nail and the remaining six with an intramedullary nail. There were nine patients (90%) who were able to ambulate with an aid (no weight-bear or partial weight-bear) immediately after operation. There was one patient who was lost to follow-up. With respect to clinical parameters, the mean time to full weight-bearing was 8.2 months (3.1 to 14.6) and cessation of fracture site pain occurred at a mean of 8.8 months (2.4 to 14.1) in the remaining nine patients at follow-up.



Fig. 1a



Fig. 1b

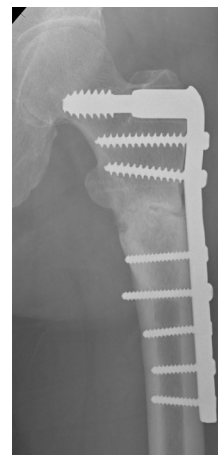


Fig. 1c

Anteroposterior radiographs of patient 15 showing a) when full weight-bearing was achieved at three months, b) implant failure at four months and c) bone union at 18 months after the original fixation.

The mean time to radiological union was 7.7 months (2.2 to 14.7). Implant failure was seen in one patient (11.1%) after 11.4 months. This patient (patient 23) was conservatively managed. Revision operation was required in two other patients (22.2%) after a mean duration of 5.5 months (4.8 to 6.2), although this was not done for patient 4 for the above-mentioned reasons.

The proportion of patients wheelchair-bound postoperatively in the extramedullary (EM) group is 0.48 while that in the intramedullary (IM) group is 0.11 ( $\chi^2 = 4.31$ ,  $p = 0.04$ ). There was no significant difference in the time to full weight-bearing for IM ( $M = 8.18$ ,  $SD = 1.49$ ) and EM ( $M = 6.71$ ,  $SD = 1.44$ ) groups ( $t = 0.58$ ,  $p = 0.56$ ). There was no significant difference in the time for pain to cease for IM ( $M = 8.72$ ,  $SD = 1.64$ ) and EM ( $M = 5.18$ ,  $SD = 1.05$ ) groups ( $t = 1.78$ ,  $p = 0.09$ ). There was no significant difference in the time to radiological union for IM ( $M = 7.7$ ,  $SD = 1.91$ ) and EM ( $M = 10.9$ ,  $SD = 1.49$ ) groups ( $t = 1.22$ ,  $p = 0.23$ ). The proportion of EM patients requiring revision surgery is 0.38, while that in the IM group is 0.22 ( $\chi^2 = 0.71$ ,  $p = 0.40$ ). The proportion of EM patients with implant failure is 0.29 while that in the IM group is 0.11 ( $\chi^2 = 1.07$ ,  $p = 0.30$ ).

We report three patients of particular interest. Patient 15 was a 65-year-old woman who was prescribed alendronate for a period of three years. She sustained a subtrochanteric fracture of her left femur in October 2006 that was fixed with a dynamic condylar screw. She was able to fully weight-bear by the third month after surgery. Radiographs taken demonstrated that the fracture had not united. Subsequently, implant failure was noted one month later and she required a revision surgery. Radiological union was only achieved 18 months after the original fixation (Fig. 1). Patient 21 was a 73-year-old woman who received alendronate for a period of seven years. She sustained a right subtrochanteric fracture in June 2007. The fracture was fixed with a proximal femoral locking plate. She was able to fully weight-bear by the fifth month after surgery.

Similarly, radiographs taken demonstrated that the fracture had not united. Implant failure was noted three months later. Revision surgery was performed with radiological union only achieved 22 months after the index surgery (Fig. 2).

Patient 23 was a 53-year-old woman who was prescribed alendronate for a period of seven years and she sustained a right subtrochanteric fracture in December 2006. The fracture was fixed with an intramedullary nail. By the seventh month after surgery she was able to fully weight-bear but the radiographs taken during that visit showed deficient callus formation over the lateral aspect (Fig. 3). Subsequently, implant failure was noted four months later. She was conservatively managed. Radiological union was only achieved 15 months after the initial fixation (Fig. 3).

## Discussion

Subtrochanteric fractures are difficult to manage as the position of the proximal fragment is influenced by the actions of the gluteal muscles (abduction) and the strong psoas muscle of the hip (flexion and external rotation) while the distal fragment position is affected by the adductors and hamstrings. These forces act upon the fixation device after operation resulting in stress concentration in the subtrochanteric region.

In our study, the mean time to union (ten months), proportion of patients requiring revision surgery (33%) and implant failure (23%) are higher than those reported in recent literature. Lee et al<sup>20</sup> studied 66 patients with a mean age of 36.1 years with subtrochanteric fractures. They found that the mean time to union was 3.8 months with only one implant failure and one delayed union requiring additional surgery to achieve bone union. Likewise, Oh et al<sup>21</sup> reported a mean time of five months to union in 20 patients fixed with a locking plate. Barquet et al<sup>22</sup> reported a mean time of 4.3 months to union in 43 patients treated with a long gamma nail. We postulate that this resulted from the difference in patient profile: our patients tended to be older,

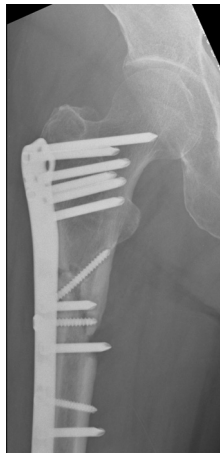


Fig. 2a



Fig. 2c



Fig. 2c

Anteroposterior radiographs of patient 21 showing a) when full weight-bearing was achieved at five months, b) implant failure at eight months and c) bone union at 22 months after the original fixation.



Fig. 3a



Fig. 3c



Fig. 3c

Anteroposterior radiographs of patient 23 showing a) when full weight-bearing was achieved at seven months, b) implant failure at 11.4 months and c) bone union at 15 months after the original fixation.

on prolonged bisphosphonate therapy and suffered atypical insufficiency fractures. In contrast, the fractures described in the literature tend to belong to younger patients with high velocity trauma. Similarly, Kulkarni and Moran<sup>23</sup> studied 58 patients with subtrochanteric fractures who were treated with the dynamic condylar screw. They found that in patients < 50 years old, 9% of their patients required revision surgery and 18% of their patients suffered implant failure. In contrast, in the elderly subgroup (> 50 years of age) 19% of their patients required revision surgery and 26% of their patients suffered implant failure.

Our results suggest that atypical subtrochanteric fractures compare poorly to other more common femoral fractures. Historically, union of femoral shaft fractures usually occurs within 13 to 16 weeks even with conservative, non-operative management.<sup>24-27</sup> Likewise, union of intertrochanteric fractures was reported to usually occur within three to four and a half months after surgery.<sup>28-30</sup>

As reported earlier, although union was achieved in all but one patient in our study, up to 80% of our patients were mobilised in a wheelchair or non weight-bearing initially. We found fracture healing to be slow and patients subjected to a prolonged period of immobility. This is of particular importance for our elderly patients as the decrease in activity can lead to complications of immobility and deconditioning. We believe that patients on bisphosphonate therapy with atypical subtrochanteric fractures are at one end of the spectrum and are associated with much poorer outcomes than those previously reported.

We highlighted three interesting patients (numbers 15, 21 and 23), all of whom started full weight-bearing before radiological union, which resulted in accelerated implant failure. We believe excessive stress shielding of the bone by the implant could have occurred in these three patients leading to a reduction in stress transfer to the bone.<sup>31</sup> With the delay in union, the implant underwent fatigue failure at

the level of the fracture.<sup>32</sup> In addition, intramedullary nails are weight-sharing implants that allow immediate weight-bearing after static locking even in unstable fractures.<sup>33</sup> They provide greater fatigue strength and stability but can still fail at the narrowest site under excessive strain or delayed fracture healing because of static interlocking.<sup>34</sup> As discussed earlier, the subtrochanteric region is an area of stress concentration; coupled with the slow healing rate in patients on bisphosphonate therapy, we recommend exercising caution when determining the transition to full weight-bearing for this group of patients.

We note the following limitations to our study. The association between long-term bisphosphonate use and atypical fractures was first described by Odvina et al<sup>10</sup> in 2005. They reported nine patients who had been treated with alendronate for three to eight years and sustained non-traumatic fractures. This and many case reports and case reviews since have suggested common features of atypical subtrochanteric fractures. Major features include no to minimal trauma and, on radiography, transverse fracture configuration. Minor features were that fractures were commonly preceded by prodromal pain and, on radiographs, the appearance of beaking of the cortex with bilateral thickened diaphyseal cortices.<sup>6,7,11,12,16</sup> However, these criteria are not diagnostic. In a case series of four patients, Tan et al<sup>15</sup> noted the presence of atypical features on radiographs in bisphosphonate-free patients. The distinction between typical stress fractures and atypical subtrochanteric fractures remains poorly defined in the literature.

Second, we had a small sample population as the incidence is relatively uncommon. Treatment, including the use of parathyroid hormone, was determined by the surgeon's experience and training. Our cohort was also mixed with patients receiving either intramedullary or extramedullary implants. Thus, most of our associations tested did not reach statistical significance. Although intramedullary devices were significantly associated with better immediate postoperative ambulatory outcomes, this may be confounded by the inherent bias in the implant design. Surgeons may have intended for early ambulation when they chose to fix a patient with an intramedullary device. We were unable to identify factors that may impact outcome significantly. Intramedullary devices appear to be superior with respect to complications of treatment and time to radiological union. A larger study with randomisation and stratification into treatment groups would be required to account for potentially confounding variables.

In summary, subtrochanteric fractures led to considerable morbidity in all our patients. A significant proportion of patients required revision surgery (33%) and suffered implant failure (23%). This fracture is also associated with slow healing and prolonged post-operative immobility.

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