

Femoral medialisation, fixation failures and functional outcome in trochanteric hip fractures treated with either a sliding hip screw or intramedullary nail from within a randomised trial

Abstract

Objectives

The aim was to determine if femoral medialisation influences residual pain and mobility and to determine if fixation method or fracture pattern influences the tendency to medialise.

Design

This study used data from within a randomised controlled trial.

Setting

Peterborough City Hospital

Patient/ Participants

844 patients presenting with a trochanteric hip fracture were randomised. 538 were available for 1-year follow-up. Fractures were classified according to AO classification as 31 A1, A2, A3.

Intervention

Randomised to fixation with a Targon PF Nail or Sliding Hip Screw (SHS)

Outcome Measures

Femoral medialisation was calculated from follow up x-rays at a minimum of 28 days post fixation. Pain and mobility scores were assessed at 1 year by an independent blinded observer. Fixation failure and revision procedures were assessed at a minimum of 1 year from injury.

Results

Patients with >50% medialisation had worse pain ($p=0.012$) and mobility scores ($p=0.013$) at one year. They also had more fracture healing complications ($p=0.021$) and required more

revision procedures ($p=0.014$). Fractures treated with SHS were more likely to medialise $>50\%$ compared to intramedullary nail (IM) ($p<0.001$). A2 and A3 fractures were more likely to medialise and A3 fractures were more likely to undergo $>50\%$ medialisation ($p<0.001$).

Conclusion

Our study demonstrates the previously theoretical predisposition for unstable hip fractures treated with SHS to undergo femoral medialisation and correlates this with worse functional outcomes. It supports the use of IM nails for A3 fractures, which have a significant tendency to medialise.

Level of Evidence - II

Introduction

Femoral medialisation refers to medial displacement of the femoral shaft relative to the proximal fragment of a trochanteric fracture of the proximal femur and has been associated with fixation failure.¹ Theoretically intramedullary devices decrease the risk of medialisation by acting as a buttress to the femoral neck and to the lateral cortex of the distal fragment.² Numerous studies have compared extramedullary versus intramedullary implants, with the primary outcome being fixation failure or revision.^{3,4,5,6} Historically intramedullary implants had a significant risk of fracture distal to the implant resulting in a higher revision rate.^{3,4,6} With the improvement in implant design, recent studies have found there is no difference in revision rate between intramedullary and extramedullary devices.⁵

Only a proportion of fractures with femoral medialisation will go onto failure and require revision.¹ To our knowledge no studies have examined the affect of femoral medialisation on residual pain and mobility after fixation of a trochanteric hip fracture. We used data from patients that had been entered in a randomised trial comparing the Targon Proximal Femoral

(PF) intramedullary nail (BBrown, Tuttlingen) with the Sliding Hip Screw (SHS) (Corin PLC, Cirencester)(Biomet Ltd, Bridgend).⁷ The aim of this study was to determine if femoral medialisation affects residual pain and long-term mobility and to determine if fracture pattern and type of implant (extramedullary versus intramedullary) predispose to medialisation.

Patients and Methods:

From April 2002 to December 2013 patients sustaining a trochanteric fracture of the proximal femur within Peterborough and Stamford NHS trust were randomised to treatment with either a Targon PF nail or SHS by pre-operatively selecting a sealed envelope prepared by an independent investigator. The results for the first 600 patients admitted to this study have been published.⁷ A standardised proforma was used to record patient information on admission. Mobility was assessed using a scale of 0 to 9.^{8,9} Nine represents full mobility indoors and outdoors without walking aids; Zero represents a bed-bound patient. Fractures were grouped by OTA classification as trochanteric (31A) stable (A1), unstable (A2), and transverse or reverse oblique (A3). Fracture of the greater trochanter had no effect on treatment methods or on measurement of medialisation.

Fractures which had subtrochanteric extension requiring a plate longer than five holes to achieve fixation of eight cortices distal to the fracture site were excluded. All fractures were reduced using the fracture table to achieve either a valgus or anatomical reduction. If necessary limited open reduction was undertaken to achieve this. A standard sliding hip screw was used with a 135° plate; if the lag screw measured 80mm or less, a short barrel plate was used with an additional compression screw to prevent the plate separating from the lag screw. No trochanteric side plates were used. The standard nail was 220mm long, with a 130° angle telescoping screw and barrel and anti-rotation pin, locked with a single screw distally.

For both implants, the lag screw tip-apex distance¹⁰ was always aimed to be between 15-20mm. All operations were performed or supervised by the senior author (MJP). All patients were mobilised without restriction as soon as possible post operatively. The majority of post-op x-rays were taken during clinic follow up at 6 weeks from discharge (Range 28 – 1893 days, mean 117 days, median 63 days). Patients who had no follow up x-ray or no x-ray beyond 28 days post surgery were excluded (figure 1). When patients had serial x-rays, the x-ray closest to the median (6 week clinic follow up) was used to assess femoral medialisation.

Femoral medialisation was assessed using the method demonstrated in figure 2 by the primary author (CPB). Only the Antero-Posterior (AP) view was interpreted. A nurse blinded to the treatment method assessed mobility and pain at one year at a telephone follow-up call. Pain was assessed using the Charnley score from 1 (no pain) to 6 (constant and severe).¹¹ Fixation failure was defined as cut-out or penetration of the implant from the bone, detachment of the plate from the femur, dis-assembly of the implant, re-fracture around the implant, breaking of the implant or non-union of the fracture. Revision surgery was defined as any patient who required removal or exchange of the original implant.

Statistical analysis: All statistical analysis was performed with IBM SPSS Statistics v.21 (IBM, Armonk. New York). A p-value below 0.05 was considered to be significant. The Shapiro-wilk test indicated all variables were non-normally distributed. Patient characteristics grouped by treatment method were compared using a Mann-Whitney U test or a chi-squared test. Outcomes were compared using Fishers exact test or chi-squared test for categorical data and Mann-Whitney U test for ordinal and continuous data.

Results

Patient Characteristics. 266 patients in the Targon PF Nail group and 272 in the SHS group had adequate X-ray follow up to assess femoral medialisation. Table 1 indicated the characteristics of the patients treated by the different implants were similar ($p>0.05$). 538 patients were assessed for mobility and 510 for pain at 1 year.

Results related to medialisation. The overall mean degree of medialisation was 6.4%. When testing medialisation on a continuous or ordinal scale there was no significant association with pain or mobility (table 2). The mean pain score for those with $<50\%$ medialisation was 1.6 and for those with $>50\%$ medialisation was 2.3 $p=0.012$. The mean change in mobility score for those with $<50\%$ medialisation was -0.94 and for those with $>50\%$ medialisation was -1.90 $p=0.013$. The number of fracture healing complications for those with $<50\%$ medialisation was 13/517 (2.5%) and for those with $>50\%$ medialisation was 3/21 (14.3%) $p=0.021$. The number of revision procedures for those with $<50\%$ medialisation was 11/517 (2.1%) and for those with $>50\%$ medialisation was 3/21 (14.3%) $p=0.014$. The deterioration in pain and mobility scores remained significant in the group that medialised $>50\%$ after excluding patients that had fixation failure or required revision surgery (pain $p=0.026$, mobility $p=0.028$).

Medialisation related to fracture type. Patients with A3 fractures were more likely to medialise and to experience $>50\%$ medialisation ($p<0.001$). Femoral medialisation was more common in A2 fractures when compared to A1 fractures $p=0.002$, though there was no significant difference in fractures that medialised $>50\%$ between the A1 and A2 groups (table 3).

Medialisation related to implant. The mean degree of medialisation for those treated with the SHS was 10.9% and for those treated with the nail 2.0% ($p<0.001$). 19/272 (7.0%) of patients treated with a SHS had $>50\%$ medialisation compared with 2/266 (0.8%) of those treated with an intramedullary nail $p<0.001$.

Discussion

Unstable trochanteric hip fractures, particularly those of the transtrochanteric (A3) type continue to pose difficulty for the treating orthopaedic surgeon. They are associated with higher failure and revision rates, irrespective of fixation method used.² A review by Kokoroghiannis² discussed theoretical arguments for this but found few clinical studies that explained the phenomenon, suggesting further consideration is required to elucidate factors which will predict failure or poor outcome. Integrity of the lateral femoral wall¹⁴ has been implicated, though not clinically correlated to fixation method. One radiological study of 48 patients by Pajarinen¹⁵ demonstrated a greater degree of femoral neck shortening in A2 fractures treated with SHS vs IM Nail but did not examine the clinical significance of this finding.

Haidukewych¹⁶ in a study of 47 patients demonstrated that dynamic condylar screws have lower revision rates than SHS for reverse obliquity fractures. Other studies have failed to find a lower complication rate for the fixed angle plates.¹⁷ In separate randomised control trials Pelet¹⁸ and Sadowski¹⁹ demonstrated lower revision rates for reverse oblique/ transtrochanteric fractures treated with intramedullary devices versus dynamic condylar screws. Similar findings by Matre²⁰ in a report of the Norwegian Hip fracture registry comparing SHS vs IM Nails demonstrated superior results when treating A3 fractures with intramedullary devices. In the United Kingdom (UK) it is not clear what proportion of A3 fractures are still treated with SHS as the UK National Hip Fracture Database does not yet distinguish between A1/A2 and A3 fractures.²¹

The SHS remains the standard implant for treatment of stable trochanteric hip fractures and is

rarely associated with femoral medialisation.¹ There is some evidence that the incidence of unstable trochanteric fractures is increasing²² and in the United States there has been a dramatic increase in the use of intramedullary devices for these fractures,²³ despite a recent Cochrane review that has failed to demonstrate the perceived advantage of new designs of intramedullary nails.⁶

Of randomised trials that have directly compared the intramedullary nail and SHS, few assessed the influence of fracture pattern on outcome. Hardy²⁴ and Utrilla²⁵ reported results by fracture pattern and found no difference in revision rate, but agreed that intramedullary devices are associated with earlier return to mobility, especially when used to treat unstable fractures. At Peterborough the results of our previously published randomised trial mirrored these findings.⁷ We are aware that the trend for improved mobility occurs in studies from expert centres, usually comparing specific implants and only represents a small proportion of trials which otherwise find no difference in outcome. With this study we wished to further examine our previous findings and explore the anatomical explanation for this trend and determine if femoral medialisation is associated with long term-functional outcome. As the trend relates only to mobility, we examined this separately using the widely utilised^{9,26} new mobility score for hip fractures⁸ rather than a combined outcome score. We felt it important to also assess residual pain and used the Charnley pain score,¹¹ which has been validated and suitable for blinded telephone assessment.

We acknowledge a number of limitations to this study. We assessed pain and mobility at one year but in most cases final x-rays were taken and interpreted earlier than this. We cannot be sure that fractures had united at time of x-ray and could have gone on to medialise further or fail by one year. The only previous study to examine this found that femoral medialisation

arose early and no further medialisation occurred between 6 weeks and 4 months post-operatively.¹⁵ In our study, of 21 patients that had serial x-rays, 2 patients had further medialisation from initial x-ray. They had an increase from 0% – 25 % medialisation from 32 – 122 days and 65 – 191 days respectively. Further investigation is required to determine the timeframe of femoral medialisation. Femoral medialisation is only one of the postoperative anatomical deformities that is seen. Since we only assessed the AP radiograph we do not know how other factors such as posterior displacement contributed to the results or even affected our measurements of medialisation. The degree of rotation can affect measurement of femoral neck shortening by up to 5mm.²⁷ In this study x-rays were all taken using the same method and at approximately the same time from surgery, thereby reducing potential bias. Though all fractures were fixed in either valgus or anatomical reduction, objectively measuring the quality of intra-operative reduction and lag screw position may have helped to interpret the affect of any confounding factors on outcome. In addition, we acknowledge only 21 patients (3.9%) had > 50% medialisation, highlighting the relatively low prevalence of this issue for trochanteric fractures as a whole (table 3).

In accordance with existing literature¹, our study demonstrates that post-operative femoral medialisation of >50% is associated with more fracture healing complications ($p=0.021$) and revision procedures ($p=0.014$). In addition our study is the first to demonstrate that medialisation is associated with increased pain scores ($p=0.012$) and poorer mobility scores ($p=0.013$) at one year. Femoral medialisation is more common in trochanteric fractures treated with SHS versus intramedullary nail ($p<0.001$) and we found that A2 ($p=0.02$) and A3 ($p=0.006$) fractures treated with SHS are more likely to experience >50% medialisation. The addition of a trochanteric stabilising plate to the side of the SHS may resist femoral

medialisation and negate the adverse effects, but to date this has not been demonstrated within clinical studies.

Conclusion

This study adds to a building body of evidence, suggestsing that intramedullary devices should be the standard of treatment for A3 fractures and that both intra- and extramedullary implants provide satisfactory results for A1 fractures. Some of the recent randomised trials have found earlier return to mobility in unstable A2 fractures treated with IM nails. Femoral medialisation may be a factor in explaining this emerging trend and if future trials find similar outcomes, femoral medialisation may warrant further investigation. We recommend that future trials comparing intra- and extramedullary devices for trochanteric fractures exclude A3 fractures and examine unstable A2 fracture patterns as a separate group from two-part A1 fractures.

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