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Mobility after intertrochanteric hip fracture fixation with either a sliding hip screw or a cephalomedullary nail: Sub group analysis of a randomised trial of 1000 patients

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ABSTRACT

Aims: The aim of this study was to determine if different patient groups have superior mobility regain following intertrochanteric hip fracture fixation with a cephomedullary nail compared to a sliding hip screw (SHS).

Patients and methods: The present study is a subgroup analysis of patients which were enrolled into a randomized controlled trial which randomized 1000 patients with an intertrochanteric hip fracture to fixation with either a short cephomedullary nail (Targon® PF or PFT) or a SHS. In the present study the two treatment groups were dicotomised on the basis of six variables determined at the time of admission; age (<80; ≥80 years), sex, residence (admitted from own home; institutional care), mobility (mobility score ≥7 [good]; <7 [poor]), mental status (AMTS < 7 [cognitively impaired]; ≥7) and health status (ASA < 3; ≥3). The primary outcome measure was the difference between mobility score pre-fracture and mobility score during the year after hip fracture fixation.

Results: Patients less than 80 years of age, those admitted from their own home, cognitively intact patients and patients who mobilised without assistance pre-fracture, recovered superior mobility when fracture fixation was performed with a nail compared to a SHS. Those patients admitted from institutional care, those with significant cognitive or mobility impairment at the time of the injury did not have any significantly improved benefit in mobility regain with a nail compared to a SHS.

Conclusion: Fixation of an intertrochanteric hip fracture with a cephomedullary nail results in superior recovery of mobility for younger patients who prior to the injury were more mobile, cognitively intact and living at home.

Introduction

Intertrochanteric hip fractures are common in the elderly and important because they result in significant morbidity and mortality. The annual incidence of hip fractures in the United Kingdom is approximately 77,000 [1]. Intertrochanteric fractures account for between one third and half of all hip fractures [2,3]. Debate continues over the merits of extramedullary fixation with a sliding hip screw (SHS) versus intramedullary fixation with a cephalomedullary nail. Numerous studies have documented the results of both SHS and nail fixation. Historically studies showed equivalent results for mortality and functional outcomes but an increased risk of fixation failure and re-operation for nails, due predominantly to fracture around the distal tip of the implant [4,5]. Nail designs have evolved and randomized trials studying more modern designs show no difference in terms of fracture healing complications between implants [6–8]. The two procedures are very similar in terms of mortality, complications, mobility, pain, blood transfusion requirements, length of operation and length of hospital stay. We have previously reported superior regain of mobility for those treated with a nail in comparison to a SHS [14,15] and this has been also demonstrated in a number of other similar randomized trials [9–12].

Pre-fracture mobility has been shown to predict rehabilitation after hip fracture fixation [13,14]. We hypothesize that different patient groups will have different mobility outcomes following intertrochanteric hip fracture fixation with either a nail or a SHS. We used data from patients who entered a randomized trial comparing the Targon® proximal femoral (PF) nail (BBrawn, Tuttlingen,

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Germany) with a SHS (Corin PLC, Cirencester, United Kingdom or Biomet Ltd, Bridgend, United Kingdom) [12]. The aim of this study was to determine if different patient groups have superior mobility regain following hip fracture fixation with a nail compared to a SHS.

Patients and methods

The study protocol has been published previously [12,15,16]. The trial included patients with stable (A1), unstable intertrochanteric (A2) and transtrochanteric fractures (A3) treated surgically [17]. Exclusion criteria included fractures with subtrochanteric extension, pathological fractures and fractures in patients with significant hip arthritis. One thousand patients were randomized to surgical treatment with either a SHS or the Targon® proximal femoral nail using consecutively numbered, sealed, opaque envelopes prepared by a person independent to the study. The study was approved by the hospital research and development committee and the local research ethics committee. Patients gave informed consent for inclusion in the study. For patients with dementia consent was obtained from the next of kin or legal guardian.

All operations were undertaken or supervised by a single surgeon specializing in hip fractures. All fractures treated with a SHS were fixed with a four or five hole

135° plate and no supplementary fixation. All nails were 220 mm long, had a distal diameter of 10 mm, lag screw angle of 130° and were fixed distally with a single 4.5 mm dynamic locking screw. The first 300 nail fixations were with the Targon® PF nail and the last 200 with the Targon® PFT nail [15,16]. Apart from upgraded instrumentation the only difference between the two nails was a change to a one-piece dynamic telescoping (PFT) lag screw. Post-operatively all patients were mobilised fully weight-bearing. Patient characteristics for those treated with a nail versus a SHS and results comparing mortality, complications, pain and mobility scores, discharge destination and residence one year post-operatively have been published previously for this cohort of patients [12,15,16].

The primary outcome measure for the present study was a validated mobility score (Table 1), which measures mobility on a scale from 0 (no mobility) to 9 (full mobility) [12,18–20]. The mobility scores were completed on admission and at each follow-up by a research nurse who was blinded to the treatment allocation. All surviving patients were assessed in fracture clinic eight weeks from the date of admission to hospital. Subsequent assessments were undertaken by telephone at three, six, nine and twelve months from injury.

The two treatment groups were dicotomised on the basis of six variables; age, sex, residence, mobility, mental status and health status. The variables were chosen due to their previously established influence on patient outcome after hip fracture surgery [14,18,21]. For age, patients <80 years of age were compared to those ≥80. Residential status at the time of hip fracture was used to dicotomise the treatment groups into two groups classified as admitted from own home and admitted from institutional care. For measure of mobility the treatment groups were dicotomised into two categories based on pre-fracture mobility score; <7 and ≥7. Patients with a pre-fracture mobility score ≥7 can mobilise independently whereas those with a mobility score <7 require assistance. The ten-point Abbreviated Mental Test Score (AMTS) was used to evaluate mental status with low scores representing cognitive impairment [22]. The treatment groups were dicotomised based on an AMTS; ≤ 6 versus >6. The American Society of Anesthesiologists (ASA) rating was used to evaluate health status [23]. The treatment groups were divided into two categories those with ASA < 3 (good) and ≥3 (poor).

Statistical analysis was performed on an intention-to treat basis. Mobility results are presented as the difference in mobility score between pre-fracture and mobility score at each follow-up interval. Statistical analysis was performed using GraphPad InStat v.3.00 (GraphPad Software, San Diego California). Mobility scores were compared using the unpaired t-test. A p-value < 0.05 was considered statistically significant.

Results

Mean differences in mobility score at various intervals of follow-up compared to pre-fracture (regain in mobility) for the two treatment groups dichotomised by age, sex, residence, mental status, mobility and health status are displayed in Figs. 1 to 6.

Age

Mobility improved for both the SHS and nail groups of patients <80 years of age from 8 weeks post fracture until latest follow-up, 1 year after fracture (Fig. 1). Patients <80 years of age lost less mobility when fixation was performed with a nail compared to a SHS. For those aged less than 80, the mean difference in reduction of mobility between both groups were statistically significant for all follow-up intervals. This difference was still present for those aged ≥80 years, however it was only statistically significant at follow-up six months post fracture fixation.

Sex

A better regain of mobility was seen for both male and female patients treated with nail fixation compared with the SHS at each follow-up interval (Fig. 2). At one year after hip fracture fixation the difference in mobility improvement were statistically significant for both males ($p = 0.01$) and females ($p = 0.04$).

Residence

Improvements in mobility were superior for patients treated with a nail compared to a SHS for patients admitted from their own home at all follow-up intervals (Fig. 3). These differences were statistically significant at all time points. This difference between implants was not seen for those from institutional care.

Mental status

Mobility scores for patients with an AMTS ≥ 7 improved at all times points within the first year after hip fracture surgery, with greater improvements for those treated with a nail (Fig. 4). These differences were statistically significant at all time points. For patients with an AMTS < 7 there was little improvement in mobility regardless of fixation method at any follow-up interval (Fig. 4).

Table 1
Mobility score.

Mobility	No difficulty and no aid	With a walking aid	With help from another person	Not at all
Able to get about the house (indoor walking)	3	2	1	0
Able to get out of the house (outdoor walking)	3	2	1	0
Able to go shopping (walking during shopping)	3	2	1	0

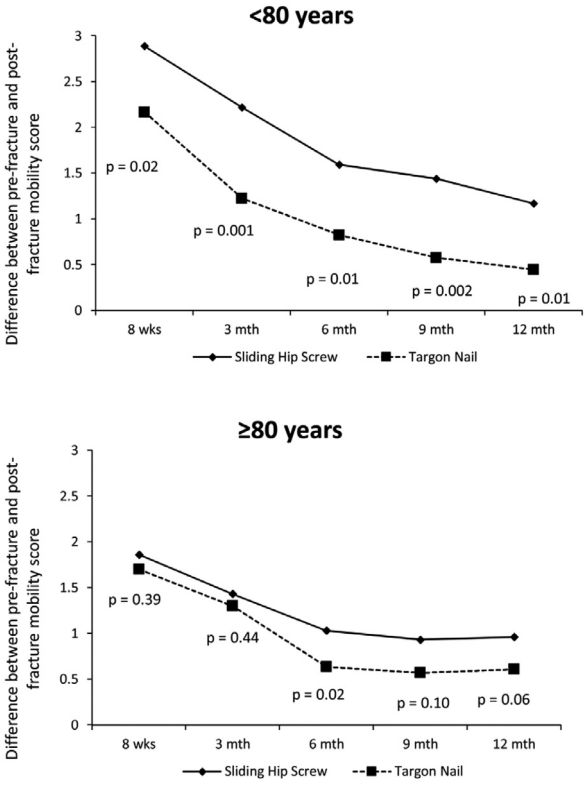

Fig. 1. Difference in mobility score post hip fracture fixation compared to pre-fracture for patients <80 years and those ≥80 years of age, treated with a cephomedullary nail versus a sliding hip screw (mean; p-values displayed for unpaired t-test).

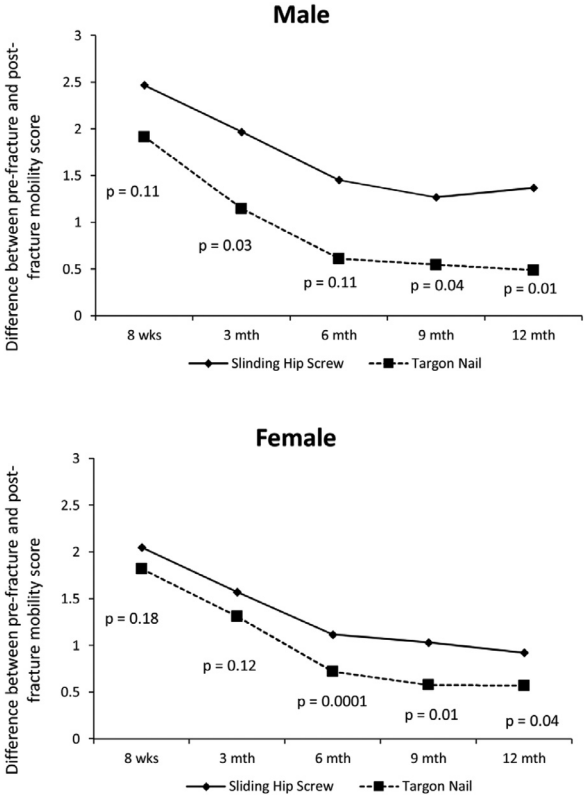

Fig. 2. Difference in mobility score post hip fracture fixation compared to pre-fracture for male and female patients treated with a cephomedullary nail versus a sliding hip screw (mean; p-values displayed for unpaired t-test).

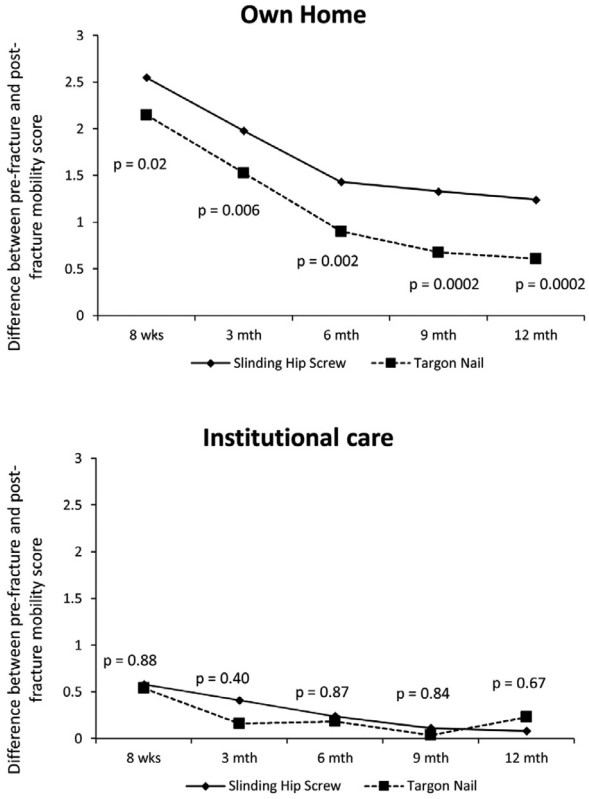

Fig. 3. Difference in mobility score post hip fracture fixation compared to pre-fracture for patients admitted from their own home and those from institutional care treated with a cephomedullary nail versus a sliding hip screw (mean; p-values displayed for unpaired t-test).

Mobility

Patients with greater pre-fracture mobility (mobility score ≥7) showed improvements in mobility score throughout the first year after hip fracture surgery regardless of fixation device. Improvements in mobility were superior for patients with a mobility score ≥7 treated with a nail compared to a SHS at all follow-up intervals, with statistical significance at all follow-up intervals after 8 weeks (Fig. 5). For patients with a poorer pre-fracture mobility (mobility score <7) there was only a small improvement in mobility for both treatment groups in the year after hip fracture surgery.

Health status

Improvements in mobility were superior for patients treated with a nail compared to a SHS regardless of whether ASA was <3 or ≥3 although for patients with ASA < 3 differences in mobility between patients treated with a nail versus a SHS were not statistically significant at any time point (Fig. 6).

Discussion

The original study which compared all patients treated with a nail to all patients treated with a SHS found a trend towards superior recovery of mobility for patients with an intertrochanteric fracture treated with a cephomedullary nail compared to a SHS [12]. The subgroup analysis performed in the present study has better defined which groups of patients regain superior mobility in the year after hip fracture following fixation with a nail. The findings are that those patients who are more mobile, cognitively intact, admitted from their own home, of younger age will achieve

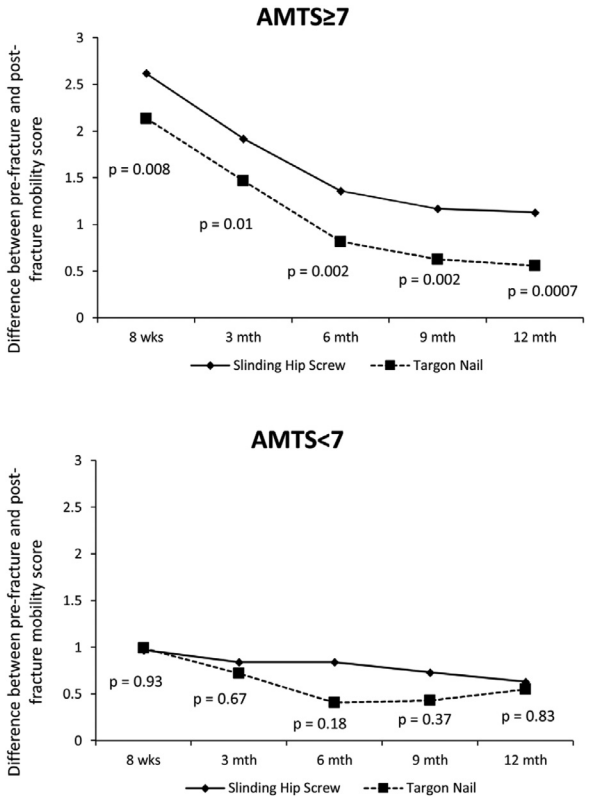

Fig. 4. Difference in mobility score post hip fracture fixation compared to pre-fracture for patients with a pre-fracture abbreviated mental test score ≥7 and those with a score <7 (cognitively impaired) treated with a cephomedullary nail versus a sliding hip screw (mean; p-values displayed for unpaired t-test).

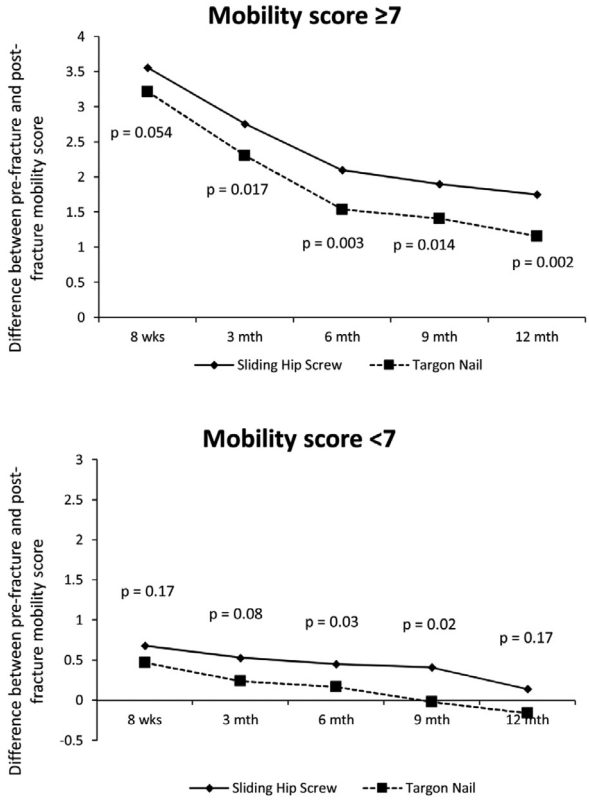

Fig. 5. Difference in mobility score post hip fracture fixation compared to pre-fracture for patients with a pre-fracture mobility score ≥7 (good) and those with a score of <7 (poor) treated with a cephomedullary nail versus a sliding hip screw (mean; p-values displayed for unpaired t-test).

the greater benefit if their fracture is fixed with a nail rather than a SHS. Conversely those patients with limited mobility, cognition or living in institutional care achieve similar outcomes regardless of the fixation method used. Patient gender and ASA grade were not strong predictors of which implant would fare best.

The nine-point ordinal mobility score used in this study provides a means of quantifying functional outcomes, it has been used in multiple trials assessing mobility following hip fracture and has been shown to have excellent inter-observer reliability [19,24].

After recovery from hip fracture fixation most patients are left with inferior mobility compared to pre-fracture. When considering mobility as an outcome measure for hip fracture fixation, patients with poor mobility pre-fracture are unlikely to have good mobility following rehabilitation from hip fracture. Therefore, in order to regain mobility post hip fracture, patients must have been mobile prior to hip fracture; whilst those with the best mobility pre-fracture have the most to lose following hip fracture, but also the most to gain or preserve with optimal hip fracture fixation.

The results of this study confirm that patients with superior pre-fracture mobility benefit more from fracture fixation with a nail compared to a SHS. While age and cognition have been shown to correlate with mobility and could be confounding factors there may be other reasons why younger, cognitively intact patients who live in their own home regain superior mobility when hip fracture fixation is performed with a nail [19]. Superior cognition enhances the ability of patients to follow physiotherapy instructions which may aid a patient's rehabilitation potential. Patients who live in their own home may be more motivated as a decline in mobility could result in requirement for carers or even institutionalisation. Kristensen et al showed that older age is independently associated with not regaining independence in basic mobility following hip fracture [14]. For the patient groups which regain the greatest mobility, recovery of mobility may continue to improve even beyond a year after hip fracture fixation however caution should be exercised in extrapolating the trends beyond the follow-up period within this study. This therefore may enhance the benefits of the nail in comparison to the SHS.

Two reasons have been hypothesized to explain why nail fixation might result in superior mobility following intertrochanteric hip fracture. Firstly, fixation with a nail can be performed through a minimally invasive approach with less soft tissue disruption compared to fixation with a SHS. Secondly, nail fixation has been shown to result in less collapse and medialisation of the femur [25,26]. Bretherton and Parker performed an analysis of over 500 patients randomized to fixation with either a SHS or cephomedullary nail and assessed radiographic femoral medialisation [27]. They reported less femoral medialisation for patients treated with a nail and a correlation between increased femoral medialisation and inferior mobility. Zlowodzki et al have also shown an association between femoral neck collapse and low physical function in patients treated with cannulated screws for an intracapsular hip fracture [28]. The reason nails reduce femoral medialisation is because the proximal part of the nail acts as a lateral buttress which sits inside the proximal femur, this reduces the potential space for fractured osteoporotic bone to collapse into. Cephomedullary nails have been recognized to have a biomechanical advantage over the SHSs as nails are located more closely to the weight bearing axis and therefore the load transmission pathway is closer to the intact femur. Hence after fracture fixation with a nail there is said to be load sharing between the implant and the fracture site whereas a SHS is described as a load bearing implant [29,30].

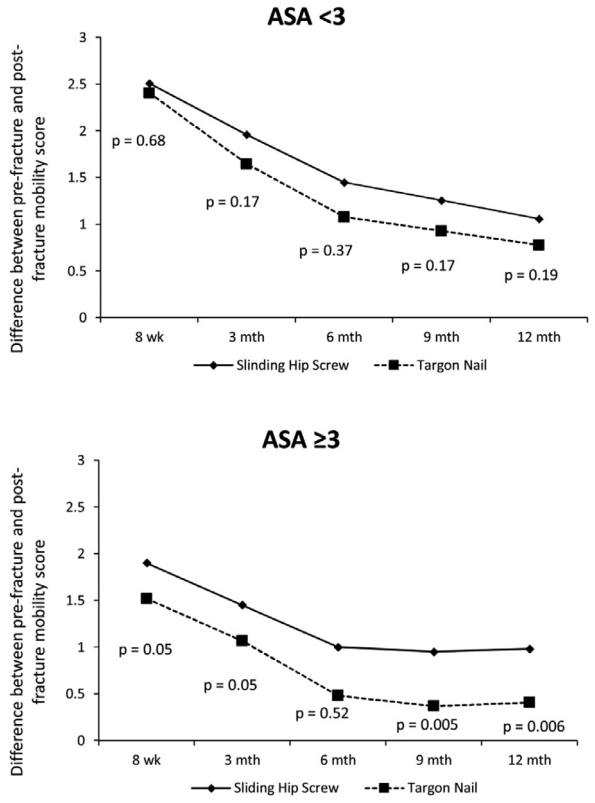

Fig. 6. Difference in mobility score post hip fracture fixation compared to pre-fracture for patients with an ASA rating <3 and those with an ASA rating ≥3 treated with either a cephomedullary nail versus a sliding hip screw (mean; p-values displayed for unpaired t-test).

We acknowledge a number of limitations to this study. Firstly, all operations were performed or supervised by a single surgeon with a specialist interest in hip fracture surgery. Therefore, the results of this study may not be applicable to different units and differing levels of surgical experience. Secondly, the subdivision of treatment groups results in smaller numbers of patients than the original study was designed for, this could result in a type II statistical error. Thirdly, the results may not apply to other designs of nail and therefore further research is required to assess if other designs also confer a mobility benefit for selected patients.

In summary, this study shows superior mobility recovery for certain patient groups when intertrochanteric hip fracture fixation is performed with a cephomedullary nail. Where surgical expertise permits we advocate fixation of trochanteric hip fractures with a nail for younger patients, patients who live in their own home, patients who are cognitively intact and patients which mobilised independently pre-fracture. Intertrochanteric hip fracture fixation with a nail in these groups results in superior recovery of mobility.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.injury.2019.06.015.

CRediT authorship contribution statement

Joshua C.Y. Ong: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **James R. Gill:** Conceptualization, Investigation, Methodology, Software, Validation, Visualization, Writing - review & editing. **Martyn J. Parker:** Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Resources, Supervision.

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