**Abstract**

**Aims**

To explore whether time to surgery affects functional outcome in displaced proximal humeral fractures.

**Patients and Methods**

250 patients presenting within three weeks of sustaining a displaced proximal humeral fracture involving the surgical neck were recruited at 32 acute UK National Health Service hospitals between September 2008 and April 2011. 109 of 125 participants received surgery (fracture fixation or humeral head replacement) as per randomisation. Data were included for 101 and 67 participants at 6 month and 5 year follow-up, respectively. Oxford shoulder score collected at 6, 12, and 24 months and 3, 4, and 5 years post-randomisation was plotted against time to surgery. Long-term recovery was explored by plotting 6 month scores against 5-year scores and agreement was illustrated with a Bland-Altman plot.

**Results**

The mean time from initial trauma to surgery was 10.5 days (range 1-33 days). Earlier surgical intervention did not appear to improve Oxford shoulder score throughout follow-up. Nor when stratifying by participant age (<65 versus ≥65 years old) and fracture severity (1- and 2-part versus 3- and 4-part fractures). Participants managed later than reported international averages (3 days in the USA/Europe, 8 days in the UK) did not have worse outcomes. At 5 year follow-up, 76% of participants had the same or improved Oxford shoulder scores compared with 6 months (r=0.613). A Bland-Altman plot demonstrated a positive average mean difference (+3.3 Oxford Shoulder Score points, ± 7.92) with wide 95% limits of agreement (-12.2 and 18.8 points).

**Conclusion and Relevance**

Timing of surgery did not affect Oxford shoulder scores at any follow-up time-point, irrespective of age or fracture type. Most participants had the same or improved functional outcome at 5 years compared with 6 months. These findings may help guide providers of trauma services on surgical prioritisation.

**Trial Registration:** isrctn.com Identifier: ISRCTN50850043

**Introduction**

Fractures of the proximal humerus are the third most common osteoporotic fracture, accounting for 5-6% of adult fractures.1 Many (20%) are displaced fractures and typically occur following minimal trauma.2–6 Management ranges from non-surgical options to surgical interventions including: internal fixation (locking plate and screws, intramedullary nailing, and screw-only fixation) and hemi-arthroplasty.6–9 Considerable variation in surgical management occurs internationally, both between hospitals in the same country and between surgeons.6,10

The Proximal Fracture of the Humerus Evaluation by Randomization (PROFHER) trial provides rigorous evidence that surgical management is neither superior nor cost-effective compared with non-surgical treatment for displaced proximal humeral fractures involving the surgical neck.8,11–13 This excludes fracture dislocations, head splitting fractures and open fractures which necessitate surgical intervention and represent urgent cases. There is evidence, however, that whilst delayed surgery does not impact upon short-term mortality in patients with fractures of the proximal humerus it can increase morbidity in the immediate post-operative period and length of stay.14 Long-term complications can also be more severe and common if surgery is delayed.4,12,14–16

Internationally, there is variation in time from initial trauma to surgery. Patients in the United States of America (USA) receive surgery within 3 days and is consistent with practice in a European country (Germany).14,17 An average of 8 days to surgery has been reported in the United Kingdom (UK).11 The window of opportunity for surgical benefit could therefore be earlier than the mean time of around 11 days to surgery achieved in PROFHER.8 Currently the National Institute for Health and Care Excellence in the UK does not recommend when surgical management of proximal humeral fractures should be undertaken despite well-established guidelines for other common fractures.18,19

In this post hoc sub-analysis, data from the PROFHER randomised clinical trial were used to explore whether the time from initial trauma to surgical management affected patient-reported functional outcome using the Oxford Shoulder Score (OSS) at 6 months, 1, 2, 3, 4, and 5 year follow-up. This was compared across international averages and whether this differed across important participant characteristics. We also explored the stability of OSS between short and long-term follow-up.

**Patients and Methods**

*Study design*

We conducted a post hoc analysis of data from the participants allocated to surgery in the PROFHER trial. Patients aged over 16 years who presented within 3 weeks of sustaining a displaced fracture of the proximal humerus involving the surgical neck were recruited at orthopaedic departments of 32 UK National Health Service (NHS) hospitals between September 2008 and April 2011. PROFHER excluded open fractures, fracture dislocations and head-splitting fractures.

*Outcomes*

The Oxford Shoulder Score (OSS) was the primary outcome of the PROFHER trial. The OSS consists of 12 items that are summed to a total score of a patient’s subjective assessment of shoulder pain and function that ranges from 0 (worst outcome) to 48 (best outcome).20,21

*Statistical analysis*

The data were limited to the surgical arm alone. All analyses were descriptive and performed using Stata version 15 (StataCorp). Due to this being an exploratory study, no formal null hypothesis was stated. Figure 1 summarises the planned analyses. The baseline characteristics of participants were described and grouped by different waiting times to surgery. This illustrates potential factors that may have influenced the decision to undertake surgery earlier. These included: age, fracture severity, sex, smoking status, arm dominance, diabetes and history of previous fracture(s). Waiting times to surgery were compared by center size, approximated by the number of surgical procedures in the trial period: small (1-4 operations), medium (5-9 operations) and large (10 or more operations). Raw OSS scores were plotted against time to surgery in days at each follow-up, in total and stratified for the sub-groups specified in PROFHER (age and fracture severity). Cut-offs based on average surgery times recorded in international practice were included for reference: 3 days (standard indicated by USA and German practice) and 8 days (UK average). The stability of recovery between OSS at 6 months and 5 years was investigated using correlation, illustrated by plotting the two scores against each other and by a Bland-Altman plot of the extent of agreement. Differences in baseline characteristics were explored for participants who improved or deteriorated between 6 months and 5 years.

**Results**

Of the 1250 patients screened for inclusion, 250 were recruited into PROFHER. The mean age of the 125 participants allocated to surgery was 66 years (range, 27-92 years), 97 (78%) were female and 124 (99%) were white. Of these participants, 109 received surgery as planned. There were 90 (83%) who were managed with locking plate fixation, 10 (9%) received hemiarthroplasty, 4 (4%) intramedullary nail fixation and the remaining 5 (5%) a range of other surgical procedures. There were valid OSS responses at 6 months for 101 participants (93%), at 12 months for 99 participants (91%) and 95 participants (87%) at the original 24 month end-point. Consent to long-term follow-up was obtained from 79 participants (73%) who received an unconditional £5 incentive for each follow-up from 12 months onwards. Valid responses were acquired at 3, 4, and 5 years for 75 participants (69%), 70 participants (64%), and 67 participants (61%), respectively (see Figure 1 for participant flow). Of the 67 participants with follow up data at the 5 year follow-up, valid OSS data at the initial follow up of 6 months was not available for 1 participant.

Table 1 shows that older participants tended to undergo surgical management earlier on: mean age of 71.5 (SD ± 7.3) years for patients with surgery within 3 days post-injury, 66.3 (SD ±13.6) years for surgery between 4 and 8 days, 65 (SD ± 11.0) years for surgery after more than 8 days. There was little difference in the profile of participants at baseline and those retained at follow-up in terms of age, fracture severity and all other characteristics.

*Time to surgery and OSS*

Participants who received surgery as allocated (109 (87%)) waited a mean of 10.5 days (range 1-33 days, ± 6.51 days, 95% confidence interval 9.26 to 11.7 days) from initial trauma to surgical management.8 The mean waiting time was 12.9 days (± 6.03) for participants managed in small sites (n=42 in 21 hospitals), 11.2 days (± 7.86) in medium sized sites (n=34 patients in 5 hospitals) and 8.24 days (± 5.10) in large sites (n=33 patients in 2 hospitals).

Timing of surgery did not appear to be associated with OSS score at any time point (Figure 2). Participants who underwent surgery later than either the USA or UK averages did not appear to have worse OSS scores. Similarly, Figure 3 shows no obvious association between time to surgery and outcome for any of the sub-groups of age (<65 and ≥65 years old) and fracture severity (1- and 2-part versus 3- and 4-part fractures) at any follow-up.

*Comparison between OSS at 6 months and 5 years*

Of the participants managed surgically, 66 had complete OSS data available at both 6 months and 5 years. A correlation coefficient (r) of 0.613 indicated a moderate to strong positive correlation between these two time-points. Improved OSS scores at the end of follow-up were seen for 47 patients (71%), scores remained the same for 3 patients (5%) and deteriorated for 16 patients (24%) (Figure 4a). The majority of patients who deteriorated at 5 years had fractured their dominant shoulder (n=13, 81%), whereas the majority of patients who improved had injured their non-dominant shoulder (n=28, 59%). There appeared to be no other differences in baseline factors (data not presented). A Bland-Altman plot (Figure 4b) illustrates that the average score change over time was positive (3.3 OSS points, ± 7.92). The 95% limits of agreement were wide between -12.2 and 18.8 OSS points. There was no obvious pattern in the direction of score differences or the extent of agreement by the level of OSS performance.

**Discussion**

In recent years, there has been a considerable increase in research about fractures of the proximal humerus, particularly their surgical management.4 This has included the optimisation of internal fixation and hemiarthroplasty to achieve stable fixation in osteoporotic bone.6,9 However, this has yielded studies demonstrating only modest reductions in complication rates when augmentation (cementation or allograft) of locking plate fixation is undertaken or conversion to reverse total shoulder arthroplasty, respectively as well as their own unique complications and higher costs.6,9,22 There has, however, been limited focus on whether timing of surgery influences functional outcome, despite heterogeneity in practice internationally.15,23–25 This post hoc analysis provides evidence that there does not appear to be an obvious difference in functional outcome (measured using the OSS) in relation to timing of surgery. This applies to international thresholds of 3 and 8 days post-injury throughout follow-up from 6 months to 5 years. Exploring the effect of important participant characteristics of age and fracture severity did not alter these findings.

Proximal humeral fractures are a leading cause of lasting morbidity and it has been reported that patients do not regain function comparable to pre-injury.4,15 However, symptoms are thought to improve over time, irrespective of management modality.2,5,7,26–29 We have shown that on average most (76%) participants experienced a modest improvement in OSS at 5 years compared with 6 months. This, however, was less (3.3 OSS points) than the minimal threshold of approximately 5 OSS points (a standard effect size of 0.4) proposed to be clinically important.8,20 Surgical fixation of midshaft fractures of the clavicle has also been found not to generate functional benefit at the shoulder joint compared to conservative management beyond 6 months post-surgery.30 There was also considerable variation in the extent of improvement in our cohort of participants. Given the paucity of research into long-term (beyond 24 months) functional outcomes, this evidence represents the longest known period of post-operative follow-up. 2,24,28,31

Treatment decisions are informed by factors including patient age, sex, fracture severity and comorbidities. Younger patients and more complex fracture patterns are more likely to be managed surgically and tend to undergo surgical management within a shorter time frame.2,3,32 In contrast, in PROFHER, older participants tended to be operated on earlier and neither age (<65 and ≥65 years old) nor fracture severity (1- and 2-part versus 3- and 4-part) were associated with the primary outcome. Injury of the dominant shoulder has also been considered to be important in predicting worse functional outcome post-surgery.9,16,24 Our findings support this in that the large majority of patients with worse 5 year functional outcome compared with at 6 months had fractured their dominant shoulder.

Whilst our study in the UK provides evidence that time to surgery does not influence patient-reported shoulder function, a study in the USA found that surgery carried out more than 3 days following trauma correlated with prolonged hospital stay and significant in-patient adverse events (including infection, reintubation and acute kidney injury) whilst not impacting on mortality rates.14 An ethnic minority background and having no insurance were independent risk factors for surgery after the third day post-trauma. This could possibly explain the poorer outcomes when surgery was delayed beyond 3 days. In the USA, access to healthcare is a major factor in determining time to surgery in this patient population. Whereas in the UK, access to NHS provided health care is free at the point of delivery, without requiring additional insurance or additional costs beyond those levied from taxation.14 Issues with accessing care following a fracture of the proximal humerus is less likely to act as a limiting factor when considering time to surgery in the UK.

No known guidelines are published about when surgical management should be undertaken in fractures of the proximal humerus in contrast with neck of femur fractures.2,18,19,33 The consequences of fractures of the femoral neck include a 1-year mortality rate of around 30% whereas fractures of the proximal humerus are not associated with comparable mortality rates.34 Internal fixation of the proximal humerus is associated with high complication rates (including, but not limited to, glenoid damage and screw perforation), with correspondingly high reoperation rates.22 Prompt surgical management (within 5 days of trauma) can, however, significantly reduce rates of serious complications (loss of fixation and avascular necrosis) following internal fixation of displaced or comminuted proximal humeral fractures.14,17 Furthermore, a small prospective study showed delayed surgery correlated with an increased incidence of acute post-operative infection, with an appreciable increase in skin bacterial load observed from day 2 post-injury and a statistically significant increase at around 5 days post-injury.25 There is contrasting evidence, however, that operating within 48 hours does not reduce complication rates (including loss of fixation and avascular necrosis) compared to performing surgery between post-injury days 3 and 5 although operating beyond 5 days correlated with increased risk of complications and infection.17,27 In contrast with other fractures - such as the femoral neck – therefore, there is inconsistent evidence about the benefits or complications of timing of surgery in the management of patients with displaced fractures of the proximal humerus.17,33

Limitations of this study include loss to follow-up with lower response rates at 5 years (61%) compared with 6-month follow-up (93%). However, the reasonably stable characteristics of participants for all important prognostic factors at baseline and across the key follow-up periods of 6 months and 5 years suggests that non-response is unlikely to have introduced bias. The inclusion criteria for PROFHER meant that patients could be enrolled up to three weeks post-injury and could have delayed the timing of surgery.8,35 The evidence presented here, however, suggests this was unlikely to have had an effect on functional outcome and reassuringly did not harm the welfare of trial participants. The average time to surgery of 10.5 days in PROFHER (based on 30 hospitals involving 66 surgeons) was reasonably comparable with the 8 days this took in a UK study of 12 NHS hospitals in routine clinical practice.11 Fracture types (head-split and fracture dislocations) included in other studies to illustrate international practice were excluded from PROFHER.14 These injuries were excluded as they represent clear indications for – often urgent - surgical management and hence, are more likely to undergo rapid intervention. Therefore the generally shorter times indicated from trauma to definitive surgical management internationally may be a consequence of the inclusion of urgent surgical cases.8 This difference in case-mix between PROFHER and international studies has implications for the observed differences in time to surgery and subsequent complications rates, which would be anticipated to be lower in PROFHER.14,25 Consequently, this may explain why the primary outcome (OSS) was unaffected by more prompt surgery in this particularly (non-urgent) cohort. Finally, outcome data was obtained via self-reported (OSS) questionnaires mailed to participants, rather than clinical or radiological follow-up. The OSS is both standardised and joint specific, whilst demonstrating an excellent correlation with Constant scores (a specific objective assessment of motion and strength in fractures of the proximal humerus)36 thus obviating the need for clinical or radiological follow-up of functional impairment which are inherently subjective in assessment.20

**Conclusion**

The main conclusion is that shorter time to surgery does not appear to benefit the management of proximal humeral fractures involving the surgical neck regardless of patient age or fracture severity using a patient-reported outcome measure. Most participants experienced the same or improved functional outcome at 5 years compared to 6 months, although there was substantial variation in the extent of any improvement. These findings may help guide providers of trauma services on surgical prioritisation. As a post-hoc analysis of a limited trial sub-sample, these findings should be interpreted with caution.

**Take home message**

* Proximal humeral fractures are common injuries associated with considerable morbidity. Optimal management remains uncertain including variation in time to surgery across international practice.
* Timing of surgery for these fractures does not influence patient-reported functional outcome, regardless of patient age or fracture pattern.

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**Conflict of Interests**

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**Role of the Funder/Sponsor**

Teesside University managed the grant application process and monitored the study but it had no direct role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

**Disclaimer**

The views expressed are those of the authors and not necessarily those of the UK National Institute for Health Research, the UK National Health Service, or the UK Department of Health and Social Care.

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**Figure Legends and Tables**

**Table 1:** Baseline characteristics of participants randomised to surgery, stratified by time to surgery and follow-up

**Figure 1:** Scheme of analysis

**Figure 2:** Oxford Shoulder Scores throughout follow-up with indications of international variations in average time to surgery

**Figure 3:** Oxford Shoulder Scores throughout follow-up stratified by participant age and fracture severity

**Figure 4:** Exploration of relationship between Oxford Shoulder Score at 6 months and 5 years follow-up