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TRAUMA

A review of current surgical practice in the operative treatment of proximal humeral fractures

DOES THE PROFHER TRIAL DEMONSTRATE A NEED FOR CHANGE?

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Objectives

The PROximal Fracture of the Humerus: Evaluation by Randomisation (PROFHER) trial has recently demonstrated that surgery is non-superior to non-operative treatment in the management of displaced proximal humeral fractures. The objective of this study was to assess current surgical practice in the context of the PROFHER trial in terms of patient demographics, injury characteristics and the nature of the surgical treatment.

Methods

A total of ten consecutive patients undergoing surgery for the treatment of a proximal humeral fracture from each of 11 United Kingdom hospitals were retrospectively identified over a 15 month period between January 2014 and March 2015. Data gathered for the 110 patients included patient demographics, injury characteristics, mode of surgical fixation, the grade of operating surgeon and the cost of the surgical implants.

Results

A majority of the patients were female (66%, 73 of 110). The mean patient age was 62 years (range 18 to 89). A majority of patients met the inclusion criteria for the PROFHER trial (75%, 83 of 110). Plate fixation was the most common mode of surgery (68%, 75 patients), followed by intramedullary fixation (12%, 13 patients), reverse shoulder arthroplasty (10%, 11 patients) and hemiarthroplasty (7%, eight patients). The consultant was either the primary operating surgeon or supervising the operating surgeon in a large majority of cases (91%, 100 patients).Implant costs for plate fixation were significantly less than both hemiarthroplasty ($p < 0.05$) and reverse shoulder arthroplasty ($p < 0.0001$). Implant costs for intramedullary fixation were significantly less than plate fixation ($p < 0.01$), hemiarthroplasty ($p < 0.0001$) and reverse shoulder arthroplasty ($p < 0.0001$).

Conclusions

Our study has shown that the majority of a representative sample of patients currently undergoing surgical treatment for a proximal humeral fracture in these United Kingdom centres met the inclusion criteria for the PROFHER trial and that a proportion of these patients may, therefore, have been effectively managed non-operatively.

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Keywords: Proximal humerus; Fracture; Surgery; PROFHER; Surgical neck

Article focus

- The recently published PROximal Fracture of the Humerus: Evaluation by Randomisation (PROFHER) trail demonstrated that surgery was non-superior to non-operative treatment for fractures of the surgical neck of humerus.
- The objective of this study was to assess current surgical practice in the context of the PROFHER trial in terms of patient demographics, injury characteristics and the nature of the surgical treatment.

Key messages

- The demographics of a representative sample of patients undergoing surgery at the 11 centres revealed a majority of females with a mean age of 62 years

which is similar to those participating in the PROFHER trial.
- The majority of patients met the inclusion criteria for the PROFHER trial.
- The mode of surgical treatment was variable with both reverse shoulder arthroplasty and hemiarthroplasty significantly more expensive than both plate and intramedullary fixation in terms of implant costs.

Strengths and limitations

- No previous study has assessed current surgical practice in the United Kingdom relating to proximal humeral fractures.
- The study is retrospective and has not analysed those fractures managed non-operatively.
- Practice has been analysed at 11 centres and may not be wholly representative of practice throughout the United Kingdom.

Introduction

Proximal humeral fractures are the third most common type of osteoporotic 'fragility' fracture after wrist and hip fractures.[1] Epidemiological data from Finland has demonstrated that the number of proximal humerus fractures is rising rapidly.[2] The United Kingdom's population is also becoming increasingly elderly and consequently the incidence of fragility fractures is on the rise,[3,4] meaning that the disease burden related to proximal humerus fractures can only increase over the years ahead.

Research from the United States has shown that although the incidence of proximal humeral fractures in the elderly did not change between 1999 and 2005, the rate of surgical treatment increased significantly.[5] The use of surgery in the treatment of proximal humeral fractures is also increasing in Finland[6] with the incidence of surgical treatment quadrupling between 1987 and 2009. Both these studies have shown that with the exception of plating and arthroplasty, the incidence of all other surgical treatment options has decreased with time.[5,6] It is likely that similar trends would be seen in developed nations from the United States or the European Union given the close ties between practice in these countries.

The evidence supporting the use of surgery is extremely limited[7,8] with the recent PROximal Fracture of the Humerus: Evaluation by Randomisation (PROFHER) trial demonstrating that surgery was not superior to non-operative treatment in the treatment of displaced proximal humeral fractures.[9] In this context the overall objective of this project was to assess current surgical practice in the United Kingdom in the treatment of proximal humeral fractures prior to the publication of the PROFHER trial results. The primary aim was to assess the patient demographics and injury characteristics of those treated with surgical intervention. Secondary aims were to determine which patients currently treated surgically met the inclusion criteria of the PROFHER trial;[9] assess which modes of surgery were used and which grade of surgeon performed the surgery; and to investigate whether there were any differences between surgical groups in terms of the patient characteristics and implant costs.

Patients and Methods

A total of ten consecutive patients undergoing surgery for the treatment of a proximal humeral fracture from 11 United Kingdom hospitals were retrospectively identified using theatre database searches over a 15 month period between January 2014 and March 2015. Orthopaedic surgeons in higher training were invited to take part via BONE (British Orthopaedic Network Environment) and local regional contacts. We did not exclude any hospitals and no hospital declined inclusion in the study. Data gathering was approved at each centre via each Trust's audit department. A standardised data entry spreadsheet was completed for ten consecutive patients who underwent any form of surgery for a 'radiographically confirmed displaced fracture of the proximal humerus involving the surgical neck'. Cases were identified retrospectively and consecutively from electronic theatre records at each hospital. Therefore fractures of the proximal humerus not involving the surgical neck were excluded.

The collected data included patient age, gender, date of injury, date of surgery, fracture type according to Neer classification (types 1 to 4), injury characteristics (open or closed, whether joint dislocated, soft tissue compromise including nerve, pathological fracture), patient characteristics (mental competence, multiple injuries), the type of surgery performed, the grades of surgeon involved and the cost of the surgical implants. These characteristics encompassed the documented inclusion criteria for the PROFHER trial[9] which were that patients were of adult age and presenting to the participating centre within three weeks of injury with a radiographically confirmed displaced fracture of the proximal humerus involving the surgical neck. The exclusion criteria were: associated dislocation of the injured shoulder joint, open fracture, mentally incompetent patient, comorbidities precluding anaesthesia, clear indication for surgery including soft tissue compromise/nerve dysfunction, multiple injuries, pathological fractures/terminal illness and patient non-resident in catchment area. The proximal humerus fractures were classified by two blinded observers independently (higher surgical trainee and consultant Orthopaedic surgeon), according to the original Neer classification system. Type 1 fractures are minimally displaced. Type 2, 3 and 4 fractures are two-, three- and four-part, respectively, and are displaced by more than 1 cm or angulated more than 45°. Each local finance

Table I. Participating centres and patient demographics

Centre	Centre name	Major trauma centre (yes/no)	Time for 10 consecutive patients (days)	Mean age (SD)	Gender
1	Barnsley Hospital	No	116	71 SD 11	1M 9F
2	Kettering General Hospital	No	268	64 SD 9	1M 9F
3	John Radcliffe Hospital, Oxford	Yes	194	52 SD 23	3M 7F
4	Queen Elizabeth Hospital, Birmingham	Yes	320	58 SD 21	3M 7F
5	Royal Berkshire Hospital, Reading	No	311	65 SD 13	4M 6F
6	Royal Bolton Hospital	No	112	63 SD 20	4M 6F
7	Royal London Hospital	Yes	119	57 SD 15	5M 5F
8	Stepping Hill Hospital, Stockport	No	336	66 SD 13	4M 6F
9	Morriston Hospital, Swansea	Yes	134	60 SD 15	4M 6F
10	Great Western Hospital, Swindon	No	168	61 SD 19	4M 6F
11	Stoke Mandeville Hospital, Aylesbury	No	374	66 SD 16	4M 6F
Overall	-	-	194	62 SD 16.4	37M 73F

department was asked to supply the costs of the implants used for each patient.

Statistical analysis. This was carried using GraphPad Prism version 5.00 for Windows (GraphPad Software, San Diego, California). Histograms for all data sets were analysed. Data was normally distributed unless otherwise stated. Results are expressed as mean standard deviation (SD) unless otherwise stated. Unpaired *t*-tests and Mann Whitney U-tests were used to test for differences between two groups for parametric and non-parametric data respectively. The one way ANOVA was used to test multiple groups of parametric data with Tukey's multiple comparison test used to detect differences between individual groups. The Kruskal Wallis one way analysis of variance was used to test multiple groups of non-parametric data with Dunn's multiple comparison test used to detect differences between individual groups. Fisher's exact test was used to test for differences between two categorical variables. Statistical significance was set at a level of $p < 0.05$. Cohen's kappa was calculated as a measure of inter-rater reliability.

Results

Patient demographics and centres. The 11 participating centres and the time period over which the ten surgically treated patients were operated upon, as well as patient demographics in terms of age and gender, are detailed in Table I. In total four of the 11 centres were major trauma centres. The median time over which the ten patients had surgery was 194 days (interquartile range 116 to 320). A majority of the patients were female (66%, 73 of 110). The mean patient age was 62 years (18 to 89).

Injury details and mode of surgery. Table II shows the median time from injury to surgery, the number meeting the PROFHER trial inclusion criteria, fracture type according to Neer classification, type of surgery performed and the grade of operating surgeon. The median time to surgery from injury was eight days (interquartile range 4 to 12), while only two patients had a gap of greater than three weeks between injury and surgery. Inter-rater reliability of the Neer classification revealed a Cohen's Kappa of 0.449 which is interpreted as 'moderate agreement'.[10]

A majority of patients met the inclusion criteria for the PROFHER trial (75%, 83 of 110). Of the 27 patients who did not meet the PROFHER inclusion criteria it was most commonly the result of a single exclusion criterion (time to presentation in two patients, dislocation in ten patients, mentally incompetent in three patients, soft tissue compromise in two patients and multiple injuries in six patients). In three patients there were two reasons for exclusion (dislocation/multiple injuries in two patients and dislocation/soft tissue compromise in one) and in one patient there were four reasons (open fracture/soft-tissue compromise/mentally incompetent/multiple injuries).

There were only three Neer type 1 fractures with types 2/3/4 being far more prevalent. The breakdown in terms of the Neer classification were as follows: three type 1 (3%), 44 type 2 (40%), 36 type 3 (33%) and 27 type 4 (25%). Plate fixation was the most common mode of surgery (68%, 75 patients), intramedullary fixation being next most common (12%, 13 patients), followed by reverse shoulder arthroplasty (10%, 11 patients), hemiarthroplasty (7%, eight patients) and the remaining 3% consisting of open reduction alone (2%, two patients) and k wire fixation (1%, one patient). The operating surgeon was a consultant in 73% of cases (80 patients), post CCST fellow in 10% of cases (11 patients) and registrar in 17% of cases (19 patients). The CCST fellow was supervised by a consultant in 55% of cases (six patients) and unsupervised in the other 45% (five patients), while the specialist registrar was supervised by a consultant in 74% of cases (14 patients) and unsupervised in the remaining 26% (five patients). Overall a consultant was either the primary operating surgeon or supervising the operating surgeon in 91% of cases (100 patients).

Table II. Time from injury to surgery, number meeting PROximal Fracture of the Humerus: Evaluation by Randomisation (PROFHER) trial inclusion, Neer types, mode of surgery and grade of operating surgeon

Centre	Median time to surgery (days)	Number out of 10 meeting PROFHER inclusion criteria	Neer types 1/2/3/4	Type of surgery	Grade of operating surgeon
1	9	8	2/2/4/2	Plate 9/Hemi 1	Cons 9/Reg 1
2	9	10	0/5/5/0	Plate 7/IM 1/Reverse 2	Cons 9/Reg 1
3	2	4	0/5/2/3	Plate 8/Hemi 2	Cons 6/Fellow 2/Reg 2
4	12	9	0/3/2/5	Plate 10	Cons 9/Reg 1
5	10	6	0/4/4/2	Plate 3/IM 1/Reverse 3/open reduction only 2/K wires 1	Cons 7/Fellow 3
6	12	10	1/5/3/1	Plate 8/Reverse 2	Cons 7/Reg 3
7	11	8	0/3/4/3	Plate 7/Hemi 1/Reverse 2	Cons 3/Fellow 1/Reg 6
8	6	10	0/3/4/3	Plate 7/Hemi 1/Reverse 2	Cons 5/Fellow 5
9	7	7	0/5/4/1	Plate 10	Cons 8/Reg 2
10	12	4	0/5/2/3	Plate 6/IM 2/Hemi 2	Cons 8/Reg 2
11	6	7	0/4/2/4	IM 9/Hemi 1	Cons 9/Reg 1
Overall	8	83 of 110	3/44/36/27	Plate 75/IM 13/Hemi 8/Reverse 11/open reduction only 2/K wires 1	Cons 80/Fellow 11/ Reg 19

Cons, consultant; Reg, registrar; IM, intramedullary; Hemi, hemiarthroplasty

Table III. Characteristics of mode of surgery groups

Type of surgery	Number	Mean age (SD)	Gender	Neer types 1/2/3/4	PROFHER inclusion	Median cost of implants (£)
Plate fixation	75	58 SD 17	28M 47F	3/33/27/12	49 of 75	783
IM fixation	13	67 SD 14	3M 10F	0/8/1/4	11 of 13	476
Reverse	11	74 SD 10	1M 10F	0/1/5/5	9 of 11	2800
Hemi	8	71 SD 8	4M 4F	0/0/2/6	2 of 8*	2129
Other	3	70 SD 15	1M 2F	0/2/1/0	2 of 3	290
Total	110	62 SD 16.4	37M 73F	3/44/36/27	83 of 110	783

*Proportion meeting PROximal Fracture of the Humerus: Evaluation by Randomisation (PROFHER) inclusion criteria from Hemi group lower than that of plate group ($p = 0.05$), and significantly lower than that of the IM fixation group ($p = 0.02$) and reverse group ($p = 0.02$) as calculated using Fisher's exact test
SD, standard deviation; IM, intramedullary

Mode of surgery groups. Table III demonstrates the 110 patients divided into groups based on the mode of surgery. Table III and Figure 1 show the ages of the different surgical groups. The plate fixation group was significantly younger than the reverse shoulder arthroplasty group ($p < 0.05$ Dunn's multiple comparison test). Table III and Figure 2 show the costs of the different surgical implants. Plate fixation was significantly cheaper than both hemiarthroplasty ($p < 0.05$) and reverse shoulder arthroplasty ($p < 0.0001$). Intramedullary fixation was significantly cheaper than plate fixation ($p < 0.01$), hemiarthroplasty ($p < 0.0001$) and reverse shoulder arthroplasty ($p < 0.0001$) (all Dunn's comparison test). The proportion meeting the PROFHER inclusion criteria from hemiarthroplasty group was significantly lower than that of plate group ($p = 0.05$), IM fixation group ($p = 0.02$) and reverse group ($p = 0.02$) as calculated using Fisher's exact test.

Discussion

Our study has shown that the majority of a representative sample of patients currently undergoing surgical treatment for a proximal humerus fracture in the United Kingdom would have met the inclusion criteria for the recently published PROFHER trial. It is possible that a proportion of these patients may have been effectively managed non-operatively. Overall the patient demographics from the 11 centres were broadly similar to those taking part in the PROFHER trial with a majority of female patients and a mean age in the seventh decile for both cohorts. In all, three quarters of patients undergoing surgery in these 11 centres met the inclusion criteria for the PROFHER trial. The mode of surgical fixation varied between centres with plate fixation being dominant. Over 90% of operations were performed or supervised by a consultant. Those patients undergoing reverse shoulder replacement were significantly older than those patients undergoing plate fixation. Implant costs of both reverse shoulder arthroplasty and hemiarthroplasty were significantly greater than both intramedullary fixation and plate fixation. Patients undergoing hemiarthroplasty were significantly less likely to meet the inclusion criteria for the PROFHER trial than patients undergoing plate fixation, intramedullary fixation or reverse shoulder arthroplasty.

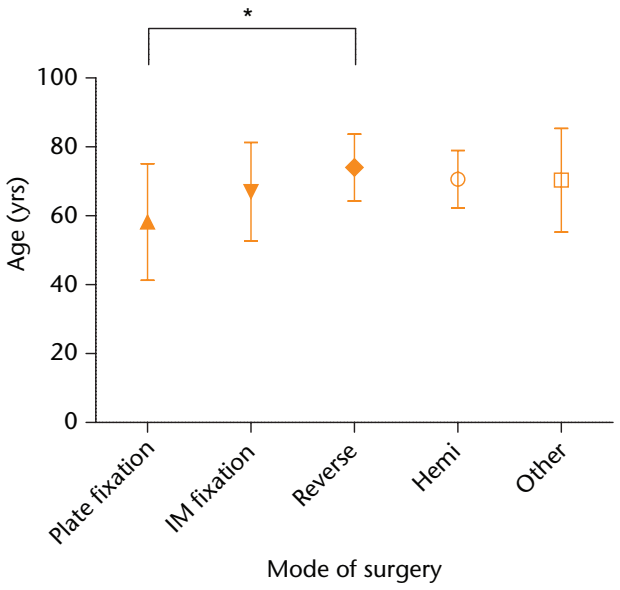

Fig. 1

Graph demonstrating the ages of the different modes of surgery groups. The symbols represent mean, while the bars represent a standard deviation above and below the mean. Statistical significance denoted by *p < 0.05, **p < 0.01, ***p < 0.0001 (Tukey's multiple comparison test).

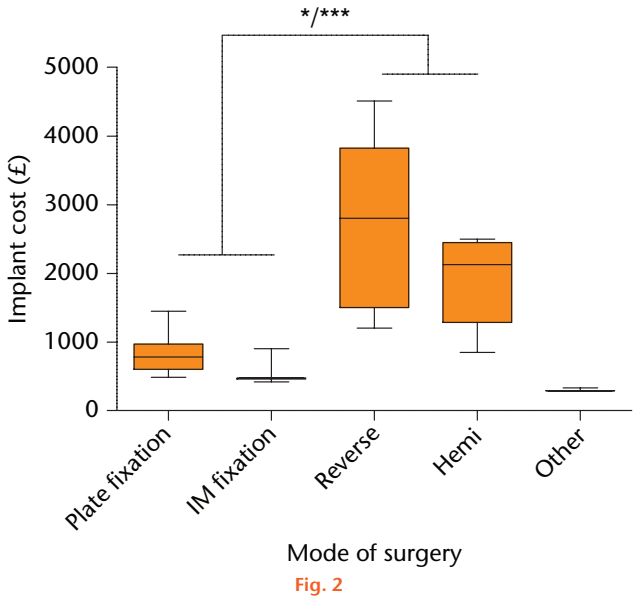

Fig. 2

Box and whisker plot demonstrating the relative implant costs of the different modes of surgery groups. The boxes represent median and interquartile range, while the whiskers represent range. Statistical significance denoted by *p < 0.05, **p < 0.01, ***p < 0.0001 (Dunn's multiple comparison test).

This study demonstrates that the PROFHER trial participants are generally demographically representative of those currently operated upon for proximal humerus fractures involving the surgical neck in the United Kingdom. The breakdown of fractures according to the Neer classification was slightly different in our study to the PROFHER trial. The proportion of Neer 2 (48% *versus* 40%) and 3 types (36% *versus* 33%) were fairly similar in both the PROFHER and our study respectively; however the Neer 4 types were more common in our study (25% in our study *versus* 5% in PROFHER). One key criticism of the PROFHER trial was the potentially subjective exclusion criterion of a 'clear indication for surgery'.[9] It is worth observing that of the 1250 assessed for eligibility in the PROFHER trial, 87 were excluded because there was a 'clear indication for surgery' other than dislocation or open fracture, while 195 were excluded for 'other reasons' which were not specified. It may be therefore argued that the patients who participated in PROFHER were not entirely representative of those currently undergoing surgery in the United Kingdom. However, the PROFHER supplementary material demonstrates that eligible patients were more likely to have fractures involving the tuberosities than ineligible patients. It is therefore possible that some of the difference in the proportion of Neer type 4 types relates to differences in the use of the Neer classification system between studies.

It is imperative to be clear that the PROFHER trial did not demonstrate non-operative treatment to be equivalent to surgery; it demonstrated surgery was not superior. While given the heterogeneity of fracture types included in PROFHER, it may well be true that specific subgroups may benefit from surgery and this may not have been detected. In this context the finding that the majority of patients met the inclusion criteria for the PROFHER trial remains of potential significance. It is certainly possible that a proportion of patients in our study who met the PROFHER trial inclusion criteria may have been effectively managed without surgical intervention. However, it is certainly also arguable that some of the patients in our study who met the inclusion criteria for PROFHER may well have benefited from surgery; the results of our study simply highlight that there is not enough high quality evidence to guide the management of many patients who are currently operated upon in the United Kingdom today. It is interesting that a relatively small number of proximal humeral fractures were treated surgically relative to the high incidence of these injuries (5.7% of all fractures).[11]

There is now high quality evidence demonstrating that surgery is not superior to non-operative treatment in the management of proximal humeral fractures, while the complication rate and costs associated with surgery are significantly higher.[8,9] Our study demonstrates that the implant costs for hemiarthroplasty and reverse shoulder arthroplasty are significantly higher than for plate or intramedullary fixation. There is also a relative paucity of evidence to justify the use of reverse shoulder arthroplasty over hemiarthroplasty, with the former having a higher complication rate.[12] One recent study does demonstrate

that superior clinical outcomes are associated with reverse shoulder arthroplasty over hemiarthroplasty,[13] however the outcomes following hemiarthroplasty in this study were particularly poor, with a mean Constant score of 40 which is out of sync with that seen in the rest of the literature.[12] This single centre study is at a high risk of bias and needs to be supported by future high quality research to justify the increasing use of reverse shoulder arthroplasty. It is likely that the higher morbidity, mortality and costs associated with the reverse shoulder arthroplasty in the elective setting may be translated into the trauma setting.[14] The increasing use of the reverse shoulder arthroplasty for trauma also seems to be heavily influenced by surgeon preference rather than any robust evidence of a functional benefit for patients.[15,16] Our study demonstrates that only the hemiarthroplasty group were less likely to meet the inclusion criteria for the PROFHER trial, implying that only this group and not those undergoing reverse shoulder arthroplasty were less suitable for non-operative treatment. While descriptively the mode of surgery appeared to vary greatly between our 11 centres; although plate fixation was generally the dominant mode, one centre favoured intramedullary fixation and the usage of reverse shoulder arthroplasty appeared variable. The costs reported in this study related to the implant costs only and this represents only a small proportion of the total costs involved.

A key strength of this work is that little is known about the surgical treatment of proximal humerus fractures in the United Kingdom. Although this study is retrospective and over a single period of time it gives a novel insight into current surgical practice in a way that also reveals details about the injury characteristics and patient demographics in the specific relative context of the recently published PROFHER trial. The data was gathered before the PROFHER trial was published with the specific aim to repeat this process at a later date to determine whether practice has been affected by this emergent evidence. A significant limitation of the current study is that the number of proximal humeral fractures treated at the 11 centres is unknown and it is not possible to determine the proportion of fractures that are operated upon. How representative these 11 centres are of the totality of practise in the United Kingdom can only be speculated upon; it is worth noting that the centres are fairly diverse in terms of hospital type (trauma centre versus district hospital) and geographic location. With respect to implant costs, there may be a degree of variability in how local finance departments reported these costs, however as they were asked to provide the costs of the implants used this should represent the actual cost to the hospital and include any discounts.

It is important to consider that our analysis which demonstrated that a majority of patients may have met the inclusion criteria for the PROFHER trial does not mean they are wholly representative of patients within the study. When interpreting the results of our study it is important to consider that the PROFHER trial was designed to test for superiority and not equivalence. It is important to note that this study was undertaken prior to the PROFHER trial's publication. It therefore allows the assessment of changing surgical practice in response to this study and other factors. Certainly there is an avenue for future research to determine trends in surgical practice and the potential influence of the PROFHER trial.

In conclusion, our study has shown that a majority of patients currently undergoing surgical treatment for a proximal humerus fracture in the United Kingdom would have met the inclusion criteria for the PROFHER trial and that a proportion of these patients may have been effectively managed non-operatively. When new high quality evidence becomes available it is important that surgical decision making responds to reflect this. In the context of proximal humeral fractures this may mean a significant reduction in the number of patients being offered and undergoing surgery. If uncertainty still exists then new trials should be designed to address this; areas of uncertainty include which mode of surgical treatment is best for which patients, but also whether any mode of surgery is superior to non-operative treatment for any particular groups of patients.[17] It is therefore arguable that in the absence of a clear indication for surgery, patients should not be offered surgical treatment for proximal humeral fractures unless they are part of a trial investigating ongoing uncertainty.

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Author Contribution

- B. J. F. Dean: Study conception and design, Data collection and analysis, Drafting of the article and critical revision of the article.
- L. D. Jones: Study conception and design, Data collection and analysis, Drafting of the article and critical revision of the article.
- A. J. R. Palmer: Study conception and design, Data collection and analysis, Drafting of the article and critical revision of the article.
- R. D. Macnair: Data collection and analysis, Critical revision of the article.
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- R. S. Nandra: Data collection and analysis, Critical revision of the article.
- R. S. Aujla: Data collection and analysis, and the critical revision of the article.
- A. E. Sykes: Data collection and analysis, Critical revision of the article.
- A. J. Carr: Study conception and design, Data collection and analysis, Drafting of the article and critical revision of the article.

ICMJE conflict of interest

- None declared.