Early Mobilisation in Proximal Humerus Fractures: Is a Stratified Rehabilitation Protocol Safe?

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ABSTRACT

Introduction: There remains little evidence on rehabilitation protocols for proximal humerus fractures (PHFs), although early mobilisation has been associated with positive clinical outcomes. There may be a potential role in allowing patients with more stable fractures to undergo an accelerated rehabilitation process to facilitate quicker return to function, although it must be balanced with safety concerns of premature mobilisation and logistical concerns of implementation with excessive stratification. The study aim was to report the overall safety and outcomes of a simple and implementable 2-tier stratified rehabilitation protocol based on fracture stability adopted by our institution for non-operatively treated PHFs.

Materials and methods: Patients in our institution (level 1 trauma centre) with non-operatively treated PHFs underwent a stratified rehabilitation protocol that classified patients into Accelerated versus Standard arms - with more stable fractures undergoing an accelerated rehabilitation programme. The Oxford Shoulder Score (OSS), Quick Disabilities of the Arm, Shoulder and Hand Score (QuickDASH), EuroQol-5-Dimensions (EQ5D) questionnaires, shoulder range of motion (ROM) and grip strength were measured at six months and one year post-injury. The frequency of adverse events requiring surgical intervention was noted.

Results: We included 164 patients and 43% (71/164) went through the accelerated protocol. Overall, patients had favourable OSS (median[range] 47[44-48]), EQ5D (median [range] 1.0[0.82-1.00]), QuickDASH scores (median[range] 2.3[0- 10.7]), and shoulder ROM and grip strength above the requirement for functional activities of daily living at 1 year. There were no adverse events reported 1-year post-injury.

Conclusion: This study was the first to report the safety and outcomes of a stratified rehabilitation protocol for PHFs. Our simple 2-tier stratified rehabilitation protocol which allowed a shorter period of rehabilitation and earlier return to function for patients with more stable PHFs is implementable, safe and had overall favourable functional outcome scores.

Keywords:
proximal humerus fractures, rehabilitation, stratified, non-operative, personalised

INTRODUCTION

Proximal humerus fractures (PHFs) are common upper-limb fractures accounting for a large percentage of osteoporotic fragility fractures in the elderly population[1,2]. PHFs have been known to cause significant disability and burden of disease[3,4], and with the world's aging population, PHFs numbers are likely to increase[5]. Therefore, achieving a better understanding of the optimal interventions for the treatment of proximal humerus fractures is paramount in improving patient outcomes and minimising its associated burden on the individual and society[6].

The majority of PHFs are currently managed non-operatively in the older population, with the landmark PROFHER (PROximal Fracture of the Humerus: Evaluation by Randomisation) trial showing no significant difference in clinical outcomes of operative versus non-operative treatment of PHFs in the elderly population[7]. Non-operative treatment of PHFs typically consists of a rehabilitation program involving a period of immobilisation followed by passive and active range of motion exercises, and subsequently strengthening and functional exercises[6,8]. Compliance to rehabilitation has been associated with better clinical outcomes in non-operatively treated PHFs[9]. However, when it comes to rehabilitation protocols, there is no optimal timing that is agreed upon for the initiation of physical therapy, although early mobilisation and compliance to rehabilitation have been associated with positive short term clinical outcomes in more stable fractures[10,11]. While early mobilisation has been associated

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with positive PHFs outcomes, a balance must be achieved between early mobilisation and avoiding excessive or premature mobilisation in unstable PHFs fractures treated non-operatively.

Therefore, in the move towards personalised care, there is a potential role of a stratified rehabilitation protocol for non-operatively treated PHFs in allowing patients with more stable fractures to undergo a more aggressive program with earlier mobilisation allowing a shorter period of rehabilitation to recovery, while patients with more unstable fractures undergoing a more graduated rehabilitation program. Nonetheless, there remains very little evidence on rehabilitation protocols for PHFs, with most rehabilitation protocols for PHFs being one-size-fit-all programmes involving a period of immobilisation without standardisation and no description of a stratified rehabilitation protocol in current available evidence[12]. A careful balance must be achieved in stratification of rehabilitation for patients with non-operatively treated PHFs, to prevent premature mobilisation resulting in negative clinical outcomes and also ensuring logistical and economic implementabilty of the protocol by avoiding excessively complex stratification. Further research is warranted to explore the practicality, safety and outcomes of a stratified rehabilitation protocol in the treatment of non-operatively treated PHFs.

In our institution, we developed and adopted a stratified rehabilitation protocol for patients with non-operatively treated PHFs based on fracture stability (Fig. 1). The primary aim of this study was to report the outcomes and safety of the stratified rehabilitation protocol by prospectively evaluating patient-reported outcome measure (PROM) scores, functional outcomes (ROM, grip strength) and the presence of any adverse events in patients who underwent the stratified rehabilitation protocol after one year. The secondary aim of the study was to compare the outcomes (PROM, ROM, grip strength, adverse events) between the accelerated and standard arms of the stratified rehabilitation protocol.

MATERIALS AND METHODS

This was a prospective cohort study conducted at a single Level 1 trauma centre from September 2017 to March 2021. Results were reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines[13]. This study was approved by our Institutional Review Board (IRB), National Healthcare Group (NHG) Domain Specific Review Board (DSRB) (reference number 2016/01241).

We included patients above 21 years of age who received non-operative treatment for a proximal humerus fracture which was presented within 3 weeks of sustaining the injury. The inclusion and exclusion criteria for the patients are detailed in Table I.

All patients underwent a stratified rehabilitation protocol developed by our institution that customised the rehabilitation time frame and targets based on the stability of the fracture. The stability of the fractures was determined by the surgeon after examination and radiographic evaluation. The patients were then split into two main groups (Accelerated protocol and Standard protocol) based on the stability of the fracture - patients who had more stable fractures underwent an accelerated rehabilitation program. Stability of PHFs is a complex concept involving a myriad of patient factors (e.g. age, compliance, risk factors for poor bone quality or healing such as smoking or alcohol use, bone density seen on radiographs, history of osteoporosis) and fracture factors (e.g. extent of displacement (varus/valgus), cortical contact, medial hinge, progress over serial radiographs) which could predispose to higher risk of fracture displacement and poor healing[14]. There is no established literature currently that describes fixed factors that define a stable or unstable fracture but rather requires holistic consideration of all the patient and disease factors to make a reasonable decision. For the purpose of our study, fellowship trained orthopaedic trauma surgeons from our institution classified patients into the stable/unstable groups after consideration of the patient/fracture factors affecting fracture stability for each individual patient. The rehabilitation process for both protocols consisted of four main phases - namely the early protective phase, mobilisation phase, strengthening (early callus) phase, and strengthening (mature callus) phase. For the accelerated protocol, these phases were started earlier with a shorter overall duration to completing the rehabilitation programme. The details of the stratified rehabilitation protocol can be found in Fig. 1.

The baseline demographic and social characteristics of patients included were: age, gender, race, employment status, household income, educational level, presence of domestic workers, housing type and smoking status. Charlson Comorbidity Index (CCI), Parker Mobility Score (PMS), Barthel Index (BI) were collected too[15-18]. The CCI is a weighted index based on a patient's comorbidities that is predictive of mortality[15]. PMS is a composite measurement of the patient's mobility indoor, outdoors and during shopping as a measure of mobility and has also been shown to be a predictor of mortality[17]. BI is an ordinal scale used to measure performance in activities of daily living as a measure of functional independence[16].

The Oxford Shoulder Score (OSS), Quick Disabilities of the Arm, Shoulder and Hand Score (QuickDASH) and EuroQol-5 Dimensions (EQ5D) questionnaires were used to assess the functional outcomes of patients at six months and one-year after injury. OSS is a validated scoring system evaluating the extent of shoulder pain, activities of daily living, and

function experienced by patients in the last four weeks based on a 12-item questionnaire[19]. The 12 items in OSS are scored from 0 (worst function) to 4 (best possible function), with a total score of 48 indicating the best possible function and 0 indicating poorest function[20]. An OSS score of 40 and above was defined to be a favourable outcome[21]. QuickDASH is another scoring system involving a 11-item questionnaire which evaluates the function and patient-reported symptoms of the whole upper limb[22]. The QuickDASH questionnaire consist of 11 items which add up to a total score ranging from 0 (best symptoms/ function) to 100 (worst symptoms/ function)[22]. EQ5D is a widely used validated tool for the assessment of overall quality of life (QoL), comprising of five questions on pain, mobility, psychological status, usual activities and self-care[23]. A score between one (no issues) to three (severe issues) is reported by patients for each of the five questions, and a summary index can be calculated using the total score from the five questions - with lower scores indicating better patient reported quality of life[23]. QuickDASH scores of 15 or lower were defined to be a favourable outcome[21].

The grip strength and shoulder range of motion (ROM), including flexion, extension, abduction, internal rotation and external rotation were also assessed at six months and one year after PHF. The frequency of adverse events, defined as any event e.g. significant fracture displacement that resulted in the need for surgical intervention, was also monitored at six months and one year as an additional measure to assess the overall patient outcomes. The initial plain radiographs of the fractures were classified by a trained orthopaedic senior resident using the Neer Classification[18].

Sample size was calculated based using G*Power 3.1.9.4. The primary objective of the study was to explore the differences in various outcomes primarily functional outcomes between the stratified rehabilitation protocols (standard and accelerated). To detect a 0.50 medium effect size with 0.05 type 1 error, the study will need to recruit 128 samples to achieve 80% power of study. The final sample size to be included into the study was 154 patients after accounting for 20% attrition rate.

Data was cleaned, explored, and analysed using STATA version 14.0. Descriptive statistics were used to describe the demographic characteristics and health related outcomes of the patients. The distribution of the continuous data was checked using skewness, kurtosis and histogram, and presented as median as the data were not normally distributed. Categorical variables were presented as frequency and percentage.

The difference in patients' characteristics between different rehabilitation protocols were tested using Mann Whitney U test, Pearson chi-squared test and Fisher Exact test whichever appropriate. The differences were further explored using multiple linear regression analysis adjusting for the differences in patients' characteristics between the two groups to address the potential confounding effect. Multicollinearity were checked using the variance inflation factor (VIF) and heteroskedasticity of the final model were checked using Breusch-Pagan / Cook-Weisberg test. Statistical significance was denoted as $p<0.05$.

RESULTS

A total of 219 patients presented with a proximal humerus fracture between September 2017 to March 2021 in our institution. Among these patients, 48 received operative treatment and 7 patients who did not report their rehabilitation protocol were excluded. Overall, 164 patients were included in this study. Among the included patients, the median age was 69 years (62, 78) and 76% (125 out of 164) were females. Using the Neer classification, 9% (14 of 164) of patients had a type 1 PHF, 62% (102 of 164) had a type 2 PHF, 27% (45 of 164) had a type 3 PHF and 2% (3 of 164) had a type 4 PHF. Overall, 57% (93 of 164) and 43% (71 of 164) went through the standard and accelerated rehabilitation protocol respectively (Table II). Patients who went through the accelerated rehabilitation protocol were of a younger age ($p<0.001$) and had a lower radiographic severity based on the Neer classification compared to patients who went through the standard rehabilitation protocol ($p<0.001$) (Table II). Patients who went through the accelerated rehabilitation protocol also had less premorbid comorbidities measured by CCI ($p=0.002$) and higher premorbid functional status measured by PMS ($p=0.001$) (Table II). Details of the demographic characteristics are further summarised in Table II.

Overall, patients with non-operatively treated proximal humerus fractures who went through the stratified rehabilitation protocol had generally favourable patient-reported quality of life and functional outcomes at 6 months and 1 year after fracture. At 6 months, the median OSS score was 44 ([range] [41 to 48]) (Table III), indicating a favourable OSS outcome score of 40 or higher[21]. The median QuickDASH score at 6 months was 9 ([range] [2 to 20.5]) (Table III), indicating a favourable QuickDASH outcome score of 15 or lower[21]. At 1 year, the median OSS score was 47 ([range] [44 to 48]) (Table III). At 1 year, the median QuickDASH scores were 2.3 ([range] [0 to 10.7]) (Table III). Shoulder ROM (flexion, extension, abduction and external rotation) and grip strength above the requirement for functional activities of daily living (ADL)[24,25] were reported at 1 year (median [range]: flexion 140° [120 to 160], extension 60° [60 to 70], abduction 130° [110 to 150], external rotation 60° [50 to 70], grip strength 18kg [13 to 22] (Table III). Of note, there were no adverse events in both the accelerated and standard protocol one year after PHF.

After adjustment for potential confounding factors including

Table I: Inclusion and exclusion criteria of patients.

Inclusion criteria	Exclusion criteria
More than 21 years of age	Presentation was delayed more than 3 weeks post-injury
Presented within 3 weeks of the injury	Open fracture
Received non-operative treatment	Mentally incompetent
	Severe soft-tissue compromise
	Neurovascular injury
	Multiple injuries
	Pathological fractures
	Pregnant at time of injury
	Multiple comorbidities and deemed unfit for surgery
	Received operative treatment

Table II: Demographic characteristics of the patients (n=164).

Variables	Overall 93 (56.71)	Standard 71 (43.29)	Accelerated	P value
Age in years, median (IQR)	69 (62, 78)	73 (65, 80)	65 (59, 71)	<0.001[a]
Age in category, n (%)				0.004[b]
<65 years old	54 (32.93)	22 (23.7)	32 (45.1)	
≥65 years old	110 (67.07)	71 (76.3)	39 (54.9)	
Gender, n (%)				0.433[b]
Male	39 (23.78)	20 (21.51)	19 (26.76)	
Female	125 (76.22)	73 (78.49)	52 (73.24)	
Ethnicity, n (%)				0.922[c]
Chinese	143 (87.20)	80 (86.0)	63 (88.8)	
Malay	11 (6.71)	7 (7.5)	4 (5.6)	
Indian	6 (3.66)	4 (4.3)	2 (2.8)	
Others	4 (2.44)	2 (2.2)	2 (2.8)	
Smoking status, n (%)				0.635[b]
Non-smoker	140 (85.37)	78 (83.9)	62 (87.3)	
Current smoker	11 (6.71)	6 (6.5)	5 (7.0)	
Ex-smoker	13 (7.93)	9 (9.6)	4 (5.7)	
Neer classification, n (%)				<0.001[c]
1	14 (8.54)	1 (1.08)	13 (18.31)	
2	102 (62.20)	55 (59.14)	47 (66.20)	
3	45 (27.44)	34 (65.56)	11 (15.49)	
4	3 (1.83)	3 (3.23)	0 (0.00)	
CCI, median (IQR)	0 (0, 1)	1 (0, 2)	0 (0, 1)	0.002[a]
Barthel index, median (IQR)	20 (20, 20)	20 (20, 20)	20 (20, 20)	0.051[a]
Parker Mobility Score, median (IQR)	9 (9, 9)	9 (7, 9)	9 (9, 9)	0.001[a]

age, fracture severity (Neer classification), premorbid comorbidity (CCI) and functional status (PMS) which were significantly different between the accelerated and standard population, we found that there were no differences in outcomes of OSS, EQ5D and QuickDASH between the accelerated and standard arms of the rehabilitation protocol at 6 months and 1 year ($p > 0.05$; Table IV). No difference was also found between the accelerated and standard protocol for both shoulder ROM ($p>0.05$) and grip strength ($p>0.05$) at 6 months and 1 year after adjustment for the potential confounding factors (Table IV). Details of the outcome comparison between the accelerated and standard arm of the rehabilitation protocol are described in Table IV.

DISCUSSION

This was the first study to describe a stratified rehabilitation protocol for non-operatively treated PHFs used in our institution (Fig. 1). The primary aim of our study was to determine the overall outcomes (patient-reported and functional outcomes) and safety (number of adverse events) of the stratified rehabilitation protocol based on fracture stability. Our findings show that the protocol was both safe and effective in allowing earlier mobilisation and quicker return to function for patients with more stable PHFs, showing good overall outcomes shown by the improvement in functional outcome scores (OSS/EQ5D/QuickDASH) and the absence of adverse effects reported in any of the patients. Comparing the two arms of the stratified rehabilitation protocol, we found no significant difference in outcomes of patients, with both arms achieving favourable outcomes overall.

Rehabilitation protocols for the non-operatively

Table III: Quality of life and functional outcomes at different time points.

	n	Median (IQR)
6 months		
OSS	138	44.0 (41.0, 48.0)
QuickDASH	131	9.0 (2.0, 20.5)
EQ5D	140	0.86 (0.72, 1.00)
Flexion	118	130 (110, 145)
Extension	118	60 (50, 68)
Abduction	117	120 (100, 145)
Internal rotation	117	65 (56, 70)
External rotation	117	55 (40, 62)
Grip strength	118	14 (10, 19)
1 year		
OSS	137	47.0 (44.0, 48.0)
QuickDASH	108	2.3 (0.0, 10.68)
EQ5D	137	1.0 (0.82, 1.00)
Flexion	63	140 (120, 160)
Extension	60	60 (60, 70)
Abduction	63	130 (110, 150)
Internal rotation	63	70 (65, 80)
External rotation	63	60 (50, 70)
Grip strength	63	18 (13, 22)

Table IV: Summary of patient characteristics and outcomes of the stratified rehabilitation protocol.

Variables	Standard	Accelerated	Coef (95% CI)	P value[d]
PROMs				
OSS, median (IQR)				
6 months	44 (39, 48)	45 (42, 48)	75.94 (-117.32, 269.20)	0.438*
1 year	46 (42. 48)	48 (44, 48)	-32.78 (-138.34, 72.78)	0.915*
EQ5D, median (IQR)				
6 months	0.83 (0.73, 1.00)	0.89 (0.72, 1.00)	-0.01 (-0.12, 0.09)	0.788*
1 year	0.91 (0.81, 1.00)	1.00 (0.89, 1.00)	-0.04 (-0.12,0.04)	0.338*
QuickDASH, median (IQR)				
6 months	10.5 (3.4, 21.0)	7.0 (0.0, 13.6)	-2.54 (-6.90, 1.83)	0.252
1 year	7.0 (0.0, 13.6)	0.0 (0.0, 5.0)	-3.15 (-8.03, 1.73)	0.202
ROM				
Flexion, median (IQR)				
6 months	120 (100, 140)	130 (115, 150)	4.31 (-8.37, 16.99)	0.535
1 year	130 (100, 143)	148 (135, 160)	5.36 (-8.41, 19.12)	0.437
Extension, median (IQR)				
6 months	60 (45, 62)	60 (55, 70)	4.27 (-2.41, 10.95)	0.208
1 year	60 (50, 68)	60 (60, 75)		0.249
Abduction, median (IQR)				
6 months	116 (90, 135)	130 (110, 150)	6.15 (-6.29, 18.59)	0.332
1 year	115 (100, 140)	143 (130, 158)	14.56 (-2.07, 31.19)	0.062
Internal rotation, median (IQR)				
6 months	60 (55, 70)	70 (60, 70)	1.86 (-3.52, 7.24)	0.506
1 year	70 (60, 75)	70 (70, 80)	668.82 (-80.35, 1418.00)	0.124*
External rotation, median (IQR)				
6 months	50 (40, 60)	60 (60, 70	2.77 (-4.06, 9.60)	0.409
1 year	60 (45, 70)	60 (60, 70)	2.21 (-5.24, 9.67)	0.548
Grip Strength, median (IQR)				
6 months	12 (10, 18)	16 (12, 20)	0.58 (-1.66, 2.81)	0.609
1 year	16 (12, 20)	19 (17, 23)	1.21 (-3.59, 6.00)	0.616

dMultivariable model adjusting for age, Neers classification, Charlson Comorbidity Index, and Parker Mobility Score
*Squared transformation was performed to fulfil the assumption of heteroskedasticity
OSS: oxford shoulder score; QuickDASH: quick disabilities of the arm, shoulder and hand score; EQ5D: EuroQol-5 dimension; PROMs: patient reported outcome measures; ROM: range of motion

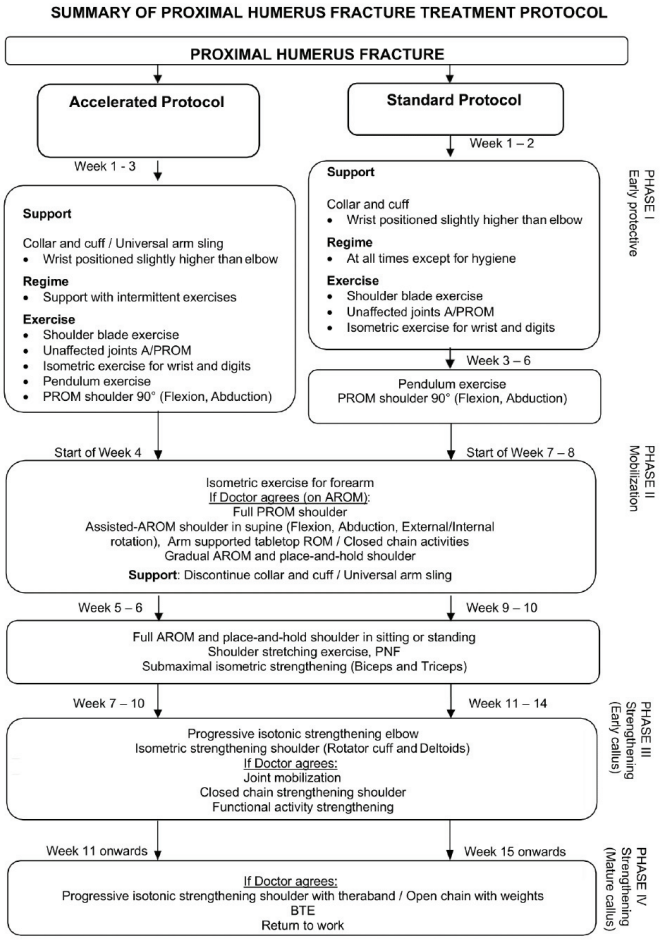

Fig. 1: Summary of stratified rehabilitation protocol for proximal humerus fracture.

management of proximal humerus fractures conventionally include a gradual progression from immobilisation to passive, active then resisted exercises, before return to full function[8]. These were largely standard protocols applied to all patients in a one-size-fit-all approach, with the lack of any recommended definitive rehabilitation strategy for various PHFs types in current available evidence[26]. Early mobilisation has been associated with positive outcomes of PHFs but should be carefully balanced with patient and fracture factors such as pain and fracture stability[10,11]. Premature or overly aggressive rehabilitation in excessively unstable fractures may result in fracture displacement and non-union requiring surgical intervention[27]. In the move towards a more personalised care, a stratified system for PHF rehabilitation would allow for a more tailored rehabilitation program that could better meet the needs of each patient; patients with more stable fractures could undergo an accelerated rehabilitation protocol with the aim of accelerated recovery and return to function, while patients with greater pain or fracture instability could undergo a more graduated program that is comfortable for them. Ideally, such a stratified rehabilitation protocol should be custom-made for each individual patient in terms of its rehabilitation components and timelines. However, the implementation of highly differentiated rehabilitation programs at an institutional level is often too difficult and resource-heavy[28]. Therefore, in a bid to achieve more personalised care for patients while still maintaining simplicity in implementation, our institution adopted the described stratified rehabilitation protocol which segregated patients into only two main groups (accelerated vs standard). Having a simple stratified protocol negates the need for further evaluation by a senior therapist once the patients are separated into each group, allowing this to be the middle ground of both a tailored yet resource-efficient rehabilitation protocol.

Overall, our study found positive patient reported and functional outcomes for patients who underwent the stratified rehabilitation protocol. Of note, there were also no cases of complications arising from an overly aggressive rehabilitation protocol (under the accelerated arm) resulting in excessive displacement of fracture or non-union requiring

surgical intervention in our protocol. In line with previous evidence in support of early mobilisation and recovery in PHFs, our study showed that the stratified rehabilitation protocol not only allowed for an accelerated rehabilitation program with shorter time required to be spent in rehabilitation to recovery for patients with more stable PHFs but was also an implementable and safe option in providing PHF rehabilitation with good overall outcomes[10,11].

This was the first study reporting the outcomes and safety of a stratified PHF rehabilitation protocol based on fracture stability that allows for quicker rehabilitation and recovery in more stable PHFs. Nonetheless, this was a prospective cohort study of the outcomes of patients enrolled in the stratified protocol, and the overall outcomes of the stratified protocol was not comparable to a standard non-stratified rehabilitation protocol. Future randomised controlled trials could be conducted to compare the outcomes of stratified versus non-stratified rehabilitation protocols for PHFs. Moreover, the stratified rehabilitation protocol customised the rehabilitation time frame and disposition (standard vs accelerated) for the patients based on fracture stability which were at the surgeon's discretion. The determination of fracture stability is a complex concept which involves the holistic consideration of a multitude of fracture factors such as fracture displacement, eccentric head index (EHI) and Neer classification, together with patient factors like handedness, compliance, functional demand and bone quality[18,29,30]. As such, no literature currently exists that describes a set of quantifiable fixed factors that define a stable or unstable PHF. Therefore, it is insufficient to use a few select metrics to define fracture stability and their subsequent disposition into the standard or accelerated protocol, but best left to the experienced surgeon who would take into account these factors holistically to make a decision. While it is not possible to quantify the decision on the PHF stability based on a few metrics due to the complex interplay of factors affecting fracture stability, our results showed that the decisions made by the fellowship trained surgeons in our study were congruent with the principles of the stratified protocol, whereby the accelerated protocol was being prescribed to younger patients with lower radiographic severity (patients with more stable PHFs and likely to tolerate an accelerated rehabilitation programme).

CONCLUSION

This study was the first to report the safety and outcomes of a stratified rehabilitation protocol for PHFs. Our study found that the simple 2-tier stratified rehabilitation protocol that facilitated earlier mobilisation and return to function for patients with more stable PHFs is safe and had good overall functional outcome scores (OSS/EQ5D/QuickDASH/ROM/grip strength). The protocol is a step towards better personalised care for rehabilitation of non-operatively treated PHFs, allowing patients with more stable PHFs to undergo a shorter period of rehabilitation to recovery, while maintaining safety, favourable outcomes and implementability at an institutional level in our experience.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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