Outcomes of Proximal Humerus Fractures in Children

Dr Samuel Richard Abbot, MBBS (Hons)

Surgical Specialties,
Faculty of Health and Medical Sciences,
University of Adelaide

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Abstract

Proximal humerus fractures (PHFs) in children are relatively rare, comprising <3% of all paediatric fractures. As with most paediatric fractures, PHFs in children have historically been treated non-operatively with acceptable functional and quality-of-life outcomes. However, there is a growing trend towards the surgical management of severely displaced PHFs in older children, who have a lesser capacity to remodel. While recent studies in adults have demonstrated no benefit of surgery for certain PHFs, there remains a paucity of evidence to guide the management of PHFs in children, and there is considerable heterogeneity in the literature regarding the indications for the different management options.

Aims of this thesis:

To analyse the functional and quality-of-life outcomes for a cohort of paediatric patients with PHFs, in attempt to inform the future management of the various types of PHFs in children.

To determine the clinical factors that predict a poorer clinical outcome for paediatric PHFs, including patient demographics, fracture pattern and treatment method.

List of Publications

Published

1. Abbot S, Proudman S, Ravichandran B, Williams N. Predictors of outcomes of proximal humerus fractures in children and adolescents: A systematic review. *Journal of Children's Orthopaedics*. 2022 Oct;16(5):347-354. doi: 10.1177/18632521221117445. Epub 2022 Aug 16. PMID: 36238150; PMCID: PMC9550992.
2. Abbot S, Proudman S, Sim YP, Williams N. Psychometric properties of patient-reported outcome measues used to assess upper limb pathology: a systematic review. *ANZ Journal of Surgery*. 2022 Dec;92(12):3170-3175. doi: 10.1111/ans.17973. Epub 2022 Aug 12. PMID: 35959939.
3. Abbot S, Proudman S, Hall K, Williams N. Outcomes of proximal humerus fractures in children: a study protocol for a retrospective cohort study. *BMJ Open*. 2022 Sep;12(9):e062586. doi: 10.1136/bmjopen-2022-062586. PMID: 36104126; PMCID: PMC9476141.

Submitted for Publication

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Chapter 1: Introduction: Literature Review

Definitions

Paediatric proximal humerus fractures (PHFs) include fractures of the proximal humeral epiphysis, physis, and metaphysis in a patient aged under 18 years. A pathological fracture is a fracture which occurs without adequate trauma, and is caused by a pre-existent pathological bone lesion (such as a tumour or infection).(1) For the purposes of this thesis, pathological fractures were considered to be a separate entity and were excluded from the analysis. ‘Surgical management’ included any surgical operation that involves making an incision to treat a PHF. ‘Conservative management’ and ‘nonoperative management’ both refer to non-surgical therapy, and included closed reduction, immobilisation and physiotherapy.

Classification and Epidemiology of Paediatric PHFs

Paediatric PHFs can be classified as either physeal (involving the proximal humeral growth plate) or metaphyseal (occurring distal to the proximal humeral growth plate). Metaphyseal fractures account for approximately 70% of paediatric PHFs, and are most commonly seen in children aged 5-12 years.(2-5). Physeal fractures account for the other 30%, and show a bimodal distribution, with peaks occurring in patients aged <3 years (who typically sustain Salter-Harris type I physeal fractures) and over 12 (who typically sustain Salter-Harris type II physeal fractures).(4-6) Previous studies have estimated the incidence of paediatric PHFs to be between 31.4 and 680 fractures per 100,000 children per year, with a major proportion occurring between the ages of 11 and 15 years.(2, 3, 7, 8) Paediatric PHFs usually occur with at least a 3:1 male preponderance.(9, 10) In 1965, Neer and Horowitz introduced a system to classify the severity of physeal paediatric PHFs based on their degree of displacement.(11, 12) Neer-Horowitz (NH) grade I fractures are either nondisplaced or displaced by less than 5mm; grade II are displaced between 5mm and one-third of the width of the proximal humeral shaft, grade III are displaced greater than one-third but no greater than two-thirds of the shaft width, and grade IV are displaced by more than two-thirds of the shaft width.(13) 85% of physeal paediatric PHFs are either nondisplaced or minimally displaced (NH grade I or II), with only 15% being severely displaced (NH grade III or IV).(13, 14)

Aetiology and Pathoanatomy of Paediatric PHFs

There are two common responsible mechanisms that lead to a paediatric PHF, namely a backwards fall onto an out-stretched hand with the arm hyperextended and externally rotated, or direct trauma to the lateral aspect of the shoulder.(2, 3, 5, 8, 9) The usual cause of injury is age-dependent. In neonates, physeal separations can occur as a result of birth trauma.(5, 8, 9) PHFs in older children typically result from moderate-energy trauma during high-contact sports (such as football, horse-riding and gymnastics) or motor vehicle accidents.(2, 9) A PHF occurring in an otherwise healthy infant should be considered suspicious for non-accidental trauma.(8)

Prognosis of Paediatric PHFs

PHFs that occur prior to skeletal maturity rarely lead to a clinical, functional or cosmetic deficit for a number of reasons.(8) Firstly, they have a profound ability to remodel, due to the proximal humeral growth plate having the highest proximal to distal physis growth ratio among all long bones.(4, 8, 15-17) This ability to spontaneously correct residual deformities is age-dependent, with older children having less remodelling potential.(12, 18) Secondly, the periosteum in the immature proximal humerus is metabolically active, which enhances its ability to rapidly form callus and heal when fractured.(2) Thirdly, the glenohumeral joint has the widest range of motion of any joint in the body, meaning it can accommodate a large degree of displacement and angulation without causing any significant functional impairment.(3, 19, 20)

Treatment of Paediatric PHFs

Due to the remarkable healing and remodelling potential of the paediatric proximal humerus, PHFs in children have historically been treated non-operatively, irrespective of their severity.(21, 22) Indeed, in their history study of PHFs in children and adolescents in 1965, Neer *et al.* declared that, regardless of the degree of displacement, open surgery for the treatment of PHFs in children is rarely justified.(11) The findings of this paper, as well as the classification system created by Neer and Horowitz are commonly used even today.(7) Since the study by Neer *et al.*, conservative management has remained the mainstay of treatment for minimally displaced PHFs in children, however the management of severely displaced fractures has become the subject of considerable debate, particularly for older children with limited remaining growth and remodelling potential.(14) Some authors maintain that even the most displaced PHFs should be managed conservatively in paediatric patients, provided it is a closed fracture without any neurovascular compromise.(23-25) On the other hand, there have been many recent studies that have advocated for the surgical management of severely displaced PHFs in adolescents patients, citing superior patient-reported pain and quality-of-life outcomes.(12, 13, 16, 26, 27) Evidently, there is considerable heterogeneity in the literature regarding the optimal management of paediatric PHFs, and there is currently no age- and displacement-based treatment algorithm that has been generally accepted. This is further confounded by the fact that previous studies examining outcomes of paediatric PHFs tend to be retrospective analyses of small cohorts of patients, with only a short period of follow-up.(7, 8) Consequently, there is a paucity of well-powered studies that have examined long-term functional and quality of life outcomes following PHFs.

Purpose

The purpose of this thesis was to attempt to address the current paucity of literature that addresses the functional and quality-of-life outcomes of surgical and non-operative management of PHFs in children. Additionally, the thesis aimed to clarify the indications for surgical management of paediatric PHFs and identify factors that have been associated with a poorer clinical outcome, including patient demographics, fracture pattern and treatment method. By doing this, the aim was to inform the optimal management of paediatric PHFs, dependent on fracture pattern and patient demographics.

Hypothesis

The hypothesis for this thesis was that adolescent patients treated non-operatively have a higher risk of a poor clinical outcome, especially when the initial displacement of their fracture is greater.

Chapter 2: Materials and Methods

The thesis began with a systematic literature review that investigated the risk factors for a poor functional and quality-of-life outcome following a paediatric PHF (Chapter 3). The aim of this systematic review was to determine what had already been established with regards to the outcomes of PHFs in children and adolescents, and identify demographic, radiological and clinical factors that have led to a poorer clinical outcome. The methodology of the systematic review is outlined in detail in Chapter 3. Another systematic literature review was then completed, which investigated the psychometric properties of patient-reported outcome measures (PROMs) that have been used to assess upper limb pathology (Chapter 4). The purpose of this systematic review was to identify whether there were any existing PROMs that have been validated to be used to assess upper limb pathology in children and adolescents, which could be utilised in the thesis' original research study. The methodology of this systematic review is outlined in detail in Chapter 4. Once this had been established, the study protocol for the original research study was finalised. This study protocol, which thoroughly outlines the original research study's intended purpose, study design and statistical methodology, can be found in Chapter 5. The two systematic reviews and the study protocol for the original research study have all been published in peer-reviewed scientific journals. Finally, Chapter 6 features the original research study, which has been submitted for publication.

Chapter 3: Predictors of outcomes of proximal humerus fractures in children and adolescents: a systematic review(28)

Statement of Authorship

Title of Paper	Predictors of outcomes of proximal humerus fractures in children and adolescents: A systematic review.
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Principal Author

Name of Principal Author (Candidate)	Samuel Abbot		
Contribution to the Paper	Performed the initial literature search, selected relevant articles, extracted data from each article, synthesised the data, wrote the manuscript and acted as the corresponding author.		
Overall percentage (%)	90%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	24/10/2023

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);

ii. permission is granted for the candidate in include the publication in the thesis; and

iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Susanna Proudman

Contribution to the Paper	Assisted with study design and editing of the manuscript.		
Signature		Date	24/11/2023

Name of Co-Author	Bhuvanesh Ravichandran		
Contribution to the Paper	Assisted with selection of articles to be included in the literature review, and with the data extraction process.		
Signature		Date	21/11/2023

Name of Co-Author	Nicole Williams		
Contribution to the Paper	Assisted with study design and editing of the manuscript.		
Signature		Date	24/11/2023

Abstract

Purpose:

Minimally displaced paediatric proximal humerus fractures can be reliably managed non-operatively; however there is considerable debate regarding the appropriate management of severely displaced proximal humerus fractures, particularly in older children and adolescents with limited remodelling potential. The purpose of this study was to perform a systematic review to answer the questions: “What are the functional and quality-of-life outcomes of paediatric proximal humerus fractures?” and “What factors have been associated with a poorer outcome?”

Methods:

A review of Medline and Embase was performed on 4 July 2021 using search terms relevant to proximal humerus fractures, surgery, non-operative management, paediatrics, and outcomes. Studies including ≥10 paediatric patients with proximal humerus fractures, which assessed clinical outcomes by use of an established outcome measure, were selected. The following clinical information was collected: patient characteristics, treatment, complications, and outcomes.

Results:

Twelve articles were selected, including four prospective cohort studies and eight retrospective cohort studies. Favourable outcome scores were found for patients with minimally displaced fractures, and for children aged less than 10 years, irrespective of treatment methodology or grade of fracture displacement. Older age at injury and higher grade of fracture displacement were reported as risk factors for a poorer patient-reported outcome score.

Conclusion

An excellent functional outcome can be expected following non-operative management for minimally displaced paediatric proximal humerus fractures. Prospective trials are required to establish a guideline for the management of severely displaced proximal humerus fractures in children and adolescents according to fracture displacement and the degree of skeletal maturity.

Level of evidence:

Level V.

Keywords:

Proximal humerus, fractures, treatment

Purpose

Proximal humerus fractures (PHFs) comprise between 0.45% and 2% of all paediatric fractures,(2, 9, 14, 21) with an estimated incidence between 31.4 and 680/100,000 children per year and a 3:1 male preponderance.(9, 10) 85% of paediatric PHFs are minimally displaced, Neer-Horowitz (NH) Grade I or Grade II fractures.(13, 14) It has been suggested that PHFs that occur prior to skeletal maturity rarely lead to a functional or cosmetic deficit.(8) These fractures have a profound ability to remodel, as the proximal humeral growth plate is responsible for 80% of humeral longitudinal growth.(3, 4, 12, 15-18) The glenohumeral joint has the widest range of motion of any joint in the body and can accommodate a large degree of deformity without causing significant functional impairment.(3, 19, 20) Because of these unique attributes, paediatric PHFs have historically been treated non-operatively.(21, 22) This practice continues to be accepted for NH Grade I and Grade II fractures; however, there is considerable debate regarding the management of NH Grade III and Grade IV fractures, particularly in teenagers with relatively limited remodelling potential.(9, 14, 15, 18, 29, 30) Proposed treatment algorithms are based on patient age and grade of displacement,(7, 10, 21), however, no generally accepted guideline has been established.(14, 26, 31) The aim of this systematic review was to synthesise the current literature regarding the functional and quality-of-life outcomes of paediatric PHFs, and identify factors associated with a poor clinical outcome.

Methods

This study was carried out according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, and is registered at the International Prospective Register of Systematic Reviews (PROSPERO). The published protocol for this review can be found on the PROSPERO website, registration no. CRD42021241929.(32)

Eligibility Criteria

Included articles were original research studies written in English and published in a scientific journal. The studies must have reported the clinical outcomes of paediatric patients treated for PHF, by use of an established outcome measure, such as the Constant-Murley Score (CMS), the disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, or American Shoulder and Elbow Surgeons score (ASES).(33, 34) Only studies with at least 10 subjects aged 18 years or younger at the time of injury were included. Studies that evaluated the efficacy of a novel surgical technique were excluded.

Search Strategy

A librarian-assisted search was performed on Medline and Embase on 4 July 2021, from inception until the date of the search (see Supplementary Files 1 and 2). The search syntax consisted of six categories of keywords and/or subject headings intersected by the Boolean terms “AND” or “OR”. These categories were terms related to: (1): the proximal humerus; (2) fractures; (3) surgery; (4) non-operative management; (5) paediatrics; and (6) outcomes. The reference lists of studies selected for full-text review were reviewed, to ensure literature saturation. All citations were uploaded to Endnote 20®, where duplicates were removed. Relevant articles were read in full text by the two reviewers (S.A. and B.R.), and any discrepancies were resolved with discussion.

Data Collection

Standardised extraction forms were developed with the use of the Covidence® tool for systematic literature reviews. The study data extracted included study type, year of publication, methodology, number of participants, participant characteristics, treatment, complications, and outcomes.

Data Synthesis

Results of the individual studies were synthesised qualitatively, with consideration made for study design and potential biases.

Risk of Bias Within Studies and Quality Assessment

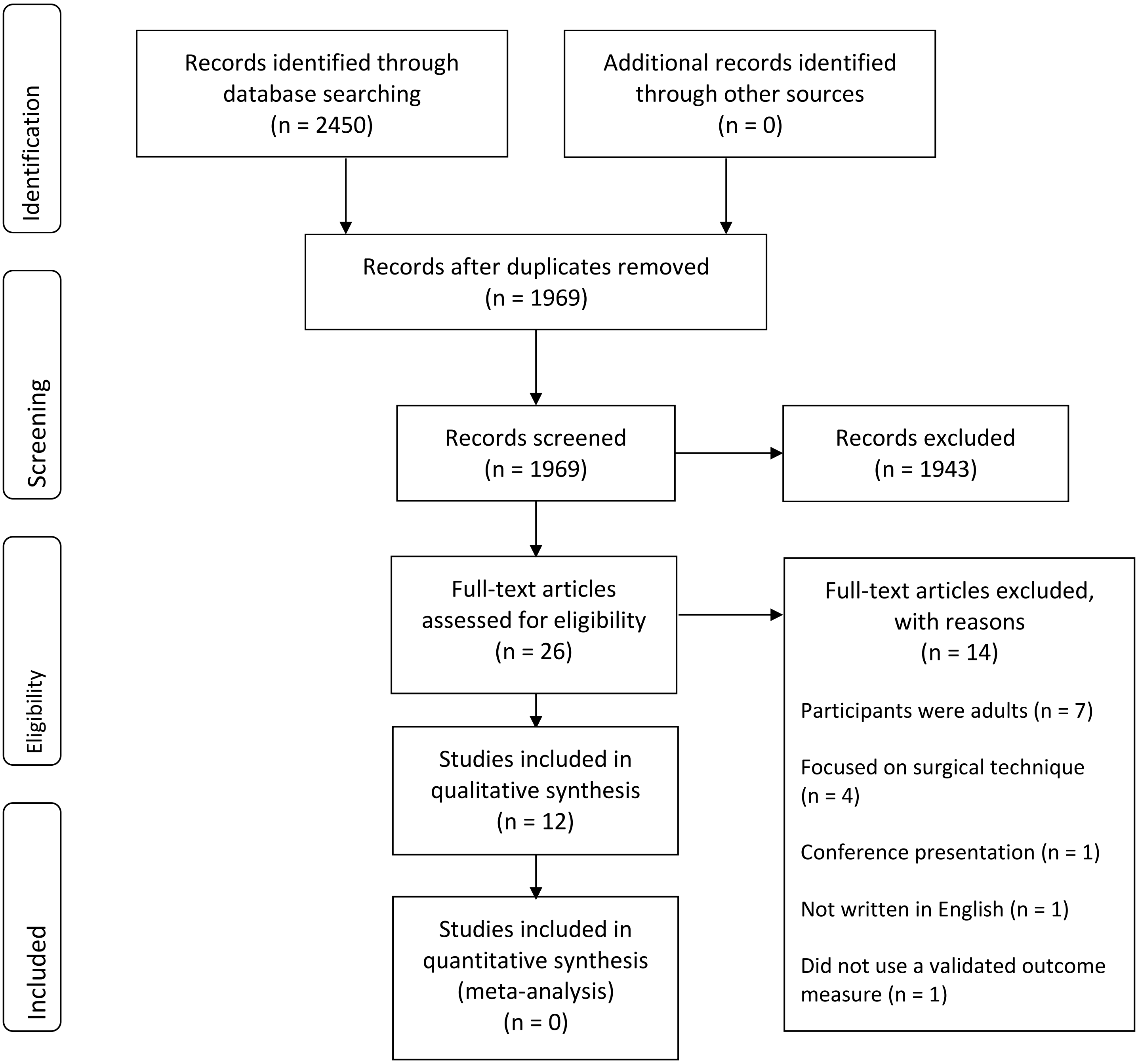
The quality of the selected studies was assessed using the Coleman Methodology Score (CMS).(35, 36) The CMS allocates up to 100 points according to 10 criteria: study size, mean duration of follow-up, number of different surgical procedures discussed, the study type, diagnostic certainty, whether a description of the surgical procedure is given, whether outcome measures are clearly defined, methods of reporting outcomes, and description of the subject selection. A study with a perfect CMS of 100 is largely devoid of the influences of chance, biases, and confounding factors.(7)

Results

Study Selection

The search retrieved 2450 results, 481 of which were duplicates. Of the 1969 individual articles screened, 1943 were excluded because of an irrelevant title or abstract. Therefore, twenty-six articles underwent full-text review. The initial agreement on articles selected for final inclusion was 68% (kappa = 0.429; moderate agreement). Fourteen were excluded on full-text review for the following reasons: involved adult subjects only,(37-43) focused on surgical technique,(44-47) conference presentation,(24) non-English language,(48) and did not evaluate outcomes using a validated instrument.(10) Twelve articles were ultimately deemed eligible for inclusion.(12, 13, 15-19, 26, 27, 49-51) This process is outlined in the PRISMA diagram (Figure 1).

Figure 1: PRISMA flow diagram outlining the process by which articles were screened



Study Design

There were four prospective cohort studies and eight retrospective cohort studies, including a total of 791 subjects. The mean age was 10.8 years (standard deviation = 3.2, range = 1-18), and 56.5% were male. 685 (86.6%) participants were followed-up for a median duration of 2 years (range = 2 weeks-18 years). Seven studies only included physeal fractures and graded fractures by use of the NH classification.(12, 13, 17, 18, 26, 27, 51), while one study included only metaphyseal fractures and categorised fractures according to the degree of fracture angulation.(16) Four studies included both physeal and metaphyseal fractures; two classified fractures according to the AO system,(49, 50), one categorised patients according to the degree of fracture angulation,(19) and one used both the NH classification (for physeal fractures) and degree of angulation (for metaphyseal fractures).(15) Six of the eight studies that analysed physeal fractures excluded participants with NH Grade I and Grade II fractures,(12, 13, 15, 26, 27, 51), while the other two included all grades.(17, 18) Six studies included only skeletally immature patients, as indicated by an open epiphyseal plate on plain radiographs.(13, 17, 26, 49-51) The functional outcome measures reported are shown in Table 1. They were as follows: CMS (six studies),(12, 13, 16-18, 27) QuickDASH (four studies),(13, 26, 49, 50) ASES (one study),(51) Neer Shoulder Score (NSS) (one study),(15) and the functional classification of Razemon and Baux (one study).(19, 52) Pavone *et al.*(13) used the QuickDASH as well as the "Delta Constant", namely, a comparison of the CMS of the affected shoulder with that of the contralateral shoulder, and Kraus *et al.*(12) used both the DASH and the CMS.

Consideration was given as to whether a meta-analysis could be performed on the included articles. However, the degree of heterogeneity amongst the papers with regards to their methodology, the fracture characteristics of included patients, and treatment method, was such that a meta-analysis was not possible.

Table 1: Study Design of the Included Articles

Study	Prospective or Retrospective Cohort Study	Number of Participants	Mean Follow-Up	Proportion Followed-Up	Types of PHF Included	Outcome Measure(s) Utilised
Bahrs *et al.* 2009	Prospective	43	39 months (12 – 118)	91%	All types	CMS
Binder *et* al. 2016	Retrospective	231	5.1 weeks (2 – 8)	100%	All types	CMS
Bisaccia *et al.* 2016	Prospective	31	24 months (13 – 36)	100%	NH Grade IV	CMS
Canavese *et al.* 2014	Prospective	58	18.3 months (6 – 39.5)	89.7%	Displaced (≥ 50% angulation and/or translation)	QuickDASH
Chaus *et al*. 2014	Retrospective	32	4.8 years (range NR)	100%	NH Grade III and IV	QuickDASH
Khan *et al.* 2013	Prospective	27	15.2 months (6.1 – 28.5)	88.9%	Displaced (≥ 50% angulation and/or translation)	QuickDASH
Kohler *et al*. 1983	Retrospective	136	5 years (1 – 18)	38.2%	All types	The functional classification of Razemon and Baux
Kraus *et al*. 2014	Retrospective	40	5.8 years (1 – 12.5)	77.5%	NH Grade III and IV	DASH and CMS
Li *et al*. 2021	Retrospective	75	1 year	100%	NH Grade III and IV	ASES
Pavone *et al*. 2016	Retrospective	26	34 months (10 – 55)	100%	NH Grade III and IV	Delta Constant and QuickDASH
Wang *et al*. 2014	Retrospective	37	24 months (12 – 36)	100%	NH Grade III and IV	Neer shoulder score
Wei *et al*. 2019	Retrospective	55	2 years	80%	All types	CMS

CMS indicates Constant-Murley score; QuickDASH, the Quick Disabilities of the Arm, Shoulder and Hand score; ASES, American Shoulder and Elbow Surgeons score; Delta Constant, a comparison of the CMS of the affected shoulder and the contralateral shoulder

Quality Assessment

One study matched participants who underwent surgical versus non-operative management of their PHF.(26) All other studies were level IV case series, as according to the Oxford Centre for Evidence-Based Medicine. The mean Coleman Methodology Score was 68.8/100 (standard deviation = 10.2, range = 53-84, see Table 2).

Table 2: Quality Assessment of the Included Articles

Study	**Level of Evidence**	**Coleman Methodology Score**
Bahrs *et al.* 2009	IV	77
Binder *et al.* 2016	IV	57
Bisaccia *et al.* 2016	IV	78
Canavese *et al.* 2014	IV	79
Chaus *et al.* 2014	III	62
Khan *et al.* 2013	IV	84
Kohler *et al.* 1983	IV	55
Kraus *et al.* 2014	IV	72
Li *et al.* 2021	IV	69
Pavone *et al.* 2016	IV	73
Wang *et al.* 2014	IV	66
Wei *et al.* 2019	IV	53

Functional Outcomes

Studies Including Only Physeal Fractures

All participants in the study by Wei *et al.*(18) were managed conservatively for physeal PHFs of all grades of severity. A significantly higher number of cases in the <11 year-old group had an “excellent” rather than “good” CMS at 2-year follow-up compared with the ≥11 year-old group (*p* <0.05). In Bisaccia *et al.*’s(27) study of NH Grade IV PHFs treated with an external fixator for 6 weeks, all patients had at least a very good functional outcome, with an average CMS at 6-month follow-up of 97.5. The patient with the lowest CMS (84) was 15 years old, while the lowest CMS for patients <11 years old was 94. Bahrs *et al.*(17) treated 43 participants either surgically or non-operatively according to NH grade and whether they were older or younger than 10 years. All patients with non-displaced fractures had a perfect CMS at final follow-up, and there was no statistically significant difference between the CMS of any groups of participants according to age, NH grade, or treatment modality. Participants treated non-operatively for NH Grade III and Grade IV fractures in the study by Chaus *et al.*(26) had a mean QuickDASH score that was 1.8 points higher (i.e. worse) than the surgical group; however, this difference was not statistically significant ($p = 0.1723$). With every 1-year increase in age at initial injury for patients treated non-operatively, the odds ratio of a less than desirable outcome increased by a factor of 3.81 (95% CI = 1.31-21.0).(26) Pavone *et al.*(13) similarly favoured surgical management for NH Grade III and Grade IV PHFs in their cohort with a mean age of 12.8 years. The mean QuickDASH score at final follow-up was excellent (0.56; range = 0-1.7); however, the authors found significantly worse Delta Constant scores for participants with NH Grade IV rather than Grade III fractures ($p<0.01$).(13) In a study with a similar cohort (mean age 11.3 years, treated surgically for severely displaced PHFs), Kraus *et al.*(12) found that patients had favourable outcomes, irrespective of whether they underwent K-wire fixation or ESIN ($p = 0.26$). Li *et al.*(51) found excellent functional results in adolescents treated for severely displaced PHFs either with K-wire fixation or external fixation, with a mean ASES of 93.6 or 93.7 at 6-month follow-up, respectively.

Studies Including Only Metaphyseal Fractures

Binder *et al.*(16) reviewed the short-term functional outcomes of patients treated surgically versus non-operatively for metaphyseal PHFs after an average follow-up of 5 weeks. The authors found that all seven patients who were treated non-operatively for fractures with >20 degrees angulation had only an “average” outcome, whereas all patients treated non-operatively for fractures with <20 degrees had excellent outcomes.(16)

Studies Including Both Physeal and Metaphyseal Fractures

Khan *et al.*(50) found promising functional outcomes for children with displaced PHFs treated surgically with elastic stable intramedullary nailing (ESIN), in their study with a mean age of 11.2 years. The mean QuickDASH scores for patients with metaphyseal fractures were 1.8 compared to 2.7 for those with physeal fractures (*p* >0.05), indicating a lower level of impairment. Canavese *et al*.(49) also analysed the outcomes of 58 patients with PHFs treated with ESIN by use of the QuickDASH. The mean QuickDASH score at final follow-up for patients with physeal fractures was 1.6, and for those with metaphyseal fractures was 1.0, although this difference was not statistically significant. The authors did not comment on any relationship between functional outcome and patient age.(49) All participants in the study by Kohler *et al.*(19) had either good (*n* = 15) or very good (*n* = 37) functional outcomes as per the functional classification of Razemon and Baux. The authors did not categorise patients according to age, fracture pattern, or treatment modality. Similarly, Wang *et al.*(15) did not report a relationship between functional outcome and their participants' age or fracture pattern in their study of 37 patients treated surgically (14 with physeal fractures and 23 with metaphyseal fractures). The mean NSS at final follow-up was 96.65 (range = 83-100), indicating an excellent outcome. The authors did not comment on any relationship between NSS and fracture pattern.

Factors Associated with a Poor Outcome

Higher grade of fracture displacement was associated with a worse outcome in three studies.(13, 16, 19) For patients with severely displaced fractures treated surgically, two studies found no correlation between fracture severity and outcome,(26, 50) while Pavone *et al.*(13) found superior outcomes for patients with NH Grade III rather than Grade IV fractures. Older age at initial injury was predictive or a poorer patient-reported outcome score in three studies, especially for children ≥12 years old who were managed non-operatively.(16, 18, 26) Chaus *et al.*(26) found that, for patients treated non-operatively, an overall worse treatment outcome was significantly associated with increasing age (*p* =

0.0043), but not with sex (p = 0.81). No other study commented on any correlation between sex and functional outcome.

Complications Reported

Among the 546 patients treated surgically, there were 35 reported superficial infections,(12, 13, 19, 26, 27, 51) but no cases of deep infection or systemic sepsis. There were 21 reported cases of arm-length discrepancy >5mm. 5 of these occurred in the study by Wei *et al.*,(18) in which all patients were managed conservatively, and 16 occurred in the study by Kohler *et al.*,(19) in which the authors did not specify the treatment received. Wei *et al.*(18) also reported that 8 patients had loss of reduction at final follow-up; 5 in the <11 year-old group and 3 in the ≥11 year-old group, 2 of whom required operative intervention. Two patients in the study by Pavone *et al*.(13) who were managed with closed reduction and percutaneous pin fixation were found to have loss of reduction at 2-week follow-up, requiring open reduction and internal fixation. There were 18 reported cases of severely displaced PHFs who underwent an unsuccessful closed reduction due to interposition of soft tissues within the fracture site, requiring subsequent open reduction.(15-17, 49) 12 were due to entrapment of the long head of biceps tendon, and 6 were due to interposition of the periosteum. Moderate radiological deformities at final follow-up occurred in 2 patients treated surgically: one case of the humerus in varus with an Alsberg angle of <30 degrees, and one in valgus with an Alsberg angle of >65 degrees.(19) No study demonstrated a significant difference between the degree of deformity at final follow-up for patients treated surgically versus non-operatively, or for patients aged greater or less than 12 years.(12, 13, 18) There were no cases of non-union reported in any study.(13, 15, 17, 18, 49-51) Table 3 shows the relative numbers of complications for each grade as per the Clavien-Dindo classification.(53, 54)

Table 3: Clavien-Dindo Classification of Reported Complications(53, 54)

Grade	Definition	Number of Cases
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are as follows: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.	23
Grade II	Requiring pharmacological treatment with drugs other than such allowed for Grade I complications. Blood transfusions and total parenteral nutrition are also included.	35
Grade III	Requiring surgical, endoscopic, or radiological intervention.	
Grade IIIa	Intervention not under general anaesthesia	0
Grade IIIb	Intervention under general anaesthesia	22
Grade IV	Life-threatening complications (including CNS complications) requiring IC/ICU management.	
Grade IVa	Single organ dysfunction (including dialysis)	0
Grade IVb	Multiorgan dysfunction	0
Grade V	Death of a patient	0

CNS: central nervous system; IC: immediate care; ICU: intensive care unit

Discussion

In this review of functional and quality-of-life outcomes of paediatric PHFs, excellent outcomes were experienced for the vast majority (88.1%) of patients. This likely reflects the appropriate selection of treatment in each of the studies, for participants of different ages and degrees of fracture displacement. The oldest study suggested that the outcomes of paediatric PHFs are always satisfactory, regardless of their anatomy or treatment, and thus recommended non-operative management.(19) However, in this study, there were 16.patients with an arm-length discrepancy >5mm at final follow-up, and 2 with moderate persisting deformities. The other 5 cases of limb-length inequality occurred in Wei *et al.*'s(18) study, in which all fractures were treated conservatively regardless of the degree of displacement; 2 occurring in the group <11 years old and 3 in the group ≥11 years old.

The two papers in which an arm-length discrepancy was reported, were the papers by Wei *et al.*(18) and Kohler *et al.*(19) Wei *et al.* only included patients with physeal fractures, so it is conceivable that the arm-length discrepancy reported in five of their patients may have been due to growth arrest resulting from the fracture. While the authors stated that there were 3 cases in the group <11 years old and 2 cases in the group ≥11 years old who had an arm-length discrepancy at final follow-up, they did not make any comment as to the degree of angulation of these individual patients' fractures, nor did they make comment on whether this was attributed to growth arrest. Kohler *et al*. included patients with both physeal and metaphyseal fractures. The methodology in this paper, written in 1983, was comparatively less structured than that of the article by Wei *et al.*, in that they did not categorise their patients according to age, fracture pattern, or treatment modality. Six patients with metaphyseal fractures in their study had a limb length discrepancy versus ten patients with physeal fractures. It is unlikely that the limb length discrepancy of the patients with metaphyseal fractures was the result of growth arrest as, by definition, metaphyseal fractures do not involve the growth plate. Unfortunately, it is again not possible to determine whether the limb length discrepancy noted in the patients with physeal fractures was due to growth arrest, as this was not reported by the authors.

There was a general consensus in the studies written since 2013 that adolescents managed conservatively for severely displaced fractures are at risk of a poorer clinical outcome.(12, 13, 15, 16, 18, 26, 27, 49-51) Excellent outcomes were observed for patients ≥12 years old with severely displaced PHFs treated surgically with K-wire fixation,(12, 13, 51) ESIN,(12, 15, 49, 50) and external fixator.(16, 51) Pavone *et al.*(13) reported only two adolescent patients with Grade IV PHFs who had a "fair" outcome following surgery; the remaining 14 patients with Grade IV fractures treated surgically had either a good or excellent outcome.

Similarly, Bisaccia *et al.*(27) found that 27 of their 31 participants treated surgically for a NH Grade IV PHF were “very satisfied”, with the other 4 being “satisfied” at final follow-up. Conversely, four (17.3%) patients with a mean age of 13.9 years had a less than desirable outcome after being managed non-operatively for a severely displaced PHF in the study by Chaus *et al*.(26) In their subgroup analysis of patients treated non-operatively, the authors identified that for every 1-year increase in age at injury, the odds radio of a poor clinical outcome increased by a factor of 3.81. While there are possible selection and publication biases of recent studies aiming to demonstrate the efficacy of different surgical techniques for severely displaced PHFs in older children, it is evident that these patients do better with surgery. The ongoing dilemma is ascertaining a coherent guideline for what constitutes a surgical indication, on the basis of age and degree of fracture displacement. Based on their analysis of 28 patients with NH Grade III and Grade IV PHFs, Dobbs *et al.*(10) recommended a protocol for patients following closed reduction. For patients <7 years old, a post-reduction angulation of <70 degrees can be accepted; for patients aged 8-11 years, <60 degrees can be accepted; and for patients ≥12 years, <45 degrees can be accepted. It was concluded that greater deformities require open reduction and internal fixation. The protocol suggested by Binder *et al.*(16) was more aggressive for patients over 10 years old. They recommended non-operative management for children <10 years old with <20 degrees angulation, and surgery for children ≥10 years old with >20 degrees angulation, citing an increased risk of soft tissue interposition in fractures with >20 degrees of angulation. The results of this review confirm that NH Grade I and Grade II physeal fractures, as well as metaphyseal fractures with <20 degrees angulation, can be managed non-operatively. The difficulty determining an age- and displacement-based guideline for the management of severely displaced paediatric PHFs is due to the fact that the ability of the proximal humerus to remodel depends on the degree of skeletal maturity, rather than exact chronological age.

This is further confounded by the typically earlier age at which girls reach skeletal maturity compared to boys. While six studies excluded skeletally mature patients, the degree of skeletal maturity was not accounted for in any study, and the relationship between gender and functional outcome was only assessed in one study.(26) Designing a prospective study analysing outcomes of paediatric PHFs for participants according to their bone age, chronological age, and sex may be useful to assist with this predicament.

Conclusion

An excellent functional outcome can be expected following conservative management for minimally displaced paediatric PHFs. The current literature suggests that adolescents may benefit from surgical management of NH Grade III and Grade IV PHFs; however, based on the current evidence, it is not possible to make recommendations regarding surgery versus non-operative management for individual patients Prospective clinical trials are required to establish a guideline for the management of severely displaced PHFs in children and adolescents according to fracture displacement and the degree of skeletal maturity.

Author Contributions

Samuel Abbot: literature search, screening of articles, data extraction, data analysis, and writing of the manuscript.

Susanna Proudman: data analysis, interpretation of data, and critical revision of the manuscript.

Bhuvanesh Ravichandran: screening of articles and data extraction.

Nicole Williams: data analysis, interpretation of data, and critical revision of the manuscript.

Declaration of Conflicting Interests

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ORCID iD

Samuel Abbot ID: https://orcid.org/0000-0001-8829-862X

Supplementary Files

Supplementary File 1: Search Strategy Used for Medline

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily <1946 to July 04, 2021>
Search Strategy:

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1 exp humerus/ or humeral head/ (10970)

2 ((Humer* and growth plate) or (Humer* and epiphys*) or proximal humerus or subcapital or sub-capital or shoulder joint or glenohumeral joint).mp. (27875)

3 1 or 2 (35615)

4 exp Fracture Dislocation/ or exp Fractures, Bone/ or exp Shoulder Fractures/ (189395)

5 (fracture* or Salter-Harris or Salter Harris or greenstick or green-stick or buckle or Neer-Horowitz or displace* or angulate* or grade* or proximal humerus fracture*).mp. (908390)

6 4 or 5 (910529)

7 exp Orthopedics/ or exp Orthopedic Procedures/ or exp Surgical Procedures, Operative/ (3258135)

8 exp Open Fracture Reduction/ or exp Fracture Fixation, Intramedullary/ or exp Fracture Fixation, Internal/ or exp Fracture Fixation/ (63519)

9 (K wire* or K-wire* or intramedullary* or ESIN or elastic stable intramedullary nail* or elastic nail* or plate fixation or osteosynthesis or plate osteosynthesis open reduction or open-reduction or internal fixation or internal-fixation or fracture fixation or fracture-fixation).mp. (91081)

10 7 or 8 or 9 (3276414)

11 exp Closed Fracture Reduction/ or exp Immobilization/ (27871)

12 (management or treatment or immobilisation or immobilization or sling or cast or plaster* or brace or bracing or Sarmiento or backslab or back-slab or U slab or U-slab or collar* or closed reduction or closed-reduction).mp. (6095519)

13 11 or 12 (6104797)

14 10 or 13 (8193597)

15 exp Adolescence/ or exp adolescent/ or exp child/ or exp childhood disease/ or exp infant disease/ or exp Pediatrics/ or exp Child/ or exp Infant/ (3675314)

16 (adolescen* or babies or baby or child* or infant* or juvenil* or neonat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or preschool* or pre-school* or pubescen* or school child* or schoolchild* or teen* or toddler* or youth* or preteen*).mp. (4524043)

17 15 or 16 (4524043)

18 exp "Quality of Life"/ or exp treatment outcome/ or exp Hospitalization/ or exp Prognosis/ or exp Survival Rate/ or exp Postoperative Complications/ or exp Pain/ or exp Pain, Postoperative/ or exp "Recovery of Function"/ or exp "Range of Motion, Articular"/ or exp Fractures, Ununited/ (2895727)

19 (outcome* or treatment outcome* or result* or complication rate or complication* or pain* or deformit* or union or malunion or non union or non-union or infect* or function* or power* or strength*).mp. (16919564)

20 (quality adj1 life).mp. (8530)

21 18 or 19 or 20 (17283974)

22 3 and 6 and 14 and 17 and 21 (1474)

23 limit 22 to english language (1143)

24 limit 23 to humans (1100)

25 limit 24 to animals (7)

26 23 not 25 (1136)

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Supplementary File 2: Search Strategy Used for Embase

Database: Embase <1974 to 2021 July 04>

Search Strategy:

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1 exp humerus/ or humeral head/ (13278)

2 ((Humer* and growth plate) or (Humer* and epiphys*) or proximal humerus or subcapital or sub-capital or shoulder joint or glenohumeral joint).mp. (15081)

3 1 or 2 (25324)

4 exp fracture dislocation/ or exp fracture/ or exp shoulder fracture/ (307215)

5 (fracture* or Salter-Harris or Salter Harris or greenstick or green-stick or buckle or Neer-Horowitz or displace* or angulate* or grade* or proximal humerus fracture*).mp. (1261078)

6 4 or 5 (1268590)

7 exp orthopedics/ or exp orthopedic surgery/ or exp surgical technique/ (2114034)

8 exp open fracture reduction/ or exp intramedullary nailing/ or exp osteosynthesis/ or exp fracture fixation/ (89478)

9 (K wire* or K-wire* or intramedullary* or ESIN or elastic stable intramedullary nail* or elastic nail* or plate fixation or osteosynthesis or plate osteosynthesis or open reduction or open-reduction or internal fixation or internal-fixation or fracture fixation or fracture-fixation).mp. (104366)

10 7 or 8 or 9 (2127073)

11 exp closed fracture reduction/ or exp immobilization/ (76300)

12 (management or treatment or immobilisation or immobilization or sling or cast or plaster* or brace or bracing or Sarmiento or backslab or back-slab or U slab or U-slab or collar* or closed reduction or closed-reduction).mp. (9191670)

13 11 or 12 (9199266)

14 10 or 13 (10318782)

15 exp adolescence/ or exp adolescent/ or exp child/ or exp childhood disease/ or exp infant disease/ or exp Pediatrics/ or exp Child/ or exp Infant/ (4630486)

16 (adolescen* or babies or baby or child* or infant* or juvenil* or neonat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or preschool* or pre-school* or pubescen* or school child* or schoolchild* or teen* or toddler* or youth* or preteen*).mp. (4591102)

17 15 or 16 (5425750)

18 exp "quality of life"/ or exp treatment outcome/ or exp hospitalization/ or exp prognosis/ or exp survival rate/ or exp postoperative complication/ or exp pain/ or exp postoperative pain/ or exp "range of motion"/ or exp fracture nonunion/ (4844272)

19 (outcome* or treatment outcome* or result* or complication rate or complication* or pain* or deformit* or union or malunion or non union or non-union or infect* or function* or power* or strength*).mp. (21436041)

20 (quality adj1 life).mp. (17820)

21 18 or 19 or 20 (21919732)

22 3 and 6 and 14 and 17 and 21 (1592)

23 limit 22 to english language (1314)

24 limit 23 to humans (1271)

25 limit 24 to animals (0)

26 23 not 25 (1314)

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Chapter 4: Psychometric properties of patient-reported outcome measures used to assess upper limb pathology: a systematic review(55)

Statement of Authorship

Title of Paper	Psychometric properties of patient-reported outcome measures used to assess upper limb pathology: a systematic review.
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Principal Author

Name of Principal Author (Candidate)	Samuel Abbot		
Contribution to the Paper	Performed the initial literature search, selected relevant articles, extracted data from each article, synthesised the data, wrote the manuscript and acted as the corresponding author.		
Overall percentage (%)	90		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	24/10/2023

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);
ii. permission is granted for the candidate in include the publication in the thesis; and
iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Susanna Proudman
Contribution to the Paper	Assisted with study design and editing of the manuscript.

Signature		Date	24/11/2023

Name of Co-Author	Yih Ping Sim		
Contribution to the Paper	Assisted with study selection and data extraction.		
Signature		Date	29/11/2023

Name of Co-Author	Nicole Williams		
Contribution to the Paper	Assisted with study design and editing of the manuscript.		
Signature		Date	24/11/2023

Abstract

Background:

With the continued development of patient-centred healthcare models, patient-reported outcome measures (PROMs) are increasingly used to evaluate outcomes in patients with upper limb pathology. The aim was to identify valid, reliable and responsive PROMs used to assess outcomes following upper limb pathology, and ascertain how their psychometric properties had been established. A secondary aim was to identify PROMs that have been validated to assess upper limb pathology in the paediatric population.

Methods:

A review of the Medline and Embase databases was performed. Articles that analysed the validity of an established PROM used for upper limb pathology were included. Extracted study data included: author, country, PROM(s) investigated, year of publication, study type, sample size, demographics and duration of follow-up.

Results:

Twenty-five articles were included, which together investigated the psychometric properties of 23 different PROMs that have been used to assess outcomes in adults following upper limb pathology. No study evaluated the psychometric properties of PROMs used in the paediatric population. Among PROMs that have been used in adults, the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) had strong content- and construct validity, reliability and responsiveness in comparison to others.

Conclusion:

There are currently no studies that have analysed the content validity of PROMs used to assess upper limb pathology in the paediatric population. Prospective studies are required for the development of PROMs that can be utilised in children to assess upper limb pathology.

Keywords

Construct validity, content validity, orthopaedic surgery, psychometric properties, upper limb.

Introduction

With the continued development of patient-centred healthcare models, patient-reported outcome measures (PROMs) are increasingly used to evaluate outcomes in patients with upper limb pathology.(56) PROMs allow for an insight into a patient's subjective experience of their health condition and its therapy, and are required to evaluate functional and quality-of-life outcomes.(57) A large variety of PROMs have been utilised in orthopaedic research, and it can be challenging to ascertain which PROM is most suitable for a given population and condition. The ideal PROM must be valid, reliable and responsive to change in clinical status, without being overly arduous to complete.(56, 58) While numerous studies have investigated the psychometric properties of PROMs used to assess upper limb pathology in adults, relatively few studies have evaluated their use in the paediatric population. As previous studies have demonstrated, it is important to evaluate the psychometric properties of PROMs prior to implementing their use in the target population.(56) The aim of this systematic review was to identify valid, reliable and responsive PROMs that have been used to assess upper limb pathology, and ascertain how their psychometric properties had been established. A secondary aim was to identify PROMs that have been validated to assess upper limb pathology in children and adolescents.

Materials and Methods

This systematic literature review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.(32)

Definitions

Content validity refers to the degree to which elements of a PROM are relevant to a representative of the targeted construct for a particular assessment purpose.(59) It addresses whether a questionnaire has enough items to cover the area of interest adequately, and whether it measures important elements of the pathology for which it is used.(60) This is distinct from construct validity, which is established by examining relationships between the PROM of interest and other instruments that are expected to be related, and can be measured using convergent and divergent validity approaches.(61) Reliability refers to the reproducibility of scores from one assessment to another, and is usually expressed in the forms of internal consistency (measured as Cronbach's alpha) and test-retest reliability (measured as the intraclass coefficient, ICC).(62) Responsiveness refer to the ability of a PROM to distinguish important clinical change from measurement error, and is a measure of longitudinal validity.(58) The most commonly reported measures of responsiveness are effect size (ES) and standardised response mean (SRM). Floor and ceiling effects are another important consideration when analysing the psychometric properties of a PROM. They are considered to be present if more than 15% of participants achieve the lowest or highest possible score, indicating that further impairment or improvement cannot be detected in these patients, respectively.(63) If present, floor and ceiling effects are detrimental to the content validity, reliability and responsiveness of a PROM.(58)

Eligibility Criteria

Included articles were original research studies written in English that analysed the validity of an established PROM used for pathology of the upper limb. There was no restriction on publication date. Articles were excluded if they did not mention how the validity of the PROM was established.

Search Strategy

A librarian-assisted search was performed on the Medline and Embase databases on fourth December 2021 (see Supplementary Files 1 and 2). The search syntax consisted of four categories of keywords and/or subject headings. These categories were: terms related to (i) upper limb pathology; (ii) outcome measures; (iii) psychometric properties and (iv) paediatrics. Articles with a relevant title and abstract were read in full text by two authors (SA and YPS), and those that fulfilled the eligibility criteria were selected. Discrepancies in selection between the two authors were resolved by discussion.

Data Collection

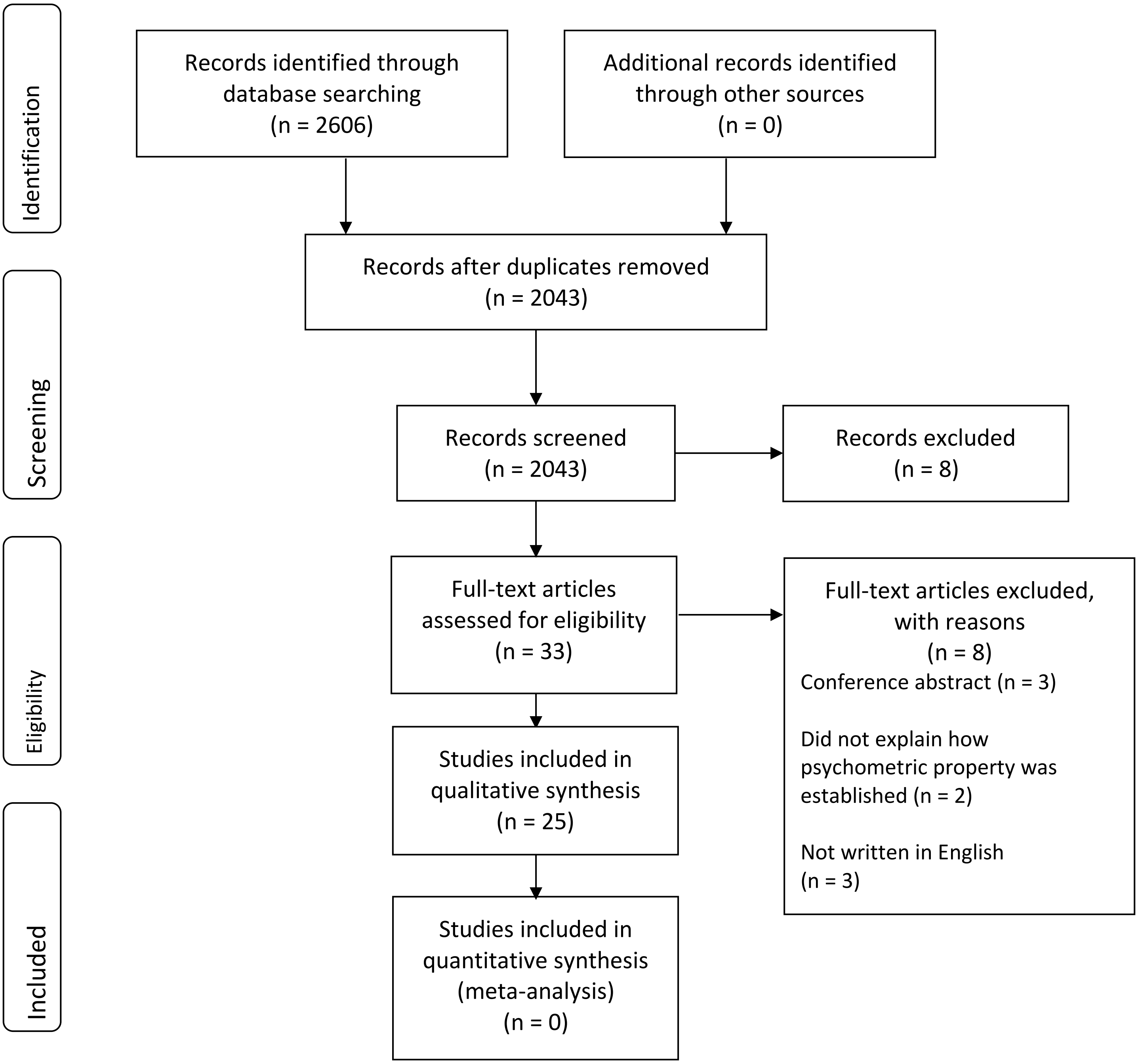
The included articles were reviewed for established PROMs that have been used for upper limb pathology, the psychometric properties of the PROMs that were analysed (including validity, responsiveness and reliability), and the method by which the psychometric properties of the PROM were established. The study data extracted were author, country, PROM(s) investigated, year of publication, study type, sample size, demographics and duration of follow-up.

Results

Study Selection

The search yielded 2606 results, of which there were 563 duplicates. Therefore, 2043 articles were screened. Thirty-three articles were read in full text after studies were excluded based on title and abstract. Eight were excluded on full-text review for the following reasons: did not sufficiently explain how the discussed psychometric properties were established (two), conference presentations (three) and non-English language (three). Thus, 25 articles were finally selected for inclusion. This is outlined in the PRISMA diagram (Figure 1). There was not a single article yielded by the search strategy that evaluated the validity of PROMs used for assessing upper limb pathology in the paediatric population; all 25 eligible articles evaluated the psychometric properties of PROMs used in adults.

Figure 1: PRISMA flow diagram depicting the process by which articles were screened



Study Design

All 25 articles were prospective cohort studies. There was a total of 4757 participants with a mean age of 54.4 years (*SD* = 8.8 years); 61% were female and the median follow-up was 9 months (range = 5 days-3.3 years). 15 studies examined content validity, 23 calculated construct validity, 19 assessed reliability and 12 examined the responsiveness of the PROMs that they reviewed.

PROMs Discussed

Twenty-three reported PROMs were identified (Table 1). The 30-item, patient-reported disabilities of the arm, shoulder and hand (DASH) questionnaire was the most commonly investigated PROM, being reviewed in 17 studies.(33) The DASH is designed to measure a patient's perception of their physical function, symptoms, quality of life and ability to conduct activities of daily living (ADLs) in relation to their upper extremity pathology.(56) Development of this PROM allowed for the disability experienced by patients affected by upper limb pathology to be estimated, and for any changes in their symptoms and perceived functional status to be monitored over time.(64) It has been shown that the DASH is an effective tool in these roles and can be used for research purposes and clinical practice.(64, 65) The shortened, 11-item version of the DASH, namely the 'QuickDASH', was reviewed in six studies.(66) The items in the QuickDASH were selected from the original tool on the basis of them having the highest reliability, validity and responsiveness within each domain of the DASH.(65) There are seven questions related to the patient's ability to perform ADLs that involve the upper limb, three questions related to pain and paraesthesia and one question related to social functioning. The Constant-Murley Score (CMS) was discussed in five studies.(34) Since its inception in 1987, the CMS has been widely utilised to evaluate overall shoulder function in research related to upper limb pathology. The CMS is a combined patient- and clinician-reported outcome measure, consisting of four domains: pain, ADLs, range of motion (ROM) and strength.(56) The patient is given a score out of 100, with a higher score being indicative of better shoulder function. The patient rated wrist evaluation

(PRWE) is a 15-item PROM specific to wrist-related pain and disability, and was reviewed in six studies.

Table 1: Patient-reported outcome measures (PROMs) discussed within the included articles

PROM	**Number of Studies**
Disabilities of the Arm, Shoulder and Hand (DASH)	17
QuickDASH Patient-Rated Wrist Evaluation (PRWE)	6
Constant-Murley score (CMS) Short Form 36 (SF-36)	5
Patient-Reported Outcome Measurement Information System – Upper Extremity (PROMIS-UE)	4
Oxford Elbow Score (OES) Oxford Shoulder Score (OSS) Visual analogue scale (VAS)	2
PROMIS-Pain Interference (PROMIS-PI) PROMIS-Physical Function (PROMIS-PF) American Shoulder and Elbow Score (ASES) Single Assessment Numeric Evaluation (SANE) 8-Item Physical Functional Short Form (PF-SF8a) Manchester-Modified DASH (M2 DASH) Penn Shoulder Score (PSS) Patient-Specific Functional Scale (PSFS) Jebsen-Taylor Hand Function Test (JTT) European Quality of Life Five Dimension (Euro-QoL 5D) Short-Form Six-Dimension (SF-6D) Shoulder Function Index (SFiNX) Mayo Elbow Performance Index (MEPI) Nottingham Health Profile (NHP)	1

Psychometric Properties of PROMs

Disabilities of the Arm, Shoulder and Hand

Fourteen of the seventeen studies that reviewed the DASH concluded that it has strong psychometric properties and is appropriate to use in clinical research and practice.(60, 61, 63, 67-77) The convergent validity of the DASH with other PROMs was, in all cases, statistically significant and moderate to very strong. The DASH was calculated to have a Pearson's correlation coefficient of 0.57 with the Short Form 36 (p <0.001),(63) 0.60 with the

Nottingham Health Profile,(60) -0.78 with the Shoulder Function Index (SFinx),(74) 0.85 with the Oxford Shoulder Score,(75) and 0.96 with the QuickDASH.(67) Three studies found a strong correlation between the DASH and PRWE, with Spearman's correlation coefficient values ranging between 0.59 and 0.90 (p <0.01).(61, 71, 73) The DASH also had a strong Spearman's correlation coefficient with the Patient-Reported Outcome Measurement Information System – Upper Extremity (PROMIS-UE), Manchester-Modified DASH (M2-DASH) and patients' overall self-assessment of shoulder function, with Spearman's correlation coefficient values of 0.79, 0.98 and -0.7, respectively.(63, 72, 78) Four studies criticised the DASH for not having satisfactory content validity when analysing the instrument individually. Two studies used Rasch analysis to determine that the DASH is not a unidimensional scale.(79, 80) In keeping with this, Van de Water *et al.* compared items within the DASH to the International Classification of Functioning, Disability and Health (ICF) and found that multiple items refer to several different domains of health, rather than the single construct of shoulder 'function'.(75) Similarly, Khan *et al.* concluded that the DASH is not specific to upper limb pathology, after finding that a group of patients with lower limb pathology had significantly higher DASH scores than a healthy control group.(78) In contrast, Van Eck *et al.* and Van Lieshout *et al.*, in their relatively large studies of 370 and 400 participants respectively, concluded that the items of the DASH assess a unidimensional trait, being 'disability', based on confirmatory factor analysis and Rasch analysis.(76, 77) No significant floor or ceiling effect for the DASH was identified in any study. The internal consistency of the DASH was excellent in all studies that analysed its reliability, with Cronbach's alpha values ranging between 0.96 and 0.97, indicating high correlation among the 30 items.(60, 68, 69, 78) Good to excellent test-retest reliability was also found for the DASH, with ICC ranging between 0.83 and 0.97, indicating a strong degree of concordance. The responsiveness of the DASH was acceptable, with ES values between 0.5 and 1.39, and

SRM between 1.51 and 2.13.(60, 63, 69, 73, 75) The ES and SRM values were proportional to the duration of follow-up of the various studies that analysed the longitudinal validity of this instrument.

QuickDASH

All six studies that analysed the QuickDASH concluded that it has strong psychometric properties.(57, 58, 67, 73, 81, 82) It had strong convergent validity with the single assessment numeric evaluation (SANE) and PROMIS-UE, with Spearman's correlation coefficients, *r*, of -0.73 and -0.8, respectively (p <0.05).(58) A high correlation was found with the PRWE (r = -0.83, p <0.001), the eight-item Physical Functional Short Form (PF-SF8a) (r = -0.79) and patients' perceived handicap (r = 0.79) and activities of daily living (ADL) scores (r = -0.73).(67, 73, 81, 82) The QuickDASH had excellent reliability, with Cronbach's alpha coefficient values ranging between 0.89 and 0.93, and an ICC of 0.94.(67, 82) All three studies that analysed the sensitivity of the QuickDASH to clinical improvement found that it has excellent responsiveness, with SRM values ranging between 1.09 and 2.17, and an ES of 1.23.(58, 67, 73) Two studies directly compared the psychometric properties of the QuickDASH to those of the DASH.(67, 73) Fayad *et al*.(67) assessed the convergent construct validity of each questionnaire by correlating the questionnaire scores with scores on variables supposedly assessing similar dimensions or concepts. They found that the QuickDASH scale had excellent correlation with the full-length DASH (r = 0.96). Tsang *et al*.(73) utilised the Bland-Altman technique to determine the level of agreement between the Quickdash and the DASH. (83) The authors found that the participants' QuickDASH scores were higher than their DASH scores, particularly at baseline, however the QuickDASh still demonstrated good concurrent validity and responsiveness.

Constant-Murley Score

The five studies that reviewed the psychometric properties of the CMS found that it has moderate to high convergent validity with other legacy PROMs. The CMS had Spearman's correlation coefficients with the DASH ranging between -0.78 and -0.86, with overall pain scores of -0.52, and with ADL scores of 0.72.(69, 75) Similarly, the CMS had a high level of concordance with novel PROMs, with a Pearson's correlation coefficient of 0.87 with the Penn Shoulder Score and 0.89 with the SFInX (p <0.01).(74, 84) Mahabier *et al.* found that the internal consistency of the CMS was significantly less than the DASH, with a Cronbach's alpha of 0.61.(69)

Patient-Rated Wrist Evaluation

The PRWE was considered to have strong psychometric properties in five of the six studies that reviewed it. One study criticised this instrument for having a significant ceiling effect, with 12% of participants having the highest possible score at final follow-up.(81) As discussed earlier, the PRWE correlated strongly with DASH and QuickDASH scores, and was found to have strong convergent validity with the SF-36 subscale for bodily pain (r = 0.31).(61) Low correlations were found with other components of the SF-36; for example, with the physical-functioning subscale (r = 0.31).(61) There was unanimous agreement that the PRWE is a reliable instrument, with ICC values ranging between 0.90 and 0.94, and Cronbach alpha values ranging between 0.85 and 0.89.(60, 68, 70, 71) Tsang *et al*. also found that the PRWE is highly responsive to clinical change, with a SRM of 2.19.(73)

Discussion

In order to be used to assess a clinical condition, a PROM much have content validity, meaning it needs to address important elements of the pathology and its impact on a patient's quality of life.(58) As demonstrated by the findings of this systematic review, there is a plethora of instruments that have been developed to assess treatment and quality-of-life outcomes following upper limb pathology. However, many of these were designed for use in patients with rotator cuff pathology or symptoms of instability, so selecting a PROM for use in a paediatric population following acute trauma is problematic.(56) The fact that there was no study yielded by our search strategy that assessed the psychometric properties of PROMs used in the paediatric population demonstrates the lack of evidence supporting their use in children and adolescents.

The DASH was, for the most part, found to have strong psychometric properties when utilised in adults. While the DASH had moderate to excellent convergent validity with a large variety of PROMs in numerous studies, there is a possibility of a significant publication bias, as many of these studies were designed to assess the quality of novel PROMs, using the DASH as a comparator.(61, 68, 70, 71, 74) Interestingly, multiple studies that investigated the content validity of the DASH in isolation concluded that it does not satisfy the assumptions of Rasch analysis, in that it was not found to be a unidimensional scale.(79, 80) As the DASH is intended to assess a single trait, being ‘disability’, the items of the DASH should be unidimensional. Furthermore, a group of patients suffering from lower limb pathology in a well-designed case-control study were found to have significantly higher DASH scores than a healthy control group, suggesting that the DASH is not specific to upper limb pathology.(78) As has been demonstrated in previous studies, PROMs that are more specific to the pathology that they are intended to assess tend to be more responsive to clinical change. The PRWE, a PROM that is highly specific to symptoms related to the wrist and hand, was found to be more responsive than the DASH in assessing clinical improvement over time in patients following fracture of the distal radius.(73) The logical explanation is that those questionnaires which target a certain body region are more able to detect symptoms related to that body part's pathology.(60) Despite its wide acceptance and frequent use, certain concerns regarding the psychometric properties of the CMS have been noted in numerous studies, with its item selection criteria, reliability and validity being suboptimal.(68) In their prospective cohort study of 140 participants with humeral shaft fractures, Mahabier *et al.* found reliability for the DASH, with a Cronbach's alpha value of 0.96, but not for the CMS (Cronbach's alpha = 0.61).(69)

On the other hand, the QuickDASH was found to have strong content- and construct-validity in all studies that reviewed its psychometric properties when used in adults, and had excellent correlation with the full-length DASH, as well as patients' perceived handicap and ADL scores.(67, 73) It was also found in multiple studies to have excellent reliability and responsiveness in comparison to other PROMs.(58, 67, 73) The strong correlation of the 11-item QuickDASH with the full-length instrument suggests that it could be the preferred scale, as it is significantly shorter and the questions are more specific to upper limb pathology.(67) Additionally, the questions are more appropriate for use in children, as items in the full-length DASH related to adult functions such as sexual activities and the ability to change a lightbulb, have been excluded in the QuickDASH. Notwithstanding this, multiple items within the QuickDASH assess activities that are not routinely carried out by children, such as 'doing heavy household tasks' and 'using a knife'. Similarly, it enquires about symptoms that would likely challenge the recall of children under the age of 11 years, such as 'tingling' in the affected arm. The language used in this questionnaire would also need to be simplified prior to its implementation for use in children. For example, the instruction to 'rate your ability to do the following activities in the last week' could be abbreviated to 'please say whether these tasks are hard for you'.

Examples of legacy PROMs that have been well-validated in children include the Paediatric Outcomes Data Collection Instrument (PODCI) and the Child Health Questionnaire (CHQ).(85, 86) While these are general health-related quality-of-life questionnaires, rather than being specific to a certain pathology, they exemplify the language and choice of items that are required for a successful paediatric instrument. The PODCI exists in three versions: a questionnaire for children under the age of 11 years (completed by the caregiver) and two surveys for adolescents aged 11 years and older (one completed by the adolescent and one by their caregiver). The CHQ exists in both parent-reported forms (CHQ-PF50 and CHQ-PF28), which are normed for children aged 5-18 years, as well as child-reported forms (CHQ-CF87 and CHQ-CF45), which are normed for children aged 8-18 years. The items included in the PODCI and CHQ to assess the child's health-related quality of life are quite similar and are relatable for children from a young age. They enquire about the child's ability to run, dress themselves and climb stairs, for example. The language utilised in the CHQ-CF45 has been validated for use in children as young as the second grade.(87) It asks in lay terms about the child's ability to 'get schoolwork done' and to 'get along with others', while the PODCI asks how often the child has been able to 'get together and do things with friends'. Constructing a questionnaire with this simplified language is one way of negotiating the variable linguistic capabilities of younger children and allowing them to provide a meaningful response.

A final consideration which must be made, is the role of third parties (parents or other designated guardians) answering questionnaires on behalf of children, and the potential impact that this may have on the questionnaire's validity. Comparative studies assessing the differences in responses provided by children themselves versus the answers provided by their caregiver may be useful in determining the significance of this potential source of bias.

There is a pressing need for concise yet robust self-reported PROMs that can be used in children to capture their health-related physical, emotional and social wellbeing.(86) There are multiple factors that challenge the development of such PROMs, including age-related vocabulary, comprehension of health concepts and determining the lower age limit at which children can provide valid and reliable responses.(88) Despite these challenges, the lack of a valid outcome measure that can be utilised to assess outcomes following upper limb pathology in children represents a significant gap in the literature. Prospective studies are required to assess whether modified versions of adult PROMs, or entirely novel paediatric PROMs, may be effective in assessing upper limb pathology in the paediatric population.

Conclusion

In conclusion, there are no studies that have analysed the content validity of PROMs used to assess upper limb pathology in the paediatric population. Upon analysis of studies reviewing the use of PROMs in adults, the QuickDASH and PRWE have been demonstrated to have strong psychometric properties. Prospective studies in children and adolescents are required to develop PROMs that may be used to assess upper limb pathology in this population.

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Conflict of Interest

None declared.

Author Contributions

Samuel Abbot: Conceptualisation; data curation; formal analysis; investigation; project administration; writing – original draft; writing – review and editing.

Susanna Proudman: Supervision; validation; writing – review and editing.

Yih Ping Sim: Data curation; formal analysis.

Nicole Williams: Conceptualisatin; methodology; supervision; writing – review and editing.

Supplementary Files

Supplementary File 1: Search strategy used for Embase

Database: Embase <1974 to 2021 December 04>
Search Strategy:
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1 Humeral Fractures/ (6461)
2 Shoulder Fractures/ (731)
3 (proximal humer* adj5 fracture*).mp. (3974)
4 (shoulder adj5 fracture*).mp. (3496)
5 (exp Upper Extremity/ or upper limb.mp.) and fracture*.mp. (21577)
6 1 or 2 or 3 or 4 or 5 (30260)
7 functional outcome*.mp. (69478)
8 "Surveys and Questionnaires"/ (750398)
9 "Quality of Life"/ (509628)
10 (quality adj1 life).mp. (17831)
11 (screen* or assess* or test* or surveill* or survey* or questionnaire* or scale* or score* or measur* or instrument* or index* or function*).mp. (18130765)
12 patient reported outcome*.mp. (49235)
13 patient reported outcome measures/ (28220)
14 7 or 8 or 9 or 10 or 11 or 12 or 13 (18247002)
15 Mayo elbow performance.mp. (1334)

16 (Disabilities of the arm, shoulder and hand).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (5736)

17 (American Shoulder and Elbow Surgeons Standardized Shoulder Assessment*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (119)

18 (Shoulder pain and disability index*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (894)

19 Simple shoulder test*.mp. (990)

20 Western ontario shoulder instability.mp. (278)

21 (Constant-Murley score* or Constant Murley score or Child Health Questionnaire or PODCI or Pediatric Outcomes Collection Instrument or SPADI or Neer shoulder score or Visual Analogue Scale or VAS).mp. (107871)

22 Shoulder disability questionnaire*.mp. (101)

23 Oxford shoulder score.mp. (484)

24 Elbow self-assessment score*.mp. (6)

25 Morrey elbow score*.mp. (27)

26 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 (114655)

27 (longitudinal construct validity or valid* or reliab* or responsiveness or content validity).mp. (1841152)

28 exp "reproducibility of results"/ (229066)

29 27 or 28 (1976800)

30 14 or 26 (18254789)

31 6 and 29 and 30 (1730)

32 (paediatric or pediatric or child* or minor or infant or baby or babies or juvenile*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (3590951)

33 31 and 32 (240)

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Supplementary File 2: Search strategy used for Medline

Database: Ovid MEDLINE(R) ALL <1946 to December 04, 2021>

Search Strategy:

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1 Humeral Fractures/ (7763)

2 Shoulder Fractures/ (3487)

3 (proximal humer* adj5 fracture*).mp. (3050)

4 (shoulder adj5 fracture*).mp. (4633)

5 (exp Upper Extremity/ or upper limb.mp.) and fracture*.mp. (8296)

6 1 or 2 or 3 or 4 or 5 (19619)

7 functional outcome*.mp. (47843)

8 "Surveys and Questionnaires"/ (495833)

9 "Quality of Life"/ (212236)

10 (quality adj1 life).mp. (8642)

11 (screen* or assess* or test* or surveill* or survey* or questionnaire* or scale* or score* or measur* or instrument* or index* or function*).mp. (13661259)

12 patient reported outcome*.mp. (26635)

13 patient reported outcome measures/ (8411)

14 7 or 8 or 9 or 10 or 11 or 12 or 13 (13706382)

15 Mayo elbow performance.mp. (1129)

16 (Disabilities of the arm, shoulder and hand).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (3520)

17 (American Shoulder and Elbow Surgeons Standardized Shoulder Assessment*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (110)

18 (Shoulder pain and disability index*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (555)

19 Simple shoulder test*.mp. (868)

20 Western ontario shoulder instability.mp. (224)

21 (Constant-Murley score* or Constant Murley score or Child Health Questionnaire or PODCI or Pediatric Outcomes Collection Instrument or SPADI or Neer shoulder score or Visual Analogue Scale or VAS).mp. (68584)

22 Shoulder disability questionnaire*.mp. (81)

23 Oxford shoulder score.mp. (395)

24 Elbow self-assessment score*.mp. (6)

25 Morrey elbow score*.mp. (22)

26 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 (73369)

27 (longitudinal construct validity or valid* or reliab* or responsiveness or content validity).mp. (1335151)

28 exp "reproducibility of results"/ (420175)

29 27 or 28 (1564201)

30 14 or 26 (13713728)

31 6 and 29 and 30 (906)

32 (paediatric or pediatric or child* or minor or infant or baby or babies or juvenile*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (3395247)

33 31 and 32 (164)

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Chapter 5: Outcomes of proximal humerus fractures in children: a study protocol for a retrospective cohort study(89)

Statement of Authorship

Title of Paper	Outcomes of proximal humerus fractures in children: a study protocol for a retrospective cohort study
Publication Status	✔ Published ☐ Accepted for Publication ☐ Submitted for Publication ☐ Unpublished and Unsubmitted work written in manuscript style
Publication Details	Abbot SR, Proudman S, Hall K, Williams N. Outcomes of proximal humerus fractures in children: a study protocol for a retrospective cohort study. BMJ Open. 2022 Sep 14;12(9):e062586. doi: 10.1136/bmjopen-2022-062586. PMID: 36104126; PMCID: PMC9476141.

Principal Author

Name of Principal Author (Candidate)	Samuel Abbot		
Contribution to the Paper	Chose the topic of the study, performed literature review and formed the research questions, aims and hypothesis of the study. Proposed the chosen methodology and wrote the initial protocol (which was then edited based on feedback given by supervisors).		
Overall percentage (%)	85%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	24/10/2023

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);

ii. permission is granted for the candidate in include the publication in the thesis; and

iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Susanna Proudman		
Contribution to the Paper	Assisted with study design and editing of the manuscript.		
Signature		Date	24/11/2023

Name of Co-Author	Kelly Hall		
Contribution to the Paper	Conducted the sample size calculation and assisted with the planned data analysis methodology. **Please Note:** At the time of writing the thesis, Kelly Hall is no longer employed by the University of Adelaide, and has not been contactable via her University of Adelaide email address (through which all prior correspondence between the candidate and Kelly Hall was made). This was discussed with the Adelaide Graduate Research School on 21/11/2023, who advised that it is permissible to have the candidate's supervisor sign on Kelly Hall's behalf in this situation. The principal supervisor, Nicole Williams, has therefore signed on Kelly Hall's behalf below.		
Signature (Nicole Williams on behalf of Kelly Hall)		Date	24/11/2023

Name of Co-Author	Nicole Williams		
Contribution to the Paper	Assisted with study design and editing of the manuscript.		
Signature		Date	24/11/2023

Abstract

Introduction

Proximal humerus fractures (PHFs) comprise <3% of all fractures in children and adolescents. While it is accepted that minimally displaced PHFs can be treated conservatively, the management of severely displaced PHFs remains controversial, especially in older children. This study will aim to analyse the functional and quality-of-life outcomes of children with PHFs, in order to inform their optimal management.

Methods and Analysis

We will conduct a retrospective cohort study to evaluate the outcomes of patients who were diagnosed with a paediatric PHF at the Women's and Children's Hospital (WCH) in South Australia. The primary outcome will be each participant's pain and quality-of-life outcome, determined by use of the Quick Disabilities of the Arm, Shoulder and Hand, Shoulder Pain and Disability Index and Paediatric Outcomes Data Collection Instrument. Secondary outcomes will include rates of non-union, persistent deformity and complications. The information for these variables will be acquired during a brief clinic appointment, and from the medical records and WCH radiology database. Multivariable logistic regression will be performed to determine the clinical variables associated with a worse clinical outcome.

Ethics and Dissemination

The study has been approved by the Women's and Children's Health Network Human Research Ethics Committee (protocol number: 2021/HRE00250). The study findings will be submitted to peer-reviewed scientific journals for publication and disseminated at conference presentations.

Trial Registration Number

Australian New Zealand Clinical Trials Registry (ACTRN12622000176763).

Strengths and Limitations of this Study

- A strength of this study is that it will evaluate that long-term functional and quality-of-life outcomes of paediatric proximal humerus fractures, whereas previous studies have only analysed radiological or short-term to medium-term outcomes.
- A limitation is the use of patient-reported outcome measures that have only been validated for assessing upper limb pathology in adults, as there is no existing patient-reported outcome measure that has been validated for use in children.
- Another limitation is the retrospective study design.

Introduction

Proximal humerus fractures (PHFs) comprise between 0.45% and 2% of all fractures in children and adolescents, and 3% - 6.7% of all physeal fractures,(2, 9, 14, 21), with an estimated incidence between 31.4 and 680 fractures per 100,000 children per year, and at least a 3:1 male preponderance.(2, 3, 7-10) There are two common responsible mechanisms, namely a backwards fall onto an out-stretched hand with the arm hyperextended and externally rotated, or direct trauma to the lateral aspect of the shoulder.(2, 3, 5, 8, 9) The usual cause of injury is age-dependent. In neonates, physeal separations can occur as a result of birth trauma.(5, 8, 9) PHFs in older children typically results from moderate-energy trauma during high-contact sports (such as football, horse-riding and gymnastics) or motor vehicle accidents.(2, 9) A PHF occurring in an otherwise healthy infant should be considered suspicious for nonaccidental trauma.(8)

In 1965, Neer and Horowitz introduced a system to classify the severity of PHFs based on the degree of displacement.(11) Neer-Horowitz (NH) Grade I fractures are either nondisplaced or displaced by less than 5mm, Grade II are displaced between 5mm and one-third of the width of the proximal humeral shaft, Grade III are displaced greater than one-third but no greater than two-thirds of the shaft width, and Grade IV are displacement by more than two-thirds of the shaft width.(13) Eighty-give per cent of paediatric PHFs are either nondisplaced or minimally displaced (NH Grade 1 or Grade II), with only 15% being severely displaced (NH Grade III or Grade IV).(13, 14) PHFs that occur prior to skeletal maturity rarely lead to a functional or cosmetic deficit for a number of reasons.(8) First, they have a profound ability to remodel, due to the proximal humeral growth plate being responsible for 80% of overall humeral longitudinal growth.(3, 4, 15-17) Second, the periosteum in the immature humerus is metabolically active, which enhances its ability to rapidly consolidate fractures and heal.(2, 49) Third, the glenohumeral joint has the widest range of motion of any joint in the body, meaning it can accommodate a large degree of displacement and angulation without causing any significant functional impairment.(3, 19, 20) Because of these unique attributes, paediatric PHFs have historically been treated non-operatively, regardless of their severity.(21, 22)

Since the study by Neer *et al*. in 1965, conservative management has remained the mainstay of treatment for minimally displaced (Grade I and Grade II) PHFs in children, whereas the management of Grade III and Grade IV fractures remains controversial, particularly in adolescents with limited remodelling potential.(11, 14) There is now an apparent consensus in the contemporary literature that adolescents managed conservatively for severely displaced PHFs are at risk of a less than desirable clinical outcome.(10, 16, 18, 26) In keeping with this, a recent trend towards operative management has been identified over the past decade.(2) Numerous algorithms for the treatment of paediatric PHFs based on patient age and grade of displacement have been proposed,(7, 10, 14, 21) although there is considerable heterogeneity as to the proposed thresholds for surgery, and no generally accepted evidence-based guideline has been established.(10, 14, 26, 31, 90) Based on their retrospective analysis of 28 patients with NH Grade III and Grade IV PHs, Dobbs *et al*. recommended a protocol for patients following closed reduction. For patients <7 years old, post-reduction angulation of up to 70^0 can be accepted; for patients aged 8-11 years, up to 60^0 can be accepted and for patients ≥12 years, up to 45^0 can be accepted. It was concluded that deformities greater than these thresholds for these groups of patients require open reduction and internal fixation.(10) The protocol suggested by Binder *et al.* was more aggressive for patients over 10 years old. They recommended conservative management for children <10 years old with up to 20^0 angulation, and surgery for children ≥10 year with more than 20^0 angulation, citing an increased risk of soft tissue interposition in fractures with more than 20^0 of angulation.(16) The protocol proposed in the systematic review by Hohloch *et al.* was considerably more conservative.(7) They recommended non-operative management for children <10 years old with a severely displaced PHF, and surgical treatment for those ≥13 years. As can be seen, there are considerable discrepancies in the various treatment algorithms that have been proposed to date. Furthermore, as PHFs represent less than 3% of fractures in children, studies that have investigated this subject tend to be retrospective analyses of small cohorts of patients, with only a short period of follow-up and low follow-up rates.(7, 8) Consequently, there is a paucity of high-quality studies that have examined long-term functional and quality-of-life outcomes following paediatric PHFs from which to derive an evidence-based guideline regarding management options.(7, 14) Our study will aim to analyse the functional and quality-of-life outcomes of a large cohort of children and adolescents with PHFs, in order to inform their optimal management. A secondary aim is to determine the clinical factors that predict a worse clinical outcome for paediatric PHFs, including patient demographics, fracture pattern and treatment methodology. The hypothesis is that adolescent patients treated non-operatively have a higher risk of a poor clinical outcome, especially when the initial displacement of their fracture is greater.

Methods and Analysis

Study Setting

This will be a retrospective cohort study. The study will be conducted at the Women's and Children's Hospital (WCH) in South Australia, the tertiary referral paediatric centre for orthopaedics for the state of South Australia and surrounding regions of south-western New South Wales and western Victoria.

Patient and Public Involvement

Patients were not involved in the design or proposed methodology of the study. The findings of the study will be disseminated to the study participants by mail, at the conclusion of the study.

Eligibility Criteria

The principal investigator will identify potential participants from the medical records and radiology database of the WCH based on a diagnosis of a PHF when under the age of 18 years. The diagnosis will be confirmed on examination of the plain-film radiographs. The inclusion and exclusion criteria for the study are listed in Table 1.

Table 1: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
1. Participants aged under 18 years at the time that they sustained a PHF. 2. All clinical subtypes of PHF, as outlined by the Neer-Horowitz and AO classifications. 3. Participants must have been diagnosed with their PHF at the WCH between 1st January 2010 and 1st June 2020, and had their definitive treatment either there, or at the private practice of WCH-co-employed orthopaedic surgeons.	1. Patients whose fracture was the result of reported or suspected domestic violence, or required mandatory reporting. 2. Patients less than 2 years of age 3. Patients who are unwilling to give consent. 4. Patients who the researcher believes would be unable to participate in the study (e.g. patients who are too young to provide answers in the structured questionnaire). 5. Patients with pathological fractures of the proximal humerus. 6. Patients who are under the Guardianship of the Minister.

PHF, proximal humerus fracture; WCH, Women's and Children's Hospital

Case Ascertainment

The study will begin with a retrospective analysis of the medial records at the WCH as well as the records at private practices of WCH co-employed orthopaedic surgeons. The records of consecutive patients diagnosed and managed with PHFs between 1 January 2010 and 1 June 2020 will be reviewed. Cases will be ascertained from the inpatient and outpatient records using International Classification of Diseases codes. Additionally, the WCH radiology database (Kestrel) will be reviewed using keyword search for “shoulder”, “humerus” and “fracture” to identify fractures of the proximal humerus that have occurred between 1 January 2010 and 1 June 2020.

Recruitment

Once potential participants have been identified, their vital status will be reviewed in the state-wide clinical information system to ensure that families of deceased patients are not contacted. Each potential participant will be mailed a copy of the Letter of Invitation to Participants, the Participant Information Sheet and the Informed Consent Form. If they do not opt out of the study by emailing or calling the principal investigator, they will then be contacted via telephone 2 weeks later and given verbal information about the research project. During this telephone call, the participant will be asked to sign the informed consent form if they have not already done so.

Data Collection and Assessment Tools

Participants who consent to participate in the study will complete a structured questionnaire over the telephone. This questionnaire will include the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), the Shoulder Pain and Disability Index (SPADI) and the Paediatric Outcomes Data Collection Instrument (PODCI).(66, 85, 91)

The original Disabilities of the Arm, Shoulder and Hand (DASH) score takes into account daily activities, symptoms and social function, and has been shown to have strong reliability and validity for assessing patients with PHFs.(85) From the original 30-item DASH questionnaire, the shorter 11-item QuickDASH was developed, which reduces the completion time and the administrative burden. The items in the QuickDASH were selected from the original instrument on the basis of them having the highest reliability, validity and responsiveness within each domain of the DASH.(65) The SPADI questionnaire was created in 1991 by Roach *et al* and consists of two components—one that assesses the participant's pain levels, and one that assesses the participant's ability to carry out various functional activities. The QuickDASH and SPADI have been validated for use via telephone.(92, 93) The PODCI is a well-validated musculoskeletal health questionnaire that addresses a child's mobility, upper limb function, sports and physical function, pain and happiness.(94) While there is precedence for the PODCI being administered via telephone in previous studies,(95, 96) the authors were not able to identify any study which has evaluated its validity for telephonic review. Additionally, participants will complete a questionnaire developed by the researchers that asks demographic and clinical questions related to the participant's current occupation, highest level of education, comorbidities and other musculoskeletal injuries that they have sustained.

At the conclusion of the telephone interview, participants will be invited to have either an in-person clinic appointment, or an online video meeting, to allow for a standardised clinical examination to assess their range of motion and strength. Participants who agree to an in-person clinic appointment will be asked to bring their signed consent form with them, so that a scanned copy can be made for our records. Those who undergo a video interview will be asked to scan and email their signed consent form to the principal investigator. The range-of-motion examination will involve three tests, namely the hand-to-neck, hand-to-scapula and hand-to- opposite-scapula tests.(97) Together, these tests assess movement of the shoulder joint in all dimensions, and they have been found to have strong intratester and intertester reliability.(97) Table 2 outlines the scoring system for these tests.

Table 2: Scoring System for the Range-of-Motion Tests(97)

Hand to neck (shoulder flexion and external rotation)	
0	The fingers reach the posterior midline of the neck with the shoulder in full abduction and external rotation, without wrist extension.
1	The fingers reach the midline of the neck, but do not have full abduction and/or external rotation.
2	The fingers reach the midline of the neck, but with compensation by adduction in the horizontal plane or by shoulder elevation.
3	The fingers touch the neck.
4	The fingers do not touch the neck.
Hand to scapula (shoulder extension and internal rotation)	
0	The hand reaches behind the trunk to the opposite scapula or 5cm beneath it in full internal rotation.
1	The hand almost reaches the opposite scapula, 6-15cm beneath it.
2	The hand reaches the opposite iliac crest.
3	The hand reaches the buttock.
4	Subject cannot move the hand behind the trunk.
Hand to opposite scapula (shoulder adduction)	
0	The hand reaches to the spine of opposite scapula in full adduction without wrist flexion.
1	The hand reaches to the spine of opposite scapula in full adduction.
2	The hand passes the midline of the trunk.
3	The hand cannot pass the midline of the trunk.

Participants who are examined in-person will also undergo an assessment of their shoulder's strength. Shoulder strength in forward-elevation, extension, abduction, adduction, internal rotation and external rotation will be scored out of 5, as according to the classification tool of the American Spinal Injury Association (see table 3).(98)

Table 3: Scoring System for Strength Assessment(98)

0	Total paralysis.
1	Palpable or visible contraction.
2	Active movement, full range of motion with gravity eliminated.
3	Active movement, full range of motion against gravity.
4	Active movement, full range of motion against gravity and moderate resistance in a muscle-specific position.
5	Normal active movement, full range of motion against gravity and full resistance in a muscle-specific position expected from an unimpaired person.

The strength of participants who undergo a video meeting will be assessed using the techniques introduced by Laskowski *et al.*(99) In these techniques, shoulder internal rotation and external rotation are assessed by the participant's ability to perform these movements against resistance, provided by either a doorframe or another person. Abduction strength is assessed by asking the participant to abduct their arm to 90^0 and apply self-resistance with the opposite arm. This technique could also be used to assess forward elevation, by asking the participant to maintain their arm 90^0 of forward elevation while applying a down- ward force with the opposite arm.

Outcomes

Primary Outcome Measures

The primary outcome measure will be pain and quality-of- life outcomes, as determined by the QuickDASH, SPADI and PODCI questionnaires. Consistent with the methodology of two previous studies that have investigated paediatric PHFs, by Canavese *et al.* and Khan *et al.*,(49, 50) a poor outcome for the QuickDASH will be defined as a score of 2 or more out of a possible 11 points. To the authors' measure functional outcomes of PHFs in the paediatric population. A poor outcome will be defined as a SPADI score of greater than 3 out of a possible 10 points, based on the findings of the studies by Chester *et al.*, Merolla *et al.* and Kuhlmann *et al.*,(100-102) who found that the mean SPADI scores for their cohorts of patients with shoulder pathology were between 3 and 4 out of a possible 10 points. Similarly, the authors were not able to identify any previous study that has measured the functional and quality-of-life outcomes of paediatric PHFs by use of the PODCI. However, multiple previous studies have used the PODCI to quantify outcomes following supracondylar humeral fractures in children, and have considered a score of less than 90 at final follow-up to be poor.(103, 104) Based on the finding of these studies, a PODCI score of less than 90 will be defined as 'poor'.

Secondary Outcome Measures

Secondary outcome measures will include objective clinical and radiological assessments, including rates of union and non-union for fractures treated with the different treatment modalities, persistent deformity, degree of fracture angulation and NH grade of fracture displacement at final follow-up, complications of treatment (such as infection and need for re-operation), and shoulder strength and range of motion. The information for these variables will be acquired during the clinic/video appointment, and from the medical records and radiology database at the WCH and the private rooms of WCH co-employed orthopaedic surgeons. The radiological assessment of each participant's fracture will be carried out by the principal investigator, who is an orthopaedic registrar at the WCH, on examination of the plain-film radiographs.

Baseline Data

The following data will be obtained from the medical records and radiology database at WCH:

- Current age, gender, ethnicity.
- Age at fracture relative to expected age of skeletal maturity, as per the Menelaus rule-of-thumb.(105)
- Radiographic evidence of skeletal immaturity or maturity at the time of fracture, as evidenced by an open or closed proximal humeral physis on X-ray, respectively.
- Mechanism of injury.
- Fracture pattern.
- Treatment methodology.
- Duration of follow-up.
- Radiological outcome.
- Complications of treatment.

Data Collected During Interview and Clinic Appointment

The following data will be obtained during the telephone interview and subsequent clinic appointment:

- Comorbidities and medications.
- Pain and quality of life outcomes (QuickDASH, PODCI and SPADI questionnaires).
- Shoulder strength and range-of-motion.

Participant Timeline

Table 4 outlines the process by which participants will be identified, consent will be obtained, and data will be collected from each participant.

Table 4: Schedule of enrolment, data collection and assessments

Assessment/Procedure	Screening of Medical Records and Radiology Database	Telephone Interview	Clinic Appointment	Review of Medical Records and Radiology Database
Identification of potential participants	X			
Send out Letter of Invitation to Participants, Participant Information Sheet and Informed Consent Form	X			
Ensure Informed Consent Form has been Signed		X		
Structured Questionnaire		X		
Range of Motion and Strength Examination			X	
Demographic Information				X
Fracture Pattern				X
Treatment Methodology				X
Complications of Treatment				X

Sample Size Calculation

Our sample size estimation, justification and power calculations were made by a University of Adelaide statistician, on the basis of the studies by Canavese *et al.* and Khan *et al.*, which suggest that between 26% and 37% of paediatric patients with a PHF will experience a poorer outcome, defined as a QuickDASH score of 2 or more out of a possible 11 points.(49, 50)

Five items will be investigated as potential risk factors for a poorer clinical outcome: age at fracture, gender, fracture severity, comorbidities and treatment methodology. The data analysis will be with multivariable logistic regression, which requires a minimum of 10 events per variable to ensure adequate power and model stability. To allow for more complex relationships (e.g., interactions or non-linear functions) in the data, this will be increased to 15 events per variable. The risk factors of interest translate into 10 predictors. As per the findings of previous studies, it is reasonable to expect that 30% of patients will have a QuickDASH score of at least 2.(49, 50) If 10 predictors are used, this equates to a required sample size of 500 participants.

Since one of the key hypotheses of this study is that the adolescent group (aged 12–18 years) will have poorer outcomes than the younger group (2–11 years), power calculations were made to determine the level of power that the study would have to assess the difference in outcomes between these two groups, based on the number that will also be required to ensure a stable model when fitting a multivariable logistic regression model. With the assumed overall proportions being 30% and the hypothesis that the adolescent group will have worse outcomes than the younger group, the following calculations assume that 40% of the adolescent group (n_1) will have a poorer outcome, and 20% of the younger group (n_2) will have a poorer outcome. As shown in table 5, if 500 participants are recruited, this would confer 99.9% power.

Table 5: Power Calculation for Adolescent and Younger Group

Total sample ($n = n_1 + n_2$)	Power
950	100%
800	100%
650	100%
500	99.9%

Assuming 80% power to detect a proportion of 0.4 in the adolescent group and 0.2 in the non-adolescent group with a two-sided α of 0.05, with continuity correction applied this would require 91 patients per group, with an overall sample of n=182. As outlined above, however, we hope to identify 500 participants so that the multivariable logistic regression model can be performed.

Data Analysis

Multivariable logistic regression will be performed to determine the clinical variables that are associated with a worse clinical outcome. Subgroup analyses will also be performed on:

1. Participants aged 16-18 years old at the time they sustained the PHF.
2. Participants who sustained NH Grade III or Grade IV fractures.
3. Participants who were skeletally mature at the time of diagnosis.

These subgroups will allow us to assess the efficacy of treating adolescent patients conservatively rather than operatively, depending on the severity of their PHF.

Ethics and Dissemination

Research Ethics Approval

The study has been approved by the Women’s and Children’s Health Network Human Research Ethics Committee (protocol number: 2021/HRE00250).

Safety Considerations

As there is no intervention involved in this study, but rather simply a telephone interview with a structured questionnaire and a clinic appointment with a brief shoulder examination, the safety or well-being of the participants is unlikely to be compromised. The questionnaire is unlikely to cause any offence or distress. Participants will be allowed to have a family member present during the interview, to optimise their emotional security and support. Patients whose fracture was the result of reported or suspected child abuse, or required mandatory reporting, will be excluded from the recruitment process. Finally, any health concerns that are raised during the clinic interview will be addressed, and the participant will be offered a referral to the appropriate outpatient clinic or advised to consult their general practitioner about the health issue, if appropriate.

Consent

The principal investigator will obtain informed consent. The consent form will be completed by participants aged over 18 years, and by the guardian of participants who are under the age of 18 years.

Confidentiality

Clinical and radiological data will be collected using REDCap electronic data capture tools hosted at SA Health.(106, 107) Participants will be listed by their WCH Unit Record Number with names removed. Data will be uploaded to Figshare, the University of Adelaide's data and digital object repository, where it will be stored until 30 years after the completion of the project, in accordance with the Government of South Australia General Disposal Schedule No. 28.(108) At this time, the data will be permanently deleted from Figshare and REDCap.

Access to Data

Access to the raw data set will be limited to the statistician and the principal investigator.

Dissemination Policy

The study findings will be submitted to peer-reviewed scientific journals for publication, and will also be disseminated at local, national and international conference presentations.

Contributors

SRA, NW and SP developed the study. SRA is the principal investigator and drafted the protocol. NW and SP are the supervisors of the study, and have actively contributed in reviewing the protocol and methodology. KH is the statistician who is responsible for the statistical methodology and analysis. All authors have read and approved the final manuscript of the study protocol. All authors meet the ICMJE criteria for authorship.

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Competing Interests

None declared.

Patient and Public Involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient Consent for Publication

Not applicable.

Provenance and Peer Review

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ORCID iD

Samuel Richard Abbot https://orcid.org/0000-0001-8829-862X

Chapter 6: Outcomes of proximal humerus fractures in children: a retrospective cohort study [submitted for publication]

Statement of Authorship

Title of Paper	Outcomes of proximal humerus fractures in children: a retrospective cohort study.
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Principal Author

Name of Principal Author (Candidate)	Samuel Abbot		
Contribution to the Paper	Created the research question and topic, primarily designed the study protocol, carried out the data collection (interviewed and examined all participants via telehealth), wrote the initial draft and edited the manuscript according to supervisors' recommendations.		
Overall percentage (%)	90		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	11/11/2023

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);

ii. permission is granted for the candidate in include the publication in the thesis; and

iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Susanna Proudman

Contribution to the Paper	Assisted with study design and editing of the manuscript.		
Signature		Date	24/11/2023

Name of Co-Author	Jana Bednarz		
Contribution to the Paper	Was the statistician who constructed the data analysis methodology, and completed the data analysis. Assisted with editing of the manuscript.		
Signature		Date	22/11/2023

Name of Co-Author	Nicole Williams		
Contribution to the Paper	Assisted with study design and editing of the manuscript.		
Signature		Date	24/11/2023

Abstract

Background

Paediatric proximal humerus fractures (PHFs) have historically been treated non-operatively. However, the management of severely displaced PHFs in older children has been debated over the years, with contemporary studies advocating for surgery. The purpose of this study was to review the outcomes of a cohort of paediatric patients treated for a PHF, in order to guide management of future paediatric PHFs.

Methods

The records of the Women's and Children's Hospital in South Australia were reviewed to identify paediatric PHFs that occurred between 1st January 2010 and 1st June 2020. Participants completed an interview over the phone, which included the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), the Shoulder Pain and Disability Index, and the Paediatric Outcomes Data Collection Instrument. Each participant's shoulder range-of-motion was assessed via telehealth using Zoom. Multivariable logistic regression was used to identify patient and clinical variables that were associated with a poorer outcome.

Results

Of 307 patients contacted, 125 participated. 46 met the definition of a poorer clinical outcome, defined as a QuickDASH score of 2 or more. Fractures of greater severity were predictive of a poorer outcome, and patients aged ≥12 years old at the time of injury had higher total QuickDASH scores. The findings did not suggest that these subgroups of patients have superior outcomes if treated surgically.

Conclusion

The majority of paediatric PHFs have an acceptable clinical outcome, irrespective of treatment methodology. Multicentre prospective studies are required to establish the indications for surgery for adolescent patients with severely displaced PHFs.

Introduction

Proximal humerus fractures (PHFs) in children are relatively rare, occurring with an incidence of 6.8 fractures/10,000 children per year.(7) As with most paediatric fractures, the majority are treated non-operatively with good results.(109) However, the management of severely displaced PHFs has been the subject of considerable debate over the past 60 years, especially in adolescents who have relatively limited remodelling potential. While some authors have advocated for the surgical management of severely displaced PHFs in children,(13, 16, 26, 109) others reserve surgery for patients with severely displaced fractures who have had failed attempts at closed reduction,(17, 110) and others do not advocate for surgery under any circumstance.(19, 111) The purpose of this study was to retrospectively review the functional and quality-of-life outcomes of a cohort of patients treated for a PHF at a paediatric tertiary referral centre, in an attempt to guide the future management of these fractures in children.

Materials and Methods

Eligibility Criteria

In order to be included, each participant must have been diagnosed with a PHF at the Women's and Children's Hospital (WCH) in South Australia. The fracture must have been sustained between 1st January 2010 and 1st June 2020 inclusive. The diagnosis was confirmed by review of the plain film radiographs by the principal investigator. The inclusion and exclusion criteria are listed in Table 1.

Table 1: Inclusion and exclusion criteria

Inclusion Criteria	**Exclusion Criteria**
4. Patients aged <18 years at the time they sustained a PHF. 5. Participants must have been diagnosed with their PHF at the WCH between 1st January 2010 and 1st June 2020, and had their definitive treatment either there, or at the private practice of WCH-co-employed orthopaedic surgeons.	7. Patients whose fracture was the result of domestic violence, or required mandatory reporting. 8. Patients <2 years of age 9. Unwilling to give consent. 10. Patients who the researcher believed would be unable to participate in the study (e.g. patients who are too young to provide answers in the structured questionnaire). 11. Pathological fractures 12. Patients under the Guardianship of the Minister.

Case Ascertainment

Cases were ascertained primarily from the WCH radiology database, using a keyword search for “shoulder”, “humerus” and “fracture” to identify PHFs that occurred between 1st January 2010 and 1st June 2020. Additional cases were identified using International Classification of Diseases codes on the WCH electronic medical records.

Data Collection

Eligible participants who consented to participate were invited to complete a structured interview by telephone. This included questions pertaining to patient demographics, age at injury, mechanism of injury, treatment method and comorbidities. It also included the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), the Shoulder Pain and Disability Index (SPADI), and the Paediatric Outcomes Data Collection Instrument (PODCI), which have been validated for assessing outcomes following upper limb pathology. Each participant underwent a brief clinical examination via telehealth in which the range-of-motion of the shoulder ipsilateral to the PHF was assessed, using the hand-to-neck, hand-to-scapula and hand-to-opposite-scapula tests.(97) Up to three attempts on separate dates were made to contact each participant. If they did not answer any attempt, they were excluded from the study.

Definitions

Fracture severity was defined using an ordinal categorisation from 1 (low grade) to 4 (severe) based on fracture type (physeal or metaphyseal) and associated Neer-Horowitz (NH) grade, or degree of angulation, for physeal and metaphyseal fractures, respectively. Metaphyseal fractures with less than or equal to 20 degrees angulation were considered lowest grade of severity and comparable to NH-I; fractures with 21-30 degrees of angulation were considered comparable to NH-II, fractures with 31-40 degrees of angulation were considered comparable to NH-III, and fractures with >40 degrees of angulation were considered comparable to NH-IV. Treatment method was defined as either surgical or non-operative. The degree of angulation (for metaphyseal fractures) and NH-grade (for physeal fractures) was calculated by the principal investigator upon examination of the plain-film radiographs taken at the time of each participant's initial diagnosis, by use of the hospital's IntelePACS viewer system.

Outcome Measures

The primary outcome measure was each participant's pain and quality-of-life, as determined by their QuickDASH score. A poorer outcome was defined as a QuickDASH score of >2. Secondary outcome measures included results of radiological and clinical assessments, including rates of union, persistent deformity, complications of treatment, shoulder range of motion, SPADI score and PODCI score.

Data Analysis

Associations of patient and clinical variables with poorer clinical outcome were investigated.(89) Following recommendations from Ponkilainen *et al.*, causal diagrams were constructed to visualise assumed relationships between variables and to inform variable selection for statistical modelling (Supplementary Files 1-3).(112) For each variable of interest (i.e. for each exposure), multivariable logistic regression was used to estimate the total effect of the exposure on the odds of poorer outcome, with potential confounders included as suggested by the corresponding causal diagram. For continuous exposures, a linear relationship with the log-odds of the outcome was assumed. Estimates are presented as odds ratios (poorer vs acceptable clinical outcome) with 95% confidence intervals to indicate the level of uncertainty around the effect. The analyses were repeated using linear regression to examine the association between each exposure and the outcome (QuickDASH score) measured continuously. The level of statistical significance was set at 0.05. Causal diagrams were created using a web-based version of the R package DAGitty and statistical analyses were conducted using Stata 18 (StataCorp, 2023, College Station, TX).(113) Pre-specified exposures of interest were age at fracture in years, gender, fracture severity, comorbidities and treatment method.

Exploratory analyses were conducted within specific subgroups of patients based on Grade 4 fracture severity and age ≥12 years old at the time of the PHF, respectively. Associations between treatment method and acceptable clinical outcome were assessed using Fisher's exact tests, separately within each subgroup. Mean differences in observed SPADI and PODCI scores according to selected patient and clinical factors were described using univariable linear regression.

Ethics Approval

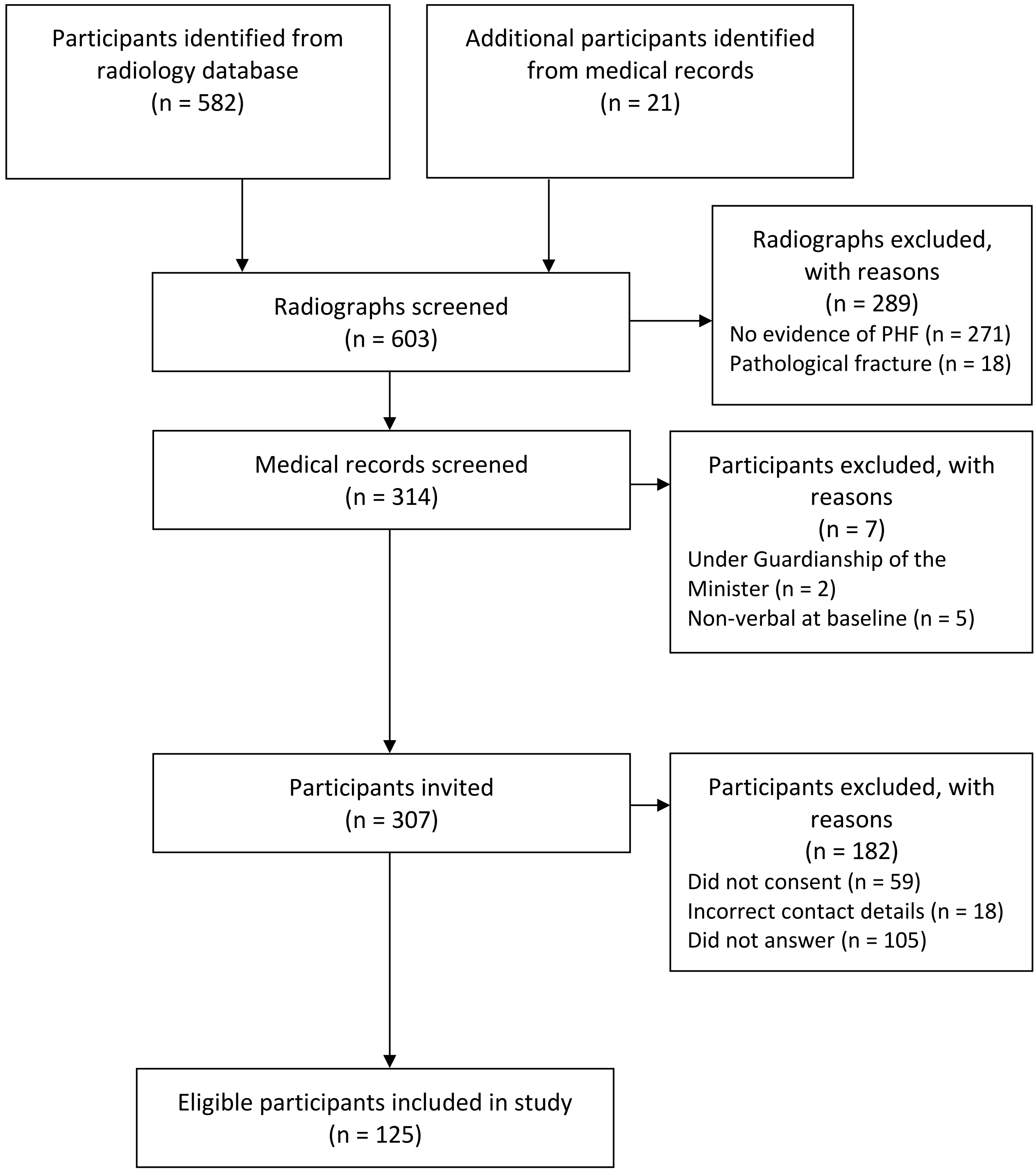
This study was approved by the WCH Network Human Research Ethics Committee (reference number: 2021/GEM00405) and The University of Adelaide Human Research Ethics Committee (application ID: 35543).

Results

Sources of Case Ascertainment

The radiology database search yielded a potential 582 potential participants, and the electronic medical records yielded an additional 21 potential participants. Of the 603 potential participants identified, 296 did not meet the eligibility criteria. Hence, a total of 307 eligible participants were invited, of whom 125 consented to participate (Figure 1).

Figure 1: Case Ascertainment Process



Patient Demographics, Fracture Pattern and Co-Morbidities

67 (53.6%) participants were female, and the mean age at injury was 9.4 years (range: 2-17 years). 105 (84.0%) sustained a metaphyseal fracture and 20 (16.0%) sustained a physeal

fracture. 51 (40.8%) participants had fractured another bone in their lifetime, 13 (10.4%) had attention-deficit/hyperactivity disorder (ADHD, Australian prevalence: 3-7%) and 7 (5.6%) had autism spectrum disorder (ASD, Australian prevalence: 1.5-2.5%).(114, 115)

Patient, Clinical and Fracture Characteristics Associated with Poorer Clinical Outcome

Total QuickDASH scores ranged from 0.0 to 45.5, with a mean of 2.9 (SD 7.2). 46 (36.8%) participants met the definition of a poorer clinical outcome. The patient and clinical characteristics of the patients who had an acceptable clinical outcome versus a poor clinical outcome are outlined in Supplementary Information 4. Notably, 21.7% of patients with a poorer outcome had a physeal fracture, versus 12.7% of those with an acceptable outcome. Relative to the lowest severity of fractures (Grade 1), Grade 4 fractures (NH grade IV physeal fracture or a metaphyseal fracture with >40 degrees angulation) were predictive of a poorer clinical outcome (adjusted odds ratio (95% CI) = 5.97, $p = 0.02$).

Surgeries performed

Ten participants underwent surgery for their PHF. The procedures performed, and each participant's respective grade of fracture and age at injury are outlined in Table 2.

Table 2: Summary of the surgeries performed

Participant	Primary Surgery Performed	Type of Fracture	Grade of Fracture†	Age at Injury (Years)	Additional Procedures Performed
1	CR + K-wire fixation	Metaphyseal	2	11	-
2	CR + K-wire fixation	Physeal	4	14	-
3	CR + K-wire fixation	Physeal	3	11	-
4	ORIF	Metaphyseal	2	15	-
5	Open reduction + TEN insertion	Metaphyseal	3	15	-
6	CR + K-wire fixation	Metaphyseal	4	5	-
7	ORIF	Physeal	4	11	-
8	CR + K-wire fixation	Metaphyseal	4	9	-
9	Open reduction + K-wire fixation	Metaphyseal	4	13	-
10	ORIF	Physeal	4	11	-

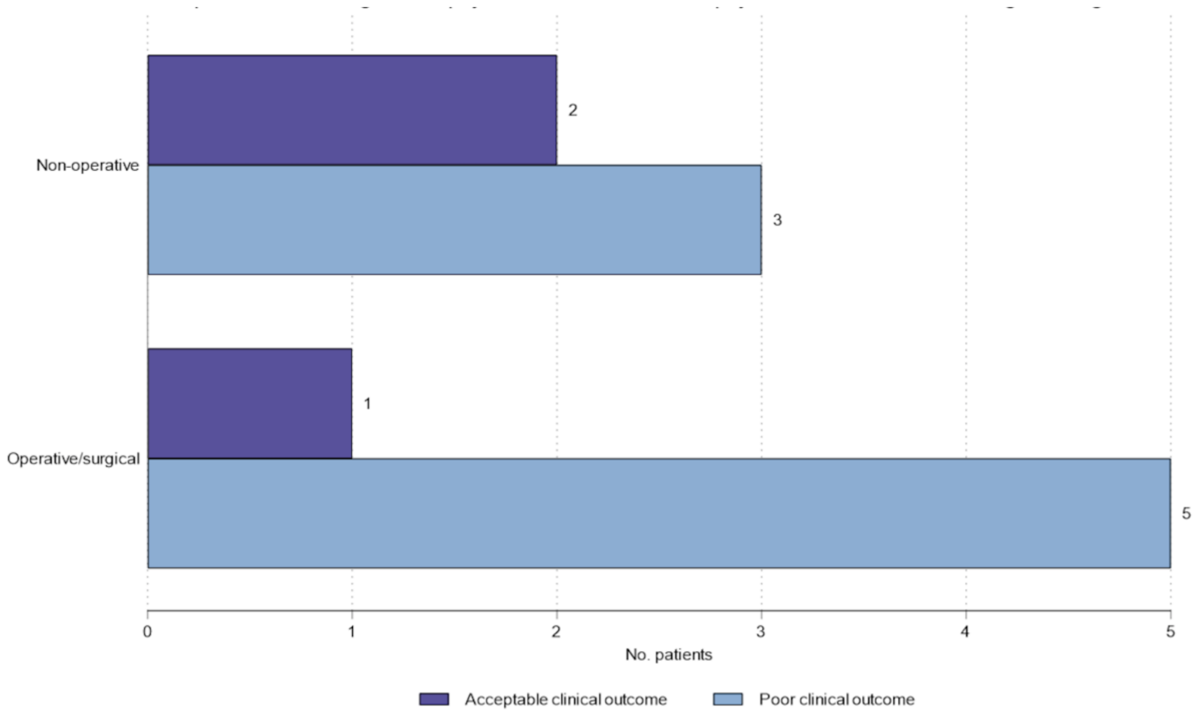
Abbreviations: CR, Closed Reduction; K-wire, Kirschner wire; ORIF, Open Reduction + Internal Fixation (plate osteosynthesis); TEN, Titanium Elastic Nail

† NH grade for physeal fractures. Metaphyseal fractures graded as described in Materials and Methods (Definitions) section.

Clinical Outcomes for Participants with Grade 4 Fractures According to Treatment Method

There were 11 participants with Grade 4 fracture severity, 8 of whom had a QuickDASH score of >2. Among those managed surgically, 1 (16.7%) had an acceptable clinical outcome, versus 2 (40.0%) of those who were managed non-operatively (Fisher's exact $p = 0.55$, Figure 2).

Figure 2: Clinical outcome* by treatment method for patients with NH grade IV fractures and metaphyseal fractures with >40 degrees angulation



* Poor clinical outcome defined as a QuickDASH score of ≥2

Clinical Outcomes for Participants Aged ≥12 Years Old at Time of Injury

34/125 (27.2%) participants were ≥12 years old at the time of injury, 16 (47.1%) of whom had a poor clinical outcome. Among those ≥12 years old at the time of injury who were managed surgically, 5 (71.4%) had a poor clinical outcome, versus 11 (40.7%) of those who were treated non-operatively (Fisher's exact $p = 0.21$). 47.1% of participants ≥12 years old at the time of injury had a poorer clinical outcome versus 33.0% of those aged <12 years old, however this did not meet statistical significance ($p = 0.148$). The mean total QuickDASH score of patients aged ≥12 years old at the time of injury, however, was higher than that of patients aged <12 years (5.1 versus 2.1; 95% CI 0.19, 5.85; $p = 0.04$).

Patient and Fracture Characteristics and Their Effect on SPADI and PODCI Scores

The mean standardised PODCI Pain/Comfort Scale score was lower for those with Grade 4 fractures than for those with Grade 3 fractures (69.5 versus 86.7, mean difference -17.3, 95% CI -34.9, 0.3; $p = 0.05$), indicating a greater degree of pain (Table 3). Patients with Grade 4 fractures managed surgically had a mean SPADI score of 9.4 versus 8.0 for those managed non-operatively (mean difference 1.4, 95% CI -11.1, 13.8; $p = 0.81$), and a mean PODCI Pain/Comfort Scale score of 71.8 versus 66.6 (mean difference 5.2, 95% CI -31.5, 42.; $p = 0.76$). The mean SPADI score for patients aged ≥12 years old at the time of injury was higher than those aged <12 years (5.1 versus 2.4, mean difference 2.7, 95% CI 0.31, 5.09; $p = 0.03$), indicating a higher level of pain and dysfunction. There was no significant difference in either the SPADI and PODCI scores for patients aged ≥12 years old at the time of injury who underwent surgical versus non-operative management.

Table 3: Summary of total QuickDASH, SPADI, PODCI and range-of-motion scores

	QuickDASH score	SPADI score	PODCI Pain/Comfort Scale standardised score†	PODCI Global Functioning Scale score‡	ROM total score
All patients	2.9 (7.2) [N=125]	3.2 (6.2) [N=125]	86.4 (17.2) [N=125]	95.2 (5.4) [N=125]	0.2 (0.6) [N=125]
By age					
<12 years at time of injury	2.1 (5.6) [N=91]	2.4 (5.7) [N=90]	87.2 (16.1) [N=90]	95.4 (4.8) [N=90]	0.1 (0.4) [N=90]
≥12 years at time of injury	5.1 (10.1) [N=34]	5.1 (7.0) [N=35]	84.5 (20.0) [N=35]	94.5 (6.7) [N=35]	0.5 (1.0) [N=35]
By sex					
Female	3.2 (7.4) [N=67]	3.0 (6.8) [N=67]	85.8 (17.5) [N=66]	94.9 (5.6) [N=66]	0.1 (0.4) [N=67]
Male	2.6 (7.0) [N=58]	3.4 (5.4) [N=58]	87.1 (17.0) [N=59]	95.4 (5.1) [N=59]	0.3 (0.8) [N=59]
By fracture severity					
NH grade I fracture (or <20 degrees angulation for metaphyseal fracture)	1.9 (5.5) [N=84]	1.9 (4.5) [N=84]	88.9 (14.5) [N=84]	95.8 (4.6) [N=84]	0.1 (0.3) [N=84]
NH grade II fracture (or 20-30 degrees angulation)	3.6 (8.0) [N=15]	4.0 (5.5) [N=15]	84.9 (18.2) [N=15]	94.7 (5.3) [N=15]	0.5 (0.7) [N=15]
NH grade III fracture (or 30-40 degrees angulation)	3.8 (6.1) [N=15]	5.9 (9.4) [N=15]	86.7 (18.0) [N=15]	95.5 (5.4) [N=15]	0.3 (0.7) [N=15]
NH grade IV fracture (or >40 degrees angulation)	8.9 (14.2) [N=11]	8.7 (8.7) [N=11]	69.5 (25.6) [N=11]	90.0 (8.3) [N=11]	1.0 (1.5) [N=11]
By treatment methodology for aged 12 years and older					
≥12 years at time of injury, treated surgically	5.8 (10.6) [N=7]	6.8 (9.7) [N=7]	87.9 (24.6) [N=7]	95.3 (9.1) [N=7]	0.4 (0.5) [N=7]
≥12 years at time of injury, managed non-operatively	5.0 (10.2) [N=27]	4.7 (6.3) [N=28]	83.7 (19.1) [N=28]	94.4 (6.1) [N=28]	0.5 (1.1) [N=27]

	QuickDASH score	SPADI score	PODCI Pain/Comfort Scale standardised score†	PODCI Global Functioning Scale score‡	ROM total score
By treatment methodology for severe fractures					
NH grade IV fracture (or >40 degrees angulation) treated surgically	8.0 (11.0) [N=6]	9.4 (9.5) [N=6]	71.8 (31.4) [N=6]	91.0 (10.0) [N=6]	0.7 (0.8) [N=6]
NH grade IV fracture (or >40 degrees angulation) managed non-operatively	10.0 (18.6) [N=5]	8.0 (8.7) [N=5]	66.6 (19.7) [N=5]	88.8 (6.5) [N=5]	1.4 (2.1) [N=5]

† Standardised score for Pain/Comfort scale ranging from 0 to 100, with 100 representing least pain.
‡ Composite of physical function and symptoms, calculated as the mean of the standardised mean scores for the four core PODCI scales. Range is from 0 to 100, with 100 representing the best health status.

Secondary Outcomes

52 participants had follow-up radiographs at least four weeks after their initial injury, all of which demonstrated radiological union. There were 18 participants with a self-reported persistent deformity at final follow-up. This group had a median age of 13 years at the time of injury, 7 had physeal fractures, and only 2 had been managed surgically. There were no reported complications for the 10 patients who were managed surgically. Patients with Grade 4 fractures had a mean range-of-motion score of 1.0 versus 0.3 for those with Grade 3 fractures, indicating a greater restriction to range, however this was not statistically significant (mean difference 0.67, 95% CI -0.24, 1.57; $p = 0.14$). For patients with Grade 4 fractures, those who were managed surgically had a mean range-of-motion score of 0.7, versus 1.4 for those managed non-operatively (mean difference -0.7, 95% CI -2.8, 1.3; $p = 0.44$).

Discussion

This is the first study that has reviewed the outcomes of paediatric PHFs in an Australian context. On review of the functional and quality-of-life outcomes of the cohort in this retrospective study, 63.2% of participants had an acceptable clinical outcome. This is an equivalent proportion of patients to previous studies that have only included patients with Grade-3 and -4 fractures. In the cohort study by Khan *et al.*, 58.3% of the patients treated with elastic stable intramedullary nailing (ESIN) had a QuickDASH score of <2,(50) while 71.1% patients in the study by Canavese *et al.* had an acceptable outcome, all of whom were similarly treated with ESIN for severely displaced fractures.(49) Given that only 20.8% of participants in our study had Grade-3 or -4 fractures, it may be surprising that there was a similar proportion of participants with a poor clinical outcome, as compared to studies that have excluded patients with minimally displaced fractures. Our mean QuickDASH score of

2.9, however, is comparable to that of a recent retrospective cohort study by Liebs *et al*., who reviewed the outcomes of 190 children treated for PHFs of all grades of severity either surgically or non-operatively, as according to their institution's displacement-based treatment algorithm.(116) Patients with 'minimally displaced' fractures were treated conservatively and those with 'severely displaced' fractures were treated with closed reduction and ESIN. At a median follow-up of 7.6 years, the mean QuickDASH score was 4.3. The logical explanation is that patients have been treated according to similar treatment algorithms and have thus achieved similar functional and quality-of-life outcomes. The issue that remains to be resolved, however, is determining whether paediatric patients of a given degree of skeletal maturity, with a given grade of PHF, benefit from being managed surgically rather than non-operatively.

In our study, there were no cases of non-union and no cases of a clinically significant reduction in range-of-motion. A Grade 4 fracture was predictive of a poorer clinical outcome, as in previous studies.(13, 16, 19) Previous studies have similarly reported older age at initial injury to be a risk factor for a poor clinical outcome.(16, 18, 26, 116) This was reflected in our study, as participants aged ≥12 years old at the time of injury had higher total QuickDASH scores, and a higher mean SPADI score, than those aged <12 years old at the time of injury. However, the findings of our study did not suggest that patients with Grade 4 fractures, or patients aged ≥12 years old at the time of injury, have a superior outcome if managed surgically rather than non-operatively. At final follow-up, the participants in each of these subgroups who were managed surgically had equivalent QuickDASH, SPADI and PODCI scores to their non-operative counterparts. This is in keeping with the findings of a recent retrospective cohort study by Lähdeoja *et al.*, who reviewed the outcomes of 209 patients treated for a PHF.(111) Their cohort, with a mean age of 13 years at time of injury, included participants with all grades of fracture, 37 of whom were managed surgically. The authors did not identify a clinically significant difference between the QuickDASH scores of their cohort and that of normal healthy adults, and there was no difference in outcomes between operative and non-operative treatment in their propensity-matched analysis.(111) This led the authors to conclude that PHFs in adolescents generally heal well, irrespective of whether they are treated operatively. This is consistent with Neer's teaching in his historic study in 1965, in which he declared that, regardless of the degree and severity of displacement, open surgery for the treatment of PHFs in children is rarely justified.(11)

Study Limitations

This study had a number of limitations. Of the 307 eligible participants identified within the 10-year time period, only 125 agreed to participate, such that the study was likely powered to detect only very large effect sizes in the outcomes of patients according to treatment method. In our original study protocol, a required sample size of 500 participants was calculated to be necessary to identify differences in outcomes between surgical and non-operative patients.(89) Given the 40.7% response rate that was achieved, this means a total of 1,228 eligible participants would have needed to be identified and invited to participate, for the study to be adequately powered. In order to have identified this many paediatric PHFs within the 10-year time period, a multi-centre study would be required. A further limitation was the cross-sectional study design, which meant that participants were interviewed at varying time intervals since the date of their initial injury, which may have impacted on their self-reported pain and quality-of-life scores. To our knowledge, there has not yet been a PROM that has been validated to assess upper limb pathology in the paediatric population. Because of this, PROMs that have only been validated for use in adults were utilised in this study. The uncertain validity of these questionnaires for use in our paediatric cohort, particularly in patients with ADHD and ASD, is another key limitation of the study. Studies assessing the validity of PROMs in paediatric patients with ADHD and ASD would be very valuable for future studies investigating outcomes following musculoskeletal injuries in the paediatric population. An additional limitation was the lack of a standardised protocol by which the plain film radiographs were taken at the time of injury. For example, some participants had their X-rays performed with their arm immobilised in a broad-arm sling or back-slab, whilst the majority had their X-rays performed without any form of immobilisation in-situ. A prospective study using a standardised imaging protocol, with three-dimensional imaging modalities (such as computerised tomography), would be able to achieve a more accurate calculation of the true magnitude of fracture displacement. Furthermore, our method of categorising metaphyseal PHFs as Grade 1 to Grade 4 based on the degree of angulation does not represent a recognised scoring system, and has not been validated as such. Finally, the range-of-motion tests that were used in our study have not been validated for use via telehealth, although examining joints via telehealth is becoming accepted practice.(99, 117) In order for future studies to delineate differences in outcomes between surgical and non-operative patients, and in turn, establish the clinical and radiological indications for surgery, a prospective study design is recommended, with patients reviewed at consistent time intervals following their injury. A prospective study, with patients being given questionnaires to complete at their routine follow-up appointments, would likely achieve a better response rate as well.

Conclusion

The vast majority of the study cohort achieved an acceptable clinical outcome, irrespective of treatment method. Grade 4 fractures and age ≥12 years old at the time of injury were predictive of a poorer outcome, however the findings did not suggest that these patients do better if treated surgically. Prospective, multicentre studies are required to compare the outcomes of adolescent patients treated surgically versus non-operatively for severely displaced PHFs.

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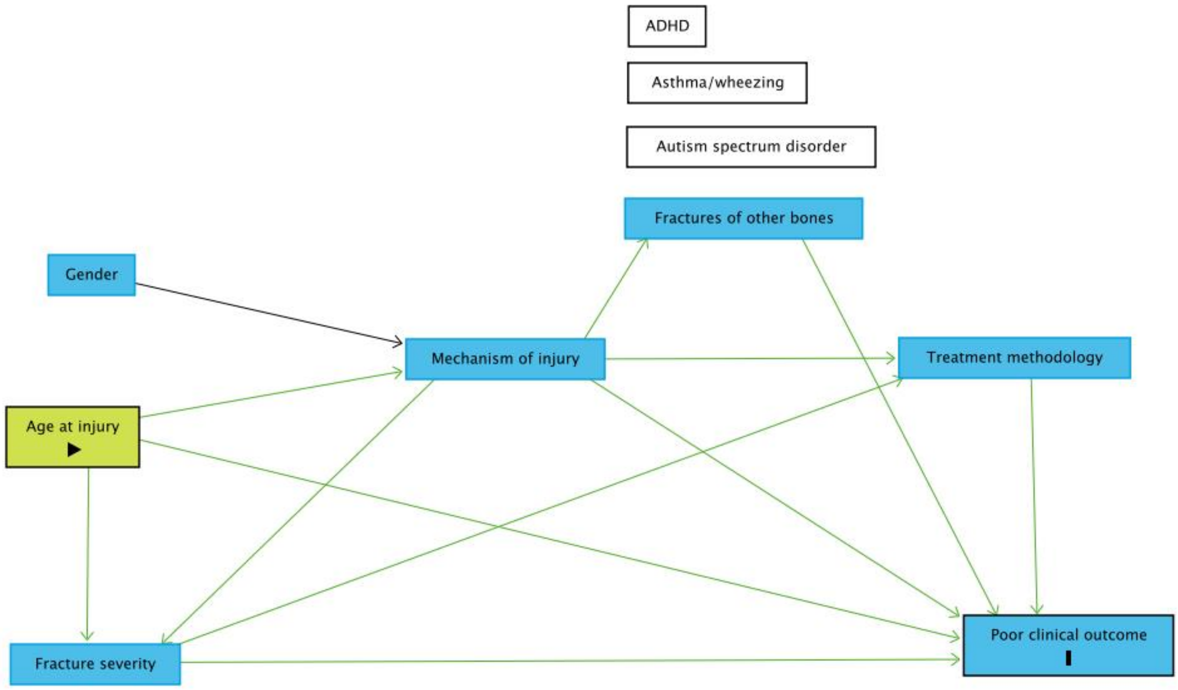
Supplementary Files

Supplementary Information 1: Directed acrylic graph (DAG) for age at injury



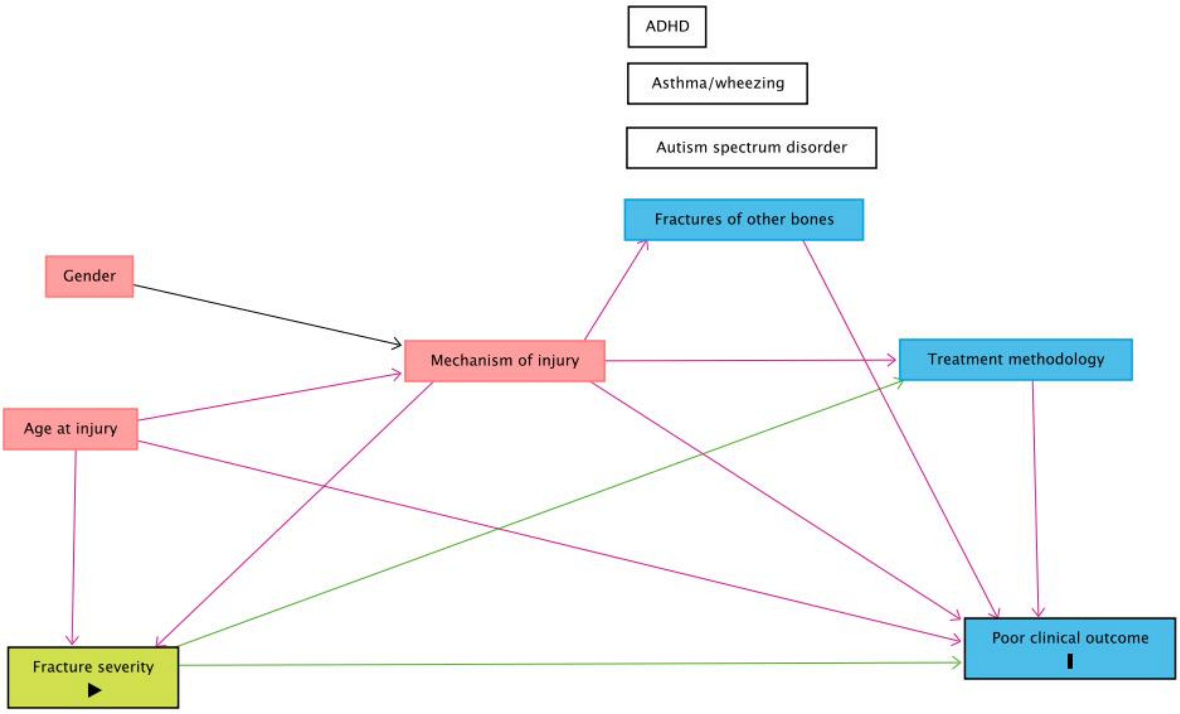
Exposure: Age at injury

Outcome: Poor clinical outcome

No open biasing paths.

No adjustment is necessary to estimate the total effect of Age at injury on Poor clinical outcome.

Supplementary Information 2: Directed acrylic graph (DAG) for fracture severity



Exposure: Fracture severity

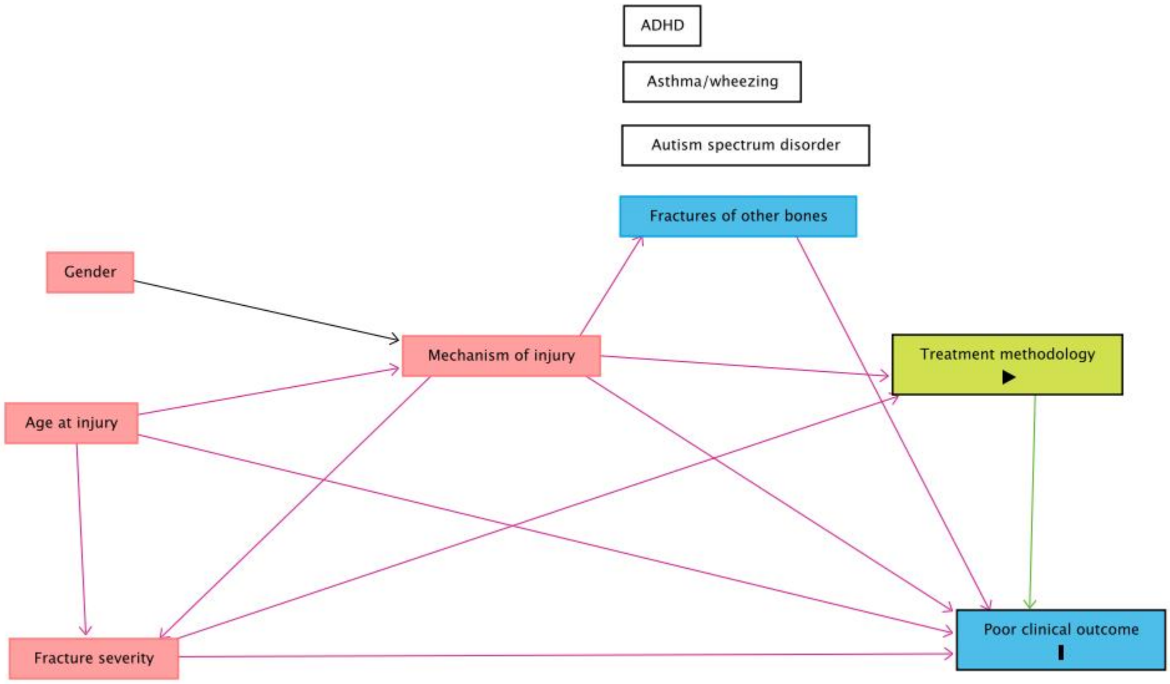
Outcome: Poor clinical outcome

Biasing paths are open.

Minimal sufficient adjustment sets for estimating the total effect of Fracture severity on Poor clinical outcome:

- Age at injury, Mechanism of injury

Supplementary Information 3: Directed acrylic graph (DAG) for treatment methodology



Exposure: Treatment methodology

Outcome: Poor clinical outcome

Biasing paths are open.

Minimal sufficient adjustment sets for estimating the total effect of Treatment methodology on Poor clinical outcome:

- Fracture severity, Mechanism of injury

Supplementary Information 4: Associations between selected patient and clinical characteristics and poorer outcome (QuickDASH score >2)

	Acceptable clinical outcome: QuickDASH ≤ 2 (N=79)	Poorer clinical outcome: QuickDASH > 2 (N=46)	Unadjusted Odds Ratio* (95% CI)	p-value	Adjusted^ Odds Ratio (95% CI)	p-value
Age at injury in years†: mean (SD)	9.3 (3.3) [N=79]	9.6 (4.3) [N=46]	1.02 (0.93, 1.13)	0.65	1.02 (0.93, 1.13)	0.65
Female gender†: no./total no.(%)	41/79 (51.9)	26/46 (56.5)	1.20 (0.58, 2.50)	0.62	1.20 (0.58, 2.50)	0.62
Mechanism of injury‡: no./total no.(%)						
Low energy trauma	10/79 (12.7)	8/46 (17.4)	1.00 (ref)	-	1.00 (ref)	-
High energy trauma	69/79 (87.3)	38/46 (82.6)	0.69 (0.25, 1.89)	0.47	0.53 (0.17, 1.70)	0.29
Fracture severity§: no./total no.(%)				#0.09		#0.11
1 (low grade; Neer-Horowitz Grade I OR metaphyseal with ≤20° angulation)	58/79 (73.4)	26/46 (56.5)	1.00 (ref)	-	1.00 (ref)	-
2 (Neer-Horowitz Grade II OR metaphyseal with 21°-30° angulation)	9/79 (11.4)	6/46 (13.0)	1.49 (0.48, 4.61)	0.49	1.47 (0.46, 4.68)	0.51
3 (Neer-Horowitz Grade III OR metaphyseal with 31°-40° angulation)	9/79 (11.4)	6/46 (13.0)	1.49 (0.48, 4.61)	0.49	1.49 (0.48, 4.67)	0.49
4 (Neer-Horowitz Grade IV OR metaphyseal with >40° angulation)	3/79 (3.8)	8/46 (17.4)	5.95 (1.46, 24.25)	0.01	5.97 (1.40, 25.43)	0.02
Treatment method‖: no./total no.(%)						
Non-operative	76/79 (96.2)	39/46 (84.8)	1.00 (ref)	-	1.00 (ref)	-
Operative	3/79 (3.8)	7/46 (15.2)	4.55 (1.11, 18.56)	0.03	2.25 (0.43, 11.70)	0.33

	Acceptable clinical outcome: QuickDASH ≤ 2 (N=79)	Poorer clinical outcome: QuickDASH > 2 (N=46)	Unadjusted Odds Ratio* (95% CI)	p-value	Adjusted^ Odds Ratio (95% CI)	p-value

* Odds ratio from logistic regression describing the odds of poor clinical outcome vs acceptable clinical outcome.
^ Adjusted for assumed potential confounders.
† No open biasing paths suggested by the causal diagram; no adjustment necessary.
‡ Adjusted for age at injury.
§ Adjusted for age at injury and mechanism of injury.
‖ Adjusted for fracture severity and mechanism of injury.
Overall p-value.

Chapter 7: Thesis Summary and Conclusion

This thesis has focused on the functional and quality-of-life outcomes of paediatric PHFs, and sought to identify risk factors that predict a poorer clinical outcome. This is of clinical importance with the current lack of an evidence-based guideline to guide the management of PHFs in children and adolescents. In our systematic review of the psychometric properties of PROMs used to assess upper limb pathology, there was no PROM identified that had been validated for use in the paediatric population, which was an unanticipated finding (Chapter 4).(55) Given the strong evidence for the content validity, internal consistency and responsiveness of the QuickDASH in adults, we chose to utilise this assessment tool in our original research study. The rationale for additionally utilising the SPADI (a surrogate measure for shoulder-related pain and dysfunction) and the PODCI (a questionnaire that provides a more holistic picture of a patient's overall wellbeing), was to allow for further analysis of our participants' functional and quality-of-life outcome.

Our systematic literature review (Chapter 3) and original research study (Chapter 6) both identified higher grade of fracture displacement, and age $\geq$12 years old at the time of injury, as significant risk factors for a poorer functional and quality-of-life outcome, which was consistent with the hypothesis.(28) On the other hand, while the findings of the systematic literature review suggested that adolescents may benefit from surgical management of severely displaced PHFs, which was in keeping with the initial hypothesis, this was not supported in our original research study.

There were a number of areas where the original research study diverged from the methodology proposed in the published study protocol (Chapter 5). Firstly, due to the COVID-19 pandemic, it was not feasible to interview participants in person, so all participants underwent their clinical examination via telehealth. It became apparent during these telehealth consultations that the proposed methods of assessing the participants' shoulder power via telehealth were unreliable, and difficult to reproduce for participants of varying ages. Hence, the participants' shoulder power scores were excluded from the data analysis process. Secondly, as was outlined in the manuscript of the original research study, the sample size that was achieved was not adequate to identify statistically significant differences between the outcomes of participants who were managed surgically versus non-operatively, after the multivariable logistic regression was performed. In the study protocol, a required sample space of 500 participants was calculated to be necessary to achieve this. With the response rate that was achieved in the study, 1,228 eligible participants would have needed to be identified, which was not possible within the scope of this single-centre study. Furthermore, due to the lower numbers of participants who were aged between 16-18 years at the time of injury, and who were skeletally mature at the time of diagnosis, it was not possible to perform the proposed subgroup analyses on these participants. Notwithstanding this, we feel that this thesis demonstrated that the adolescent participants in our cohort had similar functional and quality-of-life outcomes, irrespective of whether they were treated surgically versus non-operatively. In this respect, this thesis has challenged the findings of recent studies that have favoured the surgical management of severely displaced PHFs in adolescents, and will hopefully provide the impetus for future, multicentre, prospective studies that will be adequately powered to delineate differences in their functional and quality-of-life outcomes. This, in turn, could lead to the establishment of an evidence-based treatment algorithm to guide the management of PHFs in children and adolescents.

In conclusion, minimally displaced paediatric PHFs can be treated non-operatively and be expected to have an excellent functional and quality-of-life outcome. There is an increasing amount of literature supporting the surgical management of severely displaced PHFs in adolescent patients, however these have, for the most part, been retrospective cohort studies with relatively small sample sizes. Prospective, multicentre studies are required to determine whether adolescent patients with severely displaced PHFs do benefit from being treated surgically. Only then will it be possible to construct an evidence-based guideline for the management of these fractures in children and adolescents.

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