

Patient Reported Outcome (PRO) Measurement of Disability in Orthopaedic Trauma to the Upper Extremity

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Abstract

Patient reported outcome (PRO) measurement of disability is integral to a patient-centered approach to health care and gauging the biopsychosocial impact of health conditions from the patient's perspective. This thesis investigates disability after proximal humerus, elbow and distal radius fractures; conditions that constitute a major burden in musculoskeletal health care and a substantial impact on health-related quality of life (HrQoL).

Disability is defined by the World Health Organisation (WHO) International Classification of Disability, Functioning and Health (ICF) as 'a multi-dimensional construct involving a dynamic interaction between impairment, activity limitations and participation restrictions, that are influenced by contextual factors'. This international, consensus-based framework acts as a guide for the application of outcome measures in performing scientific research.

The WHO ICF also considers other patient perspectives on health and health care systems, including patient experience and patient activation within the contextual factors component. Patient experience encompasses aspects such as satisfaction, expectation management and confidence with care, and is measured using a variety of scales and questionnaires. Patient activation relates to 'the knowledge, skills and confidence a person has in managing their own health and health care'. This concept is quantified using patient activation measures (PAMs).

The overarching goal of this thesis is to identify the most influential factors predicting disability after proximal humerus, elbow and distal radius fractures. This work also aimed to define the relationship between disability, experience and activation to inform the development of a patient-centred approach to managing these challenging injuries.

The first systematic review highlights the dominance of psychosocial factors in influencing disability associated with a range of upper extremity conditions. Few studies have assessed this relationship in specific trauma populations. The second review underlines the paucity of upper extremity PRO measures incorporating fracture populations in their original development. It also reports the highly variable quality of initial studies introducing these measures. The final review demonstrates the superior measurement properties of computer adaptive tests (CATs), a contemporary form of PRO measurement, over fixed-scale instruments. Few studies apply CATs in trauma and few have been performed outside the U.S. These reviews collectively informed the selection of PRO measures for the experimental studies in this thesis.

Firstly, a pilot study establishes a methodology for addressing the key objectives and the feasibility of using a web-based platform for measuring patient outcomes. Strong correlation between PROMIS Physical function CAT, a computer adaptive measure of physical function, and the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), a region-specific, fixed scale is observed. The core experiment (n=734) expands upon this work and demonstrates correlations between a range of generic and region-specific measures in an upper extremity trauma population. Disability is shown to correlate with satisfaction, and the strength of this correlation increases over time. Applying PRO measures of disability in populations with shoulder, elbow and wrist fractures show that self-efficacy (i.e. coping ability) within 6 weeks of injury was the strongest predictor of medium-term disability at 6-9 months. In proximal humerus and elbow fractures, kinesiophobia (i.e. fear of movement) within a week of injury was also a strong predictor of disability. The final study concludes that greater patient activation is associated with greater health-related and experiential outcomes. However, psychosocial factors including self-efficacy, superseded activation in predicting disability and satisfaction.

This thesis contributes evidence for musculoskeletal health care professionals (HCPs) to consider specific psychosocial factors, such as coping abilities, and patient activation early in the recovery process to improve disability following these injuries.

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'Choose your team carefully. So much of your success is due to the people who you surround yourself with. Your friends, your family, and the people that you work with – they all play an important role in inspiring you and supporting you and giving you stability. These are the people in your life who will be honest with you.'

Tom Ford
American Fashion Designer, Film Director, Film Producer, Screenwriter

Declaration

This thesis is the candidate's own work. The nature and extent of the contributions of others have been indicated where applicable.

Chapter 1,2: The conceptual work for this thesis developed by the candidate and supervisors, Professor David Ring [DR] and Mr Stephen Gwilym [SG], including the preliminary data from systematic reviews were presented at a national conference: Jayakumar P [PJ], Ring D, Gwilym S. Patient-Reported Outcome (PRO) Measurement in Orthopaedic Trauma: Current status and Future Concepts. Oxford Trauma Research Conference, 5th January 2014.

Chapter 2: The candidate designed and conducted three systematic reviews. This included establishing review teams for secondary data extraction, quality assessment, strength of evidence assessment and analytical decisions. Members of the external review team were based at the Behavioral Medicine Service, Massachusetts General Hospital, Boston, USA (Dr A M Vranceanu [AMV], Dr C Funes [CF]) and Leiden University Medical Center, Netherlands (Dr Celeste Overbeek [CO]). One of these systematic reviews was accepted in a peer-reviewed journal: Jayakumar P, Williams M.A [MW], Ring D.C, Lamb S.E [SL], Gwilym S. A Systematic Review of Outcome Measures Assessing Disability Following Upper Extremity Trauma. JAAOS: Global Research and Reviews. 2017; 1(4):e021

Chapter 3: The pilot study was performed at the Hand & Upper Extremity Service, Department of Orthopaedics, Massachusetts General Hospital, Boston, USA. The study concepts, patient recruitment, data collection, analysis and reporting were performed by the candidate under the supervision of Professor David Ring. This work was presented at a national conference: Jayakumar P, Overbeek C, Nota S, Ring D. Correlation between PROMIS Physical Function and QuickDASH in patients with upper extremity illness. The 42nd Annual Scientific Meeting of the Percivall Pott Club, 22nd November 2014.

Chapter 4: The study concepts, design, approvals, participant recruitment, data collection and core data analysis were entirely the work of the candidate. Higher level analytical support was provided by Dr Teun Teunis, University Medical Center, Utrecht, Netherlands.

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A synopsis of this thesis has been invited for presentation as a Keynote Lecture at the British Trauma Society, 2017: Jayakumar P, Ring D, Williams M, Lamb S, Gwilym S. Patient Outcomes following Orthopaedic Trauma to the Upper Extremity: A Paradigm Shift. 27th Annual Scientific Meeting of the British Trauma Society, Sheffield. 9th November 2017.

A synopsis of this thesis was submitted as pilot evidence to support a full grant proposal for the 'AO Foundation Clinical Priority Program in Patient Outcomes, 2017'. The candidate is a principle investigator and lead for one of three consortia that successfully met the criteria for the full award on 7th January 2017.

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Abbreviations

AO	Arbeitsgemeinschaft für Osteosynthesefragen
CACI	Age-adjusted Charlson Comorbidity Index
CAT	Computer Adaptive Test
CBT	Cognitive Behavioural Therapy
CI	Confidence interval
COSMIN	Consensus standards for selection of health measurement instruments
DASH	Disabilities of the Arm, Shoulder and Hand Questionnaire
EQ-5D-3L	European Quality of Life Index-3L
FDA	U.S. Food and Drug Administration
HCP	Health Care Professional
HrQoL	Health-related Quality of Life
ICF	International Classification of Disability, Functioning and Health
IQR	Inter-quartile range
IMD	Index of Multiple Deprivation 2015
IRT	Item Response Theory
KMO	Kaiser-Meyer-Olkin measure
MCID	Minimal Clinically Important Difference
MDC	Minimal Detectable Change
NIH	National Institute for Health
NRS	Numerical Rating Scale
OES	Oxford Elbow Score
OSS	Oxford Shoulder Score
OTA	Orthopaedic Trauma Association
PAM	Patient Activation Measure
PCS	Pain Catastrophizing Scale
PIPS	Psychological Inflexibility in Pain Scale
PREM	Patient Reported Experience Measure
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measure
PROMIS	Patient Reported Outcome Measurement Information System
PROMIS ES	PROMIS Emotional Support CAT
PROMIS IS	PROMIS Instrumental Support CAT
PROMIS PI	PROMIS Pain Interference CAT
PROMIS PF	PROMIS Physical Function
PROMIS UE PF	PROMIS Upper Extremity Physical Function CAT
PRWE	Patient Reported Wrist Evaluation
PSEQ-2	Pain Self-Efficacy Questionnaire-2
QuickDASH	Quick Disabilities of the Arm, Shoulder and Hand Questionnaire
SD	Standard Deviation
TSK-11	Tampa Scale for Kinesiophobia-11
U.S	United States of America
VAS	Visual Analogue Score
VIF	Variance Inflation Factor
WHO	World Health Organisation

† Abbreviations listed above are contained within the manuscript of this thesis. Those abbreviations contained within the tables of this thesis are not included in this list but are detailed in the footnotes of the relevant table.

Chapter 1

1. Background

Patient reported outcome (PRO) measurement of disability is integral to a patient-centred approach to health care and gauging the biopsychosocial impact of health conditions on individuals. This thesis investigates disability, the subjective impact of health from the patient's perspective following proximal humerus, elbow and distal radius fractures (1). A selection of PRO measures were used to quantify the factors influencing disability and disability itself. In order to achieve a more complete understanding of patient perspectives on health and health care systems, it also considers patient experience, which encompasses aspects such as satisfaction, expectation management and confidence; and patient activation i.e. the knowledge, skills and confidence a person has in managing their own health and health care (2). Patient experience is measured using a variety of scales and questionnaires and patient activation is quantified by patient activation measures (PAMs).

The overarching goal of this thesis was to identify the most influential factors predicting disability after proximal humerus, elbow and distal radius fractures using a range of PRO measures. This work also aimed to define the relationship between disability, patient experience and patient activation to inform future patient-centred approaches to managing these challenging injuries.

1.1 The Impact of Orthopaedic Trauma to the Upper Extremity

Musculoskeletal conditions present a substantial burden on health care resources worldwide, a problem that is only set to intensify with a rise in active and ageing populations (3)(4)(5)(6)(7) (Figure 1).

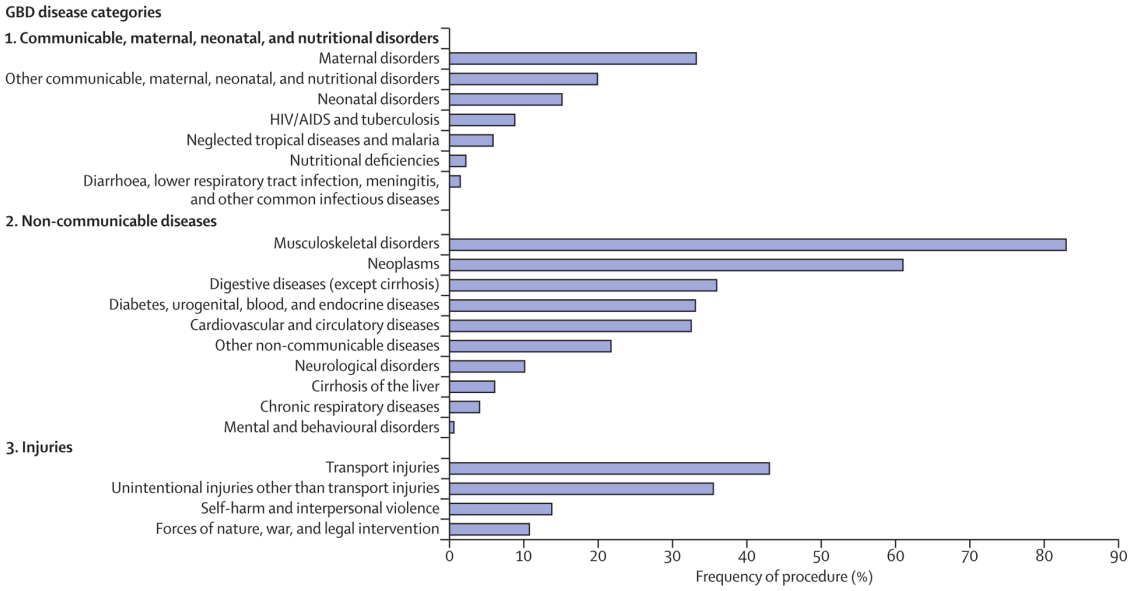


Figure 1. Frequency of operations per Global Disease Burden 2010 category for patients admitted to well-resourced hospitals (Permissions from the Lancet) (3)(8)

Orthopaedic trauma to the upper extremity including fractures of the distal radius, hand and proximal humerus compose a substantial proportion of this burden (Figure 2) (6)(8)(9). The increasing incidence is accelerated by the rise in osteoporosis and fragility fractures, particularly involving the shoulder and wrist (10)(11).

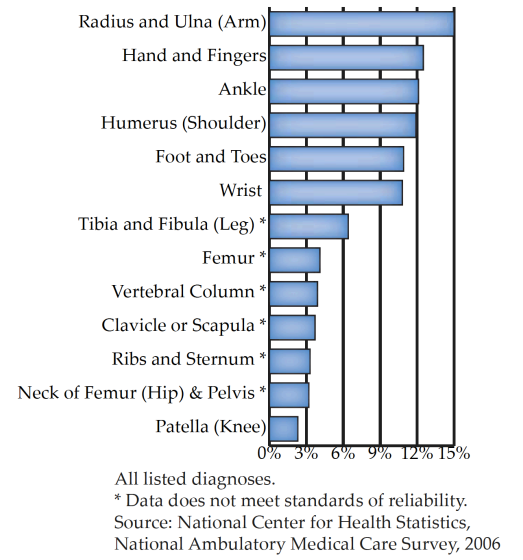


Figure 2 Visits to Physicians in Office-based Practice for Fractures at Selected Anatomic Sites, US 2006. (Permissions from The Burden of Musculoskeletal Diseases in the United States, 2011) (6)

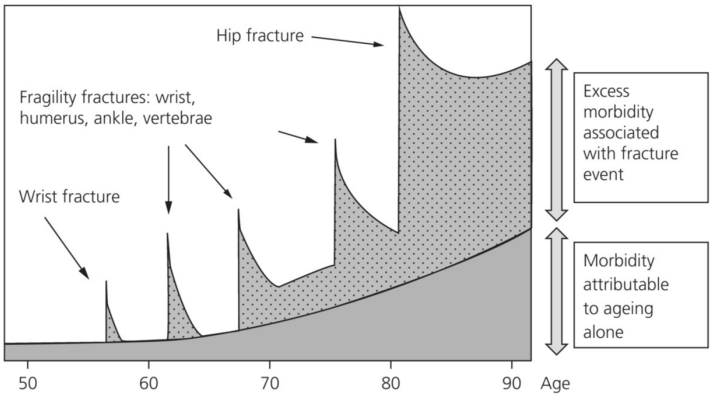


Figure 3. Fracture and morbidity/quality of life over the life span.
(Permissions from the British Orthopaedic Association/British Geriatric Society, UK. 2007) (12)

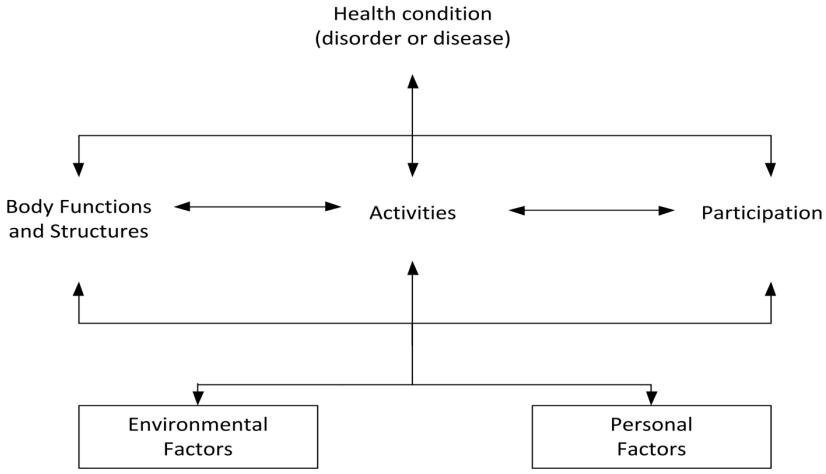
The global impact of these conditions occurs at a clinical and socio-economic level, and at the patient level generates substantial morbidity, affecting an individual's health-related quality of life (HrQoL) (Figure 3) (13)(14). HrQoL is a concept that encompasses the biopsychosocial model of health originally proposed by Engel in 1977 (15)(16). It incorporates the psychological and social influences on the patient and their health, combined with the physical and biological aspects of disease (15)(16). The latter forms the focus of more traditional biomedical frameworks (15)(16). Whilst some authors have drawn clear distinctions between HrQoL and disability, the common underlying element is the health and wellbeing of patients (17).

In the context of orthopaedic trauma, studies show that disability following upper extremity injuries exceeds the health consequences of patients with injuries involving other body regions in the short and long-term (13)(14). The proportion of patients with upper extremity injuries experiencing limitations in terms of self-care, usual activities and complaints of pain and/or discomfort was higher at all time points up to 2 years following trauma (13). Being female, older, having a lower level of education, co-morbidities, shoulder or upper arm injuries and hospitalisations were all associated with longer term reduction in HrQoL (13). Intuitively, one can appreciate that the inability to feed, clean, clothe, and partake in activities of daily life, particularly when a dominant arm is involved, can be extremely disabling.

1.2 A Definition of Disability

A contemporary understanding of health and disability is fundamental in evaluating disease, injury and outcomes following interventions (5). In 1948, the World Health Organization (WHO) defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (18). This has since been conceptualized, through a global consensus-building process, into the WHO International Classification of Functioning, Disability and Health (ICF) (19)(20). Introduced in 1980, this model defines disability as a "multi-dimensional construct involving a dynamic interaction between impairment, activity limitations and participation restrictions, that are influenced by contextual factors" (Figure 4). In practical terms, disability represents the subjective limitations of physical functioning influenced by impairment, psychological, social and symptomatic factors within life situations. Impairment relates to problems with the structure and function of the body leading to significant deviation and loss (19). Physical functioning is itself defined as a person's 'capacity' to function and manage barriers to functioning in specific situations e.g. accessibility and use of aids, within the contexts of their physical and social environments (21).

The biopsychosocial components of health are incorporated within the WHO ICF and observed from the perspective of the individual and their place in society (17)(19)(22). Today, the framework is an accepted international standard incorporating previously established models, such as the Nagi Model of Disablement, with the aim of providing a common language in this field (19)(23)(24)(25). Whilst there are some limitations to the WHO ICF, such as the lack of definition within the 'personal factors' component, the benefits of a standardised approach to understanding disability are clear (20)(23). These limitations are largely due to societal and cultural variations and are discussed within the concluding chapter of this thesis. Further resolution of the components and qualifiers of the WHO ICF are required to achieve widespread acceptance (23). This provides both a challenge and opportunity for further scientific research (20).



4a.

ICF Component		Definition
Functioning		A term encompassing body functions, body structures, activities and participation, denoting the positive aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors).
Disability		A term encompassing impairments, activity limitations and participation restrictions, denoting the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors).
Health condition		Diseases, disorders, injury and or trauma ageing and congenital anomaly
Level of Human Functioning (a) and dysfunction (b)		
I Body or body parts	a. Body functions and structures - Body functions - Body structure	 Physiological functions of body systems (including physiological functions) Anatomical parts of the body e.g. organs, limbs and their components
	b. Impairment	Problems in body function or structure resulting in significant deviation or loss
II Whole person	a. Activities	Execution of task or action by an individual
	b. Activity limitation †	Difficulties an individual may have in executing activities
III Whole person in complete environment	a. Participation	Involvement in a life situation
	b. Participation restriction †	Problems an individual may experience in involvement in life situations
Contextual Factors		
	Environmental §	Aspects of physical, social and attitudinal environment in which people live and conduct their lives. These are either barriers or facilitators of a person's functioning
	Personal ‡	Features of the individual not part of health condition or health states that influence how disability is experienced by the individual

4b.

† Activity and participations organized into subdomains: Learning and applying knowledge; General tasks and demands; Communication; Mobility; Self-care; Domestic life; Interpersonal international and relationships; Major life areas; Community, social and civic life

§ Environmental subdomains: Products and technology, natural environment and human made changes to environment, support and relationships, attitudes, services, systems, policies

‡ Personal subdomains: Sex, age, race, lifestyle habits, coping styles, social backgrounds, education, overall behaviour patterns, psychological assets

Figure 4. 4a. The WHO ICF Framework, 2001. 4b. Definitions from the full WHO ICF Report. (Permissions from the WHO, Geneva) (19)(26)

Coding the WHO ICF components with outcome measures is an accepted application of the classification (25)(27). Although the WHO has developed its own generic outcome measure of disability (WHO Disability Assessment Schedule, WHODAS v2.0), it does not formally stipulate which outcome measures to use in quantifying disability or its contributory factors, nor does it specify the point in time in which to administer them (28). Rather, it broadly promotes use of the framework as a guide to selecting the most appropriate and relevant tools for measuring disability specific to the population being investigated (23)(25)(27).

1.3 Outcome Measurement in Orthopaedics

Outcome measurement in orthopaedics has evolved rapidly over the last 20 years (29)(30). A multitude of outcome measures have been designed to reflect the full scope of physical, psychological and social health domains (21)(30)(31). One way of classifying these is to divide them into performance-based, clinician-based and patient-reported outcome measures (21). Performance-based measures are patient-derived but investigator-reported measures of discrete physical actions ideally captured in a standardized manner, using predefined criteria (21)(31). They range from common musculoskeletal practices, such as range of motion or grip strength assessment, to automated data capture involving technologies such as wearable digital devices (32). These measures are not purely objective as they can be influenced by contextual, psychosocial or symptomatic factors at the point of performance, affecting what is observed by an investigator or recorded by a device (32). For instance, the fear of pain, lack of motivation due to emotional distress and learned behaviours may substantially influence metrics (32). Whilst performance-based measures alone may not always capture an individual's limitations in the real world, they provide a relatively rapid form of outcome measurement that can contribute to more of a complete view of disability (21). Clinician-based outcome measures, by definition, are purely objective measures of impairment, and include pathophysiological or radiographic classification (29)(31). In reality, such measures traditionally incorporate performance-based metrics usually captured within clinician-reported outcome questionnaires (29).

PRO measures have been extensively developed over recent decades as part of the paradigm shift toward patient-centered health care (29)(33)(34). This modern approach to health care delivery aims to actively incorporate the preferences, needs and values of patients beyond treating their pathophysiology alone (29)(33)(34). In practical terms, patient-centered health care promotes the use and reporting of data to optimise care and potentially improve outcomes for an individual (35). The U.S Food and Drug Administration (FDA) defines PRO measures as, "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (36).

Evaluating the impact of conditions and interventions at an individual level requires PRO measures that can capture aspects of health that matter most to patients (37)(38). Underlying this is the perception that clinicians have traditionally held a narrow view on understanding the impact of disease from the patient's perspective (30)(31)(37). This has led to substantial expansion of clinical and research activity in the field of PROs including a well-defined set of PRO measurement properties (Figure 5) (37)(39)(40). It is recommended that such properties should be considered in relation to their proposed application and the population being assessed rather than a set of criteria that must be met for every PRO measure (39)(40).

PRO Measurement Property	Definition
Appropriateness	The extent to which instrument content is appropriate to the specific application and objectives i.e. discriminative and / or evaluative and / or predictive
Acceptability	The extent to which the instrument is acceptable to patients e.g. administration time, response rates, levels of missing data
Feasibility	The ease with which the instrument is administered and processed
Interpretability	The meaningfulness of scores produced by an instrument e.g. using comparison of change scores, comparison with normative population data, minimal clinically important difference
Precision	The number and accuracy of distinctions made by an instrument i.e. based on scaling and scoring of items, floor and ceiling effects
Reliability	The reproducibility or test-retest reliability e.g. using intra-class correlation coefficient, and internal consistency e.g. using Cronbach's alpha, and extent to which it is free of error
Validity	The extent to which an instrument measures what it claims to measure i.e. Content or Face validity, Criterion validity and Construct validity
Responsiveness	The ability of PRO measures to detect changes over time that matter to patients e.g. using effect size statistics and standardized response mean

Figure 5. PRO measurement properties and their definitions

This thesis broadly encompasses one or more of these properties within each experimental chapter but more explicitly assesses the validity (construct validity) and precision (floor-ceiling effects) of different forms of upper extremity disability measure in the first main experiment in Chapter 4. The selection of PRO measures used to represent disability can be classified by type e.g. generic or specific, and mode of administration e.g. fixed scale or computerized adaptive test. Generic PRO measures encompass multiple health domains and specific PRO measures either focus on health domains related to a region or condition of interest (31). The PRO measurement selection in this thesis was informed by the systematic reviews in Chapter 2.

1.3.1 PRO Measures: Fixed Scale or Computer Adaptive Test?

In orthopaedic surgery, there are several PRO measures designed to capture aspects of physical, psychological and social health (29). These commonly involve fixed length scales and a set of questions often developed using classic test theory, where a response is required for most, if not all questions to achieve a valid score (29)(31). This mode of PRO measurement may result in a trade-off between the range of questions assessed and the precision of scores achieved (41) (Figure 6a). Although most current fixed length scales consist of a manageable set of questions in isolation, administering a battery of tests to score multiple health domains may generate a substantial burden on patients. Abbreviated versions have been developed but require stringent techniques of item (i.e. question) reduction to avoid loss of accuracy (42)(43)(44).

CATs have been developed with the aim of overcoming these limitations (41) (Figure 6b). Introduced in the 1970's in the field of aptitude testing, they have more recently been developed to measure health outcomes (45)(46). CATs are based on Item Response Theory (IRT), a mathematical model enabling the formation of adaptive algorithms designed to optimise question administration (45)(46)(47)(48). Only relevant questions are administered based on a participant's previous response and their estimated level within a specific domain (45)(46)(48).

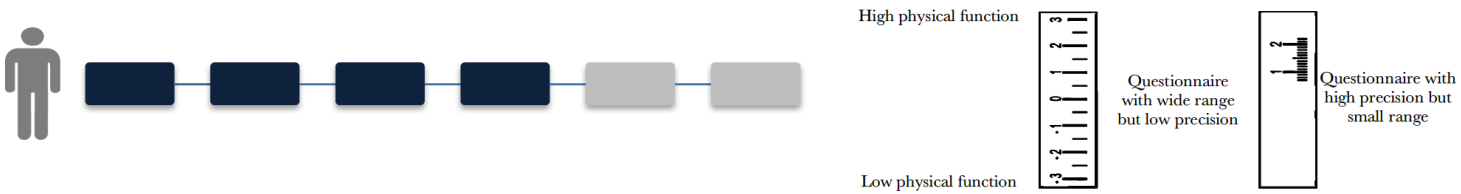


Figure 6a. Schematic of question administration process and measurement qualities of Fixed-length PRO measures. The sequential administration of questions is independent of responses and questionnaires either have a wide range but low precision or high precision but small range.

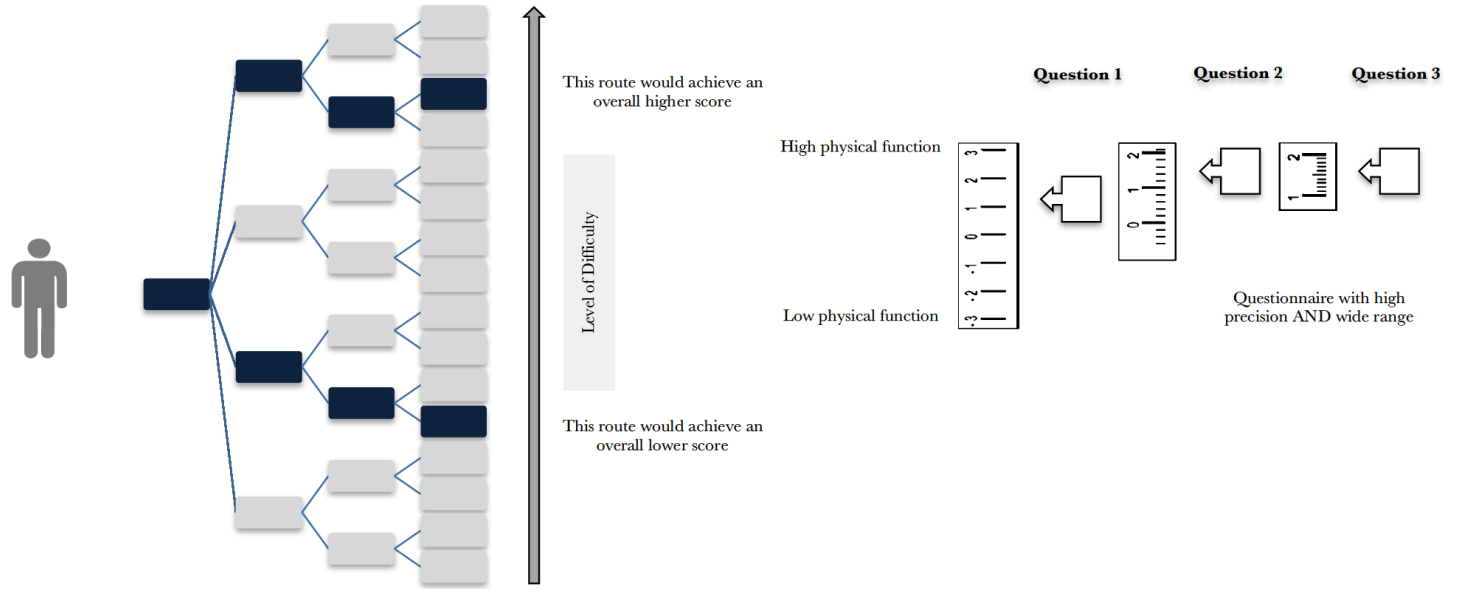


Figure 6b. Schematic of question administration process and measurement qualities of CAT PRO measures. The administration of questions is based on prior responses. Questionnaires usually have high precision and a wide range.

Figure 6. Schematic of fixed-scale and computer adaptive PRO measurement process

A CAT for physical function, for instance, will not ask how easily an individual can walk 100 yards if they have previously responded they could run 10 miles with ease. CATs utilise large populations to form extensive, highly calibrated question banks that aim to provide broad and precise coverage of a health domain. This offers the possibility of more tailored, precise and efficient PRO measurement (49)(50)(51)(52). The wide range may also minimise floor and ceiling effects which can be an issue in some fixed scale measures where measurement at extremes ends of a domain are shown to be poor (44)(46)(49)(53)(54). This thesis utilises both CAT and fixed scale PRO measures of disability.

1.3.2 The Scope of Patient Outcomes Measurement

The increased focus placed on patients in health care delivery has generated other forms of subjective outcomes assessment that aim to expand our understanding of patient perspectives toward their health and the health care systems that surround them. These include patient reported experience measures (PREMs) and PAMs (55). PREMs aim to capture facets of health care experience such as expectation management, education, satisfaction and confidence with care (56). PAMs are more targeted at the behaviours, attitudes and values exhibited by patient's toward their health and health care (57)(58)(59)(60). Numerical rating scales (NRS) of patient experience were applied in Chapter 4 and Chapter 8 alongside PAMs.

The growing interest in these concepts is reflected in the expansion of clinical and research activity around empowering patients to play an active role in managing their health and partaking in shared decision-making with their health care providers (61)(62). From a broader perspective, today's health care systems are facing unprecedented clinical and socioeconomic challenges against a backdrop of solutions providing limited benefit (63). There is a demand for moving toward a system of value based health care, which is defined as the health outcomes benefiting patients over cost (63). PRO measures were originally developed for use in clinical research but may evolve to inform health care policy and practices, with expert groups recommending consideration of their wider value implications (34)(63)(64)(65)(66)(67).

1.4 Patient Outcomes after Orthopaedic Trauma to the Upper Extremity

Using PRO measures, a growing number of studies have demonstrated that the magnitude of disability correlates more with the subjective, psychosocial aspects of illness and pain, than impairment and pathophysiology in orthopaedic conditions (68)(69)(70)(71). The substantial impact of psychosocial factors following orthopaedic trauma is also well recognised (72)(73). Bhandari et al demonstrated in a prospective study of 215 orthopaedic trauma patients that 1 in 5 met a threshold for psychological distress (72).

This impact may be particularly relevant in orthopaedic conditions involving the upper extremity (74). Upper extremity disability in older patients is shown to be associated with poor general physical *and* mental health whilst lower extremity disability was only related to the former (74). Multiple studies demonstrate the strong influence of psychosocial factors on disability experienced by populations with a range of upper extremity problems, frequently involving non-traumatic conditions of the wrist and hand (75)(76)(77)(78)(79). The mediators of these interactions include anxiety, depression, post-traumatic stress, non-adaptive pain thoughts, pain catastrophizing (an exaggerated negative response to pain), pain interference (influence of pain on all aspects of life), pain anxiety (negative cognitive, behavioral and physiological responses to pain), kinesiophobia (fear of movement or re-injury), lack of support, and the inability to work leading to financial loss and secondary gain (73)(75)(76)(77)(78)(79). Secondary gain is defined as any advantage that occurs after a stated or real illness (80). These include the use of illness for personal advantage, a conscious use of symptoms for gain or unconscious presentation of symptoms without any physiological basis (80). Such responses may be countered by aspects such as self-efficacy (i.e. coping ability and confidence in managing a condition and pain), activation and other behavioural skills and assets (68)(70)(78)(79) (81)(82)(83)(84). This thesis aims to generate evidence to determine the factors that play a dominant role in influencing and predicting disability following shoulder, elbow and wrist fractures.

In the context of proximal humerus fractures, a study demonstrated that measures of impairment, such as range of motion and strength thresholds, did not correlate with PRO measures of disability (85). Factors such as social independence appeared to more accurately predict PROs and even survival in these patients (86). Considering fractures of the elbow, psychosocial aspects of illness along with pain were shown to have a strong influence on both clinician-based and patient-reported measures of elbow function (87). Studies involving distal radius fractures, demonstrate depression, anxiety, pain interference, kinesiophobia and catastrophic thinking as the important factors influencing the magnitude of disability and rate of recovery (76)(77)(88)(89). Most of these studies are observational, cross-sectional investigations.

1.5 Summary

Musculoskeletal health care is facing an unprecedented array of challenges in delivering care that maintains the health of populations and improves outcomes that matter to patients (33). Orthopaedic trauma to the upper extremity, including shoulder, elbow and wrist fractures compose a substantial portion of this challenge. The evolution of health care toward a patient-centred approach that considers the biopsychosocial impact on health conditions may hold the solutions. This is particularly relevant considering the current treatment modalities for proximal humerus and distal radius fractures that fail to show a clear improvement in outcomes and benefit to patients (90)(91)(92)(93)(94). The status quo may need to be challenged if we are to achieve the best possible outcomes rather than continue to work on the assumption that current interventions will be of universal benefit to patients.

A fundamental requirement for a patient-centred approach is a comprehensive understanding of disability related to the population in question. The WHO ICF provides a global framework for considering disability and PRO measures offer a code to operationalise this model for scientific research and discussion. This approach is central to the experimental work in this thesis.

Musculoskeletal HCPs are familiar with the impairment and pathophysiology of upper limb fractures. However, there is growing evidence to suggest that psychosocial factors play a more dominant role in influencing disability (71). If this is the case, an expanding evidence-base supporting the consideration of psychosocial aspects may minimise the potential stigma associated with these factors. This work could instead support the active incorporation of these factors into management plans. Studies focusing on specific fractures of the upper extremity are required, especially considering the core tenet of health outcomes research that PRO measures should be comprehensively evaluated for the populations they assess and not the instruments themselves (85)(95). Furthermore, the WHO ICF considers disability and its influencing factors as dynamic entities on a continuum of health (15)(19). This highlights the importance of accounting for time point when measuring disability and its influential factors, supporting a requirement for longitudinal investigations of disability during recovery following trauma.

PRO measurement in trauma settings also confers some logistical and technical challenges (30)(31). Consequently, the majority of PRO measures to date have been developed for use in chronic conditions (30)(31). Nevertheless, most investigators would agree that generating yet another PRO measure targeted at a specific condition is unlikely to yield any significant additional measurement benefit (34). Instead, existing PRO measures should be thoroughly evaluated in the population being assessed.

Consideration of patient experience and patient activation within the contextual factors component of the WHO ICF may widen the scope of this framework to gain a more complete sense of patient perceptions of their health and health care. The relationship between disability, experience and activation in orthopaedic trauma is relatively unknown. Defining this relationship in fractures of the upper extremity may identify alternative ways of optimising health-related outcomes following injury beyond focusing on biopsychosocial factors alone.

The 2017 Montreal accord is a collaboration of experts in the field of health outcomes focused on advancing PRO use, measurement of disability and integration within health care (33). Recommendations for future research include an understanding of i) disability and the capacity to physically function following a health condition in the context of one's life, ii) the impact of psychosocial, symptomatic, environmental and personal stressors on this capacity, and iii) the ability of coping and adaptation to modify the relationship between capacity and actual performance (21)(66). This thesis aims to incorporate most, if not all these components, in evolving the field of patient outcomes and disability research in orthopaedic trauma to the upper extremity.

1.6 Thesis Goals and Objectives

1.6.1 Overarching Goal

The overarching goal of this thesis was to identify the influential factors predictive of disability after proximal humerus, elbow and distal radius fractures using a range of PRO measures. This work also aimed to define the relationship between disability, patient experience and patient activation to inform a patient-centred approach to managing these challenging injuries.

1.6.2 Objectives

- To perform a systematic review that determines the influential factors of disability involving orthopaedic upper extremity trauma populations
- To perform a systematic review that identifies upper extremity PRO measures that incorporated trauma conditions in their original development
- To perform a systematic review that evaluates the performance of CATs versus fixed scale PRO measures in upper extremity conditions
- To utilise these systematic reviews to inform a selection of PRO measures for application in the experimental studies of this thesis
- To perform a pilot study that establishes the basic methodology in this thesis and assesses the feasibility of using a web-based, computerized platform for the studies
- To assess the correlation between different types of disability measure and patient satisfaction ratings in an upper extremity fracture population over the course of recovery
- To assess the construct validity (factor analysis) and precision (floor-ceiling effects) of different disability measures
- To define the influential and predictive factors of disability in proximal humerus, elbow and distal radius fractures
- To determine the relationship between patient activation and disability and patient activation and patient satisfaction in upper extremity fracture populations

Chapter 2

2. Systematic Reviews on PRO Measurement of Disability after Orthopaedic Trauma to the Upper Extremity

2.1 Background

The areas of focus in this thesis regarding the PRO measurement of disability following orthopaedic trauma to the upper extremity were introduced in the previous chapter. In this chapter, systematic reviews were conducted with the aim of establishing current evidence in three different areas of patient outcomes research involving upper extremity trauma.

The overarching goal of Systematic Review I was to define the influential factors of disability in existing studies involving upper extremity trauma populations. In Systematic Review II, the goal was to understand the developmental origins of PRO measures and assess the extent to which trauma conditions were considered in their original design. Finally, in Systematic Review III, the goal was to observe the performance of CATs versus fixed length scales in these conditions.

Collectively, these reviews aimed to define an optimal selection of PRO measures for use within the experimental studies of this thesis. The rationale for using this extensive, exploratory approach was to systematically reach a consensus on an outcome measurement set that was comprehensive, appropriate, acceptable and feasible to administer. It was also perceived that a sense of interpretability, precision, reliability, validity and responsiveness of selected PRO measures could be gauged from these reviews.

2.2 Influential Factors of Disability following Orthopaedic Upper Extremity Trauma: Systematic Review I

2.2.1 Background

There is a growing body of evidence for the dominant role played by psychosocial factors in influencing disability following orthopaedic conditions (70)(72)(96)(97). Furthermore, over three decades since the introduction of the WHO ICF framework, there is still interchangeable use of language and perceived misrepresentation of terms within this model amongst orthopaedic surgeons (26). This was a comprehensive review involving studies that investigated the influential factors of disability specifically related to patients with upper extremity trauma conditions. The process of performing a large-scale review also enabled the characterisation of disability through examining the terminology and its representation using PRO measures.

2.2.2 Objectives

The primary objective was to identify and characterise studies concerning the most influential factors contributing to disability in adults with an injured upper extremity. This included an evaluation of study designs, conditions and outcome measures utilised, together with an evaluation of methodological quality and strength of evidence. The secondary objective was to characterise the trends in representation of disability through language used and outcome measures applied within the scientific literature over the last 16 years. Beyond understanding disability in this context, the aim was also to inform good research practice around the use of terminology and provide recommendations for the use of PRO measures in orthopaedics.

2.2.3 Methods

a. Data Sources & Search Protocol

A broad search strategy was performed using the PubMED (Medline from 1946 to 2016), OVIDSP (EMBASE from 1974 to 2016) and PsycInfo (from 1806 to 2016) electronic databases initially on 11th October 2013 and repeated on 31st December 2016.

Search terms were developed with a research librarian and validated by the multi-disciplinary team. Terms related to 'upper extremity anatomy', 'outcome measurement', 'impairment, psychological, social and symptomatic' variables, and general search parameters were combined with the operator AND (Appendix 1). No restrictions were set in the search fields and terms were identified in the title and / or abstract without any limits. The review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) criteria (98) and the protocol was registered (PROSPERO: CRD42017054048).

b. Study Selection

Studies involving adult patients experiencing any musculoskeletal upper extremity trauma condition and receiving operative and/or non-operative interventions were considered eligible. Comparators were the outcome measures themselves and all outcomes were categorised into those assessing disability, impairment, psychological, social, symptomatic (pain), demographic and other factors (Appendix 2). The process of identifying articles and screening followed strict selection / exclusion criteria (Appendix 3). Only original research studies containing at least one multi-domain outcome measure that could be equated to disability were included. Studies focusing on clinimetric features alone (e.g. range of motion, patho-anatomical or radiological grading and classification, clinical examination tests), single health components (e.g. pain, depression, return to activity), broad diagnostic groups (e.g osteoarthritis, tumour classifications) and health behavior scales, were excluded. Identification and screening of titles and abstracts was conducted by four investigators [PJ/AMV/SG/CO] and eligibility assessment by two investigators [PJ/AMV]. This phase entailed a closer inspection of the abstracts and full text if there was any ambiguity in the abstract prose. The final set of full texts for inclusion were acquired and independently reviewed [PJ/AMV/CF]. The research team personnel in this and subsequent systematic reviews are detailed and credited in the declaration section of this thesis.

c. Data Extraction & Data Synthesis

Data was independently extracted and recorded using an electronic database (Microsoft Excel v15.32). A definition of variables was used as a reference throughout the review process (Appendix 2). Extracted information included the official publication date, level of evidence, study design, study population, diagnosis, region involved, and outcome measures, scales and metrics pertaining to the domains assessed. The key disability focused findings, as well as clinical and research sequelae were documented.

The next stage involved assimilating key statistical data pertaining to the factors associated with disability from the full publication including any linked supplementary files. Study populations involving traumatic and non-traumatic conditions with aggregated data on the combined cohort were reported as such unless there was specific data on the relevant sub-population with a trauma problem. Further documentation of key influential factors was subsequently performed, charting the outcome measure(s) used, any relevant statistics and clinical grading if available.

Quality assessment was subsequently performed independently by three reviewers [PJ/AMV/CF] using a 10-item checklist (Appendix 4) (99)(100). This was a modified, population-specific version of established criteria used in previous systematic reviews of prognostic factors in patients with musculoskeletal disorders (99)(100). The 10-items each had yes (+) and no (-) options, where a point (+) was awarded if there was sufficient information related to each criteria and no likelihood of potential bias. A quality score was calculated by counting all positively rated items (maximum score 10) and converted to a total percentage. Arbitrary classifications were defined a priori as low (<50%), moderate (60-70%) and high quality (80-100%). Studies scoring >60% were included in the subsequent strength of evidence evaluation. Strength of evidence for all prognostic variables associated with measures of disability were assessed using an established 5-tier system (Figure 7) (101).

Key	
Strong	Consistent findings (≥70%) in at least 2 high quality studies
Moderate	Consistent findings (≥70%) in one quality study and at least one moderate or low quality study
Weak	Findings in one high quality study or consistent findings (≥70%) in at least 3 or more low quality studies
Inconclusive	Inconsistent findings, or less than 3 low quality studies available
No evidence	No data present

Figure 7. 5-tier scoring system for evaluating Strength of Evidence

It was perceived that study comparisons could be performed as most if not all studies would have incorporated similar analytical processes including bivariate and multivariate regression. Positive findings from these analyses enabled a definition of the strength of evidence for interactions between variables and individual PRO measure of disability, as well as interactions between the variable and combinations of PRO measures of disability. Statistical pooling was considered depending on the homogeneity of the study populations and type of prognostic factors and outcome measures. All discordant judgements were resolved by consensus meetings between investigators coordinated by the lead author [PJ].

During the screening process, the investigators also agreed on classifying any relevant abstracts deemed to have a) conflicting or inappropriate use of terminology related to disability and/or b) conflicting or inappropriate use of outcome measures representing disability and its contributing factors. The benchmarks for terminology were based on the WHO ICF definitions which were used as a reference guide throughout this process (Figure 4b). Outcome measures were classified as i) objective e.g. clinician-based questionnaires, radiographic classification, ii) subjective e.g. PRO measures and patient reported scales, and iii) performance-based measures i.e. patient-derived but investigator-reported measures of physical actions that may be influenced by symptoms, psychosocial or contextual factors, such as grip strength and range of motion.

2.2.4 Results

a. Selection of Studies

The database search provided a total of 9339 citations and after adjusting for duplicates, 4385 remained. Of these, 1757 were excluded by criteria following title and abstract screening. A further assessment of eligibility through closer abstract and full text review excluded 2544 articles. This resulted in 84 studies involving disability and associated factors related to any orthopedic condition. Of 41 studies involving trauma conditions, 29 studies involved trauma diagnoses only (n=29/41, 71%) and 12 studies had combined cohorts of traumatic and non-traumatic conditions (n=12/41, 29%) (Figure 8) (Table 1).

All tables in this systematic review are presented at the end of the results section.

b. Study Characteristics

i. Definition of study designs, diagnoses and outcome measures

Most studies were cross-sectional investigations (n=25/41, 61%) with a highly variable level of evidence [(Level I, n=12/41 (29%); Level II, n=10/41 (24%); Level III, n=5/41 (12%); Level IV, n=14/41 (34%)] (Table 1). Cohort sizes ranged from n=24 (102) to 594 (103). 'Wrist and hand' trauma was most frequently investigated (n=21/41, 51%) followed by injuries involving more than one upper limb region (n=16/41, 39%) and single studies involving each of the remaining areas (n=4/41, 10%; shoulder, humerus, elbow & forearm). Diagnoses ranged from fractures, dislocations, subluxations, to soft tissue injuries. The most frequently used PRO measure for disability was the QuickDASH (n=17/41,41%) followed by the DASH (n=16/41,39%) (Figure 9). The remaining PRO measures included a range of generic or region-specific instruments that were either fixed scale or CATs.

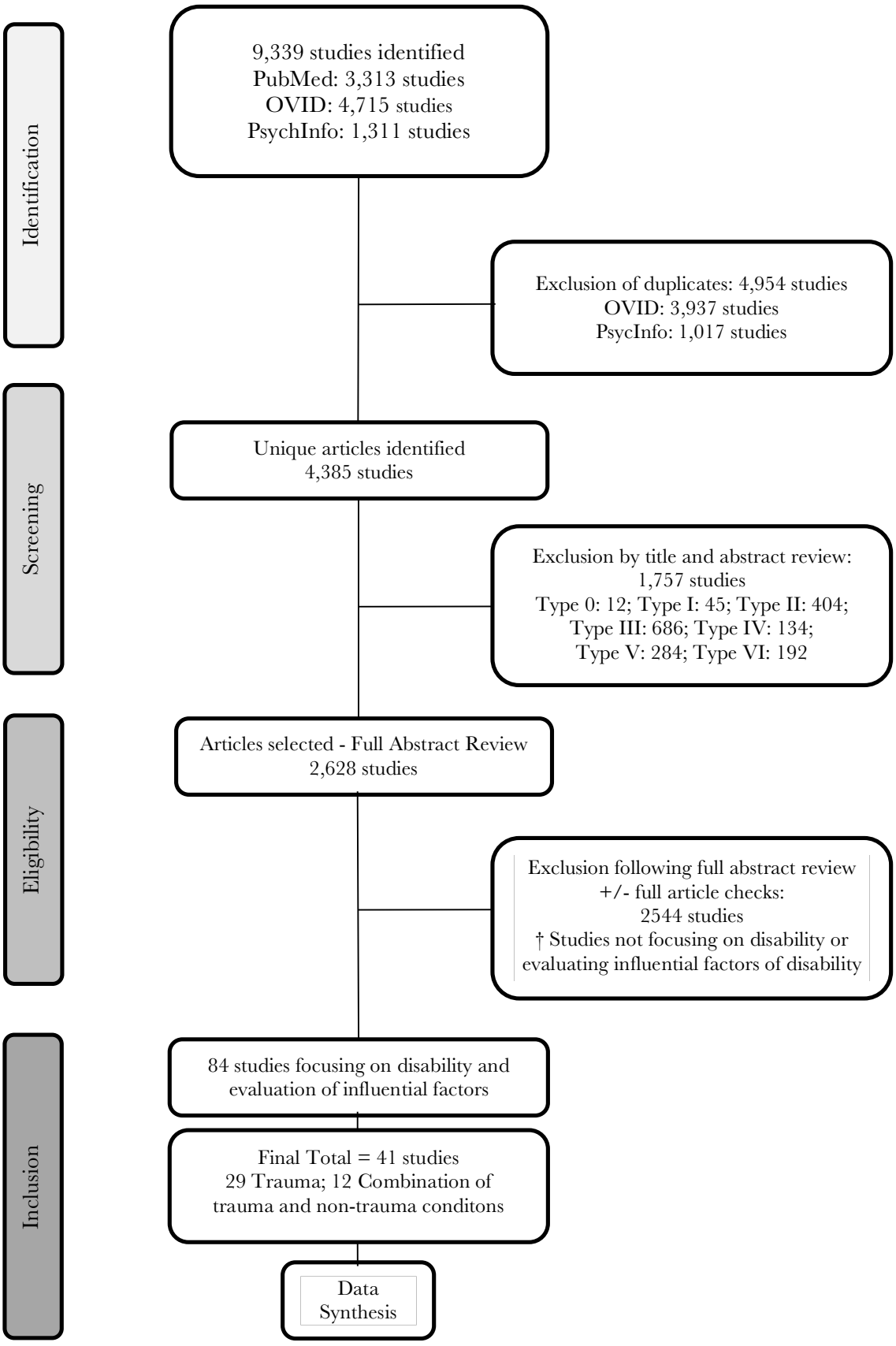


Figure 8. Systematic Review I: PRISMA Flow Chart.

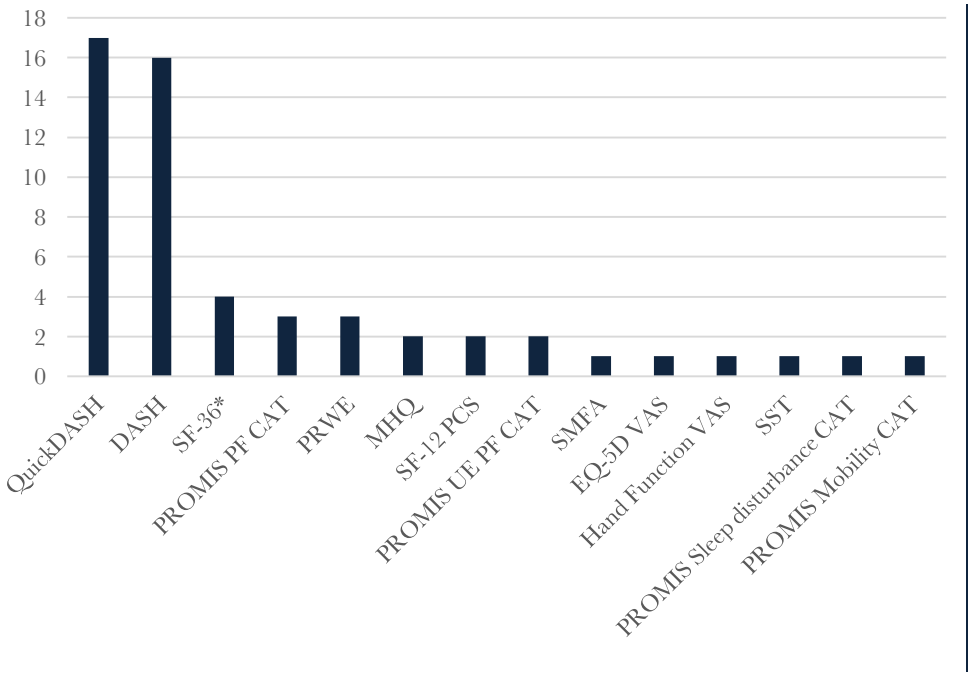


Figure 9. Frequency of PRO measurement utilisation in final inclusion set

ii. Influential Factors

The most influential factors of disability were within the symptomatic (primarily pain) and psychosocial domains (Table 2, Table 3). Psychological constructs included pain catastrophizing, symptoms of depression, pain self-efficacy, pain interference, pain anxiety, kinesiophobia, sense of coherence (a person's capacity to maintain control and cope in situations), non-adaptive pain thoughts, general anxiety, stress following trauma and combinations thereof. Symptoms of depression, catastrophic thinking, pain self-efficacy and pain interference consistently correlated with disability (Table 2, Table 3, Table 4). Six out of 14 studies identifying depression as a significant predictor provided some form of clinical grading (range; minimal (18.5-25.9%), mild (3.7-16.6%), moderate (4.7-16.6%), severe or major depression (5.5-79%) (104)(105)(106)(107)(108)(109). One of these studies reported almost a third of patients screened positive for clinically significant depression or post-traumatic stress disorder (107). The range of scores for pain catastrophizing was wide whilst those for pain interference and pain self-efficacy was narrower (Table 4). Notably, pain catastrophizing, when associated

with either depression or anxiety symptoms also correlated with range of motion and grip strength after wrist fractures, along with early and late disability, pain intensity and use of pain medications (78)(110). Pain intensity represented by the visual analogue scale (VAS), ordinal numerical rating scale (NRS), pain specific questionnaires or sub-scales of PRO instruments (e.g. McGill Pain Questionnaire, Patient Rated Wrist Evaluation (PRWE) pain subscale) also strongly correlated with disability.

Social factors associated with greater disability included lower education level (84), marital status [specifically being single (111), separated, divorced or widowed (84)(96)], work/employment status [being off work (84), unemployed (112), unemployed but able to work (113), unemployed and unable to work (96), retired (113) and being involved in worker's compensation or litigation claims (112)]. Constructs of social, emotional and instrumental support (i.e. perceived availability of support from others in fulfilling specific functions) were also found to be influential in the longer term (96)(114).

Objective measures e.g. diagnosis, Hand Injury Severity Scale, American Medical Association impairment scale, and performance-based measures e.g. wrist flexion post-distal radius fracture and grip strength, were the only impairment-related variables shown to have an association with disability. Age and sex were the only consistent demographic factors influencing disability in a moderate number of studies (n=11, 27%). Specifically, being older (75)(77)(84)(112) (115)(116)(117)(118) and being female (68)(75)(111)(116)(119) was associated with greater disability. A few longitudinal studies also identified disability itself at baseline or early post-injury as an influential factor of disability at a later stage (118). In studies performing multivariable analysis with a PRO measure of disability as the response variable, various prognostic factors explained the variance in disability which ranged from 9.6 to 63% (Table 5).

c. Methodological Quality

Quality assessment using our scoring criteria classified 17 studies with a moderate quality score and 24 studies with a high score (Table 5). The main shortcomings included a failure to represent differences between responders and non-responders (item VI), lack of comparison between two or more patient groups (item IV) and unclear descriptions of diagnoses (item III). Independent evaluation of the articles yielded over 90% initial agreement, reaching 100% following consensus meetings. All studies qualified for strength of evidence assessment.

d. Strength of Evidence Assessment

Heterogeneity of studies in terms of design, diagnoses, outcome measures, and statistical analysis meant statistical pooling was not considered feasible or appropriate. A qualitative evaluation and best evidence synthesis was performed instead to summarise the strength of evidence for each variable (Table 6). Whilst there was strong evidence for a selection of psychological, social and symptomatic factors being associated with PRO measures of disability, a significant number of factors had weak or inconclusive findings. There were a greater number of 'strong' ratings when interactions were assessed between prognostic variables and combinations of PRO measures of disability.

e. Further analysis of Trends in Representation of Disability

Studies clearing the screening phase (n=2628) were analysed providing a percentage rate for outcome measurement categories represented within the articles and reported by year of publication (2000 – 2016) (Figure 10). Gradual increases in the utilisation of specific PRO, symptomatic and psychological measures were observed whilst use of objective, clinician-based and social measures remained relatively neutral. Use of generic measures appeared to decline.

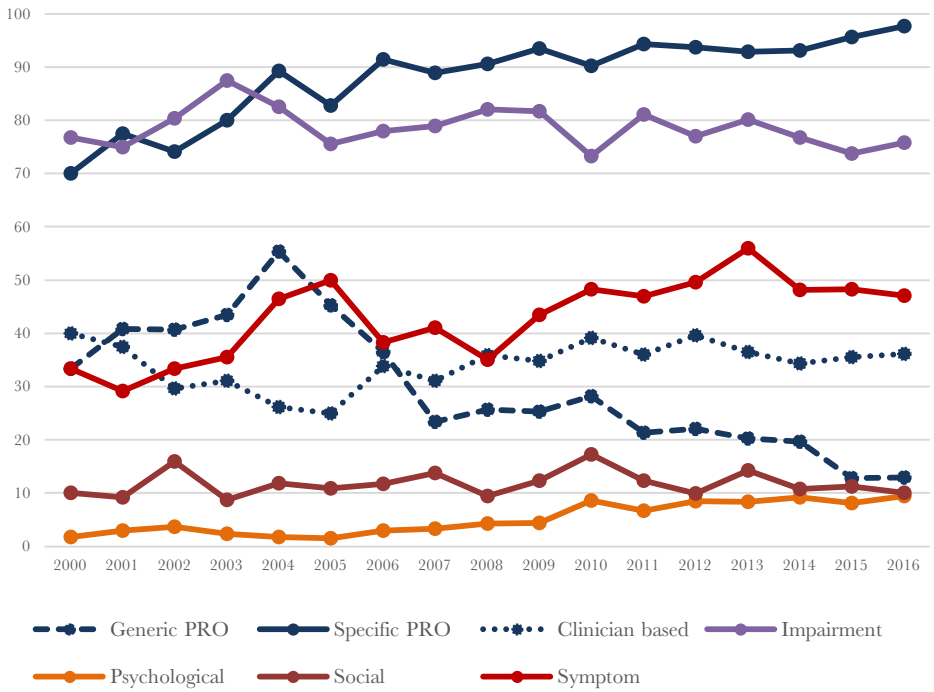


Figure 10. Outcome measurement utilisation by broad health domain (% proportion per annum) and instrument type in all identified orthopaedic upper extremity publications (2000-2016).

Most studies represented disability using the term 'function' or a derivative e.g. 'functional outcome'. The terms, 'disability', 'health-related quality of life', 'function' and related descriptors e.g. functional limitations, were frequently used interchangeably. 17.3% (n=454/2628) of studies had instances involving unclear, conflicting or inappropriate terminology related to disability (9.6%, n=251/2628) and/or the representation of outcome measures (11%, n=257/2628). Terminological irregularities included those involving the term 'disability' itself e.g. "functional disability", "subjective disability", without a clear definition, to those involving other related concepts e.g. "functional impairment", "functional function", "subjective impairment". Issues related to outcome measurement included misrepresentation of clinician-based or performance based measures e.g. "…disability was assessed by wrist accelerometry…", misrepresentation of PRO measures e.g. "clinical outcomes were assessed using the DASH questionnaire", or arbitrary application of outcome measures and thresholds without clear definition e.g. "the short-form DASH score assessed patient satisfaction…"; "…a DASH score … indicated moderate disability was present".

Table 1. Systematic Review I: Final Inclusion Study Set

							Outcome Measures					
Study	Level of Evidence	Study Design	n	Condition Type	Region	Trauma Condition +/- Intervention	Disability	Impairment	Psychology	Social	Symptoms	Other Explanatory Variables
Bear-Lehman et al., 2011(120)	Level II, Prognostic	Cross-sectional evaluation at 7.5m post-injury	24	Trauma	Arm	DRF / Bilateral wrist / elbow fracture; Finger / wrist sprain; Tendon / skin / wrist-level tendon, nerve, artery laceration; Thumb amputation; Hydraulic gun injury	QuickDASH	Injury type	IES-R			Age; Sex; Length of time since injury
Bekkers et al,.2014(121)	Level IV, Therapeutic	Cross-sectional evaluation (time point nos)	105	Combination	Wrist / Hand	Hand fracture nos; Laceration	QuickDASH		Current depression /anxiety medication	NPTQ; Education; Race; Ethnicity; Work status; Marital status	Previous pain medication	Age; Sex; Surgery; History hand or physical therapy; Hand or arm problems; HT Perception of suggestions; HT Goals and expectations
Bot et al., 2011(122)	Level IV, Therapeutic	Cross-sectional evaluation at mean 21 years post-injury	71	Trauma	Forearm	Radius and ulna diaphyseal fractures	DASH-Dutch	ROM; Radio-ulnar arc; Grip strength; open, ispilateral, nerve, associated, single, multiple injuries; XR; AO class; Anderson criteria	CES-D Dutch; PCS-Dutch	Occupation	DASH pain subscales	Age; Sex; Dominant arm injury; Mechanism / energy of injury; No. of surgeries; Follow-up time

Bot et al., 2012(81)	Level II, Prognostic	Prospective longitudinal evaluation at pre-op and 3m post-surgery	63	Trauma	Wrist / Hand	Distal radius fracture (Volar plating)	DASH	ROM; AO classification	CES-D; PCS; PASS		Pain rating (11 Point Ordinal Scale) at 3m	Age; Sex; Dominant wrist injury; Days injury to surgery; Mobilization type
Bot et al., 2014(119)	Level I; Prognostic	Cross-sectional evaluation at mean 48d post-injury	82	Trauma	Wrist / Hand	Proximal-interphalangeal joint sprain; PIPJ sprain plus volar plate bony avulsion; PIPJ dislocation	QuickDASH	ROM; Distance to palmar crease of affected finger or fingers; Diagnoses; Number of fingers injured	PHQ-9; PSEQ		Pain rating (11 Point Ordinal Scale)	Age; Injury mechanism; Dominant hand injury; Days after injury
Bot et al., 2014(123)	Level I, Prognostic	Prospective, longitudinal evaluation at mean 9d and 33d post-injury	70	Trauma	Wrist / Hand	Finger injuries distal to PIPJ; Tip laceration; Distal / middle phalanx fracture; Amputation (no revascularization, at level of distal phalanx, tip only and at level of middle phalanx)	QuickDASH	ROM; Injury type; Number of fingers injured	PHQ; PSEQ	Work status; Days off work	Pain rating (11 Point Ordinal Scale)	Age; Sex; Injury mechanism; Procedure; Dominant hand injury
Cederlund et al., 2010(124)	Level I, Prognostic	Prospective, longitudinal evaluation at 3,6,12m post-injury	45	Trauma	Wrist / Hand	Severe or major hand injury	DASH; SF-36 PCS; EQ-5D VAS; Hand function VAS	HISS; Injury severity grade; Presence of major PNI	SOC (6m only); SF-36 Mental Health	SDO; Manual work; Occupation type	Pain rating (VAS); Sensibility (VAS); CSS	Age; Sex; Hand dominance; Sleep (VAS); Joint mobility (VAS); Grip strength(VAS); Dexterity (VAS)
Chan et al., 2009(125)	Level II, Prognostic	Cross-sectional evaluation at point of admission	57	Trauma	Wrist / Hand	Hand injury nos	DASH	HISS	IPQ-R			Age; Sex; Dominant hand injury

Constand et al., 2014(126)	Level I, Prognostic	Prospective, longitudinal evaluation at baseline (less than 10d) and 3m post-injury	129	Trauma	Wrist / Hand	Distal radius fracture	PRWE		PPPC				Age; Dominant hand injury Mechanism of fracture; Surgery
DasDe et al.,2013(127)	Level II, Prognostic	Cross-sectional evaluation (time point nos)	319	Combination	Wrist / Hand	Distal radius fracture	DASH	Diagnosis	CES-D; PCS; TSK; PASS-20	Marital status; Employment status; Race; Ethnicity; WHYMPI-Partner subscale			Age; Sex
Dogu et al., 2014(104)	Level I, Prognostic	Prospective, longitudinal evaluation at <3m and 6-9m post-surgery	54	Trauma	Wrist / Hand	Hand injury nos	DASH	Site of injury	BDI; IES-R	Education level; Employment status			Age; Hand dominance; Time since injury; Mechanism of injury
Doring et al., 2014(113)	Level 1, Prognostic	Cross-sectional evaluation (time point nos)	84	Combination	Wrist / Hand	Hand, wrist fractures; Mallett finger; Soft tissue injury; Animal bite	PROMIS PF UE, PROMIS PF, PROMIS Mobility CAT; QuickDASH		PROMIS Depression, PROMIS Anxiety CATs; PHQ-2; PSEQ-2	Education; Work status; Marital status	Pain rating (NRS); Other pain condition		Age; Sex; Prior surgery; Sought treatment before
Farzad et al., 2015(75)	Level III; Therapeutic Study	Cross-sectional evaluation at mean 11m post-injury	107	Trauma	Wrist / Hand	Hand fracture; Nerve, tendon and combined injuries; Burn; CRPS; Amputation	DASH; MHQ	AMA Impairment Guide; Diagnosis	BDI	Work status; Education; Marital status; Kind of job; Current job status	Pain rating (VAS); Sensibility (VAS); CSS		Age; Sex; Dominant hand injury; Laterality; Cause of injury; Time since injury

Golkari et al., 2015(128)	Level I; Prognostic	Prospective, longitudinal evaluation at mean 5d and mean 36d post-injury	69	Trauma	Arm	Radial head fracture (minimally displaced); Distal radius fracture	DASH		CES-D; Whiteley Index; PCS	Marital status; Employment status; Years of education	Pain rating (11-point ordinal scale); "No pain, no gain" agreement	Age; Sex; Smoking status; Pre-existing pain conditions; Type of immobilizatio n
Gong et al., 2011(105)	Level I; Prognostic	Prospective, longitudinal evaluation at baseline (week 0), 2, 6, 12 and 24 weeks post-injury	50	Trauma	Wrist / Hand	Distal radius fracture	DASH	AO classification	CES-D		Pain rating (NRS)	Age; Sex; Dominant hand injury
Gruber et al., 2014(129)	Level II, Prognostic	Prospective, longitudinal evaluation at baseline (1st presentation) and 1 to 2 months after enrollment	112	Combination	Arm	Acute injuries nos	QuickDASH	Diagnosis	PHQ-2; PSEQ	Education; Marital status; Work status	Pain rating (11-point ordinal scale)	Age; Sex; Relevant medical history; PAM
Hageman et al., 2014(59)	Level II, Prognostic	Cross-sectional evaluation (time point nos)	84	Combination	Arm	Acute injuries (Closed tendon injury, Fractures, Laceration)	QuickDASH	Diagnosis	CFS; SHAI-5; PSEQ; PHQ-2	Marital status; Work status	Pain rating (11-point ordinal scale)	Age; Sex; Physician; Previous treatment sought
Helmerhorst et al., 2014(106)	Level III, Prognostic	Cross-sectional evaluation at 1 to 2m post-surgery	145	Trauma	Arm	Arm injuries nos	SMFA	AIS Fracture site Single or multiple injury sites	CES-D; PCS; PASS; PCL civilian version		Pain rating (NRS)	Age; Sex; Surgeon; Economic provider status; Work-related / prior orthopaedic / Surgery

Janssen et al., 2014(84)	Level IV, Cross-sectional	Cross-sectional evaluation at (median) 6 months	139	Combination	Arm	Fracture shoulder, elbow, forearm, wrist, hand; Finger amputation; MCPJ dislocation; Soft tissue injury hand	PROMIS PF CAT; QuickDASH		PROMIS Pain behaviour, PROMIS PI, PROMIS Depression CAT	Education level; Marital status; Work status	Pain rating (11-point ordinal scale); Other pain conditions	Age; Sex; Sought treatment before; Prior surgery
Jayakumar et al., 2015(111)	Level IV, Prognostic	Cross-sectional evaluation (time point nos)	98	Combination	Arm	Elbow, Hand, Humerus, Forearm, Wrist fractures; Soft tissue injury Hand; Animal bite	QuickDASH; PROMIS PF CAT; Activity Level	Diagnosis	PROMIS Depression, PROMIS PI CATs	Education; Marital status; Work status; Acute or chronic	Other pain condition	Age; Sex; PACES
Keogh et al., 2010(130)	Level IV, Cross-sectional	Cross-sectional evaluation at mean 11d post-injury	87	Trauma	Wrist / Hand	Hand fractures	PRWE	Fracture type	ASI, PASS, PCS, DASS		SF-MPQ	Age; Sex; Days since fracture; Dominant hand injury
Kortlever et al., 2015(131)	Level IV, Cross-sectional	Cross-sectional evaluation at baseline (prior to physician review)	134	Combination	Arm	Traumatic and non-trauma upper extremity conditions nos	QuickDASH		PCS; PIPS; PROMIS PI CAT; PSEQ	Education; Ethnicity; Race; Work status; Marital status	Other pain condition	Age; Sex; Days since injury; Sought treatment before; Prior surgery
Mayland et al., 2015(132)	Level IV, Cross-sectional	Cross-sectional evaluation at <3m since injury	84	Trauma	Arm	Elbow, wrist, hand, finger, thumb fracture; Tendon or nerve laceration; Crush injury	QuickDASH		STAI; PASS-20; RRAQ	Employment status; Ethnicity		Sex; Dominant side injury; Surgery; No. days spent as inpatient; Hospitalisation; Mechanism of injury

Niekel et al., 2009(116)	Level III, Prognostic	Retrospective evaluation	839	Combination	Arm	Distal Radius Fracture	DASH; QuickDASH	Diagnosis	CES-D; PCS; PASS-40			Age; Sex; Limb dominance
Nota et al., 2016(96)	Level I, Prognostic	Cross-sectional evaluation at time point nos	193	Combination	Arm	Acute / Trauma nos	QuickDASH	Diagnosis	PROMIS ES, PROMIS IS, PROMIS PIIP, PROMIS PI CAT	Marital status; Work status	Other pain condition	Age; Sex; Physician; Type of patient; Prior surgery
Novak et al., 2010(133)	Level IV, Prognostic	Cross-sectional evaluation of injuries 0.5 to 15y prior with minimum 6m F/U	124	Trauma	Arm	Upper extremity peripheral nerve injury (Brachial plexus, Single shoulder nerve, Distal nerve)	DASH	Nerves injured	IIS; PDI	Workers compensation / Litigation involvement; Work status	SF-MPQ; Pain rating (VAS)	Age; Sex; Dominant hand injury
Novak et al., 2011(112)	Level II, Prognostic	Cross-sectional evaluation of injuries from 0.5 to 15y prior with minimum 6m F/U	158	Trauma	Arm	Upper extremity peripheral nerve injury	DASH	Comorbidity index; Injured nerve; Imaging nos	HADS; PCS; PCL-C	DASH Work/Sport/ Arts module; Marital, employment, education, income status; Work comp; Location	SF-MPQ; Pain rating (VAS); CISS	Age; Sex; Dominant hand injury; Time since injury
Novak et al., 2012(134)	Level IV, Cross-sectional	Cross-sectional evaluation at minimum 6m post-injury	61	Trauma	Shoulder	Brachial plexus injury	DASH; SF-36		PCL-C; PCS	Work status; Workers compensation or litigation; Geographic location	SF-MPQ; CISS; Pain rating (VAS)	Age; Sex; Dominant hand injured; Time since injury

Peters et al., 2016(135)	Level IV, Cross-sectional	Cross-sectional evaluation (time point nos)	111	Combination	Arm	Sprain, dislocation, mallet finger; Hand fracture; Wrist fracture; Amputation, crush or laceration; Elbow fracture	PROMIS UE PF, PROMIS Sleep Disturbance CAT	Diagnosis; BMI	PROMIS Depression CAT; PROMIS PI CAT	Race / Ethnicity; Education duration; Working status; Marital status	Other pain conditions	Age; Sex; Visit type
Prugh et al., 2012(136)	Level IIIb, Cohort study	Prospective, longitudinal evaluation at baseline and 4w	5	Trauma	Elbow	Elbow sports-related injury (ulnar nerve compromise; medial epicondylitis; valgus overload injury; elbow hyperextension injury)	QuickDASH		FABQ; PCS; TSK-11	Ethnicity	Pain rating (NRS)	Age; Sex; Height; Hand dominance; Injured side; Mechanism of injury; No. of PT visits
Richards et al., 2011(107)	Level IV, Therapeutic	Cross-sectional evaluation of injuries from 7 to 32m prior	34	Trauma	Wrist / Hand	Hand injury (Amputations, Fratcure-dislocations, Complex lacerations, Infections, Combinations)	QuickDASH Functional Subscales	Injury type	CES-D; SPTSS; PSS	MOS-Social Support; SCS	QuickDASH Pain Subscales	Age; Sex; Ethnicity; Time since injury
Ring et al., 2006(137)	Level IV, Cross-sectional	Cross-sectional evaluation at <3m since injury	235	Combination	Wrist / Hand	Distal radius fracture	DASH		EPQ-R (Neuroticism); CES-D; PASS	Education; Work status; Marital status		Age; Sex

Roh et al,. 2014(77)	Level II, Prognostic	Prospective, longitudinal evaluation at 4, 12, 24 weeks post-op	121	Trauma	Wrist / Hand	Distal radius fracture	MHQ	ROM; Grip Strength; Radiographs; AO Classification; BMI	PCS; PASS			Age; Sex; Dominant side injury
Roh et al., 2015(117)	Level III; Prognostic Study	Prospective, longitudinal evaluation at 3 and 6m F/U	93	Trauma	Wrist / Hand	Hand fractures	QuickDASH	ROM; Grip Strength; HISS; Injury location	PCS, PASS-20			Age; Sex; Dominant side injury; Treatment
Ross et al., 2015(103)	Level IV, Cross-sectional	Cross-sectional evaluation within 28d of injury or surgery	594	Trauma	Wrist / Hand	Hand and wrist fracture (Unilateral - distal third radius or ulna, metacarpal, scaphoid, other carpal, multiple fractures)	QuickDASH		DASS-21		Pain rating (NRS)	Age; Sex; Days since fracture; Days since surgery
Shields et al,. 2015(118)	Level IV, Cross-sectional	Retrospective, cross-sectional evaluation with minimum 1 year F/U	77	Trauma	Humerus	Humeral shaft fractures	DASH; SST; SF-12 PCS	Fracture location; Associated fracture	SF-12 (MCS); History of psychiatric illness			Age; Surgical treatment; CCI; Classification as high energy
Symonette et al,. 2013(114)	Level II, Prospective Study	Prospective, longitudinal evaluation at baseline and 1y F/U	291	Trauma	Wrist / Hand	Distal radius fracture	PRWE; SF-12 PCS	Radiographs; AO classification; Open or closed injury	SF-12 (MCS-12); MOS-SSS	MOS-SSS; Injury compensation		Age; Sex; Dominant side injury; Energy of injury; Mechanism of injury; Treatment type; Complications

Vranceanu et al., 2014(68)	Level I, Prognostic	Prospective, longitudinal evaluation at 1-2m and 5-8m post-injury	136	Trauma	Arm	Arm injuries nos	SMFA	AIS	PASS-20; PCS; CES-D; PCL; Psychotherapy	Employment status; Marital status	Pain rating (NRS); Self-reported opioid use	Age; Sex; Work-related injury; Prior orthopaedic injuries
Vranceanu et al., 2015(138)	Level I, Prognostic	Randomised controlled trial evaluation within 1-2 months of injury	48	Trauma	Arm	Arm injuries nos	SMFA		PCS; PASS-20; CES-D; PCL Civilian version; Psychotherapy	Employment status; Marital status	Pain rating (NRS)	Age; Sex; Work related injury; Prior orthopaedic injuries
Williams et al., 2009(108)	Level II, Prospective Study	Cross-sectional evaluation at minimum 1m prior to injury	106	Trauma	Wrist / Hand	DRF / ulna / finger / metacarpal / mid-distal forearm / carpal bone / proximal forearm / elbow / humerus fracture; Mangled hand / flexor / extensor tendon injury; Amputation	SF-36 PCS		RCMS; BDI v.2; SF-36 MCS			Age; Sex; Time from injury to participation; Mechanism of injury; Type of insurance
Yeoh et al., 2016(109)	Level I, Prognostic	Prospective, longitudinal evaluation at baseline (7-10d post-injury), 3m, 1y	228	Trauma	Wrist / Hand	Distal radius fracture	DASH; SF-36		CES-D	Education; 3rd part claim status		Age; Sex; Comorbidity (Katz questionnaire); Smoking history

Table 2. Systematic Review I: Synopsis of key results from studies and disability focused clinical and research sequelae

Study	Key Results	Disability Focused Summary - Clinical & Research Sequelae
Bear-Lehman et al., 2011(120)	IES-R overall total, intrusion and hyperarousal subscales correlated with QuickDASH. The type of injury, length of time since injury and sex did not influence IES-R or QuickDASH.	Disability and stress reactions could impede capacity to fully participate in therapy. Learning effective coping strategies, adapting to injuries and engaging in therapy may aide recovery whilst experiencing stress reactions. Particular attention should be given toward intrusion and hyperarousal states.
Bekkers et al., 2014(121)	NPTQ correlated with and accounted for 9.6% variability in QuickDASH controlling for demographic variables. They were bi-directionally related to participant goals and interpretation of advice from hand therapists. None of the hand therapy specific questions were significantly associated with QuickDASH.	HT recommendations can affect and be affected by NPT, which in turn affects disability. Coaching should identify and generate adaptive responses to cognitive, emotional and behavioral reactions to NPT, especially during intensive exercises. Excessively cautious recommendations risk reinforcing NPT.
Bot et al., 2011(122)	Significant association between DASH and arc of forearm rotation, wrist and elbow flexion-extension, radioulnar deviation, CES-D, PCS, age at injury, pain, and associated injuries. Grip strength, pain and PCS accounted for 56% variability in DASH. Pain alone explained 40% variability in DASH.	Disability correlates better with subjective and psychosocial aspects of illness such as pain, depression and pain catastrophizing than objective measures of impairment. Culture may have a strong influence on pain intensity, particularly in terms of the correlation between impairment and disability.
Bot et al., 2012(81)	DASH had a significant association with pain, CES-D, PASS, wrist flexion and wrist extension. Pain, PCS, wrist flexion accounted for 39% variability in DASH score. "Open a tight or new jar" was the only task related question for which impaired wrist motion remained in the best multivariable model.	Variations in disability are best explained by symptoms and psychological factors than objective measures of impairment, even at the level of specific upper extremity tasks. Most variation remains unexplained. Role of cognitive and behavioral therapies during recovery merits greater study.
Bot et al., 2014(119)	QuickDASH correlated with PSEQ & PHQ-9 (high), and days from injury to enrollment (medium). PSEQ, PHQ-9 & gender accounted for 51% variability. Pain intensity associated with PSEQ, PHQ-9 & diagnosis (dislocation). Lower PSEQ & diagnosis accounted for 24% variability in greater pain intensity.	Recovery (i.e. disability, pain, stiffness) is mediated largely by mindset and coping strategies i.e., self-efficacy. Normal protective responses to discomfort (i.e. catastrophic thinking) should be appreciated. Patients should be reassured & supported in developing strategies to keep recovery on track.
Bot et al., 2014(119)	Days between injury and final evaluation, PSEQ, PHQ-9, and additional procedures were associated with QuickDASH at 1 month. Higher depression and injury mechanisms (saw-related compared with sport) explain 54% variability in QuickDASH. Injury type and mechanism have limited influence.	Psychological factors (e.g. catastrophic thinking, self-efficacy, depression) are important predictors of upper extremity disability and strong determinants of illness behavior (e.g. pain experience, time off work). General empathy, optimal support & evidence-based treatments e.g. CBT should be utilized.
Cederlund et al., 2010(124)	DASH, SF-36 Physical health, SDO and self-assessed outcomes improved over time. However, lower SOC was associated with significantly higher DASH, lower SDO, lower SD-36 Mental health, more sleep disturbances and bodily pain.	Patients with lower SOC may need extra support, more frequent F/U, verbal and written patient education, group participation, specialist review by mental health professionals and guided rehabilitation e.g. developing and using coping strategies to master ADLs. Future rehabilitation should consider SOC.
Chan et al., 2009(125)	DASH did not correlate with HISS or any IPQ-R component. Patients, especially those with severe injury, were generally over-optimistic about treatment & recovery. Those perceiving poor outcomes, chronic/cyclical duration & low illness coherence tended toward negative emotional responses.	Illness perceptions, behavior and coping strategies may be influenced by pre-existing beliefs over recent trauma or injury severity. Effective pre-& post-op symptom control may alter negative beliefs. Over-optimism could misalign expectations leading to negative responses, behaviors, compliance & outcomes.

Constand et al., 2014 (126)	PPPC and PRWE scores showed significant but not strong correlation, at initial assessment and 3m post injury. C-P alliance & PRWE specific function subscale were significantly correlated at baseline. C-P dialogues and PRWE specific, usual function, pain subscales were significantly correlated at follow-up.	Patient-centered care can optimize outcomes in the first 3m post DRF surgery. PPPC can be used to understand evolving patient perspectives e.g. C-P partnership (at baseline) to promote shared decision-making and C-P communication (at later stages of recovery). Clinician training may be required.
Das De et al., 2013(127)	DASH correlated significantly with CES-D, PCS, TSK and PASS-20 overall but not in DRFs. WHYMPI and subcategories did not correlate. Sex, diagnosis, employment status, TSK and PCS accounted for 55% variability in DASH.	Catastrophic thinking & kinesiophobia are important predictors of disability. Thoughts on pain & avoidance of pain-inducing activities may be more important than those on partner support. Greater than expected symptoms & disability should trigger strategies to manage modifiable factors.
Dogu et al., 2014(104)	DASH, BDI & IES-R significantly decreased from acute to later stages. 7.4% scored severe depression at acute stage & 5.5% at later stages. DASH, BDI and IES-R significantly correlated in both stages but only acute stage DASH & IES-R explained a significant proportion of variability in DASH at later stage.	Functional outcomes at later stages are impacted by functional status & degree of impact of events at the early stage. Psychological impact of events reduces significantly within 6-9m post-injury. Psychological evaluation considering impact of events & functional outcomes may provide timely interventions.
Doring et al., 2014(113)	PROMIS UE PF & QuickDASH had strong correlation. PROMIS PI, Work status (retired, unemployed) accounted for 63% variability in PROMIS UE PF; PROMIS PI accounted for 32% variability in QuickDASH. PROMIS UE PF & QuickDASH showed no ceiling (0%) effects.	PROMIS UE PF is a valid, reliable and efficient in measuring upper extremity disability. There is value in measuring and treating psychosocial contributors of illness and measures of disability may be determining psychological well-being & effective coping strategies than objective disease & impairment.
Farzad et al., 2015(75)	DASH had intermediate correlation with AMA impairment. Impairment plus gender accounted for 22% variability in DASH scores. MHQ had small correlation with AMA impairment and age. Impairment plus age accounted for 23% variability in MHQ scores.	Disability has a limited correlation with impairment. Other factors i.e. physical (e.g. pain, dominant injured hand), conditional (e.g. time since surgery) or psychological (e.g. depression, adapting) should be considered in managing these patients.
Golkari et al., 2015(128)	CES-D associated with not having an additional pain condition, more days between injury and final evaluation, and stronger agreement with "no pain, no gain". Symptoms of depression and catastrophic thinking, but not health anxiety, improved during recovery after injury.	Psychological measures associate with increased disability. Depression and ineffective coping, are part reactive and can be expected to improve over time. Disease phase should be accounted for in the recovery process if psychological measures are used as screening tools to predict outcome.
Gong et al., 2011(105)	Strong association between depressive symptoms, disability & pain but no differences in CES-D between DRF volar plating & casting. 73-75% had major depressive disorder (CESD threshold >16) immediately post injury. DASH & pain NRS accounted for 20% variability in CES-D at w0 & 58% at w24.	Early wrist movement post-DRF plating may not associate with reduced depression compared with cast immobilization during early rehabilitation. Pain is an important predictor of depression. Sufficient pain control should be achieved early post-op. Early wrist motion should not be overly emphasized.
Gruber et al., 2014(129)	QuickDASH (final) correlated with PAM (enrollment). Strongest predictors were older age & lower PSEQ, explaining 40% variability. QuickDASH decrease correlated with greater PHQ-2, PAM at F/U and lower PSEQ, with PSEQ explaining 4.6% variability.	Early coaching of effective coping strategies, self-management and engagement in self-care may improve disability & pain intensity. An active role in health is one aspect of self-efficacy. Future studies, ideally RCTs should assess the ability of interventions to improve self-efficacy and patient outcomes.
Hageman et al., 2014(59)	QuickDASH and pain intensity correlated with PSEQ, PHQ-2, SHAI-5 and marital status, but not CFS. Pain intensity correlated with PSEQ and PHQ-2, but not CFS. PSEQ explained 35% variability in QuickDASH and PSEQ and PHQ-2, 29% variability in pain intensity. CFS correlated with PSEQ only.	Upper extremity disability and pain intensity are limited more by self-efficacy than cognitive flexibility. Interventions to improve coping strategies whilst interpreting nociception could decrease hand specific disability than open mindedness. CBT may be required if general coaching fails to provide confidence.

Helmerhorst et al., 2014(106)	At 1-2m post-surgery, 28% used opioids and use was strongly associated with PCS, PASS-20, CES-D and PCL-C. Mean SMFA and pain intensity was significantly higher in those using opioids irrespective of fracture site, injury severity or treating surgeon.	Greater than expected pain & disability, and requests for opioids 1-2m post-fracture surgery should prompt consideration of stress, depressed mood and ineffective coping. Screening for psychological factors (e.g. low pain self-efficacy) and early deployment of CBT may reduce disability & opioid use.
Janssen et al., 2014(84)	PROMIS PI CAT, other pain conditions, being separated, divorced or widowed accounted for 64% variability in QuickDASH. PROMIS PI CAT, PROMIS depression CAT, age, other pain conditions, living with partner/being married accounted for 47% variability in PROMIS PF CAT.	Psychological and circumstantial factors consistently account for a substantial amount of variation in symptoms and disability. The influence of coaching effective coping strategies on disability should be investigated and more adaptive pain behaviors should be incorporated into care.
Jayakumar et al., 2015(111)	Greater PROMIS PI CAT, male sex, other pain conditions and separated/divorced / single status accounted for 34% variability in PROMIS PF CAT. Coping strategies were the most important contributor of disability. Age correlated with activity enjoyment & had small correlation with disability.	Disability relates less on physical impairment, including age related impairment, than adaptation and resilience. Decision-making during treatment should rely less on chronological age and more on patient preferences and values. These include prior assessment of patient expectations, goals and activity level.
Keogh et al., 2010(130)	Constructs of pain anxiety, pain catastrophizing and anxiety sensitivity, related in one form or another to pain and disability but the exact pattern was inconsistent. Anxiety sensitivity and general negative mood were strong predictors of disability but the former was negatively correlated.	Anxiety-related constructs in experiencing pain and disability may have implications on therapeutic care. The three anxiety related constructs may be important in acute pain settings, indicating the development of disability. Anxiety-related avoidance impacts pain, thus tackling such behaviors may speed recovery.
Kortlever et al., 2015(131)	PROMIS PI CAT, PCS, PIPS, and PSEQ show substantial correlation in measuring coping strategies in response to nociception. PCS, PIPS and PROMIS PI CAT reliably measure the construct and PSEQ its inverse. PROMIS PI CAT was quickest to complete with a strongest correlation with QuickDASH.	All 4 instruments measure coping in response to nociception – a factor negatively impacting upper extremity disability. PROMIS PI CAT may be preferable due to brevity, good coverage & reduced responder burden. PSEQ & PCS Qs may be useful for developing talking points & treatment foci.
Mayland et al., 2015(132)	Scores from anxiety measures posing more upper extremity-specific questions (i.e. RRAQ, PASS-20) strongly correlated with higher disability over those with general anxiety (i.e. T-anxiety, S-anxiety). 4 predictive variables accounted for 29% variability in disability. RRAQ total score explained 19% alone.	Identifying recovery related anxiety following less severe arm injuries is important & likely more relevant than general anxiety. RRAQ, pain, state & trait anxiety may decrease in order of prevalence & strength of association with disability. Anxiety-related Qs should be phrased around recovery experience.
Niekel et al., 2009(116)	CES-D, PCS, PASS-40, gender & wrist fractures accounted for 25% variability in DASH, where psychological factors alone explained 20% variability. CES-D, PCS, PASS-40, gender & age accounted for 20% variability in QuickDASH where the psychological factors alone explained 13% variability.	Psychological measures consistently explain greater % variation in DASH & QuickDASH. QuickDASH is more practical than the DASH but comparatively lower variation is explained. Disability can be improved when considering all aspects of illness, particularly psychological factors.
Nota et al., 2016(96)	PROMIS ES & PROMIS IS were weakly & inversely associated with QuickDASH. PROMIS PI along with trauma, F/U patients, unemployed/unable to work, nonspecific arm pain, initial visit & separated /divorced status explained 73% variation in QuickDASH. PROMIS PI alone explained 66% variation.	Interventions enhancing coping strategies to help adapt to pain and remain active are likely integral to musculoskeletal care. Secondarily, having someone to provide help with ADLs & emotional support may be important during the initial stages of adjustment. Future studies should assess this prospectively.
Novak et al., 2010(133)	PDI strongly correlated with DASH and IIS and had weaker correlation with pain intensity, explaining 69.9% variability in PDI. IIS and DASH scores were significantly higher in workers compensation compared to those without and those with brachial plexus injuries compared to peripheral nerve injury.	Traumatic upper extremity nerve injuries are associated with substantial pain disability, upper extremity disability and illness intrusiveness. Disability associated with pain comprises more than pain intensity and impact of injury and pain on life domains should be considered throughout the assessment.

Novak et al., 2011(112)	DASH correlated with pain intensity which in turn strongly correlated with CISS & PCS. Pain VAS, nerve(s) injured, time since injury, PCS, older age, work status, CISS, HADS, workers' compensation claim / litigation and female sex, explained 52.7% variability in DASH.	Traumatic peripheral nerve injuries are associated with substantial disability, pain, and cold sensitivity. Greater disability can be predicted by BPI, older age, pain intensity, work status, time since injury, cold sensitivity, and pain catastrophizing.
Novak et al., 2012(134)	High scores were observed in CISS, DASH and pain intensity post-injury. DASH had significant correlation with VAS pain, MPQ, PCL-C, PCS, SF-36 physical. MPQ, DASH and time since injury explained 33% variability in CISS with MPQ being the strongest predictor.	Patients with brachial plexus nerve injury reported substantial cold intolerance which was associated with the McGill pain rating index, upper extremity disability, and time since injury. Future studies to evaluate treatments to minimize cold intolerance may decrease pain and minimize disability.
Peters et al., 2016(135)	Higher PROMIS Sleep disturbance CAT scores were not associated with increased PROMIS UE PF CAT scores whilst PROMIS PI CAT scores were, accounting for 21% variability in PROMIS UE PF scores.	Sleep disturbance does not appear to be strongly or directly associated with symptom intensity and magnitude of upper extremity disability compared to ineffective coping. It may itself be a function of less effective coping in a bidirectional relationship.
Prugh et al., 2012(136)	TSK-FOI subscale demonstrated strong correlation with initial QuickDASH, change in QuickDASH and pain scale, whereas initial total FAB-Q did not. PCS did not correlate with pain scores & negatively correlated with initial & change in QuickDASH.	Fear avoidance beliefs and catastrophizing are more effectively captured using subscales of measures (e.g. TSK-FOI) than full measures in throwing athletes compared to general orthopedic trauma populations. TSK-11 may be most appropriate during initial evaluation.
Richards et al., 2011(107)	29% met or exceeded clinically significant depression and PTSD cut-offs. QuickDASH functional and pain subscales had moderate to large correlations with CES-D, SPTSS, MOS, SCS & PSS. Depression and PTSD symptoms were highly correlated. SCS & PSS positively associated with QuickDASH.	Early psychological intervention might improve patient coping as disability is strongly correlated with psychological distress, which itself relates to function & pain. Those experiencing elevated pain or psychiatric symptoms, frequently experience both – this may occur long after an injury has healed.
Ring et al., 2006(137)	DASH had a significant moderate correlation with CES-D. Variable, mild to moderate correlations were also observed with PASS. CES-D & gender were independent predictors of DASH with females having higher DASH for any given CES-D score. DASH scores had a large standard deviation.	Self-reported upper extremity-specific health status correlates with depression and pain anxiety but not neuroticism. The variability in patient perceived disability likely arises substantially from psychosocial rather than physical factors and may be common to all health status measures.
Roh et al., 2014(77)	Increase in PCS associated with decrease in grip strength, ROM, MHQ at week 4. Increase in PASS associated with decrease in grip strength, ROM and MHQ at week 4 and grip and MHQ at week 12. Only age and fracture severity associated with MHQ at week 24.	Pain-related psychological mechanisms can influence early functional recovery & should be addressed when impairment, disability or pain is expected to worsen, particularly in the first 12w post-surgery. Pre-operative PCS and PASS scores can identify those at risk & trigger early psychological interventions.
Roh et al., 2015(117)	At 3 months: PCS, PASS-20, HISS injury severity & treatment accounted for 38% variability in QuickDASH. At 6 months: Only age and injury severity accounted for 21% of variability in QuickDASH.	Poor pre-op pain coping skills associate with increased disability, weaker grip & decreased ROM at 3m post-surgery. Recovery may be enhanced by addressing coping, especially in the first 3m, where there is strong correlation between variables. Further research may demonstrate impact of screening & therapy.
Ross et al., 2015(103)	Pain was significantly associated with disability. Depression and stress but not anxiety were significant mediators of this relationship. Depression and stress accounted for 21% variability in the relationship between pain and disability. Only partial mediation was demonstrated.	Psychological interventions targeting the reduction of depression and stress may reduce pain related disability associated with wrist or hand fractures, especially in the acute post-fracture phase i.e. within 28d from injury or surgery. Many other factors are likely to mediate this relationship.

Shields et al., 2015(118)	Satisfactory DASH scores decreased with increasing age and in the under 50s increased with the absence of a psychiatric history. Satisfactory SST scores were more likely in patients without psychiatric history. Satisfactory SF-12 PCS scores more likely with no psychiatric history and in the privately insured.	Patient age, history of psychiatric illness, insurance type, fracture location and CCI scores have a significant effect on patient reported functional outcomes in humeral shaft fractures. These factors should be considered when counselling for prognosis & treatment. Impact is likely age-dependent.
Symonette et al., 2013(114)	Baseline emotional/informational support explained 4.7% variability of pain and disability outcomes at 1y regardless of age, gender and final radiographic alignment. Other MOS social support subscales had no influence.	Rehabilitative benefits of social support during initial visits should be considered & emotional / informational social support at the time of injury may have a significant impact on patient-reported pain & disability outcomes. Further research should inform when & how this support affects outcomes.
Vranceanu et al., 2014(68)	25% diagnosed with clinical depression & PTSD early on. Rate of clinical depression persisted whilst PTSD reduced 5-8m post-injury. Multiple injuries, AIS, opioid use explained 24- 29% variability in pain at rest, activity & SMFA at time 1. Addition of CES-D, PASS-20 & PCS increased this to 49 & 55%.	Psychological impact of orthopaedic trauma suggests the importance of depression & PTSD screening. Future studies should investigate treatments e.g. CBT – especially assessing impact of interventions at 1-2m on later pain intensity and disability which can continue beyond the time span for physical recovery.
Vranceanu et al., 2015(138)	CBRR intervention had a 24% decline rate and 86% completion rate. Significant differences were demonstrated between intervention and control arms in terms of pain with activity NRS, SMFA, PASS-20, CES-D and PTSD with large effect sizes. No significant effect was observed with pain at rest.	Psychosocial interventions e.g. CBRR are feasible, acceptable and potentially efficacious in decreasing pain intensity, disability and coping variables. Future large-scale RCTs are warranted to delineate actual impact versus placebo controls involving standard patient education, provider attention and support.
Williams et al., 2009(108)	32% endorsed items consistent with PTSD and 20% with depression. PTSD patients had significantly lower SF-36 subscale scores of role emotional, bodily pain, social function and mental health only. Patients with concurrent PTSD and depression had a more deleterious effect.	Psychological status, especially in terms of PTSD and depression, negatively impacts general health status. These may have greater impact on those sustaining hand injuries compared to general orthopedic injuries. Early identification & intervention may improve long-term outcomes for PTSD and depression.
Yeoh et al., 2016(109)	Levels of depression were 25%, 32% and 26% at baseline, 3m and 1y respectively. Baseline depression (CESD >16) was the strongest predictor of worse 1-year SF-36 and DASH. Baseline CESD >16 was associated with complications and CRPS at 3m.	Depression and disability are strongly correlated. Complications may associate with development of depression in those not initially depressed. Baseline depression may also contribute to the development of CRPS. Providers should be aware of the prevalence of depression and impact on outcomes.

Table 3. Systematic Review I: Synopsis of correlational and regression analysis in disability studies

Study	Disability Measure	Demographic / Other Variables	Correlation r/t/Z/F	Regression Part R2	Regression Adj R2 (model)	Impairment Variable	Correlation r/t/Z/F	Regression Part R2	Regression Adj R2 (model)	Psychology Variable	Correlation r/t/Z/F	Regression Part R2	Regression Adj R2 (model)	Social Variable	Correlation r/t/Z/F	Regression Part R2	Regression Adj R2 (model)	Symptoms Variable	Correlation r/t/Z/F	Regression Part R2	Regression Adj R2 (model)
Bear-Lehman et al., 2011	QuickDASH									**IES-R**	**0.51**										
										Intrusion	**0.57**										
										Hyperarousal	**0.45**										
Bekkers et al., 2014	QuickDASH									**NPTQ**	**0.3**	**0.24**	**9.60%**								
Bot et al., 2011	DASH	Age	0.286			Elbow flex-ext	-0.263			CES-D	0.276							**Pain (DASH)**	**0.533**	**n/a**	**Part 56% (I)**
		Age at time of F/U	0.249			Pro-sup	-0.283			**PCS**	**0.261**	**n/a**	**Part 56% (I)**					**Pain (DASH)**	**0.553**	**n/a**	**40% (II)**
						Wrist flex-ext	-0.32														
						Radio-ulnar arc	-0.311														
						Grip strength	**-0.334**	**n/a**	**Part 56% (I)**												
						Ispilateral injury	n/a	n/a	Part 56% (I)												
Bot et al., 2012	DASH					Wrist flex	-0.36	0.053	Part 27% (I)	CES-D	0.3	0.039	Part 27% (I)								
						Wrist ext	-0.27			**PCS**	**0.22**	**0.12**	**Part 27% (II)**								
										PASS-40	0.26										
	DASH					**Wrist flex**	**-0.36**	**0.072**	**Part 39% (II)**	**PCS**	**n/a**	**0.24**	**Part 39% (II)**					**Pain (Ordinal NRS)**	**0.4**	**0.15**	**Part 39% (II)**
Bot et al., 2014	QuickDASH	Injury-enrollment (d)	-0.3							**PSEQ**	**-0.5**	**0.062**	**Part 51%**								
		Gender	**-1.9**	**0.022**	**Part 51%**					**PHQ-9**	**0.59**	**0.071**	**Part 51%**								
Bot et al., 2014	QuickDASH	Injury to final (d)	-0.31							PSEQ	-0.59										
		Injury Mechanism	**n/a**	**0.14**	**Part 54%**					**PHQ-9**	**0.59**	**0.43**	**Part 54%**								
		Additional procedures	-0.27																		
Cederlund et al,. 2010	DASH									**SOC**	**n/a**										
	EQ-5D VAS									**SOC**	**0.53**										
	SF-36 PCS									**SOC**	**0.43**										
Chan et al., 2009	DASH	No correlations																			

Constand et al., 2014	PRWE (Baseline) PRWE (F/U)	**C-P Alliance** **C-P dialogue**	**0.22** **0.2**																				
Das De et al,. 2013	DASH	**Sex**		**0.041**			**Diagnosis**		**0.14 2** * DRF	**Part 55%**	**TSK** **PCS**		**0.063** **0.177**	**Part 55%**	**Work status**		**<0.012**	**Part 55%**					
Dogu et al., 2014	DASH (Acute)										**IES-R (Acute)** **BDI (Acute)**	**0.356** **0.373**	**n/a**	**48%**									
	DASH (Late)										**IES-R (Late)** **BDI (Late)**	**0.52** **0.558**											
Doring et al., 2014	QuickDASH	Sex	n/a				PROMIS Mobility	n/a			**PROMIS PI** PHQ-2 PSEQ-2	**n/a** n/a n/a	**0.33**	**32%**	Work status Years of education	n/a n/a			Pain (Ordinal NRS)	n/a			
	PROMIS UE PF	Sex	n/a				PROMIS Mobility	n/a			**PROMIS PI** PHQ-2 PSEQ-2	**n/a** n/a n/a	**0.6**	**Part 63%**	**Retired** **Unemployed** Years of education	**n/a** **n/a** n/a	**0.059** **0.057**	**Part 63%** **Part 63%**	Pain (Ordinal NRS)	n/a			
Farzad et al., 2015	DASH	**Sex**	**0.24**	**n/a**	**Part 22%**		**AMA impairment**	**0.38**	**n/a**	**Part 22%**													
	MHQ	**Age**	**-0.2**	**n/a**	**Part 23%**		**AMA impairment**	**-0.24**	**n/a**	**Part 23%**													
Golkari et al., 2015	No relevant correlational or regression analysis of predictors of disability available																						
Gong et al., 2011	DASH (w6) DASH (w12) DASH (w24)										**CES-D (w6)** **CES-D (w12)** **CES-D (w24)**	**n/a** **n/a** **n/a**											
Gruber et al., 2014	QuickDASH (Enrolment)	PAM (Enrollment)	-0.3								PHQ-2 PSEQ	0.5 -0.8											
	QuickDASH (F/U)	**Age** PAM (Enrollment)	**0.27** -0.31	**n/a**	**Part 40%**						PHQ-2 **PSEQ**	0.38 **-0.51**	**n/a**	**Part 40%**	Workers compensation Education	n/a -0.23							

		PAM (F/U)	-0.41																
	QuickDASH (△)	PAM (F/U)	-0.23					PHQ-2	-0.5										
								PSEQ	**0.45**	**0.34**	**4.60%**								
Hageman et al., 2014	QuickDASH							**PSEQ**	**-0.66**	**n/a**	**35%**	Marital status	n/a						
								PHQ-2	0.38										
								SHAI-5	0.33										
Helmerhorst et al., 2014	SMFA							**PCS**	**n/a**	**0.7**						Opioids at 1-2m	n/a		
								CES-D	**n/a**	**0.6**									
Janssen et al,. 2014	QuickDASH	Sought prior Rx	0.02					PROMIS PB	n/a			Work status	n/a			**Other pain con.**	**n/a**	**n/a**	**Part 64%**
								PROMIS Depression	n/a			**Marital status**	**n/a**	**n/a**	**Part 64%**				
								PROMIS PI	**n/a**	**n/a**	**Part 64%**	Education	n/a						
	PROMIS PF	**Age**	**n/a**	**n/a**	**Part 47%**			PROMIS PB	n/a			Work status	n/a			**Other pain con.**	**n/a**	**n/a**	**Part 47%**
								PROMIS Depression	**n/a**	**n/a**	**Part 47%**	**Marital status**	**n/a**	**n/a**	**Part 47%**	Pain	n/a		
								PROMIS PI	**n/a**	**n/a**	**Part 47%**					(Ordinal NRS)			
Jayakumar et al., 2015	PROMIS PF	**Male sex**	**n/a**	**0.074**	**Part 34%**			**PROMIS PI**	**-0.39**	**0.14**	**Part 34%**	**Separated divorced**	**n/a**	**0.079**	**Part 34%**	**Other pain con.**	**n/a**	**0.059**	**Part 34%**
								PACES	0.31			**Single**	**n/a**	**0.04**	**Part 34%**				
								PROMIS Depression	0.18			Years of education	0.24						
Keogh et al., 2010	PRWE	**Days since injury**	**n/a**	**-0.36**	**Part 55% (I)**	**Fracture type**	**0.4**	**Part 55% (I)**	**DASS**	**0.33**	**0.34**	**Part 55% (I)**				SF-MPQ	0.25		
									ASI	n/a	-0.25	Part 5% (II)				**PRWE Pain**	**0.58**	**0.57**	**Part 55% (I)**
									PCS	n/a	0	Part 5% (II)							
									PASS-20	n/a	-0.13	Part 5% (II)							
												*Total=60%							
Kortlever et al., 2015	QuickDASH							PCS	n/a	0.0117									
								PIPS	n/a	0.0003									
								PROMIS PI	**n/a**	**0.1227**	**Part 57%**								
								PSEQ	**n/a**	**0.0264**	**Part 57%**								
Mayland et al., 2015	QuickDASH							**RRAQ**	**0.446**	**0.19**	**Part 29%**								

										PASS-20 Pain anxiety	0.354	0.029	Part 29%									
										STAI-Trait Anxiety	n/a	0.001	Part 29%									
										STAI-State Anxiety	n/a	0.008	Part 29%									
Niekel et al., 2009	DASH	**Sex**	**n/a**	**n/a**	**Part 25% (I)**					**CES-D**	**0.31**		**Part 25% (I)**									
										PCS	**-0.21**		**Part 25% (I)**									
										PASS-40	**0.31**		**Part 25% (I)**									
	DASH									**CES-D**	**n/a**		**Part 20% (II)**									
										PCS	**n/a**		**Part 20% (II)**									
										PASS-40	**n/a**		**Part 20% (II)**									
	QuickDASH	**Age**			**Part 20% (I)**					**CES-D**	**0.28**		**Part 20% (I)**									
		Sex			**Part 20% (I)**					**PCS**	**-0.17**		**Part 20% (I)**									
										PASS-40	**0.27**		**Part 20% (I)**									
	QuickDASH									**CES-D**	**n/a**		**Part 13% (II)**									
										PCS	**n/a**		**Part 13% (II)**									
										PASS-40	**n/a**		**Part 13% (II)**									
											* all diagnoses combined		* DRF only									
Nota et al., 2016	QuickDASH	**Patient type (F/U)**	**30**	**0.038**	**Part 73%**	**Trauma**	**39**	**0.047**	**Part 73%**	**PROMIS PI**	**0.83**	**0.66**	**Part of 73%**	PROMIS ES CAT	-0.18			Other pain con.	28-38				
		Patient type (New)	**31**	**0.022**	**Part 73%**	**Arm pain nos**	**27**	**0.023**	**Part 73%**	PROMIS Depression	0.48			PROMIS IS CAT	-0.19								
										PROMIS PIIP	-0.36			**Separated / divorced**	**51**	**0.021**	**Part of 73%**						
														Work status	**63**	**0.025**	**Part of 73%**						
Novak et al,. 2010	DASH					Diagnosis	n/a			**PDI**	**0.764**			Workers compensation	n/a			**Pain (VAS)**	**0.487**				
										IIRS	**0.653**			Work status	n/a								
Novak et al., 2011	DASH	**Age**	**0.16**	**n/a**	**Part 52.7%**	Nerve(s) injured	n/a	n/a	Part 52.7%	**PCS**	**n/a**	**n/a**	**Part 52.7%**	**Work compensation**	**n/a**	**n/a**	**Part 52.7%**	**Pain (VAS)**	**0.51**	**n/a**	**Part 52.7%**		
		Time since injury	**n/a**	**n/a**	**Part 52.7%**					**HADS**	**n/a**	**n/a**	**Part 52.7%**	**Work status**	**n/a**	**n/a**	**Part 52.7%**	**CISS**	**n/a**	**n/a**	**Part 52.7%**		
		Sex	**n/a**	**n/a**	**Part 52.7%**																		

Novak et al., 2012	DASH					**PCL-C**	**0.277**					**CISS**	**0.329**
						PCS	**0.274**					**Pain (VAS)**	**0.385**
						SF-36 Mental	**-0.293**					**MPQ**	**0.385**
Peters et al., 2016	PROMIS UE PF	Sex	-2.3	BMI	-0.2	PROMIS SD	-0.38			Education	0.27	Other pain con.	2.9
						PROMIS PI	**-0.71**	**0.21**	**49%**	Working status	4.6		
						PROMIS Depression	-0.44						
Prugh et al,. 2012	QuickDASH (Initial)					**TSK FOI**	**0.47**						
						TSK FOP	-0.26						
						TSK SOMF	0.36						
						FABQ	-0.27						
						PCS-M	-0.2						
						PCS-R	-0.36						
	QuickDASH (△)					**TSK FOI**	**0.52**						
						TSK FOP	-0.16						
						TSK SOMF	0.46						
						PCS-M	-0.23						
						PCS-R	-0.39						
Richards et al., 2011	QuickDASH					**CES-D**	**0.69**					**Pain**	**0.79**
						SPTSS	**0.6**					**(QuickDASH Qs)**	
						SCS	**0.52**						
						PSS	**0.52**						
Ring et al., 2006	DASH	Age	n/a			**CES-D**	**0.52 ***	* DRF only					
		Gender	n/a			**CES-D**	**0.44 ****	** All diagnoses combined					
						PASS-40 PEB	0.30 **						
						PASS-40 FOP	0.22 **						
						PASS-40 Cog. anxiety	0.27 **						
						PASS-40 Phys. anxiety	0.29 **						
						PASS-40	**0.31 ****						

Roh et al,. 2014	MHQ	**Age (w12)**	**-0.38**			Fracture type (w4)	0.01			**PCS (w4)**	**-0.41**							**Pain (Ordinal NRS)**	**0.344**	
		Age (w24)	**-0.39**			Fracture type (w12)	0.02			**PASS-20 (w4)**	**-0.44**									
						Fracture type (w24)	0.02			**PASS-20 (w12)**	**-0.4**									
Roh et al., 2015	QuickDASH	**External fixation**	**n/a**	**0.07**	**Part 38% (I)**	**HISS**	**n/a**	**0.08**	**Part 38% (I)**	**PCS**	**n/a**	**0.12**	**Part 38% (I)**							
		Age	**n/a**	**0.09**	**Part 21% (I)**	**HISS**	**n/a**	**0.12**	**Part 21% (II)**	**PASS-20**	**n/a**	**0.11**	**Part 38% (I)**							
Ross et al., 2015	QuickDASH									**DASS-21 Depression**	**0.31**	**n/a**	**Part 21%**					**Pain (Ordinal NRS)**	**0.344**	
										DASS-21 Anxiety	0.272									
										DASS-21 Stress	**0.315**	**n/a**	**Part 21%**							
										* Mediation / stress analysis										
Shields et al,. 2015	DASH (Overall)	**Age**	**n/a**																	
	DASH (Under 50s)									**Psychiatric history**	**n/a**									
	DASH (Over 50s)	**Age**	**n/a**																	
	SST (Overall)									**Psychiatric history**	**n/a**									
	SST (Over 50s)					**Fracture locus**	**n/a**													
	SF-12 PCS (Overall)	**Private insurance**	**n/a**			**CCI**	**n/a**													
	SF-12 (Over 50s)					**CCI**	**n/a**			**Psychiatric history**	**n/a**									
Symonette et al,. 2013	PRWE (1y)													**MOS SSS Overall**	**n/a**	**n/a**	**4.70%**			
														MOS SSS ES/IS	**n/a**	**n/a**	**4.70%**			
Vranceanu et al., 2014	SMFA (Time 1)					**Multiple injuries**	**n/a**	**n/a**	**Part 29%**	**CES-D**	**n/a**	**n/a**	**Part 29%**					**Opioid pain med**	**n/a**	**n/a**	**Part 29%**
						AIS	**n/a**	**n/a**	**Part 29%**	**PCS**	**n/a**	**n/a**	**Part 29%**							
										PASS-20	**n/a**	**n/a**	**Part 29%**							
	SMFA (Time 2)					**Single/multiple injury**	**n/a**	**n/a**	**Part 40%**	**CES-D**	**n/a**	**n/a**	**Part 40%**					**Opioid pain med**	**n/a**	**n/a**	**Part 40%**
						AIS	**n/a**	**n/a**	**Part 40%**	**PCS**	**n/a**	**n/a**	**Part 40%**							

				PASS-20	**n/a**	**n/a**	**Part 40%**		
Vranceanu et al., 2015	No relevant correlational or regression analysis of predictors of disability available								
Williams et al., 2009	SF-36 PF			**BDI**	**-0.271**				
	SF-36 General			**BDI**	**-0.409**				
	SF-36 PCS			**BDI**	**-0.288**				
Yeoh et al., 2016	DASH (12m)			**CES-D >16**	**n/a**				
				CES-D <16	**n/a**				
	DASH (△)			**CES-D >16**	**n/a**	**n/a**			
				CES-D <16	**n/a**				
	SF-36 PCS (12m)			**CES-D >16**	**n/a**				
				CES-D <16	**n/a**				

† Abbreviations: con, condition; Rx, treatment; n/a, not available; C-P, clinician-patient; M, model; N-S, non-specific; Flex, flexion; Ext, extension; △, change
§ Only statistically significant variables included with significance levels selected by investigators (range, $p<0.05$ to $p<0.10$). Univariate / Bivariate analysis correlation represented as r,t,F or Z value. Multivariate regression analysis represented as adjusted or shrunken R^2 value explaining part or all % variance; Strongest predictors are in bold.

Table 4. Systematic Review I: Scores and clinical grading of most predominant psychological constructs

Study	Psychological Construct	Descriptive Statistics	Score	Clinical Grading	Outcome Measure
Bot et al., 2014(119)	Depression	Mean (SD) Range	Initial 1.9 (2.8) 0-13; Final 0.96 (1.4) 0-5.0	nos	PHQ-9
Bot et al., 2014(119)	Depression	Mean (SD) Range	Initial 2.8 (3.9) 0-17; Final 1.9 (3.6) 0-20	nos	PHQ-9
Dogu et al., 2014(104)	Depression	Mean (SD) Range	Acute 13.1 (10.2) 0-39; Late 7.1 (9.3) 0-38;	Acute: Minimal (25.9%), Mild (16.6%), Moderate (16.6%), Severe (7.7%); Late: Minimal (18.5%), Mild (3.7%), Moderate (5.5%), Severe (5.5%)	BDI
Gong et al., 2011(105)	Depression	Mean (SD)	7.4 - 20.9 (4.2 - 10.7)	73-79% major depression	CES-D
Helmerhorst et al., 2014(106)	Depression	TBC	TBC	24% met threshold for major depressive disorder	CES-D
Janssen et al., 2014(84)	Depression	Median (IQR) Range	46 (34-51) 34-69	nos	PROMIS Depression
Keogh et al., 2010(130)	Depression	Mean (SD)	14.38 (14.81); 20.74 (18.31)	nos	DASS
Niekel et al., 2009(116)	Depression	Median (Range)	9 (+/-10)	nos	CES-D
Richards et al., 2011(107)	Depression	Mean (SD) Range	13 (11) 0-44	29% exceeded threshold for both depression and PTSD	CES-D
Ring et al., 2006(137)	Depression	Mean (SD) Range	0.9 (1.3) 0-5	nos	PHQ-2
Ross et al., 2015(103)	Depression	Mean (SD) Range	6.75 (8.36) 0-42	nos	DASS-21, Depression
Vranceanu et al., 2014(68)	Depression	Mean (SD)	Time 1, 12 (9.3); Time 2, 11.8 (8.9)	nos	CES-D
Williams et al., 2009(108)	Depression	n/a	nos	Mild (7.5%), Moderate (4.7%), Severe (5.7%). 15% met threshold for depression and PTSD	BDI
Yeoh et al., 2016(109)	Depression	Mean (SD)	Baseline, 14 (0.42); 15 (0.47); 14 (0.43)	Major [(baseline (25%), 12w (32%), 1y (26%)]	CES-D
Bot et al., 2011(122)	Pain Catastrophizing	Median (SD) Range	7 (2-10) 0-40	nos	PCS
Bot et al., 2012(81)	Pain Catastrophizing	Median (IQR) Range	5 (9.0) 0-39	nos	PCS
Das De et al., 2013(127)	Pain Catastrophizing	n/s	n/s	n/s	PCS
Helmerhorst et al., 2014(106)	Pain Catastrophizing	n/s	n/s	n/s	PCS

Niekel et al., 2009(116)	Pain Catastrophizing	Median (Range)	72 (+/- 23)	nos	PCS
Novak et al., 2011(112)	Pain Catastrophizing	Mean (SD)	16 (15)	nos	PCS
Novak et al., 2012(134)	Pain Catastrophizing	Mean (SD)	15 (14)	nos	PCS
Roh et al., 2014(77)	Pain Catastrophizing	Mean (SD)	22 (9)	nos	PCS
Roh et al., 2015(117)	Pain Catastrophizing	Mean (SD)	23 (8)	nos	PCS
Vranceanu et al., 2014(68)	Pain Catastrophizing	Mean (SD)	Time 1, 19.1 (8.7); Time 2, 18.5 (9.0)	nos	PCS
Doring et al., 2014(113)	Pain Interference	Mean (SD) Range	57 (8.1) 39-70	nos	PROMIS PI
Janssen et al., 2014(84)	Pain Interference	Median (IQR) Range	55 (50-60) 39-75	nos	PROMIS PI
Jayakumar et al., 2015(111)	Pain Interference	Mean (SD) Range	52 (10) 39-84	nos	PROMIS PI
Kortlever et al., 2015(131)	Pain Interference	Median (IQR) Range	56 (51-62) 39-75	nos	PROMIS PI
Nota et al., 2016(96)	Pain Interference	Mean (SD)	55 (8.8)	nos	PROMIS PI
Peters et al., 2016(135)	Pain Interference	Mean (SD) Range	55 (8.1) 39-84	nos	PROMIS PI
Bot et al., 2014(119)	Pain Self-Efficacy	Mean (SD) Range	Cohort,54 (8.3) 11-60; Complete,55 (6.7) 35-60; Incomplete,49 (13) 11-60	nos	PSEQ
Bot et al., 2014(119)	Pain Self-Efficacy	Mean (SD) Range	Baseline, 50 (11) 13-60; Final 55 (8.7) 17-60	nos	PSEQ
Doring et al., 2014(113)	Pain Self-Efficacy	Mean (SD) Range	9.5 (3.0) 0-12	nos	PSEQ-2
Gruber 2014(129)	Pain Self-Efficacy	Mean (SD) Range	44 (15) 4-60	nos	PSEQ
Hageman 2014(59)	Pain Self-Efficacy	Mean (SD) Range	50 (11) 6-60	nos	PSEQ
Kortlever et al., 2015(131)	Pain Self-Efficacy	Median (IQR) Range	51 (36-59) 4-60	nos	PSEQ

Table 5. Systematic Review I: Quality Assessment. (Modified 10-point checklist)

	I	II	III	IV	V	VI	VII	VIII	IX	X	
Study	Demographic data	Data Collection	Diagnosis	Cohorts	Participation / Response rate	Response	Results	Statistics	Consent	Participant Selection	Total Score
Bear-Lehman et al., 2011(120)	-	+	+	+	-	-	+	+	+	+	7
Bekkers et al., 2014(121)	+	+	+	-	+	-	+	+	+	+	8
Bot et al., 2011(122)	+	+	+	+	-	-	+	+	+	+	8
Bot et al., 2012(81)	+	+	+	-	+	+	+	+	+	+	9
Bot et al., 2014(119)	+	+	+	-	+	+	+	+	-	+	8
Bot et al., 2014(119)	+	+	+	+	+	+	+	+	+	+	10
Cederlund et al., 2010(124)	+	+	-	+	+	-	+	+	+	+	8
Chan et al., 2009(125)	+	+	-	-	+	+	+	+	+	+	8
Constand et al., 2014(126)	+	+	+	-	-	-	+	+	+	+	7
Das De et al., 2013(127)	+	+	+	+	+	-	+	+	+	+	9
Dogu et al., 2014(104)	+	+	-	-	+	-	+	+	+	+	7
Doring et al., 2014(113)	+	+	-	-	+	-	+	+	+	+	7
Farzad et al., 2015(75)	+	+	+	-	-	-	+	+	+	+	7
Golkari et al., 2015(128)	+	+	+	+	+	-	+	+	+	+	9
Gong et al., 2011(105)	+	+	+	+	+	-	+	+	-	+	8
Gruber et al., 2014(129)	+	+	+	-	-	-	+	+	-	+	6
Hageman et al., 2014(59)	+	+	+	-	+	-	+	+	+	+	8
Helmerhorst et al., 2014(106)	-	+	-	-	+	-	+	+	+	+	6
Janssen et al., 2014(84)	+	+	-	-	-	-	+	+	+	+	6

Jayakumar et al., 2015(111)	+	+	+	+	+	-	+	+	+	+	9
Keogh et al., 2010(130)	+	+	+	+	+	-	+	+	+	+	9
Kortlever et al., 2015(131)	+	+	-	-	+	-	+	+	+	+	7
Mayland et al., 2015(132)	+	+	+	-	-	-	+	+	+	+	7
Niekel et al., 2009(116)	+	+	+	+	-	-	+	+	-	+	7
Nota et al., 2016(96)	+	+	+	+	+	-	+	+	+	+	9
Novak et al., 2010(133)	+	+	+	+	+	-	+	+	+	+	9
Novak et al., 2011(112)	+	+	+	+	+	-	+	+	+	+	9
Novak et al., 2012(134)	+	+	+	-	+	-	+	+	+	+	8
Peters et al., 2016(135)	+	+	+	+	-	-	+	+	+	+	8
Prugh et al., 2012(136)	+	+	+	-	+	-	+	-	-	+	6
Richards et al., 2011(107)	+	+	+	-	-	-	+	+	-	+	6
Ring et al., 2006ring(137)	+	+	+	+	+	-	+	+	+	-	8
Roh et al., 2014(139)	+	+	+	+	+	-	+	+	+	+	9
Roh et al., 2015(117)	+	+	+	-	+	-	+	+	+	+	9
Ross et al., 2015(103)	-	+	+	-	+	-	+	+	+	+	7
Shields et al., 2015(118)	-	-	+	+	+	-	+	+	-	+	6
Symonette et al., 2013(114)	+	+	+	-	-	-	+	+	+	+	7
Vranceanu et al., 2014(140)	+	+	-	+	+	-	+	+	+	+	8
Vranceanu et al., 2015(138)	+	+	-	+	+	-	+	+	+	+	8
Williams et al., 2009(141)	+	+	+	+	+	-	+	+	+	+	9
Yeoh et al., 2016(109)	+	+	+	-	+	-	+	+	-	+	7

Table 6. Systematic Review I: Strength of evidence for prognostic factors and their association with greater disability (a. by individual PRO measures. b. by measures combined)

a. By individual PRO measures of disability

Group	Prognostic Factor	Outcome (Time point*)	Cohorts (n)	Level of Evidence
Demographic /	Sex	DASH	4	Strong
Other variables	Sex	QuickDASH	3	Moderate
	Sex	PROMIS UE PF CAT	2	Moderate
	Sex	PROMIS PF CAT	1	Weak
	Age at injury	DASH	3	Strong
	Age at injury	QuickDASH	2	Moderate
	Age at injury	QuickDASH (F/U)	1	Inconclusive
	Age at injury	MHQ	2	Moderate
	Age at injury	PROMIS PF CAT	1	Inconclusive
	Age at F/U	DASH	1	Weak
	Injury to enrolment (d)	DASH	1	Weak
	Injury to enrolment (d)	QuickDASH	1	Weak
	Injury to enrolment (d)	PRWE	1	Weak
	Injury to final evaluation (d)	QuickDASH	1	Weak
	Injury mechanism	QuickDASH	1	Weak
	External Fixation	QuickDASH	1	Weak
	Sought treatment prior	QuickDASH	1	Inconclusive
	Additional procedures required	QuickDASH	1	Weak
	F/U patient	QuickDASH	1	Weak
	New patient	QuickDASH	1	Weak
	Private insurance	SF-12 PCS	1	Inconclusive

b. By PRO measures of disability combined

Group	Prognostic Factor	Cohorts (n)	Level of Evidence
Demographic /	Sex	10	Strong
Other variables	Age at injury	9	Strong
	Injury to enrolment (d)	3	Strong
	Age at F/U	1	Weak
	Injury to final evaluation (d)	1	Weak
	Injury mechanism	1	Weak
	External Fixation	1	Weak
	Additional procedures required	1	Weak
	F/U patient	1	Weak
	New patient	1	Weak
	Sought treatment prior	1	Inconclusive
	Private insurance	1	Inconclusive
	Clinician-patient alliance	1	Inconclusive
	Clinician-patient dialogue	1	Inconclusive
	PAM (Enrollment)	1	Inconclusive
	PAM (F/U)	1	Inconclusive
Impairment	Diagnosis	7	Strong
	Range of motion	2	Strong
	Grip strength	1	Weak
	Anatomical arc	1	Weak

	Clinician-patient alliance	PRWE (Baseline)	1	Inconclusive		Ipsilateral injury	1	Weak
	Clinician-patient dialogue	PRWE (F/U)	1	Inconclusive		BMI	1	Weak
	PAM (Enrollment)	QuickDASH (Enrollment)	1	Inconclusive		HISS	1	Weak
	PAM (Enrollment)	QuickDASH (F/U)	1	Inconclusive		AIS	1	Weak
	PAM (F/U)	QuickDASH (F/U)	1	Inconclusive		Multiple injuries	1	Weak
	PAM (F/U)	QuickDASH (Change)	1	Inconclusive		CCI	1	Inconclusive
						AMA Impairment Scale	1	Inconclusive
Impairment	Diagnosis	DASH	3	Strong	Psychological	PCS	13	Strong
	Diagnosis	QuickDASH	1	Weak		CES-D	12	Strong
	Diagnosis	MHQ	1	Weak		PSEQ	8	Strong
	Diagnosis	PRWE	1	Weak		PROMIS PI CAT	7	Strong
	Diagnosis	SST	1	Inconclusive		PASS-20	5	Strong
	Range of motion	DASH	2	Strong		PASS-40	4	Strong
	Grip strength	DASH	1	Weak		PROMIS Depression CAT	4	Strong
	Anatomical arc	DASH	1	Weak		PHQ-9	2	Strong
	Ipsilateral injury	DASH	1	Weak		PHQ-2	6	Moderate
	AMA Impairment Scale	DASH	1	Inconclusive		SOC	3	Moderate
	AMA Impairment Scale	MHQ	1	Inconclusive		BDI	2	Moderate
	BMI	PROMIS UE PF CAT	1	Weak		Psychiatric history	3	Weak
	HISS	QuickDASH	1	Weak		DASS	1	Weak
	AIS	SMFA	1	Weak		HADS	1	Weak
	CCI	SF-12 PCS	1	Inconclusive		ASI	1	Weak
	CCI	SF-12 Total	1	Inconclusive		IIRS	1	Weak
	Multiple injuries	SMFA	1	Weak		NPTQ	1	Weak

Psychological	ASI	PRWE	1	Weak
	BDI	DASH	1	Inconclusive
	BDI	SF-36 PCS	1	Inconclusive
	CES-D	DASH	6	Strong
	CES-D	DASH (Change)	1	Inconclusive
	CES-D	QuickDASH	2	Weak
	CES-D	SF-36 PCS	1	Inconclusive
	CES-D	SMFA	2	Moderate
	DASS	PRWE	1	Weak
	DASS-21 Anxiety	QuickDASH	1	Inconclusive
	DASS-21 Depression	QuickDASH	1	Inconclusive
	DASS-21 Stress	QuickDASH	1	Inconclusive
	FABQ	QuickDASH (Enrollment)	1	Inconclusive
	HADS	DASH	1	Weak
	IES-R	QuickDASH	2	Inconclusive
	IIRS	DASH	1	Weak
	NPTQ	QuickDASH	1	Weak
	PACES	PROMIS PF CAT	1	Weak
	PASS-20	MHQ	1	Weak
	PASS-20	PRWE	1	Weak
	PASS-20	QuickDASH	2	Strong
	PASS-20	SMFA	1	Weak
	PASS-40	DASH	3	Strong
	PACES	1	Weak	
	PASS-20 Cognitive anxiety	1	Weak	
	PASS-20 FOP	1	Weak	
	PASS-20 PEB	1	Weak	
	PASS-20 Physical anxiety	1	Weak	
	PCL-C	1	Weak	
	PDI	1	Weak	
	TSK	1	Weak	
	PROMIS PIIP CAT	1	Weak	
	PROMIS SD CAT	1	Weak	
	SF-36 MCS	1	Weak	
	SHAI-5	1	Weak	
	IES-R	2	Inconclusive	
	PCS-M	2	Inconclusive	
	PCS-R	2	Inconclusive	
	PROMIS PB CAT	2	Inconclusive	
	TSK FOI	2	Inconclusive	
	TSK FOP	2	Inconclusive	
	TSK SOMF	2	Inconclusive	
	PIPS	1	Inconclusive	
	DASS-21 Anxiety	1	Inconclusive	
	DASS-21 Depression	1	Inconclusive	
	DASS-21 Stress	1	Inconclusive	
	FABQ	1	Inconclusive	

PASS-40	QuickDASH	1	Inconclusive
PASS-40 Cognitive anxiety	DASH	1	Weak
PASS-40 FOP	DASH	1	Weak
PASS-40 PEB	DASH	1	Weak
PASS-40 Physical anxiety	DASH	1	Weak
PCL-C	DASH	1	Weak
PCS	DASH	6	Strong
PCS	QuickDASH	3	Moderate
PCS	MHQ	1	Weak
PCS	PRWE	1	Weak
PCS	SMFA	1	Weak
PCS-M	QuickDASH (Enrollment)	1	Inconclusive
PCS-M	QuickDASH (Change)	1	Inconclusive
PCS-R	QuickDASH (Enrollment)	1	Inconclusive
PCS-R	QuickDASH (Change)	1	Inconclusive
PDI	DASH	1	Weak
PHQ-2	QuickDASH	2	Moderate
PHQ-2	PROMIS UE PF CAT	1	Inconclusive
PHQ-2	QuickDASH (Enrollment)	1	Inconclusive
PHQ-2	QuickDASH (F/U)	1	Inconclusive
PHQ-2	QuickDASH (Change)	1	Inconclusive
PHQ-9	QuickDASH	2	Strong
PIPS	QuickDASH	1	Inconclusive
PROMIS Depression CAT	QuickDASH	2	Moderate
	PSEQ-2	1	Inconclusive
	PSS	1	Inconclusive
	RRAQ	1	Inconclusive
	SCS	1	Inconclusive
	SPTSS	1	Inconclusive
	STAI - Trait anxiety	1	Inconclusive
	STAI - Strait anxiety	1	Inconclusive
Social	Work status	7	Strong
	Education	6	Strong
	Separated / Divorced	2	Strong
	Workers compensation	2	Strong
	Marital status	3	Moderate
	PROMIS ES CAT	1	Weak
	PROMIS IS CAT	1	Weak
	MOS SSS	2	Inconclusive
	Work status retired	1	Inconclusive
	Work status unemployed	1	Inconclusive
Symptoms	Other pain conditions	5	Strong
	Pain (VAS)	3	Strong
	CISS	2	Strong
	Pain (Ordinal NRS)	5	Moderate
	Pain (DASH-related Qs)	2	Moderate

PROMIS Depression CAT	PROMIS PF CAT	1	Inconclusive
PROMIS Depression CAT	PROMIS UE PF CAT	1	Weak
PROMIS PB CAT	QuickDASH	1	Inconclusive
PROMIS PB CAT	PROMIS PF CAT	1	Inconclusive
PROMIS PI CAT	QuickDASH	5	Strong
PROMIS PI CAT	PROMIS UE PF CAT	2	Moderate
PROMIS PI CAT	PROMIS PF CAT	2	Moderate
PROMIS PIIP CAT	QuickDASH	1	Weak
PROMIS SD CAT	PROMIS UE PF CAT	1	Weak
PSEQ	QuickDASH	5	Strong
PSEQ	QuickDASH (Enrollment)	1	Inconclusive
PSEQ	QuickDASH (F/U)	1	Inconclusive
PSEQ	QuickDASH (Change)	1	Inconclusive
PSEQ-2	PROMIS UE PF CAT	1	Inconclusive
PSS	QuickDASH	1	Inconclusive
Psychiatric history	DASH	1	Inconclusive
Psychiatric history	SST	1	Inconclusive
Psychiatric history	SF-12	1	Inconclusive
RRAQ	QuickDASH	1	Inconclusive
SCS	QuickDASH	1	Inconclusive
SF-36 MCS	DASH	1	Weak
SHAI-5	QuickDASH	1	Weak
SOC	DASH	1	Weak
SOC	EQ-5D VAS	1	Weak
SF-MPQ	1	Weak	
PRWE Pain	1	Weak	
MPQ	1	Weak	
Opioid pain medication	1	Weak	

	SOC	SF-36 PCS	1	Weak
	SPTSS	QuickDASH	1	Inconclusive
	STAI - Trait anxiety	QuickDASH	1	Inconclusive
	STAI - Strait anxiety	QuickDASH	1	Inconclusive
	TSK	DASH	1	Weak
	TSK FOI	QuickDASH (Enrollment)	1	Inconclusive
	TSK FOI	QuickDASH (Change)	1	Inconclusive
	TSK FOP	QuickDASH (Enrollment)	1	Inconclusive
	TSK FOP	QuickDASH (Change)	1	Inconclusive
	TSK SOMF	QuickDASH (Enrollment)	1	Inconclusive
	TSK SOMF	QuickDASH (Change)	1	Inconclusive
Social	Education	QuickDASH (F/U)	1	Inconclusive
	Education	QuickDASH	2	Inconclusive
	Education	PROMIS UE PF CAT	2	Moderate
	Education	PROMIS PF CAT	1	Weak
	Marital status	QuickDASH	2	Moderate
	Marital status	PROMIS PF CAT	1	Inconclusive
	MOS SSS ES / IS	PRWE	1	Inconclusive
	MOS SSS Total	PRWE	1	Inconclusive
	PROMIS ES CAT	QuickDASH	1	Weak
	PROMIS IS CAT	QuickDASH	1	Weak
	Separated / Divorced	PROMIS PF CAT	1	Weak
	Separated / Divorced	QuickDASH	1	Weak

	Work status	DASH	2	Strong
	Work status	QuickDASH	3	Moderate
	Work status	PROMIS PF CAT	1	Inconclusive
	Work status	PROMIS UE PF CAT	1	Weak
	Work status retired	PROMIS UE PF CAT	1	Inconclusive
	Work status unemployed	PROMIS UE PF CAT	1	Inconclusive
	Workers compensation	QuickDASH (F/U)	1	Inconclusive
	Workers compensation	DASH	1	Weak
Symptoms	Pain (Ordinal NRS)	DASH	1	Weak
	Pain (Ordinal NRS)	QuickDASH	2	Weak
	Pain (Ordinal NRS)	PROMIS UE PF CAT	1	Inconclusive
	Pain (Ordinal NRS)	PROMIS PF CAT	1	Inconclusive
	Pain (VAS)	DASH	3	Strong
	Pain (DASH-related Qs)	DASH	1	Weak
	Pain (DASH-related Qs)	QuickDASH	1	Inconclusive
	Other pain conditions	QuickDASH	2	Moderate
	Other pain conditions	PROMIS PF CAT	2	Moderate
	Other pain conditions	PROMIS UE PF CAT	1	Weak
	SF-MPQ	PRWE	1	Weak
	PRWE Pain	PRWE	1	Weak
	CISS	DASH	2	Strong
	MPQ	DASH	1	Weak
	Opioid pain medication	SMFA	1	Weak

2.2.5 Discussion

Based on the primary objective, psychological factors, particularly depression, pain catastrophizing, pain self-efficacy and pain interference, along with social factors, including work, education and marital status, and symptoms i.e. pain intensity, were found to be strong and consistent correlates of the magnitude of disability. Impairment-related factors (e.g. diagnosis, range of motion) were comparatively weak. Although psychological factors appeared to impact disability prospectively, even after controlling for impairment, numerous studies indicated that a large amount of variance in disability remained unexplained. Other aspects within the environmental and personal factors component of the WHO ICF framework could account for this unknown (Figure 4b) (26). 'External support from providers', 'relationships with HCPs', and 'access to services' are qualifiers within the WHO ICF that could be reflected by patient experience and measured by PREMs. In the same way, 'behavioral styles' and 'psychological assets' could be represented by patient activation (i.e. the propensity to engage in adaptive health behaviors) and measured by PAMs. These findings provided valuable guidance in selecting PRO measures for the experimental studies in this thesis.

In terms of the secondary objective, frameworks such as the WHO ICF have undoubtedly achieved positive strides toward a common language for disability. However, based on the terminological irregularities and misuse of outcome measures identified in some studies within this review, further approaches may be required to improve awareness of the disability concept amongst orthopaedic surgeons and guide proper use of PRO measures (17)(23). This thesis anchors the concept of the disability to the WHO ICF framework and in practical terms, considers disability as the limitations faced by individuals in performing meaningful physical functions within environmental and social contexts. The concept is measured using generic and region-specific PRO measures of physical functioning at the level of tasks, broader acts and roles (21). The term 'function' itself is applied extremely liberally, and is all too often represented by a range of measures precluding a clear idea of what concept is actually being measured.

The disability concept is discussed further in Chapter 4 which investigates the relationship between different PRO measures of disability and Chapter 9 which takes a closer look at the language of disability and future research opportunities in this area.

A variety of other important insights were gained from this review. From the outcome measurement perspective, it is recognised that measures of disability and its influential factors often correlate with one another, with some commonality in the underlying constructs being measured (113)(128). For instance, measures of coping response to pain (e.g. PROMIS PI CAT, PCS, PIPS and PSEQ) demonstrate a large degree of shared variance. This highlights the potential for measurement redundancy and resolution of a minimum essential outcome measurement set that is precise, efficient and user-friendly.

A further insight is the importance of considering disability on a continuum rather than a discrete entity delineating the healthy from the disabled (23)(26). This continuum is influenced by the cognitive, emotional, and behavioral responses to disease or injury over time (125). Thus, from the experimental perspective, it is important to account for the phase of recovery when assessing disability and its influential factors after trauma (105)(128). For instance, recovery-related anxiety has been shown to have a stronger correlation with disability in the acute setting over general anxiety which has more of an influence later on (132).

If the most influential and predictive factors of disability following fractures of the upper extremity are psychosocial and symptomatic factors, these could be integrated into the early management of these injuries to improve long-term health related outcomes (104)(106)(108). With this in mind, large scale, longitudinal research may provide evidence for mapping the recovery trajectory, defining methods of screening patients and triggering non-surgical, non-pharmacological interventions, such as cognitive behavioral therapy (CBT) (77)(138).

a. Limitations

Firstly, caution should be expressed when drawing conclusions from such broad and heterogeneous datasets. Two thirds of studies involved patient populations with multiple non-traumatic and traumatic conditions. Cultural and societal differences also contribute to this issue and can influence the generalisability of findings. Secondly, from the measurement perspective, there are complexities around interpretation of findings from a range of PRO measures that assess various health domains. This is further complicated by PRO measures that cross domains e.g. pain interference incorporates pain and disability, in contrast to those measuring single constructs e.g. depression. Further evaluation of the interactions between outcome measures may be required. Finally, a degree of intrinsic selection bias may exist based on our pre-defined search criteria leading to inadvertent exclusions. Given the lack of a gold standard in this field, a pragmatic approach was taken as an exhaustive set of investigations evaluating all possible factors influencing disability was difficult to achieve.

b. Conclusion

This systematic review aimed to define the influential factors of arm-specific disability after trauma to the upper extremity. Psychosocial factors and pain intensity were shown to have a predominant influence on the magnitude of disability after injury. Thus, specific psychosocial and symptomatic factors i.e. pain, could be considered early in the recovery process and factored into management strategies that could limit future disability. A further aim of this review was to identify any irregularities in the use of terminology and PRO measurements within these studies based on established definitions of disability. Numerous examples were identified in the study set highlighting the importance of efforts toward standardising terminology in this field. Defining terms using frameworks such as the WHO ICF may enhance visibility, promote interest in this type of clinical research and achieve a common language for disability when considering orthopaedic trauma.

2.3 Outcome Measurement of Disability after Orthopaedic Upper Extremity Trauma: Systematic Review II

2.3.1 Background

Outcome measurement in orthopaedics has rapidly evolved over recent decades since its origins in the 'end results' concept introduced by Codman in 1911 (142). As a consequence, this evolutionary process has resulted in a multitude of instruments including PRO measures that are designed to better reflect the subjective impact of health conditions from a patient's perspective (29)(31)(143). In health outcomes research, it is well recognised that PRO measures should be comprehensively evaluated for the populations assessed and not the instruments themselves (95). This systematic review aimed to review the widespread utilisation of these tools in clinical and research practice within the context of orthopaedic upper extremity trauma.

2.3.2 Objectives

The primary objective was to comprehensively identify outcomes measures designed for upper extremity conditions and determine the extent to which trauma conditions were included in their original development. The secondary objectives were to characterise these measures by anatomic region, condition type, instrument type, and assess the level of psychometric evaluation and methodological quality of the original studies. Potential challenges and solutions to measuring outcomes and disability within trauma populations are discussed.

2.3.3 Methods

a. Data Sources & Search Protocol

A broad search strategy was applied to PubMED (Medline 1946 to 2016), OVIDSP (EMBASE 1974 to 2016), CINAHL (2006 to 2016) and PsycInfo (1806 to 2016) databases on 1st October 2013 and repeated on 7th July 2016. Search terms for 'upper limb anatomy', 'outcome measurement' and demographic parameters were combined (Appendix 5). No restrictions were set in search fields and terms were identified in the title and/or abstract without limits. A contemporary atlas of outcome measures was also used (29). The review was reported according to the PRISMA statement (98) and registered (PROSPERO: CRD42016046243).

b. Study Selection

Studies involving adult patients experiencing any orthopedic upper extremity condition and any outcome measurement system were identified. Abstracts were screened to i) generate a full set of outcome measures and ii) track down the original publications introducing the measure. This included any relevant initial development and PRO measure validation work (Figure 5)(40). Measures focusing on clinimetric features alone (e.g. range of motion, patho-anatomical or radiological classifications), single health components (e.g. pain, depression, return to activity), broad diagnostic groups (e.g osteoarthritis) and health behavior scales, were excluded.

c. Data Extraction & Data Synthesis

Data was extracted, synthesised and recorded using an electronic database (Microsoft Excel v15.33). Outcome measures were classified by anatomic region, conditions, instrument characteristics, and initial level of psychometric evaluation. Measures combining patient-reported and clinician-based components were classified as the latter by default. If psychometric evaluation was not performed, measures were classified has having 'no initial empirical psychometric evaluation' or 'no initial empirical psychometric evaluation and no identifiable validation studies'.

d. Quality Assessment

Quality assessment was conducted using the Consensus-based standards for the selection of health measurement instruments (COSMIN) criteria and the accompanying 4-point rating system (144)(145). This provided a standardized rating for internal consistency, reliability, measurement error, content validity, structural validity, hypotheses testing and responsiveness. Only original studies involving patients with trauma conditions in their development *and* performing psychometric evaluation were assessed. Measurement properties were evaluated with the lowest rating within each category selected as the score for that section. Data was extracted for generalisability and interpretability but not rated.

e. Further analysis of PRO measurement health domains

The questions within PRO measurements were categorised by 'best fit' into one of five health domains accounting for any factor weightings required for scoring the measures. The proportion (%) of each domain was subsequently calculated. Synthesised data was reported using descriptive statistics and discordant judgements were resolved in consensus meetings led by the lead investigator [PJ].

2.3.4 Results

a. Selection of Studies and Study Characteristics

A total of 144 outcome measures focused on the upper extremity were identified (Figure 11) (Table 7). All tables in this systematic review are presented at the end of the results section. Just under 28% (n=40/144) involved traumatic conditions (e.g. distal radius fractures, traumatic shoulder instability, rotator cuff tears) in their original development.

Most of the outcome measurement set focused on wrist/hand (41%; n=59/144) and shoulder (35%; n=51/144) conditions (Figure 12). Almost 58% (n=83/144) included patients with trauma, either in combination with other conditions or alone (Figure 13). Instrument classification revealed the majority as clinician-based (53%; n=76/144) over PRO measures (47%; n=68/144), and most were condition-specific (56%; n=80/144) over region-specific (37%; n=54/144) or multi-region measures (7%; n=10/144). Just under 46% (n=66/144) had some form of initial psychometric evaluation and around 33% (n=48/144) had no initial empirical psychometric evaluation or any subsequent validation studies. Development of clinician-based measures appears to have declined over the last two decades, whilst numbers of psychometrically evaluated PRO measures have risen substantially since the mid-1990s (Figure 14). A period of peak activity in development of condition and region-specific measures is observed during this time (Figure 15). Notably, around 7% (n=10/144) of corresponding authors were contacted due to unclear or non-specified diagnoses in their articles.

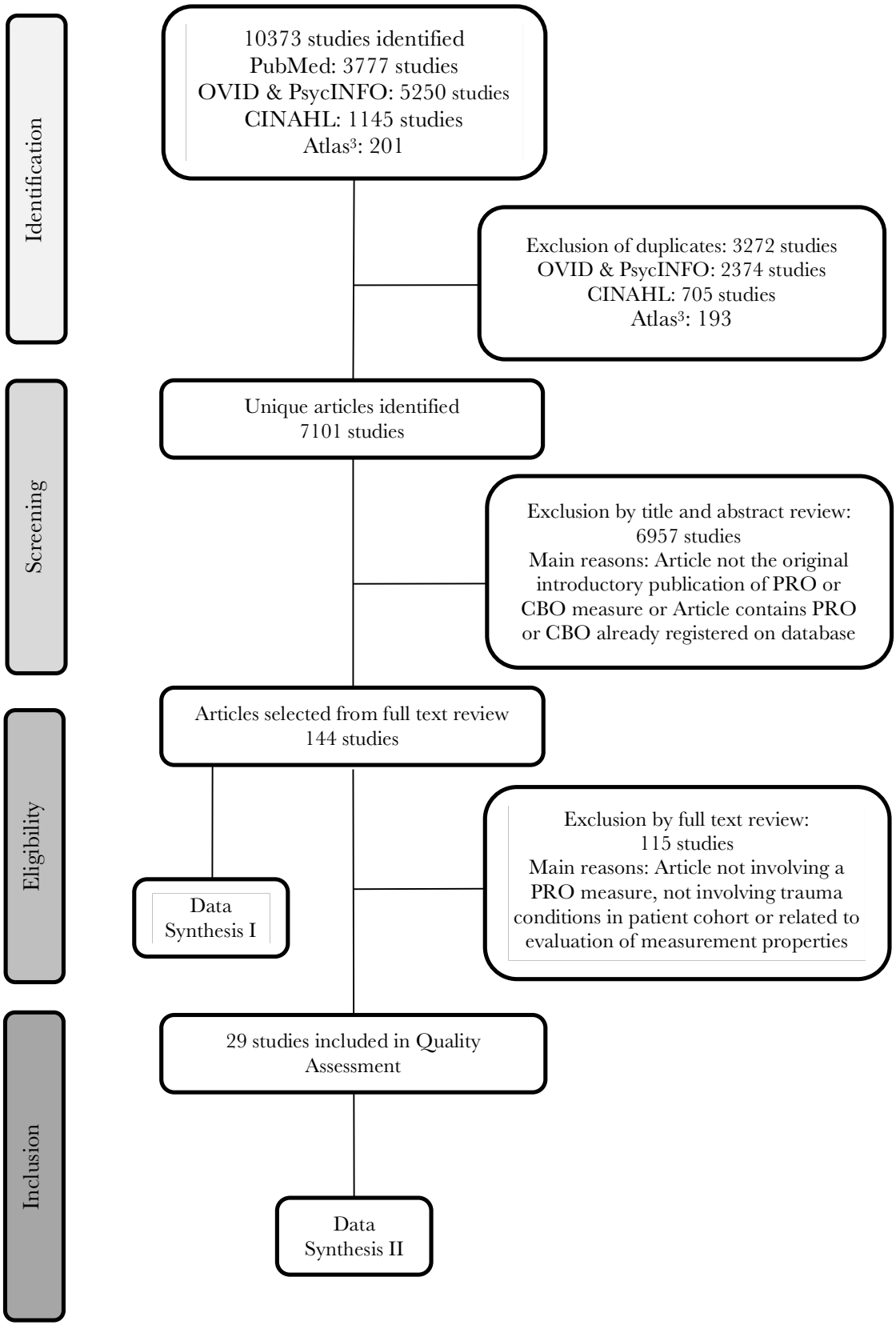


Figure 11. Systematic Review II: PRISMA Flow Chart.

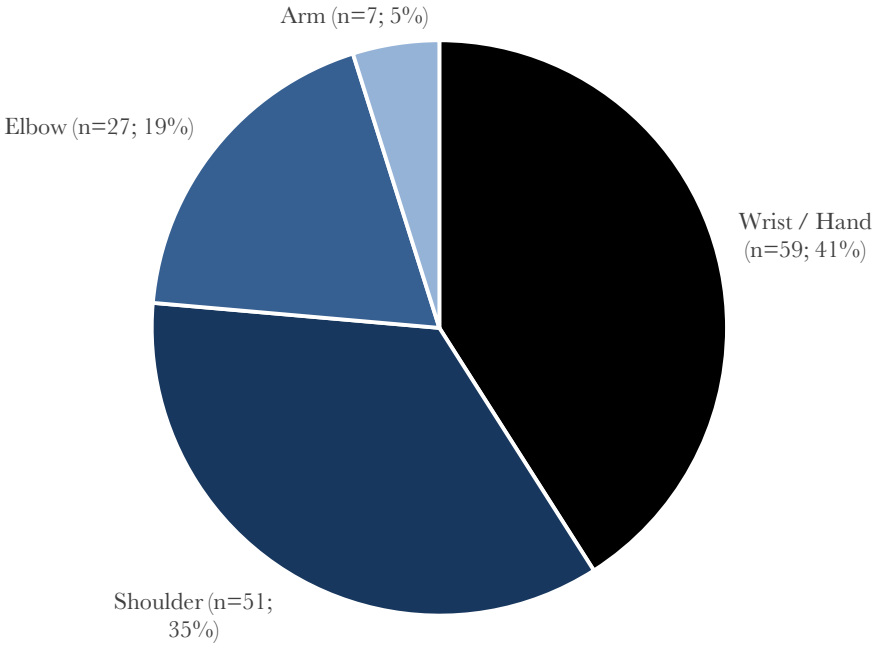


Figure 12. Outcome Measures for Upper Extremity Conditions classified by Anatomical Region

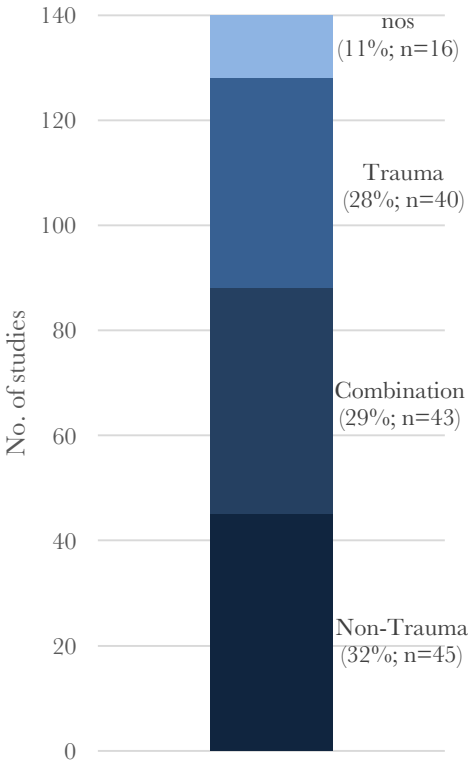


Figure 13. Outcome Measures for Upper Extremity Conditions classified by Clinical Conditions

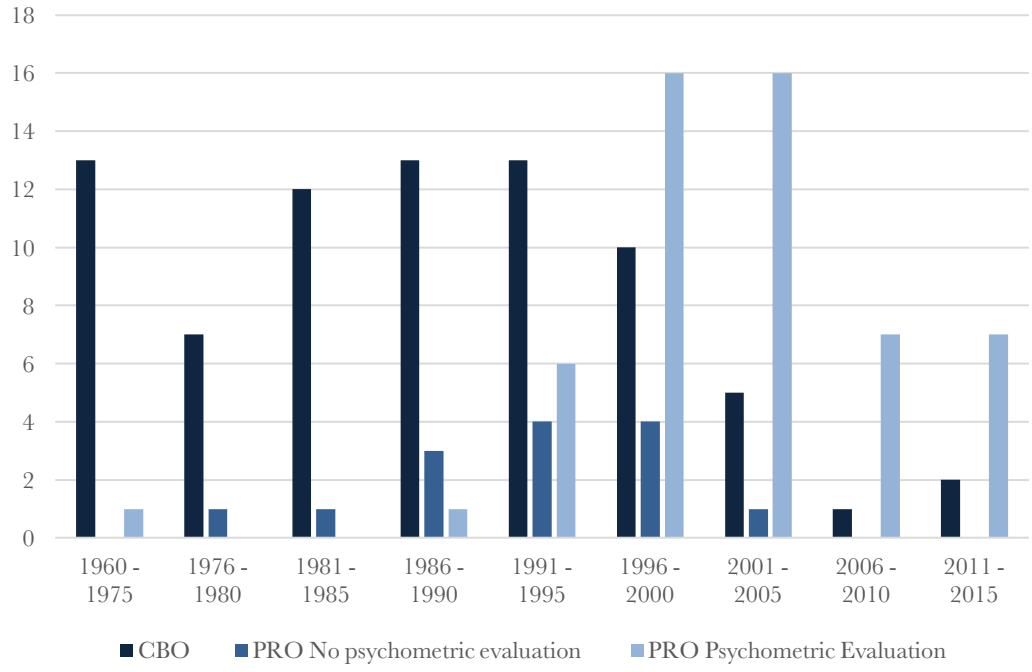


Figure 14. Trends in outcome measurement defined by clinician-based or PRO measurement and evidence of initial psychometric evaluation (1960 - 2017)

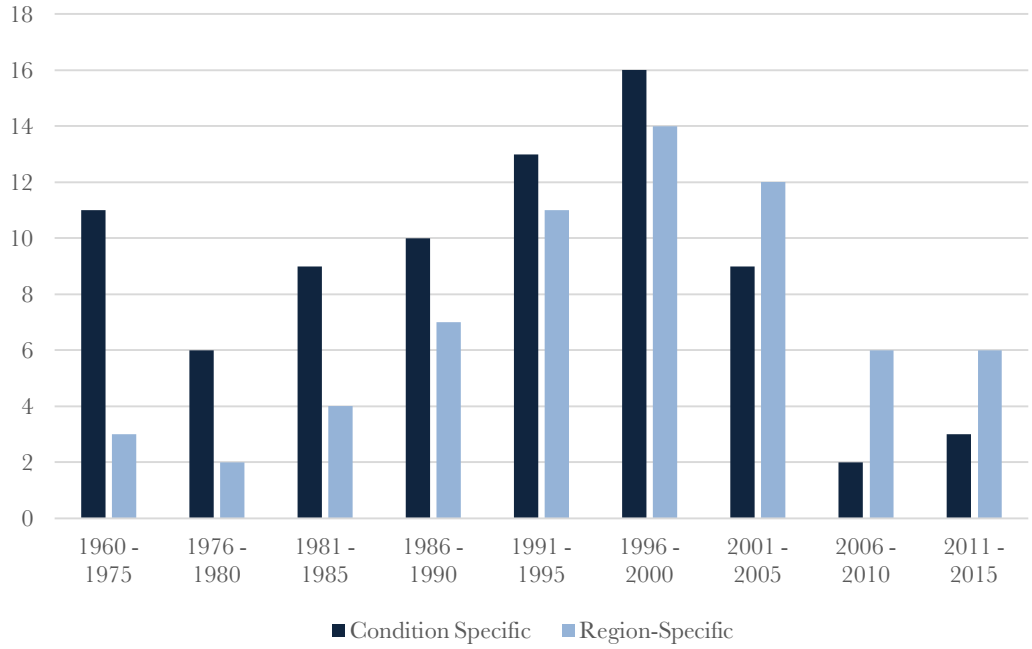


Figure 15. Trends in PRO measure by measurement type (1960 - 2017)

b. Methodological Quality

Quality assessment was conducted on the 29 original studies (20%, n=29/144) involving PRO measures, upper limb trauma patients *and* some form of psychometric evaluation (Table 8).

Based on the COSMIN rating system, test re-test reliability was assessed more frequently than internal consistency and measurement error, and ratings were classed as 'poor' to 'good' when conducted. Content (face) validity ratings were rated 'good' to 'excellent' for almost all measures. Construct validity assessed through testing of hypotheses were also given a 'good' to 'excellent' rating in two thirds of studies and 'poor' to 'fair' rating in the rest, whilst structural validity was rated 'poor' in 71% (n=17/24) when it was assessed. This was primarily due to few of the identified studies undertaking factor analysis or IRT analysis, which was a requisite for higher ratings. The lack of gold-standard measures in this field meant criterion validity was rarely assessed. Responsiveness was highly variable and although most studies allowed some interpretability through score distribution and change, few conducted analysis of floor-ceiling effects, minimal clinically important difference (MCID) or minimal detectable change (MDC). Generalisability assessment revealed low levels of reporting regarding patient consent, % of missing items and study limitations.

c. Additional Analysis

Tested items within these measures predominantly related to health domains of physical function and symptoms whilst representation of social (median 14%; range 3–35%), and psychological (median 14%; range 3–16.5%) factors was relatively low (Table 9).

Table 7. Systematic Review II: Outcome measures classified by conditions, type of instrument and characteristics of original psychometric evaluation

Region	Outcome Measure	Short Title	Clinical Conditions in Index Evaluation Study		Instrument Classification		Psychometric Evaluation	
			Condition Type	Conditions	Coverage	Type	Level	Evaluation
Arm	Disabilities of the Arm, Shoulder and Hand (1996)	DASH	Combo	Colles' fracture; Humerus fracture; Thumb CMCJ arthritis; CTS; Rotator cuff tendinopathy; Lateral epicondylitis; de Quervain's tenosynovitis; OA; RhA; Non-specific; Other	Multi-region	PRO	P	Staged psychometric evaluation
	Quick DASH (2005)	Quick-DASH	Combo	Colles' fracture; Humerus fracture; Thumb CMCJ arthritis; CTS; Rotator cuff tendinopathy; Lateral epicondylitis; de Quervain's tenosynovitis; OA; RhA; Non-specific; Other	Multi-region	PRO	P	Psychometric evaluation and validation vs DASH; VAS ability to function in daily activities, rating of problem, pain severity, ability to work.
	Upper Extremity Function Test (1965)	UEFT	Combo	Upper extremities with traumatic, neurological and arthritic impairments; amputations	Multi-region	PRO	P	Psychometric evaluation and validation vs hand activities of daily living
	Upper Extremity Functional Index (2001)	UEFI	nos	Upper extremity dysfunction nos	Multi-region	PRO	P	Psychometric evaluation and validation vs UEFS
	Upper Extremity Functional Limitation Scale (2001)	UEFLS	nos	Elderly women with difficulty performing upper extremity tasks	Multi-region	PRO	P	Psychometric evaluation and validation vs fingers to grasp or handle, lifting & carrying 10lbs, raising arms over head
	Upper Extremity Functional Scale (1997)	UEFS	Non-Trauma	Chronic work-related upper extremity disorders; CTS	Multi-region	PRO	P	Psychometric evaluation and validation vs work status; Physical findings (Grip. Pinch, Phalen's test); Duration of symptoms
	Upper Limb Functional Index (2006)	ULFI	Combo	Upper limb symptoms inc post-operative, acute post-fracture, ligament sprain patients nos	Multi-region	PRO	P	Psychometric evaluation and validation vs DASH, UEFS
Shoulder	American Shoulder and Elbow Surgeons Assessment (1994)	ASES-S	Combo	* Impingement syndrome; Instability / dislocation; RCT; Adhesive capsulitis; Hemiarthroplasty; Shoulder weakness; Humeral fracture; Rotator cuff and adhesive capsulitis; Status - post-surgery	Multi-region	* PRO	P	* Psychometric evaluation and validation vs UPenn shoulder score; SF-36
	Athletic Shoulder Outcome Scoring System (1993)		Trauma	Athletic shoulder injuries	Region-specific	CBO	NE; NV	
	Bostrom Shoulder Impairment Scale (1991)		Non-Trauma	RhA	Condition-specific	CBO	NE	
	Constant Murley Shoulder Score (1985)	CMS	Combo	Rotator cuff repair; Shoulder Arthroplasty; Adhesive capsulitis; PHF	Region-specific	CBO	NE	

Darrow Score for Acromio-clavicular Joint Separation (1980)		Trauma	Type III ACJ Separation	Condition-specific	PRO	NE; NV	
Flexi-level scale of Shoulder Function (2003)	FLEX-SF	nos	nos	Region-specific	PRO	P	Psychometric evaluation and validation vs ASES, SF-12
Harryman rotator cuff functional assessment (1991)		Non-Trauma	Chronic RCT	Condition-specific	PRO	NE; NV	
Hersovici shoulder scale (1992)		Trauma	Ipsilateral clavicle and scapular neck fractures	Condition-specific	CBO	NE; NV	
Hospital for Special Surgery Shoulder Assessment (1982)	HSS Shoulder Assessment	nos	Shoulder arthroplasty – aetiology nos	Region-specific	CBO	NE; NV	
Hospital for Special Surgery Shoulder Rating Score (1990)	HSS Shoulder Rating	Non-Trauma	Subacromial decompression for impingement; Partial / full thickness RCT	Region-specific	CBO	NE; NV	
Hospital of the University of Pennsylvania Shoulder Score (1994)		Non-Trauma	Open or arthroscopic acromioplasty; Chronic impingement syndrome	Condition-specific	CBO	NE; NV	
Imatani Acromioclavicular Separation Evaluation System (1975)		Trauma	Acute ACJ separation	Condition-specific	CBO	NE; NV	
Japanese Orthopaedic Association Shoulder Score (2004)		Combo	Shoulder stiffness; Primary idiopathic, traumatic (Proximal humerus, clavicle, glenoid fracture, contusion), prolonged immobilization (post-Colles fracture), diabetic patients	Region-specific	CBO	NE; NV	
Kerlan Jobe Orthopaedic Clinic Score (2010)	KJOC	Trauma	Athletic shoulder and elbow injury	Multi-region	PRO	P	Psychometric evaluation and validation vs DASH
Korean Shoulder Scoring System (2009)	KSS	Combo	Complete or partial RCT; Impingement syndrome; Rotator cuff tendinitis	Region-specific	CBO	P	Psychometric evaluation and validation vs UCLA; ASES; CMS; SF-36
McGinnis and Denton Rating Scale for Scapular Fractures (1989)		Trauma	Scapular fractures	Condition-specific	CBO	NE; NV	
Melbourne Instability Shoulder Scale (2005)	MISS	Combo	Shoulder instability; GHJ dislocation or subluxation	Condition-specific	PRO	P	Psychometric evaluation and validation vs SRQ; Patient subjective rating score

Modified Rowe Shoulder Score (2005)		Combo	Type II SLAP lesion	Condition-specific	CBO	NE	
Munich Shoulder Questionnaire (2012)	MSQ	Combo	ACJ / GHJ dislocation; OA; Pain / contusion; Biceps tendon tear; RCT; Impingement; Humerus bone cyst; Clavicle / Scapular / Humeral Fractures; Brachial plexus damage; Arthroplasty	Region-specific	PRO	P	Psychometric evaluation and validation vs CMS, SPADI, DASH
Neer Shoulder Score (1970)		Trauma	PHF	Condition-specific	CBO	NE; NV	
Nottingham Clavicle Score (2013)	NCS	Trauma	SCJ / ACJ injuries; Clavicle fractures	Condition-specific	PRO	P	Psychometric evaluation and validation vs CMS, OSS, Imatani, EQ5D
Oxford Instability Score (1999)	OIS	Combo	Shoulder instability	Condition-specific	PRO	P	Psychometric evaluation and validation vs CMS, Rowe, SF-36
Oxford Shoulder Score (1996)	OSS	Non-Trauma	Degenerative / inflammatory conditions; Impingement +/- RCT; Calcified rotator cuff deposits; Primary or secondary OA; inflammatory arthritis; Adhesive capsulitis	Region-specific	PRO	P	Psychometric evaluation and validation vs SF-36; HAQ; CMS
Penn Shoulder Score (2003)	PSS	Combo	Impingement; Tendonitis; RCT; Instability; Adhesive Capsulitis; PHF; ACJ / GHJ OA	Region-specific	PRO	P	Psychometric evaluation and validation vs ROM; Muscle Force
Post-Functional Rating for Long-Head Biceps Tendinitis (1989)		Non-Trauma	Primary bicipital tendinitis	Condition-specific	CBO	NE; NV	
Rockwood Score for Sternoclavicular Joint Arthritis (1997)		Non-Trauma	SCJ OA	Condition-specific	CBO	NE; NV	
Rotator Cuff Quality of Life Measure (2000)	RC-QOL	Combo	RCT (All causes)	Condition-specific	PRO	P	Psychometric evaluation and validation vs Functional Shoulder Elevation Test; SF36; ASES
Rowe Shoulder Score (1978)		Trauma	Shoulder dislocation; Bankart procedures for shoulder instability	Condition-specific	CBO	NE	
Shoulder Activity Level - Rating Scale (2005)		Combo	RCT; Shoulder pain; Instability; Impingement; Adhesive capsulitis; Other	Region-specific	PRO	P	Psychometric evaluation and validation vs SST; Age; Knee activity rating scale; Self reported shoulder activity
Shoulder Disability Questionnaire (Dutch) (2000)	SDQ-NL	Combo	Shoulder soft tissue disorders (all causes) – electrotherapy / US plus exercise therapy for RCT	Region-specific	PRO	P	Psychometric evaluation for responsiveness

Shoulder Disability Questionnaire (United Kingdom) (1994)	SDQ-UK	nos	Community and primary care subjects with Shoulder pain	Region-specific	PRO	P	Psychometric evaluation and validation vs ROM; Shoulder power
Shoulder Function Assessment Scale (1996)	SFAS	Non-Trauma	RhA	Condition-specific	CBO	P	Psychometric evaluation and validation vs VAS; subjective shoulder function; Objective shoulder function in 7 daily activities; Radiological shoulder destruction
Shoulder Function Index (2015)	SFInX	Trauma	PHF	Condition-specific	CBO	P	Psychometric evaluation and validation inc Rasch analysis
Shoulder Pain and Disability Index (1991)	SPADI	nos	Shoulder pain	Region-specific	PRO	P	Psychometric evaluation and validation vs ROM
Shoulder Rating Questionnaire (1994)	SRQ	Non-Trauma	Impingement syndrome; Glenohumeral instability; Complete RCT; GHJ OA; Adhesive capsulitis; ACJ OA	Region-specific	PRO	P	Psychometric evaluation and validation vs AIMS-2; Single Q assessing satisfaction in each domain
Shoulder Severity Index (1987)	SSI	Non-Trauma	Shoulder pain; Chronic shoulder disability nos	Region-specific	PRO	NE	
Simple Shoulder Test (1993)	SST	nos	nos	Region-specific	PRO	NE	
Single Assessment Numeric Evaluation Rating (1999)	SANE	Combo	Post-operative following shoulder dislocation; Chronic recurrent subluxations; ACJ separations	Region-specific	PRO	P	Psychometric evaluation and validation vs Rowe, ASES
Stanmore Percentage of Normal Shoulder Assessment (2012)	SPONSA	Combo	Shoulder OA / RhA; Revision arthroplasty; Subacromial impingement; Instability; RCT; Non-union of fracture; Adhesive capsulitis	Region-specific	PRO	P	Psychometric evaluation and validation vs CMS, OSS
Subjective Shoulder Rating Scale (1997)	SSRS	Combo	Anterior shoulder reconstructions; Subacromial decompressions open and arthropscopic; MUA	Region-specific	PRO	P	Psychometric evaluation and validation vs CMS; four point verbal rating scale
Subjective Shoulder Value (2007)	SSV	Combo	Rotator cuff repair; Shoulder Arthroplasty; Stabilisation for recurrent anterior instability	Region-specific	PRO	P	Psychometric evaluation and validation vs CMS
Swanson Shoulder Score (1989)		Combo	RhA; OA; Post-traumatic lesions	Region-specific	CBO	NE; NV	
Thorling Subjective Rating for Subacromial Decompression (1985)		Non-Trauma	Subacromial decompression (acromioplasty) for shoulder impingement	Condition-specific	CBO	NE; NV	

	UCLA End-Result Score (1986)		Combo	RCT	Condition-specific	CBO	NE; NV	
	UCLA Shoulder Score (1981)	UCLA Shoulder	Combo	OA; Osteonecrosis post-trauma; Pseudarthrosis post-trauma; RhA; Trauma	Region-specific	CBO	NE; NV	
	Walch-Duplay Shoulder Instability Score (1987)		Combo	Anterior shoulder instability	Condition-specific	CBO	NE	
	Watson Shoulder Score (1985)		Non-Trauma	Chronic RCT	Condition-specific	CBO	NE; NV	
	Western Ontario Osteoarthritis of the Shoulder Index (2001)	WOOS	Non-Trauma	Shoulder OA undergoing hemi-arthroplasty or total shoulder arthroplasty	Condition-specific	PRO	P	Psychometric evaluation and validation vs CMS; UCLA; ASES; SF-12; McGill pain,VAS; GROC; ROM
	Western Ontario Rotator Cuff Index (1998)	WORCI	Combo	RCT	Condition-specific	PRO	P	Psychometric evaluation and validation vs UCLA, SF-36, CMS, ASES, DASH, SIP, ROM
	Western Ontario Shoulder Instability Index (1998)	WOSI	Combo	Shoulder instability	Condition-specific	PRO	P	Psychometric evaluation and validation vs DASH, ASES, UCLA, Rowe, CMS, SF-12, Global change, ROM
	Wolfgang Criteria for Rating Results of Rotator Cuff Surgical Repair (1974)		Combo	RCT	Condition-specific	CBO	NE; NV	
Elbow	American Shoulder and Elbow Surgeons Assessment-Elbow (1999)	ASES-E	nos	nos	Multi-region	CBO	NE	
	Bishop Rating System (1989)		Combo	Cubital tunnel syndrome - Anterior intermuscular transfer of ulnar nerve	Condition-specific	CBO	NE; NV	
	Broberg and Morrey Elbow Scale (1986)	BMS	Trauma	Radial head fracture; Elbow dislocation; Ulnar fracture	Region-specific	CBO	NE; NV	
	Conway Scoring System (1992)		Trauma	Medial instability (ulnar collateral ligament reconstruction)	Condition-specific	CBO	NE; NV	
	Elbow Function Scale (1984)		Trauma	Olecranon fracture – displaced – tension band wiring	Condition-specific	CBO	NE; NV	

Elbow Functional Assessment Scale (1999)	EFAS	Non-Trauma	RhA	Condition-specific	CBO	P	Psychometric evaluation and validation vs HSS assessment scale; HSS Total elbow scoring system; MEPI
Elbow Self-Assessment Score (2015)	ESAS	Combo	Fracture distal humerus, olecranon, proximal forearm, radial head; Dislocation; Bursitis; Distal biceps rupture; TER; OA; OC; EPS; LCL lesion, reconstruction; Epicondylitis; Nerve lesion; UTS	Region-specific	CBO	P	Psychometric testing and validation vs BMS, PREE, MEPS, OES, QuickDASH
Ewald Elbow Scale (1975)		nos	nos	Region-specific	CBO	NE	
Flynn Criteria (1974)		Trauma	Supracondylar fracture (displaced) - Pinning	Condition-specific	CBO	NE	
Hospital for Special Surgery Assessment Scale (1980)	HSS Assessment Scale	Combo	Total elbow replacement; RhA; Post-traumatic OA; Juvenile RhA	Region-specific	CBO	NE	
Hospital for Special Surgery Total Elbow Scoring System (1990)	HSS2 Total Elbow Scoring System	Combo	Failed total elbow arthroplasty – infection, periprosthetic fracture, recurrent dislocation	Region-specific	PRO	NE	
Japanese Orthopaedic Association Elbow Evaluation Score (1992)		nos	Elbow conditions nos	Region-specific	PRO	NE; NV	
Jupiter Functional Rating (1985)		Trauma	Distal Humerus fractures – intercondylar fractures	Condition-specific	PRO	NE; NV	
Khalfayan Score (1992)		Trauma	Radial head fractures	Condition-specific	CBO	NE; NV	
Liverpool Elbow Score (2004)	LES	Combo	RhA; OA; post-traumatic OA; TER inc revisions; Tennis, Golfer's elbow; Loose body; OCD; Posterior impingement; synovial chondromatosis; Ulnar nerve problems	Region-specific	CBO	P	Psychometric evaluation and validation vs DASH, NHP, SF-12
Mayo Elbow Performance Index and modifications (1992)	MEPI	Combo	RhA – semi-constrained elbow arthroplasty; Elbow fracture-dislocation; Coronoid process fracture	Region-specific	CBO	NE	
Modified Bishop Scale (1997)		Combo	Ulnar nerve decompression – transposition – Z lengthening flexor pronator mass	Condition-specific	CBO	NE; NV	
Neviaser Criteria (1977)		Trauma	Elbow dislocation	Condition-specific	CBO	NE	

Wrist/Hand	Nirschl Tennis Elbow Scoring System (1992)		Non-Trauma	Tennis elbow	Condition-specific	CBO	NE	
	Oxford Elbow Score (2008)	OES	Combo	Primary OA; secondary OA; RhA; post-traumatic Stiffness; epicondylitis	Region-specific	PRO	P	Psychometric evaluation and validation vs MEPS, Score, DASH, SF-36
	Patient Rated Elbow Evaluation (2001)	PREE	Combo	Radial head, Humeral, Olecranon fracture; TER; RHR; OA; RhA; Biceps repair; Contracture; Bursitis; Implant complications; Inflammation; Chronic pain; Loose body; Lateral epicondylitis	Region-specific	PRO	P	Psychometric evaluation and validation vs ASES; SF-36; DASH
	Patient Rated Tennis Elbow Evaluation (1999)	PRTEE	Non-Trauma	Lateral epicondylitis	Condition-specific	PRO	P	Psychometric evaluation and validation vs pain-free grip strength
	Patient Rated Ulnar Nerve Evaluation (2013)	PRUNE	Non-Trauma	Ulnar neuropathy – Ulnar nerve decompression	Condition-specific	PRO	P	Psychometric evaluation and validation vs SF-36; Bishop Scale
	Pritchard Scoring System (1977)		nos	Total elbow arthroplasty	Region-specific	CBO	NE	
	Roles and Maudsley Outcome Score (1972)		Combo	Radial tunnel syndrome – Resistant tennis elbow	Condition-specific	CBO	NE; NV	
	Timmerman and Andrews Score (1994)		Trauma	Post traumatic elbow pain and stiffness; elbow injury in throwing athletes	Region-specific	CBO	NE; NV	
	Verhaar Tennis Elbow Scoring System (1993)		Non-Trauma	Tennis elbow	Condition-specific	CBO	NE	
	6-item Carpal Tunnel Syndrome Symptom Scale (2009)		Non-Trauma	CTS	Condition-specific	PRO	P	Psychometric evaluation and validation vs QuickDASH; 11-item CTS Symptom Severity Scale
	ABILHAND Manual Ability Measure (1998)	ABILHAND	Non-Trauma	RhA – Wrist arthrodesis	Condition-specific	PRO	P	Psychometric evaluation and validation inc Rasch analysis
	Alderson-McGall Hand Function Questionnaire (1999)	AMHFQ	Non-Trauma	CTS	Condition-specific	PRO	P	Psychometric evaluation and validation vs VAS for pain & function; Grip and pinch strength; Static and dynamic 2pd; Valpar ROM
	Arab Hand Function Index (2004)	AHFI	Non-Trauma	RhA	Condition-specific	PRO	P	Psychometric evaluation and validation vs Revel's functional index; Lee's functional index

Arthritis Hand Function Test (1991)	AHFT	Non-Trauma	RhA	Condition-specific	CBO	P	Psychometric evaluation and validation vs Jebsen hand function test; AIMS
Australian/Canadian Osteoarthritis Hand Index (2002)	AUSCAN	Non-Trauma	OA	Condition-specific	PRO	NE	
Boston Carpal Tunnel Questionnaire (1993)	BCTQ	Non-Trauma	CTS	Condition-specific	PRO	P	Psychometric evaluation and validation vs Grip and pinch strength; 2pd; Semmes-Weinstein monofilament test
Buck-Gramcko and Lohman Evaluation for Total Wrist Function (1985)		nos	Compression wrist arthrodesis	Region-specific	CBO	NE; NV	
Castaing Score (1964)		Trauma	DRF	Condition-specific	CBO	NE; NV	
Clawson Functional Index (1971)		Non-Trauma	RhA	Condition-specific	CBO	NE; NV	
Colville Quality of Life Hand Questionnaire (1999)		Non-Trauma	OA – trapeziectomy; RhA – Swanson's MCPJ arthroplasty	Region-specific	PRO	NE; NV	
Crawford Classification (1984)		Trauma	Mallet finger	Condition-specific	CBO	NE	
Fernandez Point-Score System (1988)		Trauma	DRF – malunion – Radial osteotomy / Bowers arthroplasty	Condition-specific	CBO	NE; NV	
Fernandez Scale (1982)		Trauma	DRF: Post-traumatic correction wrist deformity inc osteotomy, bone grafting, internal fixation	Condition-specific	CBO	NE; NV	
Forearm Symptom Severity Scale (1998)		Trauma	DRF	Condition-specific	PRO	NE; NV	
Functional Index (1984)		Trauma	DRF	Condition-specific	CBO	P	Psychometric evaluation and validation vs Gartland-Werley Scoring system; Patient's & investigator's subjective characterisation of function'
Functional Index for Arthropathies of the Hand (1995)	FIHOA	Non-Trauma	Hand OA – Digital or trapeziometacarpal OA – inactive hand OA	Condition-specific	PRO	P	Psychometric evaluation and validation vs pain severity

Gartland and Werley Scoring System (1951)		Trauma	DRF	Condition-specific	CBO	NE	
Glickel Clinical Grading system (1984)		Non-Trauma	Chronic carpal instability	Condition-specific	CBO	NE	
Grace and Eversmann Rating (1980)		Trauma	Forearm fractures	Condition-specific	CBO	NE	
Green and O'Brien Scoring System (1978)		Trauma	Carpal dislocation - open	Condition-specific	CBO	NE; NV	
Hand Function Score (1998)	HFS	Trauma	Hand trauma – rehabilitation nos	Region-specific	PRO	NE	
Hand Function Sort (1996)		nos	nos	Region-specific	PRO	NE	
Hand Functional Index (1971)	HFI	Non-Trauma	RhA	Condition-specific	CBO	NE	
Hand Injury Severity Score (1996)	HISS	Trauma	Hand injuries nos	Region-specific	CBO	P	Psychometric evaluation and validation vs return to work
Hospital for Special Surgery Wrist Scoring System (1990)	HSS Wrist	Non-Trauma	RhA – wrist – Total wrist arthroplasty	Condition-specific	CBO	NE; NV	
Jebsen-Taylor Hand Function Test (1969)		nos	nos	Region-specific	CBO	NE	
Kapandji Index (1987)		Non-Trauma	RhA	Condition-specific	CBO	NE	
Lambert and Clayton Wrist Score (1980)		Non-Trauma	RhA – wrist – Total wrist arthroplasty	Condition-specific	CBO	NE; NV	
MacBain Hand Function Test (1970)		Non-Trauma	RhA	Condition-specific	CBO	NE; NV	

Manual Ability Measure-16;-36 (2005)	MAM-16; MAM-36	Combo	RhA; OA; CTS; Median nerve neuritis; Tenosynovitis; Traumatic injuries inc fractures; Open wounds; Crush	Region-specific	PRO	P	Psychometric testing and validation vs LIFEware musculoskeletal form; SF-12 health status
Martini Score (1999)		Trauma	DRF	Condition-specific	CBO	NE; NV	
Measure of Activity Performance of the Hand (2010)	MAP-HAND	Non-Trauma	RhA	Condition-specific	PRO	P	Psychometric testing and validation vs AIMS2 arm, hand and finger function subscales; joint pain / fatigue /global disease and activity scales
Michigan Hand Outcomes Questionnaire (1998)	MHQ	Combo	Hand disorders – Hand injuries; RhA; CTS	Region-specific	PRO	P	Psychometric evaluation and validation vs SF-12
Milliken Activities of Daily Living Scale & modifications (1988)		Trauma	Simple & complex upper limb fractures; soft tissue injuries (tendon/nerve lacerations/repairs); crush; amputations; replantation	Region-specific	PRO	P	Psychometric evaluation and validation vs HFS
Modern Activity Subjective Survey of 2007 (2008)	MASS07	nos	nos	Region-specific	PRO	P	Psychometric evaluation and validation vs DASH; PRWE
Modified Gartland and Werley Scoring System (1975)		Trauma	Colles Fracture	Condition-specific	CBO	NE	
Modified Green and O'Brien Scoring System (1987)		Trauma	Wrist fractures – perilunate fracture dislocations	Region-specific	CBO	NE; NV	
Modified Martini Score (2004)		Trauma	DRF	Condition-specific	CBO	NE; NV	
Modified Score for Assessment & quantification of Chronic Rheumatic Affections of Hands (2004)	M-SACRAH	Non-Trauma	RhA; OA	Condition-specific	PRO	P	Psychometric evaluation and validation vs SACRAH; Patient global assessment; Physician global assessment; C-reactive protein concentration; ESR
Munich Wrist Questionnaire (2016)	MWQ	Combo	DRF; Metacarpal, Scaphoid, other carpal fractures; TFCC tear; Synovitis; SL Ligament tear; Wrist OA; Traumatic nerve injury; Wrist contusion	Region-specific	PRO	P	Psychometric evaluaition and validation vs PRWE; DASH; MMWS; CBS
New York Orthopedic Hospital Wrist Rating Scale (1991)	NYOH	Trauma	DRF – External fixation	Condition-specific	CBO	NE; NV	
Patient Evaluation Measure (1995)	PEM	nos	Hand surgery nos	Region-specific	PRO	NE	

Patient Focused Wrist Outcome (2003)		Combo	Wrist disorder / injury nos	Region-specific	PRO	P	Psychometric evaluation and validation nos
Patient Outcomes of Surgery-Hand/Arm (2004)	POS Hand / Arm	Non-Trauma	CTS; Dupuytren's fasciectomy; Joint surgery; Tendon surgery; Mass excision excision – pre and post-surgery	Region-specific	PRO	P	Psychometric evaluation and validation vs DASH; MHQ Pain scale
Patient Rated Wrist / Hand Evaluation (2004)	PRWHE	Trauma	Wrist / hand fractures; Carpal instabilities; OA hand; tendon lacerations; palmar fasciectomies; finger joint arthroplasty (MCPJ / PIPJ)	Region-specific	PRO	P	Psychometric evaluation and validation vs DASH
Patient Rated Wrist Evaluation (1996)	PRWE	Trauma	Scaphoid non-union; Colles fracture	Region-specific	PRO	P	Psychometric evaluation and validation vs SF-36 and impairment score (wrist ROM, Grip strength; Dexterity testing, expected changes in pain and disability)
Revel Functional Index (1989)	RFI	Non-Trauma	RhA	Condition-specific	PRO	NE	
Rheumatoid Hand Functional Disability Scale (1996)		Non-Trauma	RhA	Condition-specific	PRO	P	Psychometric evaluation and validation vs VAS for functional handicap; Hand functional index
Score for Assessment and quantification of Chronic Rheumatic Affections of the Hands (2003)	SACRAH	Non-Trauma	RhA; OA	Condition-specific	PRO	P	Psychometric evaluation and validation vs patient global assessment; Physician global assessment; C-reactive protein concentration; ESR
Sequential Occupational Dexterity Assessment (1996)	SODA	Non-Trauma	RhA - Hand surgery: CTS – release; Resection ulnar head; Tenosynovectomy; Articular synovectomy; wrist prosthesis.	Region-specific	CBO	P	Psychometric evaluation and validation vs wrist ROM; Mobility of fingers; Grip strength; Self-reported dexterity; Pain
Short version of the Sequential Occupational Dexterity Assessment (1999)	S-SODA	Non-Trauma	RhA	Condition-specific	CBO	P	Psychometric evaluation and validation vs SODA; VAS for pain; IRGL; Grip strength; Larsen Score; Wrist and finger ROM; Disease duration and activity
Solgaard Functional Score System (1988)		Trauma	DRF	Condition-specific	CBO	NE; NV	
Sollerman Hand Function Test (1995)		Combo	RhA; Finger amputations; nerve injuries; Dupuytren's contracture; shoulder-hand-finger syndromes; post-traumatic hand conditions	Region-specific	CBO	P	Psychometric evaluation and validation vs subjective estimation of hand function; Disability rating scale
Southampton Dupuytren's Scoring System (2014)	SDSS	Non-Trauma	Dupuytren's contracture	Condition-specific	PRO	P	Psychometric evaluation and validation vs QuickDASH
Stewart Scores (1984)		Trauma	DRF – functional cast bracing	Condition-specific	CBO	NE; NV	

Unité Rheumatologique des Affections de la Main scale (2011)	URAM	Non-Trauma	Dupuytren's Disease	Condition-specific	PRO	P	Psychometric evaluation and validation vs Tubiana scale
Wrightington Wrist Function Score (1998)		Combo	Scapholunate instability – Brunelli procedure	Condition-specific	CBO	NE; NV	
Wrist Outcome Measure (2002)	WOM	Trauma	DRF	Condition-specific	CBO	NE; NV	

Abbreviations: nos, non-specified or non-specific; Combo, combination of traumatic and non-traumatic conditions; ACJ, Acromioclavicular joint; CTS, Carpal tunnel syndrome; DRF, Distal radius fracture; EPS, Elbow plica syndrome; GHJ, Glenohumeral joint; LCL, Lateral collateral ligament; MCPJ, Metacarpophalangeal joint; OA, Osteoarthritis; OCD, Osteochondritis dissecans; PHF, Proximal humerus fracture; RCT, Rotator cuff tear; RhA, Rheumatoid arthritis; SCJ, Sternoclavicular joint; SLAP, Superior Labral AP tear; UTS, Ulnar tunnel syndrome; PRO, Patient-reported outcome measure; CBO, Clinician-based outcome measure; P, Confirmed psychometric evaluation; NE, no initial empirical psychometric evaluation; NV, no validation studies; ROM, Range of motion; GROC, Global rating of change; IRGL, Impact of Rheumatic diseases on General health and Lifestyle. * ASES patient reported component only – selected as clinician based measure rarely used.

Table 8. Systematic Review II: Quality Assessment using COSMIN Checklist and 4-point Rating System

			Reliability			Validity				Responsiveness	Interpretability	
						Content Validity	Construct Validity		Criterion Validity			
Outcome Measure	Instrument Items (Score range)	IRT Box	A. Internal Consistency	B. Reliability (Test-retest, inter-rater, intra-rater)	C. Measurement error (Test-retest, inter-rater, intra-rater)	D. Content (Face) Validity	E. Structural Validity	F. Hypothesis Testing	H. Criterion Validity (Concurrent validity, Predictive validity)	I. Responsiveness	Interpretability	Total Score
DASH	30 (0-100)	0	Excellent	Excellent	0	Excellent	Excellent	Excellent	0	Excellent	Score distribution & change	4
QuickDASH	11 (0-100)	0	Excellent	Excellent	0	Excellent	Excellent	Excellent	0	Excellent	Score distribution & change	4
UEFT	33 (0-99)	0	Poor	Poor	0	Poor	Poor	Poor	0	0	Score distribution & change	1
ULFI	25 (0-100)	0	Good	Good	Good	Excellent	Poor	Good	Good	Good	Missing item handling; Score distribution & change; Floor-ceiling effect; MDC	2
ASES-S	11 (0-100)	0	Good	Good	Good	Excellent	Poor	Good	0	Good	Score distribution & change; MDC, MCID	2
KJOC	10 (0-100)	0	Poor	Poor	Poor	Excellent	Good	Fair	0	Good	Score distribution & change	2
MISS	21 (0-100)	0	0	Poor	Poor	Good	Poor	Fair	0	0	Score distribution & change; MDC	2
MSQ	30 (0-314)	0	0	0	0	Good	Poor	Good	0	0	Score distribution; Floor-ceiling effects	3
NCS	10 (20-100)	0	Fair	Poor	0	Good	Poor	Good	0	0	Score distribution & change	4
OIS	12 (12-60)	0	Fair	Good	0	Excellent	Poor	Good	0	Good	Score distribution & change	3
PSS	24 (0-100)	0	Good	Fair	Fair	Excellent	Poor	Fair	0	Good	Score distribution & change; Floor-ceiling effects; MDC, MCID	2
RC-QOL	34 (0-100)	0	0	Fair	0	Excellent	Poor	Good	0	0	Score distribution & Score change	3

SAS	5+2 (0-20)	0	0	Fair	0	Excellent	Poor	Fair	0	0	Score distribution	4
SDQ-NL	16 (0-100)	0	0	0	Good	0	0	0	0	Fair	Score distribution & change; Floor-ceiling effects	3
SANE	1 (0-100)	0	0	0	0	Good	0	Good	0	0	Score distribution; Score change	2
SPONSA	1 (0-100)	0	0	Fair	0	Good	0	Good	0	Good	Score distribution; Score change	2
SSRS	5 (0-100)	0	0	Fair	0	Good	0	Fair	0	0	Score distribution; Score change	2
SSV	1 (0-100)	0	0	Fair	0	Good	Poor	Good	0	Good	Score distribution; Score change	1
WORCI	21 (0-2100)	0	0	Good	0	Excellent	Poor	Good	0	Good	Score change	7
WOSI	21 (0-2100)	0	0	Good	0	Excellent	Poor	Fair	0	Fair	Score change	8
OES	12 (0-48)	Good	Excellent	Good	Good	Excellent	Excellent	Good	0	Excellent	Score distribution; Floor - ceiling effects; Score change	3
PREE	20 (0-100)	0	0	Good	0	Excellent	Poor	Good	0	0		3
MAM-16; MAM-36	16 (0-100)	Good	0	Good	Good	Excellent	Good	Good	0	0	nil	2
MHQ	37 (0-100)	0	Poor	Poor	0	Excellent	Good	Good	0	0	nil	2
MAS	47 (47-235)	0	0	Fair	0	Excellent	Poor	Fair	Fair	0	Score distribution	1
MWS	16 (0-100)	0	Good	Good	0	Excellent	Poor	Good	0	Good	Score distribution, change; Floor-ceiling effect	4
PFWO	52 (variable)	0	0	Good	0	Good	Poor	Poor	0	Poor	Floor-ceiling effect	1
PRWHE	15 + 1 (0-100)	0	0	0	0	Excellent	0	0	0	Good	Score change	1
PRWE	15 (0-100)	0	0	Fair	0	Excellent	Good	Good	0	0	nil	5

Table 9. Systematic Review II: Characterisation of PRO measures by health domains assessed

		Outcome Measures - Health Domains as proportion (%) of total score*					Study characteristics & Psychometric Evaluation		
Outcome Measure	Instrument Items (Score range)	Physical Function (Activities / Participation)	Psychological	Social	Pain / Symptoms	Other	Level of Evidence Index Study(s)	Psychometric Analysis: Property (n)	Outcome Measures
DASH	30 (0-100)	77%	3%	3%	17%		1b	Reliability (407); Validity (407); Interpretability	VAS Overall problem; VAS Overall pain; VAS Ability to function; VAS Ability to work
QuickDASH	11 (0-100)	64%		18%	18%		1b	Reliability (407); Validity (407); Interpretability	VAS Overall problem; VAS Overall pain; VAS Ability to function; VAS Ability to work
UEFT	33 (0-99)	100%					3b	Reliability (30); Validity (79); Interpretability	Hand activities of daily living
ULFI	25 (0-100)	76%	4%	12%	8%		1b	Reliability (64, 32); Validity (64); Responsiveness (24); Interpretability	DASH; UEFS
ASES-S	11 (0-100)	45%		5%	50%		1b	Reliability (63); Validity (63); Responsiveness (63); Interpretability	UPenn; SF-36
KJOC	10 (0-100)	50%		20%	30%		3	Reliability (21); Validity (282); Responsiveness (55); Interpretability	DASH; DASH Sports / Performing arts module
MISS	21 (0-100)	57%%		18%	25%		1b	Reliability (22); Validity (64); Interpretability	SRQ; Patient subjective rating score
MSQ	30 (0-314)	62%		19%	19%		3	Validity (56); Interpretability	CMS; DASH; SPADI
NCS	10 (20-100)	20%			70%	10% (Cosmetic satisfaction)	2b	Reliability (70, 50); Validity (70); Interpretability	CMS; OSS; Imatani; EQ5D
OIS	12 (12-60)	41%	17%	25%	17%		1b	Reliability (34,92); Validity (92); Responsiveness (15); Interpretability	CMS; Rowe; SF-36
PSS	24 (0-100)	54%		6%	30%	10% (Functional satisfaction)	3b	Reliability (109,40); Validity (40); Responsiveness (109); Interpretability	ASES; CMS
RC-QOL	34 (0-100)	35%	15%	35%	15%		1b	Reliability (30); Validity (86); Interpretability	Functional shoulder elevation test; SF-36; ASES
SAS	5+2 (0-20)	100%					1b	Reliability (40); Validity (42); Interpretability	SST; Age; Knee activity rating scale; Self reported shoulder activity

SDQ-NL	16 (0-100)	94% (88% Linked to pain)	6%		88% (linked to physical function - daily activities)		1b	Reliability (180); Responsiveness (180); Interpretability	Patient VAS shoulder pain; VAS chief complaint; 8-point Likert Scale Overall change since baseline; Clinical VAS symptom severity / VAS mobility restriction
SANE	1 (0-100)					100% (Global general rating)	1b	Reliability (163); Validity (163); Interpretability	Rowe; ASES
SPONSA	1 (0-100)					100% (Global general rating inc pain and physical function)	1b	Reliability (61); Validity (61); Responsiveness (61); Interpretability	CMS; OSS
SSRS	5 (0-100)	35%		15%	50%		1b	Reliability (200); Validity (200); Interpretability	CMS; Four point verbal rating scale
SSV	1 (0-100)					100% (Global general rating)	3b	Reliability (441); Validity (441); Interpretability	CMS
WORCI	21 (0-2100)	47%	14%	10%	29%		3b	Reliability (100); Validity (97); Responsiveness (100); Interpretability	UCLA; SF-36; CMS; ASES; DASH; SIP; ROM
WOSI	21 (0-2100)	24%	14%	24%	38%		3b	Reliability (51); Validity (47); Responsiveness (47); Interpretability	DASH; ASES; UCLA; Rowe; CMS; SF-12; Global change; ROM
OES	12 (0-48)	33%	16.5%	16.5%	33%		1b	Reliability (104,52); Validity (104); Responsiveness (104); Interpretability	MEPS; DASH; SF-36
PREE	20 (0-100)	54%		13%	33%		1b	Reliability (70); Validity (70); Interpretability	ASES; SF-36; DASH
MAM-16; MAM-36	16 (0-100)	100%					1b	Reliability (115); Validity (115)	LIFEware musculoskeletal form; SF-12 health status
MHQ	37 (0-100)	46%		14%	14%	10% (Apperance); 16% (Satisfaction in relation to physical function, pain, sensation)	1b	Reliability (22); Validity (200); Interpretability	SF-12
MAS	47 (47-235)	100%					1b	Reliability (45); Validity (37); Interpretability	HFS
MWS	16 (0-100)	63%		6%	25%	6% (Satisfaction)	1b	Reliability (100); Validity (100); Responsiveness (100); Interpretability	DASH; PRWE; MWS; CBS
PFWO	52 (variable)	95% (approx)		5% (approx)			1b	Reliability (50); Validity (50, 26); Responsiveness (26); Interpretability	ADLs
PRWHE	15 + 1 (0-100)	54%		13%	33%	Plus 10 pts (Appearance)	1b	Validity (60); Responsiveness (60); Interpretability	DASH
PRWE	15 (0-100)	54%		13%	33%		3b	Reliability (38); Validity (53)	SF-36; Impairment score (wrist ROM, Grip strength; Checkers subset)

2.3.5 Discussion

Based on the primary objective, almost a third of the outcome measures targeted at the upper extremity specifically involved trauma conditions in their original development. The striking observation from the secondary objectives was that over a third of upper extremity outcome measures also lacked any initial empirical psychometric evaluation or subsequent validation. In addition, the methodological quality of those studies involving PRO measures and upper extremity trauma conditions in their development was highly variable.

Guyatt et al., highlighted the importance of considering the original development of measures in assessing their validity in the population being assessed (146). The findings from this review are relevant considering that the selection of outcome measures is of paramount importance in conducting high quality orthopedic research (29)(55). Instrument choice, particularly amongst the current assortment of PRO measures, benefits from an understanding of the origins and methodological quality of their development and relevance to study populations (29)(55). Along with the apparent transition toward the development of psychometrically validated region-specific PRO measures, there is a need for their robust evaluation in targeted populations with specific upper extremity trauma conditions (31)(95)(147).

Further insights were gained from this review alongside a consideration of the challenges and solutions related to outcome measurement in orthopaedic trauma.

Timing and recruitment of trauma patients for outcome measurement may be difficult due to a variety of clinical, environmental and logistical factors. Assessing patients when they are 'stable' enough to perform an evaluation whilst being close enough to the point of injury for measurement to be relevant can be challenging, especially considering fracture related symptoms (e.g. pain, sensory loss), and clinical sequelae (e.g. complications). Promoting the value of patient outcomes through quality research and educating patients and staff on their importance may provide the necessary shift toward their measurement in everyday practice.

Responder burden is another issue in outcome measurement following trauma, especially when lengthy measures or batteries of tests are involved. The recognised risks of incomplete scoring, poor patient experience, manipulating or gaming assessments and a tendency to over-estimate one's ability in injury, may be limited by more efficient measures such as abbreviated versions of fixed-scale instruments or CATs (148)(149). CATs may provide both efficiency and precision in outcome measurement along with the benefits of customisation and broad measurement range (45)(46)(50)(149). This is a particular advantage in individuals with injury who often experience wide-ranging variations in disability and demonstrate floor-ceiling effects (149). CATs are considered separately in the next systematic review and used throughout this thesis. Some PRO measurement developers have considered the challenges posed by measuring outcomes following trauma (150)(151). Measures have been designed to account for compensatory adaptations, 'levels of ability' and 'levels of necessity' during post-traumatic recovery, as well as capturing recall of pre-injury baseline function (150)(151)(152)(153).

a. Limitations

There are some limitations to this work. Firstly, only the original index articles relevant to each outcome measure were within the scope of this review. It is possible that more than one early investigation could have been part of the initial psychometric evaluation and inadvertently missed. Furthermore, subsequent studies may have superseded these index evaluations and demonstrated relevant psychometric credentials. Secondly, despite this comprehensive approach, it is possible that some outcome measures may have been missed. However, these were more likely to be clinician-based than PRO measures. In this regard, there may also be a risk of publication bias where authors decided not to publish unfavourable outcomes for a PRO measure they had a vested interest in promoting (154) . Finally, with the 7% of authors contacted, the enquiry was limited to diagnostic clarification only and no further information was gathered around methodological quality. Thus, it was unclear whether low ratings were down to lack of reporting or lack of quality according to COSMIN criteria.

b. Conclusion

This systematic review aimed to understand the developmental origins of upper extremity PRO measures and assess the extent to which trauma conditions were considered in their original design. There are relatively few PRO measures specifically developed and tested in upper extremity trauma conditions. In reality, most upper extremity PRO measures are chosen in these populations based on intuition, clinical culture and familiarity, with the belief they are 'fit for purpose'. Based on the importance of defining properties of PRO measures in the context of the population being tested rather than the instruments themselves, further research is required to assess their psychometric attributes in specific upper extremity trauma populations (95).

2.4 The Performance of CATs after Orthopaedic Trauma to the Upper Extremity: Systematic Review III

2.4.1 Background

CATs are contemporary forms of PRO measurement that aim to measure outcomes with greater precision and efficiency than fixed length scales (50)(46). The test design behind CATs is IRT, an advanced psychometric model that has been applied to form computerised algorithms enabling the adaptive administration of questions based on a participant's previous response (46)(49)(55) (Figure 4b). This contrasts with fixed length scales that are traditionally developed using classic test theory. The CAT development process often utilises large populations and extensive calibrated question banks, providing broader and more detailed coverage (54)(155). The National Institute of Health (NIH) PROMIS measures include a selection of CATs that were originally developed for chronic conditions (41) (Appendix 6). Fast, accurate measurement and broad coverage may make these instruments more adept at capturing outcomes following potentially more intense orthopaedic trauma situations which can impact a wide range of patient profiles (50)(51)(52). In relation to disability and its contributory factors, the developers of PROMIS describe extensive mapping of the WHO ICF framework in creating these measures and describe good coverage of health domains with initial testing (156).

2.4.2 Objectives

The primary objective of this review was to assess the psychometric properties of CATs versus fixed length scales in orthopaedic upper extremity trauma. The secondary objective was to define the study designs, diagnoses, research settings and outcome measures investigated, along with the performance of quality assessment using the COSMIN criteria (144)(145)(157). Finally, the trends in utilisation of CATs in orthopaedic research over the last decade were observed. It was also perceived that this systematic review would yield a series of CATs that could be utilised in the subsequent experimental studies in this thesis.

2.4.3 Methods

a. Data Sources & Search Protocol

A broad search strategy using the PubMED (Medline 1946 to 2016), OVIDSP (EMBASE 1974 to 2016), CINAHL (2006 to 2016), PsycInfo (1806 to 2016) and Cochrane databases (2016) was performed on 7th October 2013 and repeated on 1st January 2017. The lack of MeSH terms for CATs in PRO assessment and a wide variation in labelling led to the use of a broad search strategy. Search terms related to 'CATs' [computer* adapt* test* OR "item response theory" OR IRT OR PROMIS], 'orthopaedics', 'trauma', and 'anatomical regions' [trauma* OR orthop* OR musculoskeletal OR injury OR limb* OR extremity OR arm* OR leg* OR shoulder* OR elbow* OR wrist* OR hand* OR spine OR spinal OR pelvis OR pelvic OR hip* OR knee* OR ankle* OR foot [ti,ab] were deployed using the operator 'AND'. No restrictions were set in search fields and terms were identified in the title and/or abstract without limits. The review adhered to PRISMA criteria (98) and was registered (PROSPERO: CRD42016053886).

b. Study Selection

Study selection incorporated adults experiencing any orthopaedic upper extremity trauma managed with either non-surgical or surgical interventions, at any stage along the care pathway (e.g. surgical episode, rehabilitation). Outcome measurement with any CAT was included and only original research in peer-reviewed journals in english language were considered eligible. Non-clinical, non-orthopaedic, non-CAT related studies, and investigations involving fixed length scales and short-form versions of CATs were excluded. The search was performed by the lead investigator [PJ] followed by the screening of titles and abstracts by two investigators [PJ, MAW] using a step-wise exclusion process (Appendix 7). Three investigators [PJ, SG, MAW] independently reviewed the full texts and bibliographies for additional publications. Discordant judgments were resolved by consensus meetings coordinated by the lead investigator [PJ]. Authors of original articles were contacted if published studies lacked clarity on the specific conditions investigated or outcomes reported.

c. Data Extraction & Data Synthesis

Two investigators [PJ, MAW] independently extracted data from eligible studies onto an electronic database (Microscoft Excel ver15.33) for level of evidence, number of patients, study type, region and conditions, outcome measures and therapeutic setting. Further documentation of PRO measurement properties of CATs and fixed length scales was conducted i.e. for validity, reliability, responsiveness, precision (e.g. floor-ceiling effects) and acceptability characteristics (number of questions or time taken to complete a test) (Figure 5). Formal publication dates were also recorded to map the distribution of relevant studies over time.

Classification of study types was performed once the full study set was assessed for common themes. This included studies involving 'development', 'testing', 'outcome assessment' and combinations thereof. Development involved studies utilising various methods of outcome measurement development to construct a CAT. Testing involved analysis of their psychometric properties, and outcome assessment entailed the use of CATs to measure patient outcomes for a condition or intervention, either in combination with fixed length scales or alone.

d. Quality Assessment

Quality assessment of eligible studies was conducted using the COSMIN criteria and accompanying 4-point rating system (144)(157). The checklist provided a standardised assessment of methodological quality, design requirements and preferred statistical analysis of PRO measures developed using either classic test theory or IRT. This was particularly useful considering IRT models formed the test design underlying CATs. The rating system was applied to assess the quality of IRT models where applicable, and validity, reliability and responsiveness. Ratings of 'poor', 'fair', 'good' or 'excellent' were classified with the lowest rating of any question in an assessment category taken as the final score i.e. 'worst score counted'. Generalisability (i.e. characteristics of the study population and sampling procedure) and data regarding precision (e.g. norm scores, floor-ceiling effects which were represented as interpretability in the COSMIN checklist) were extracted but not scored.

2.4.4 Results

a. Selection of Studies

The search resulted in a total of 3777 citations and after adjusting for duplicate, non-english and non-human studies, 1763 remained (Figure 16). Of these, 1627 were excluded by criteria after title and abstract screening. This resulted in 136 studies involving CATs in orthopaedics for full text review. Of these, 31 studies (n=31/136; 23%) solely involved trauma conditions (n=6/136; 4%) or a combined cohort of trauma and non-trauma conditions (n=25/136; 18%) (Table 9). All tables within this systematic review are presented after the results section.

b. Definition of study designs, diagnoses and outcome measures

Most studies were cross-sectional (n=20/31; 65%) and level of evidence was variable [(Level 1, n=2/31 (6.5%); Level 2, n=26/31 (84%); Level 3, n=2/31(6.5%); Level 4, n=1/31 (3%)]. Cohorts ranged from n=3 (158) to 30,987 (159). The largest category of study type involved a combination of testing and outcomes assessment (n=12/31; 39%) (Figure 17). Most studies involved conditions in multiple regions (n=18/31; 58%) followed by those affecting the shoulder (n=10/31; 32%) and wrist/hand (n=3/31; 10%). Injuries ranged from fractures, dislocations, subluxations to soft tissue trauma. Only a few studies focused on specific injuries e.g. proximal humerus fractures (160)(161) and sternoclavicular joint dislocations (158). PROMIS PF, PROMIS PI and PROMIS Depression were the most frequently utilised CATs (Figure 18). All studies were performed in the U.S and mostly in outpatient clinics.

c. Comparison of CATs with Fixed Length Scales

9 studies (29%) involved the utilisation of CATs, fixed scale measures and the evaluation of one or more psychometric properties (Table 10). Moderate to strong correlations were demonstrated between CATs (e.g. PROMIS PF) and fixed length scales (e.g. DASH). CATs also consistently demonstrated minimal or no floor-ceiling effects with significantly shorter test completion times and / or fewer items for completion.

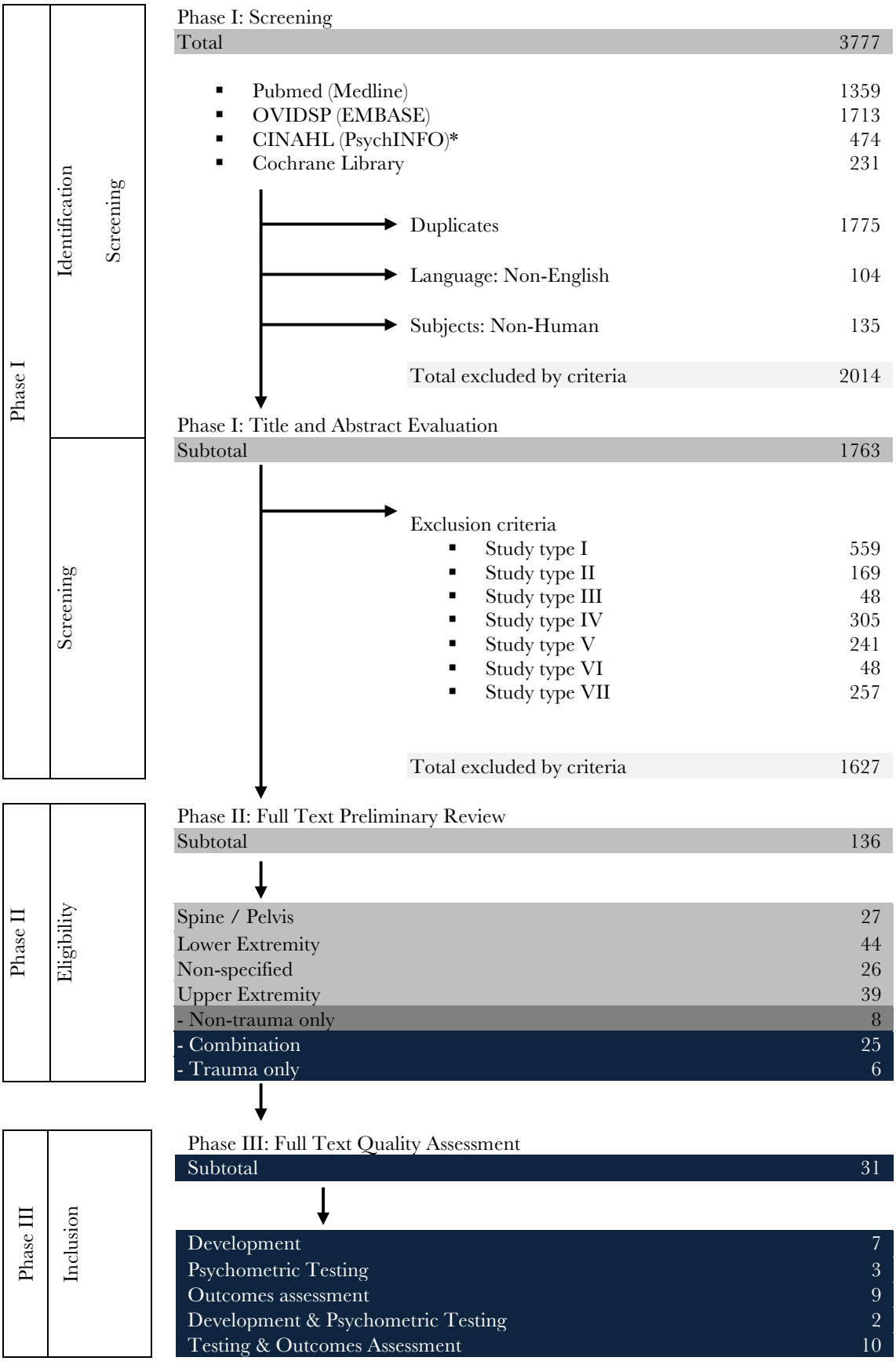


Figure 16. Systematic Review III: PRISMA Flow Chart

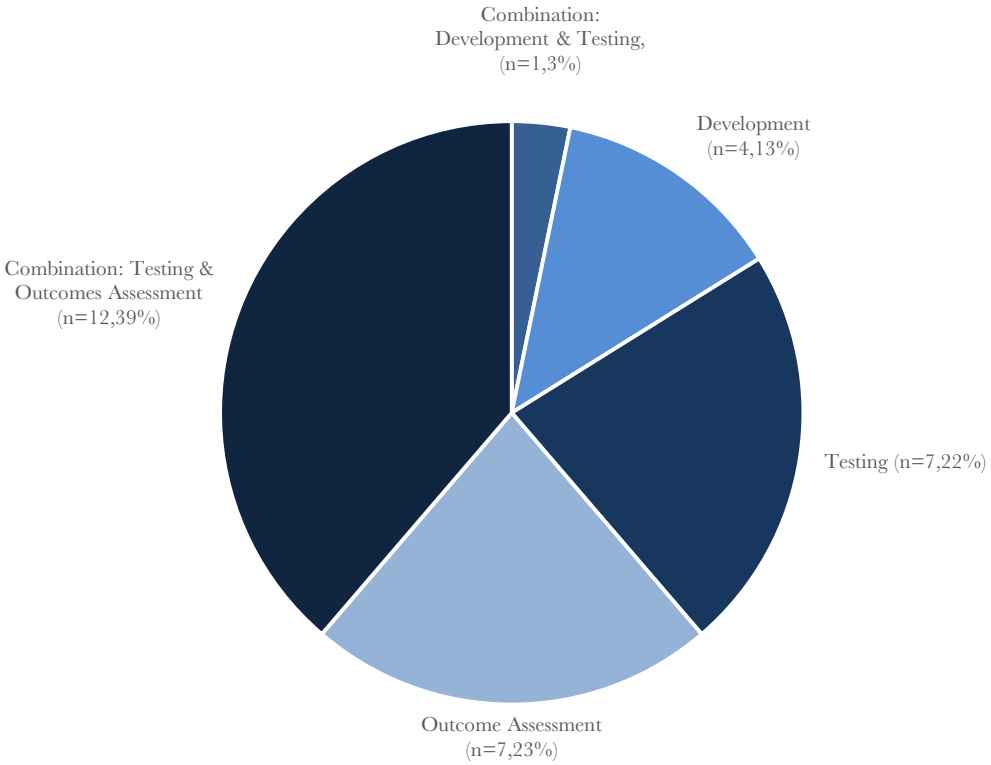


Figure 17. Studies involving CATs and Orthopaedic Extremity Trauma Conditions defined by Study Type

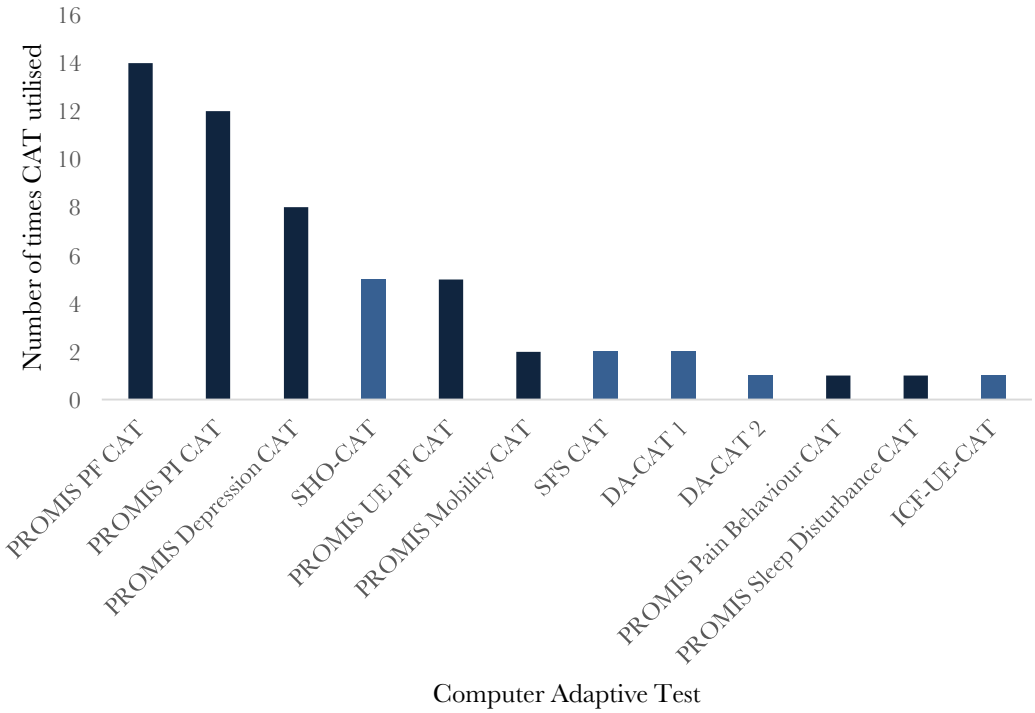


Figure 18. Frequency of CAT utilisation in Final Inclusion Study Set

d. Methodological Quality

Quality assessment demonstrated adequate definitions of study populations and overall sampling but descriptions of conditions and disease characteristics were lacking in 15 studies (43%) where contact with the corresponding authors was required for further clarification. 9 studies (29%) remained non-specified due to investigators being unable to recall diagnoses. Sample sizes within studies were adequate with few methodological flaws and sound statistical evaluation, however, reporting of missing items and measurements over time was poor (Table 11).

Studies involving IRT analysis rated 'good' or 'excellent' although descriptions of the model, the computer software package and method of estimation used and assumptions made were highly variable. One or more types of reliability (i.e. internal consistency, test-retest, intra- or inter-observer reliability and measurement error) were assessed in 15 studies (48%), and these were highly variable in quality, mostly rating 'fair' or 'good'. Validity was assessed in some form in all studies and mostly rated 'good' or 'excellent'. Greater variability in ratings were observed in the assessment of structural validity and hypothesis testing compared to content validity. Assessment of interpretability observed variable accounts of score distributions and score changes with few studies undertaking analysis of floor-ceiling effects and fewer still calculating MCID or MDC. The heterogeneity of the study set in terms of design, diagnoses, outcome measures utilised, and statistical analysis performed meant statistical pooling was not considered feasible or appropriate. Best evidence synthesis to summarise the strength of evidence for specific CATs could not be performed for the same reason.

e. Trends in CAT publications.

Research activity involving the use of CATs in orthopaedic surgery in general appears to be on the rise, with a year on year increase in the number of published articles over the course of the last decade (Figure 19).

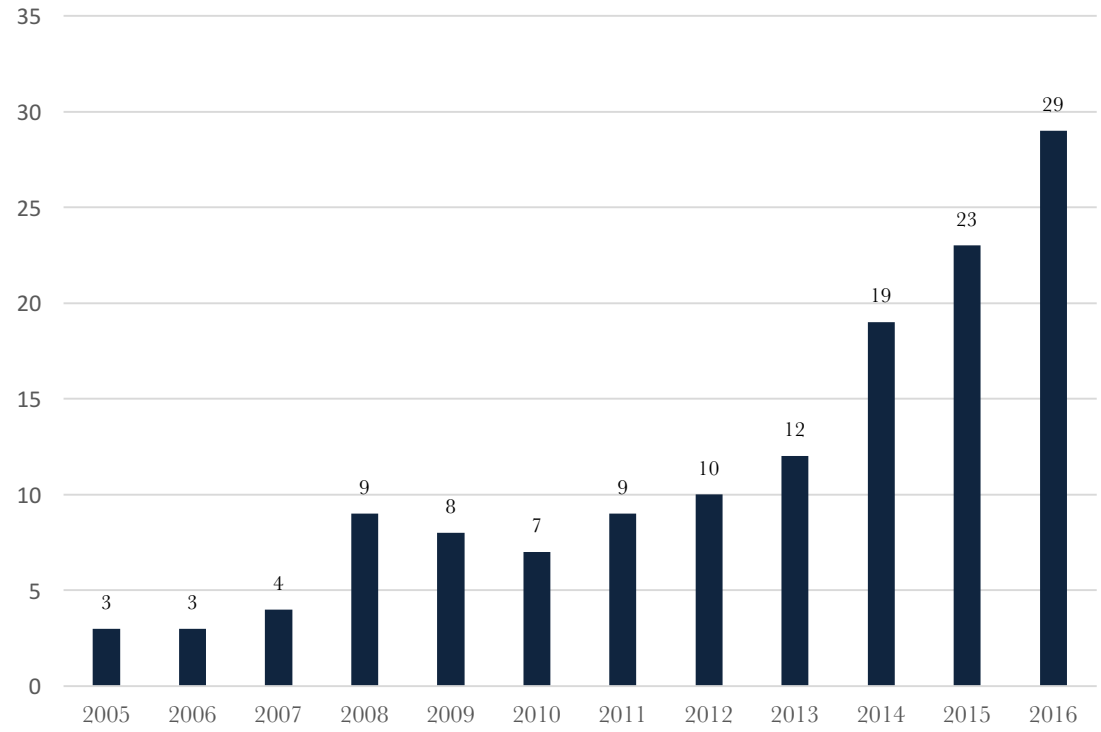


Figure 19. Volume of studies involving CATs in orthopaedics by year of publication (2005 – 2016)

Table 10. Systematic Review III: Characteristics of studies involving CATs and Upper Extremity Trauma conditions

Author (Year)	Study Design (Level of evidence)[51]	n	CAT Study Type	Upper Extremity Region	Upper Extremity Trauma Condition(s)	Trauma Conditions Alone or in Combination	CAT	Fixed length Scale and Other outcome metrics	Management / Therapy setting (Country)
Beckmann et al., 2015 [162]	Observational, Cross-sectional; Outcomes research (Level 2c)	187	Testing	Shoulder	Rotator cuff tear	Combo	PROMIS PF CAT	ASES; SST	Outpatient Clinic (USA)
Cook et al., 2005 [163]	Prospective cohort study (Level 2b)	400	Combination: Development & Testing	Shoulder	Nos	Combo	SHO-CAT	FLEX-SF; ASES; SF-12	nos (USA)
Doring et al., 2014 [113]	Observational, Cross-sectional; Outcomes research (Level 2c)	84	Testing	Multi-region	Hand, wrist fractures; Mallet finger; Soft tissue injury; Animal bite	Combo	PROMIS UE PF CAT; PROMIS PF Mobility CAT; PROMIS PI CAT	QuickDASH; PSEQ-2; PHQ-2	Outpatient Clinic (USA)
Haley et al., 2009 [167]	Observational, Cross-sectional; Outcomes research (Level 2c)	6,882	Development	Multi-region	Nos	Combo	DA-CAT1 (AM-PAC CAT); DA-CAT2	Nil	Outpatient Rehab Clinic (USA)
Hart et al., 2006 [168]	Secondary analysis of Prospective cohort study (Level 2b)	400	Development	Shoulder	Nos	Combo	SFS CAT	(FLEX-SF items used for development only)	Outpatient Rehab Clinic (USA)
Hart et al., 2010 [169]	Secondary analysis of Prospective cohort study (Level 2b)	30,987	Development	Shoulder	Rotator cuff tear; Sprains and strains; ACJ injury; Clavicle, Scapula, Humerus Fracture	Combo	Shoulder CAT; CAT-FS	(GROC only for assessing change amongst individual patients)	Outpatient Rehab Clinic (USA)
Hays et al., 2013 [170]	Observational, Cross-sectional; Outcomes research (Level 2c)	21,773	Development	Multi-region	Nos	Combo	PROMIS PF CAT	Nil	nos (USA)
Hung et al., 2011 [51]	Observational, Cross-sectional; Outcome research (Level 2c)	865	Development	Multi-region	Nos	Combo	PROMIS PF CAT	Nil	Outpatient Clinic (USA)
Hung et al., 2014 [44]	Observational, Cross-sectional; Outcomes research (Level 2c)	153	Combination: Testing & Outcomes Assessment	Multi-region	Nos	Trauma	PROMIS PF CAT	sMEA	Outpatient Clinic (USA)
Janssen et al., 2015 [84]	Observational, Cross-sectional; Outcomes research (Level 2c)	139	Outcome Assessment	Multi-region	Fracture shoulder, elbow, forearm, wrist, hand; Finger amputation; MCPJ dislocation; Soft tissue injury hand	Combo	PROMIS PB CAT; PROMIS PI CAT; PROMIS PF CAT; PROMIS Depression CAT	QuickDASH; pain rating scale (11-point ordinal scale)	Outpatient Clinic (USA)
Jayakumar et al., 2014 [111]	Observational, Cross-sectional; Outcomes research (Level 2c)	98	Outcomes Assessment	Multi-region	Elbow, Hand, Humerus, Forearm, Wrist fractures; Soft tissue injury Hand; Animal bite	Combo	PROMIS PF CAT; PROMIS PI CAT; PROMIS Depression CAT	PACES	Outpatient Clinic (USA)
Jette et al., 2007 [171]	Prospective cohort study; Outcome research (Level 2c)	1815	Development	Multi-region	Nos	Combo	AM-PAC-CAT	Nil	Outpatient Rehab Clinic (USA)
Kortlever et al., 2015 [131]	Observational, Cross-sectional; Outcome research (Level 2c)	138	Combination: Testing & Outcomes Assessment	Multi-region	Nos	Combo	PROMIS PI CAT	PCS; PIPS; PSEQ; QuickDASH	Outpatient Clinic (USA)
Lehman et al., 2011 [172]	Observational, Cross-sectional; Outcome research (Level 2c)	312	Development	Multi-region	Upper extremity fractures	Combo	ICF-based UE CAT	Nil	Outpatient Clinic (USA)
Mellema et al., 2015 [173]	Prospective cohort study (Level 1b)	136	Outcome Assessment	Wrist and Hand	Wrist fracture; Hand fracture; Sprain, rupture, dislocation; Amputation, crush, laceration	Combo	PROMIS PI CAT	Pain VAS; Patient Satisfaction (11-point ordinal scale); Patient-physician communication	Outpatient Clinic (USA)
Menendez et al., 2013 [164]	Observational, Cross-sectional; Outcome research (Level 2c)	213	Combination: Testing + Outcomes Assessment	Multi-region	Fracture shoulder, elbow, wrist, hand; Sprain, dislocation or mallet finger; Amputation, crush or laceration	Combo	PROMIS PI CAT; PROMIS Depression CAT	QuickDASH; PSEQ	Outpatient Clinic (USA)
Menendez et al., 2015 [174]	Observational, Cross-sectional; Outcomes research (Level 2c)	200	Outcome Assessment	Multi-region	Fracture elbow, wrist, hand; Sprain, dislocation or mallet finger; Amputation, crush or laceration	Combo	PROMIS UE PF CAT; PROMIS PI CAT	NVS health literacy assessment tool	Outpatient Clinic (USA)
Menendez et al., 2015 [175]	Observational, Cross-sectional; Outcomes research (Level 2c)	122	Combination: Testing & Outcomes Assessment	Multi-region	Sprain, dislocation, mallet finger; Hand, Wrist, Elbow fracture; Amputation / Crush injury	Combo	PROMIS PI CAT; PROMIS Depression CAT; PROMIS UE PF CAT	Nil	Outpatient Clinic (USA)

Menendez et al., 2015 [176]	Observational, Cross-sectional; Outcomes research (Level 2c)	112	Outcome Assessment	Wrist and Hand	Hand conditions – traumatic and non-traumatic	Combo	PROMIS PI CAT; PROMIS UE PF CAT; PROMIS Depression CAT	Satisfaction rating - CGCAHPS; CARE; NVS health literacy test; Sociodemographic survey; Waiting time in office; Duration of visit; Time from booking till appointment	Outpatient Clinic (USA)
Moradi et al., 2015 [177]	Observational, Cross-sectional (Level 3b)	155	Outcomes assessment	Wrist and Hand	Hand fracture; Distal radius fracture; Sprain, rupture or dislocation; Elbow fracture; Amputation, crush or laceration	Combo	PROMIS Depression CAT	Pain and numbness on hand diagrams; PCS; SHAI-5	Outpatient Clinic (USA)
Morgan et al., 2015 [160]	Prospective cohort study (Level 2b)	47	Combination: Testing + Outcomes Assessment	Shoulder	Proximal humerus fracture	Trauma	PROMIS PF CAT	CMS; DASH; sMFA; ROM; Shoulder strength	Operative & Non-operative/ Outpatient Clinic (USA)
Okike et al., 2015 [161]	Observational, Cross-sectional (Level 3b)	207	Outcome Assessment	Shoulder	Proximal humerus fracture	Trauma	PROMIS PF CAT	CMS; DASH; sMFA; Nonunion; Malunion; Humeral head AVN; Complications (screw perforation, loss of fixation, infection, neurovascular injury, secondary surgery)	Operative (Locking plate fixation); Non-operative / Outpatient Clinic (USA)
Overbeek et al., 2014 [165]	Observational, Cross-sectional study; Outcome research (Level 2c)	93	Combination: Testing + Outcomes Assessment	Multi-region	Hand, wrist fractures; Mallet finger; Soft tissue injury; Animal bite	Combo	PROMIS PF CAT; PROMIS Depression CAT; PROMIS PI CAT	QuickDASH; NRS (11-point ordinal scale)	Outpatient Clinic (USA)
Peters et al., 2016 [135]	Observational, Cross-sectional; Outcome research (Level 2c)	111	Combination: Testing + Outcomes Assessment	Multi-region	Sprain, dislocation or mallet finger; Hand fracture; Wrist fracture; Amputation, crush or laceration; Carpal tunnel or cubital tunnel syndrome; OA; Trigger finger; Non-specific arm pain; Elbow fracture; DeQuervain tendinopathy; Dupuytren; Other	Combo	PROMIS Sleep disturbance CAT; PROMIS UE PF CAT; PROMIS PI CAT; PROMIS Depression CAT	Nil	Outpatient Clinic (USA)
Quispe et al., 2015 [158]	Case series (Level 4)	3	Outcome Assessment	Shoulder	Sternoclavicular joint dislocations	Trauma	PROMIS PF-Mobility CAT	DASH; Restoration of complete bony alignment and stability (Chest x-ray)	Operative – Trans-articular plating (USA)
Sindhu et al., 2012 [178]	Retrospective cohort study, Longitudinal (Level 2b)	3,362	Outcome Assessment	Shoulder	Fracture clavicle, shoulder, proximal humerus; Sprains and strains	Combo	Shoulder CAT	NRS (11-point ordinal); FABQ-PA	Outpatient Rehab Clinic (USA)
Sindhu et al., 2013 [179]	Secondary analysis of Prospective cohort study (Level 2b)	3,767	Combination: Development & Testing	Shoulder	Tendon / synovial rupture; Traumatic wounds or amputation; Contusions; Crush injury; Fracture / dislocation repair or reconstruction; Proximal Humerus, GT, LT, Humeral Head, Clavicle fracture; ACJ disruption	Combo	Shoulder CAT	NRS (0-10 scale)	Outpatient Rehab Clinic (USA)
Stuart et al., 2015 [180]	Prospective cohort study (Level 1b)	55	Combination: Testing + Outcomes Assessment	Multi-region	Fracture clavicle, distal humerus, radius, proximal humerus, intra-articular elbow	Trauma	PROMIS PF CAT	Nil	Outpatient Clinic (USA)
Tyser et al., 2014 [166]	Observational, Cross-sectional; Outcomes research (Level 2c)	134	Testing	Multi-region	NOS	Combo	PROMIS PF CAT	DASH	Outpatient Clinic (USA)
Van Lecuwen et al., 2016 [181]	Observational, Cross-sectional; Outcome research (Level 2c)	124	Combination: Testing + Outcomes Assessment	Multi-region	Upper extremity injury; Lower extremity injury inc fractures	Trauma	PROMIS PF CAT; PROMIS PI CAT	IEQ; PHQ-2; PSEQ-2; PCS-4	Outpatient Clinic (USA)
Wang et al., 2010 [159]	Prospective cohort study; Outcomes research (Level 2c)	30,987	Combination: Testing + Outcomes Assessment	Shoulder	Tendon / synovial rupture; Traumatic wounds or amputation; Contusions; Crush injury; Fracture / dislocation repair or reconstruction; Proximal Humerus, GT, LT, Humeral Head, Clavicle fracture; ACJ disruption	Combo	Shoulder CAT	Nil	Outpatient Rehab Clinic (USA)

Abbreviations (in order of appearance): Combo, Combination of traumatic and non-traumatic conditions; nos, not specified or non-applicable; PROMIS, Patient Reported Outcome Measurement Instrumentation System; PF, Physical function; ASES, American Shoulder Elbow Society Score; SST, Simple Shoulder Test; SHO-CAT, Shoulder CAT; FLEX-SF, Flexi-level scale of shoulder function; SF-12, Short Form-12; nos, not specified; UE, upper extremity; PI, Pain Interference; QuickDASH, Quick Disabilities of the Arm, Shoulder and Hand' PSEQ-2, Pain Self Efficacy Questionnaire-2; PHQ-2, Patient Health Questionnaire; DA-CAT, Daily Activity CAT; AM-PAC-CAT, Activity measure for post-acute care CAT; SFS-CAT, Shoulder Functional Status CAT; CAT-FS, Functional Status CAT; GROC, Global Rating of Change; sMFA, Short Musculoskeletal Functional Assessment; MCPJ, Metacarpo-phalangeal joint; PB, Pain behaviour; PACES, Physical activity enjoyment scale; PCS, Pain Catastrophizing Questionnaire; PIPS, Psychological Inflexibility in Pain Scale; ICF, International Classification of Functioning, Disability and Health; VAS, Visual analogue scale; NVS, Newest vital sign; CGCAHPS, Clinician and Group-Consumer Assessment of Healthcare Providers and Systems survey; CARE, Consultation and relational empathy measure; SHAI, Short Health Anxiety Inventory; CMS, Constant Murrly Score; ROM, range of motion; AVN, Avascular necrosis; NRS, Numerical Rating scale; FABQ-PA, Fear avoidance beliefs questionnaire physical activities scale; GT, Greater tuberosity; LT, Lesser tuberosity; ACJ, Acromioclavicular joint; IEQ, Injustice experience questionnaire

Table 11. Systematic Review III: Comparison of psychometric properties in studies involving CATs and fixed scales

	Psychometric Properties		
	Validity, Reliability, Responsiveness	Interpretability (Floor-Ceiling Effects)	Feasibility / Ease of Use
Beckmann et al., 2015(162)	PROMIS PF CAT, ASES and SST demonstrate moderate correlation. Item reliability was excellent for all instruments. Person reliability of PROMIS PF CAT was superior (0.93, excellent) to SST (0.71, moderate) and ASES (0.48, fair).	Ceiling effects were similar among all instruments (PF, 0.53%; SST, 6.1%; ASES, 2.3%). Floor effects found in 21% for SST, 3.2% for PF CAT and 2.3% for ASES.	PROMIS PF CAT required fewer questions than ASES or SST (PROMIS PF CAT, 4.3; ASES, 11; SST, 12) for test completion.
Cook et al., 2005(163)	n/a	n/a	SHO-CAT required only a few items before the SEM-based stopping rule was reached (6% were administered <3 items, 61% <5 items and 73% <10 items)
Doring et al., 2014(113)	PROMIS UEPF CAT & QuickDASH demonstrated strong correlation (β=-.81; p<.001) & both had moderate correlation with PROMIS PF CAT & PROMIS PF Mobility CAT. PROMIS PI CAT was the strongest correlate of QuickDASH (β=-0.66; p<.001) & PROMIS UEPF CAT (β=2.0; p<.001).	PROMIS UE PF CAT showed no floor (0%) or ceiling effects (0%). QuickDASH showed no ceiling effects and 1 patient scored 0.	PROMIS PF CAT demonstrated significantly shorter completion times than QuickDASH (Mean (SD) Range: QuickDASH, 116s (47) 42-281 versus PROMIS UEPF CAT 70s (47) 25-307; p<.001)
Hung et al., 2014(44)	PROMIS PF CAT and sMFA showed extremely high item reliability (Cronbach Alpha = 0.98).	Neither instrument showed any floor effect. sMFA revealed 14.4% ceiling effect and PROMIS PF CAT had no appreciable ceiling effect.	PROMIS PF CAT administration time was 44s versus 599 s for sMFA (p<0.05)
Kortlever et al., 2015(131)	Substantial correlation between PCS (0.74), PIPS (0.84), PROMIS PI CAT (0.83), PSEQ (-0.86) & underlying trait. Interquestionnaire correlations was large-substantial with highest, PROMIS PI CAT with PSEQ (rho=-0.84, p<0.001) & lowest, PROMIS PI CAT with PCS (rho=0.67, p<0.001). Internal consistency was high. PROMIS PI CAT had strongest correlation with QuickDASH (B 0.63; SE 0.10, p<0.001).	n/a	PROMIS PI CAT was the quickest to complete (Median (IQR): PROMIS PI CAT, 30s (22-44); PCS, 91s (66-122), p<0.001; PIPS, 105s (82-141), p<0.001; PSEQ, 78s (60-101), p<0.001)

Menendez et al., 2013(164)	Large correlation between QuickDASH & PROMIS PI CAT (r=0.74; p<0.001) and between PROMIS PI CAT & PSEQ (r=-0.72, p<0.001). PROMIS Depression CAT had medium correlation with QuickDASH (r=0.37; p<0.001) & PROMIS PI CAT (r=0.40; p<0.001). 51% variability in QuickDASH is explained by PROMIS PI alone.	n/a	n/a
Morgan et al., 2015(160)	PROMIS PF CAT correlated significantly (moderate to high) with all other physical function outcome mesures (i.e. DASH, SMFA, CMS)	n/a	Patients responded to fewer PROMIS PF CAT items (mean 4, range 4-8) than other scores (6 for Constant Shoulder Score, 30 for DASH and 46 for SMFA). Time to completion of the PROMIS PF CAT was 98 secs, (median); which was significantly less than DASH (median, 482s, p<0.001).
Overbeek et al., 2014(165)	QuickDASH moderately correlated with PROMIS PF CAT (r=-0.55, p<0.001). PROMIS PF CAT and QuickDASH correlated strongly with PROMIS depression (r=-0.35, p<0.001; r=0.34, p<0.001) and PROMIS PI CAT (r=-0.51, p<0.001 and r=0.74, p<0.001) respectively. Factors accounting for variability in PROMIS scores were comparable to those for Quick DASH.	n/a	n/a
Tyser et al., 2014(166)	DASH and PROMIS PF CAT had a strong correlation (r=0.726). Item and person reliabiity were 0.97 and 0.94 respectively for DASH, and 0.99 and 0.96 for PROMIS PF CAT. DASH and PF CAT had 5% and 5% of unexplained variance respectively.	DASH exhibited 5% ceiling effect and 1% floor effect whereas PF CAT had no ceiling or floor efects.	DASH mean time to completion was 262s and PROMIS PF CAT 57s.

Table 12. Systematic Review III: Quality Assessment. (COSMIN checklist and 4-point scoring system)

		Reliability			Validity Construct Validity				Responsiveness	
Author (Year)	IRT Box	A. Internal Consistency	B. Reliability	C. Measurement error	D. Content Validity	E. Structural Validity	F. Hypothesis Testing	H. Criterion Validity	I. Responsiveness	J. Interpretability
Beckmann et al., 2015(162)*	Good	Fair	n/a	n/a	Good	Fair	Good	n/a	n/a	SD; FC
Cook et al., 2005(163)*	Good	Fair	Fair	Fair	Excellent	Poor	Fair	n/a	Fair	SD; SC; MCID
Doring et al., 2014(113)*	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD; SC; FC
Haley et al., 2009(167)*	Excellent	Good	n/a	n/a	Excellent	Good	Fair	n/a	n/a	SD; SC; FC
Hart et al., 2006(168)*	Excellent	Excellent	n/a	n/a	Excellent	Excellent	Fair	n/a	Fair	SD; SC; MDC
Hart et al., 2010(169)	n/a	n/a	n/a	Good	Good	n/a	n/a	n/a	Excellent	SD; SDC; FC; MDC; MCID
Hays et al., 2013(170)*	Excellent	Fair	n/a	n/a	Good	Fair	n/a	n/a	n/a	SD; SC; FC
Hung et al., 2011(51)*	Good	Excellent	n/a	n/a	Excellent	Excellent	n/a	n/a	n/a	SD; SC; FC
Hung et al., 2014(44)*	Good	Good	n/a	Good	Good	Good	n/a	n/a	n/a	SD; FC
Janssen et al., 2015(84)*	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD; SC
Jayakumar et al., 2014(111)	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD; SC
Jette et al., 2007(171)*	Good	n/a	n/a	Good	Excellent	Good	n/a	n/a	Good	SD; SC; FC; MDC
Kortlever et al., 2015(131)*	n/a	Good	n/a	n/a	Excellent	Good	Good	n/a	n/a	SC; FC
Lehman et al., 2011(172)	Excellent	Excellent	n/a	n/a	Excellent	Excellent	n/a	n/a	n/a	SD; FC
Mellema et al., 2015(173)	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD; SC

Menendez et al., 2013(164)	n/a	n/a	n/a	n/a	Good	n/a	Excellent	n/a	n/a	SC
Menendez et al., 2015(174)	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD
Menendez et al., 2015(175)	n/a	n/a	n/a	n/a	Good	n/a	Fair	n/a	n/a	SC
Menendez et al., 2015(176)	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD; SC
Moradi et al., 2015(177)	n/a	n/a	n/a	n/a	Excellent	n/a	Good	n/a	n/a	SC
Morgan et al., 2015(160)	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD; SC; FC
Okike et al., 2015(161)	n/a	n/a	n/a	n/a	Poor	n/a	n/a	n/a	n/a	SC
Overbeek et al., 2014(165)*	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD; SC
Quispe et al., 2015(158)	n/a	n/a	n/a	n/a	Poor	n/a	n/a	n/a	n/a	SD, SC
Peters et al., 2016 (135)	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SD
Sindhu et al., 2012(178)	Good	Good	Good	Good	Good	Poor	Good	n/a	Poor	SD; SC; MDC
Sindhu et al., 2013(179)*	Good	n/a	n/a	n/a	Excellent	n/a	Fair	n/a	n/a	SD; SC
Stuart et al., 2015(180)	n/a	n/a	Good	n/a	Good	n/a	n/a	n/a	n/a	SD; SC
Tyser et al., 2014(166)*	Good	Good	n/a	n/a	Good	Good	Fair	n/a	n/a	SD; SC; FC
Van Leeuwen et al., 2016(181)	n/a	n/a	n/a	n/a	Good	n/a	Good	n/a	n/a	SC
Wang et al., 2010(159)*	Excellent	Excellent	n/a	n/a	Excellent	n/a	n/a	n/a	n/a	SD; SC; MDC; MCID

2.4.5 Discussion

Based on the primary objective, CATs utilised in upper extremity trauma populations demonstrated moderate to strong correlations with fixed length scales along with superior floor-ceiling effects and test completion times. Computer adaptive PRO measures may be suited to outcome measurement after trauma due to these advantages along with their potential for more precise and efficient measurement over a broader range (Figure 6b). This is clearly beneficial in adult fracture populations which include a wide range of patient demographics and at times, large shifts in health status often at extreme ends of a scale. The secondary objectives also provided some interesting insights. Studies were highly variable in terms of design, diagnoses, outcome measures and methodological quality. Most investigations were cross-sectional and observational. Consequently, reliability and measurement error were rarely assessed. The few longitudinal investigations had variable definitions of test conditions, highlighting the need for high quality prospective evaluations over time.

In this review, the PROMIS measures were the most frequently used CATs. These measures provide a reference to U.S population norms. PROMIS measures of various health domains are incorporated in the experimental studies of this thesis and specific PROMIS CATs are described in further detail in the upcoming chapters. A further observation was the substantial number of studies requiring contact with corresponding authors due to the lack of clarity around population characteristics and surprising failure to recall specific diagnoses in their cohorts. This may reflect a greater focus placed on the PRO measurements over the population being assessed. Whilst appropriate evaluation of PRO measures is critical, properties of CATs, like all outcome measures, should be defined for the population tested, and not for the instruments themselves (95). Any deviation from this principle has the potential to compromise validity of the work and interpretation of findings. Greater adoption of established quality assessment standards such as the COSMIN checklist at the initial stages of study design may improve reporting quality and negate such limitations.

a. Limitations

The limitations of this review should be considered. Firstly, the broad search strategy generated a high volume of data and consequently a highly heterogeneous selection of articles. Processing such a large dataset could have led to errors in identifying studies, compromising some of the internal validity of this work. In this regard, studies observing unfavourable results from PRO measurement testing, may not have been reported or published, conferring a level of publication bias (154). Secondly, caution should be expressed regarding the interpretation of findings from a highly variable study set. However, the exploratory approach was felt necessary given the contemporary nature of this field and thus, the methodology aimed to be systematic in meeting the study objectives. Third, although the COSMIN checklist was probably the most appropriate assessment tool for this review, deploying a scoring system on a relatively heterogeneous study set is prone to some level of error. Error is also possible whenever subjective judgements are made to ensure the 'best possible fit'. The variable quality of reporting and potential differences in PRO measurement terminology between articles and the COSMIN criteria may have compounded this aspect. Independent analysis and consensus-based discussions by the research team aimed to minimise this error. Finally, due to a limited study set a quantitative evaluation of psychometric properties and strength of evidence analysis was not possible highlighting the requirement for further research in this area.

b. Conclusion

This systematic review aimed to define the performance of CATs versus fixed length scales in orthopaedic trauma to the upper extremity. The correlation with established fixed length scales, superior floor-ceiling effects and test completion times provided support for their use in these populations. Based on the increasing demand for outcome measures that are fast, accurate and place minimal burden on the responder, CATs may fast become the PRO measures of choice in assessing outcomes following orthopaedic trauma. This is also relevant in the age of value based health and comparative effectiveness of interventions where CATs may aid assessment and

comparison of specific health domains across conditions (182)(183)(184)(185). However, there is a need for longitudinal evaluations in populations with specific injuries and clinical settings outside the U.S. where most of these investigations have been performed. Clinical, technological and cultural barriers may need to be overcome before their widespread adoption in the UK where trauma services rarely assess outcomes on paper, let alone use digital platforms in the process. However, based on the observed increase in levels of research activity using these contemporary outcome measures and their favourable measurement properties, it may only be a matter of time before the large-scale utilisation of CATs in orthopaedic trauma.

Chapter 3

3. The Correlation of PROMIS Physical Function CAT with QuickDASH in Patients with Upper Extremity Conditions

3.1 Background

The systematic reviews in Chapter 2 established a range of influential factors associated with disability following orthopaedic trauma to the upper extremity, defined PRO measures that incorporated trauma patients in their original development, and highlighted the superior performance of specific CATs applied to these populations. In this chapter, a pilot study was designed to apply well-investigated PRO measures of disability and psychosocial factors, informed by the systematic reviews, in a population with upper extremity conditions. The QuickDASH (i.e. a region-specific fixed scale), PROMIS PF (i.e. a computer adaptive general measure of physical function), PROMIS Depression and PROMIS PI were selected.

The overarching goal was to establish a methodology for addressing the core objectives of this thesis and to assess the feasibility of using a web-based, computerized platform for measuring patient outcomes in an upper extremity fracture population at a UK trauma centre. The study aimed to assess the correlation between PROMIS PF and QuickDASH and the correlation between both these measures and PROMIS Depression and PROMIS PI, accounting for patient characteristics and other clinical and social factors. In practical terms, this pilot study also provided an opportunity to gain technical experience in programming the computerised outcome measurement platform for use within the core experimental studies of this thesis.

There is considerable evidence to date for the correlation between CATs and various forms of fixed length questionnaires with correlational analysis being frequently performed in the validation of PRO measures (186). However, it is recognised that further work is required to establish the interactions between specific fixed scale measures and CATs relevant to the

population being investigated (186). A correlation between the QuickDASH and PROMIS PF had not been previously assessed in upper extremity populations. The prospect of a correlation between a region-specific and generic health measure could imply the measurement of a common underlying trait, un-related to anatomical location. This may necessitate the requirement for further research to determine which specific constructs these outcome measures are actually measuring. Furthermore, if common underlying traits are being measured by multiple instruments, only certain measures may be necessary, indicating the potential for minimising responder burden, measurement redundancy and test administrations (113)(160)(166)(187)(188). Failing to appreciate this could result in increased burden, measurement fatigue, poor patient experience and inaccurate scoring (8)(9)(187)(188).

The QuickDASH was developed with responder burden in mind using stringent item reduction techniques (42)(191). Containing eleven items compared to thirty, the developers of the QuickDASH aimed to retain clinically important content and similar measurement properties of the full version (192)(193). In contrast, the PROMIS PF was developed using IRT which also aimed to ease the questionnaire burden by administering only relevant items in an adaptive fashion, limiting the number of items and test times to reach a valid score (45)(46)(50)(54)(194). PROMIS PF combines the assessment of both upper and lower extremity physical function (52)(195)(196). Interestingly the developers found minimal differences in scoring characteristics between conditions in either region within early field tests (52)(195)(196). In other words, upper extremity conditions were being scored in the same way as lower extremity activities suggesting the instrument may not be measuring the impact of health focused on the upper extremity alone. It has been suggested that psychosocial factors could mediate this relationship. Thus, PRO measures of depression and pain interference were also included in this pilot study. Instrument choice was based on performance highlighted in prior studies and the previous systematic reviews in this thesis (70)(103)(197).

3.1.1 Objectives

The primary scientific objective was to assess the level of correlation between PROMIS PF and QuickDASH in a population with a range of upper extremity conditions. The secondary objective was to assess the correlation between PROMIS PF and QuickDASH with PROMIS Depression and PROMIS PI, accounting for patient demographics, clinical and social factors.

3.2 Methods

3.2.1 Study Design

New and follow-up patients presenting to the hand surgery outpatient clinics of three surgeons were invited to participate in an institutional review board-approved observational cross-sectional study between May 2013 and June 2013 (IRB No. 2009P001019/MGH) (Appendix 8). This was a consecutive series of patients, except for those missed by investigators collecting data from other rooms. All were recruited from general outpatient clinics only and not complex upper extremity clinics. Those younger than 18 years, with diagnosed mental health conditions, and/or unable to communicate in English were excluded. 105 patients fulfilled eligibility criteria, 11 declined participation, and one ran out of time to complete an assessment.

3.2.2 Patient Characteristics

The final cohort of 93 patients included 41 men and 52 women with an average age of 50 ± 18 years (range, 21-94 years) (Table 13). All tables related to this study are presented at the end of the results section. Diagnoses ranged from non-traumatic conditions (e.g. carpal tunnel syndrome) to traumatic conditions (e.g. distal radius fractures). Informed consent and data protection approvals were obtained from all patients. Outcomes were delivered using a secure, encrypted, web-based PRO administration and data collection tool (AssessmentCenter℠, Northwestern University 2007-2013) which was used throughout this thesis (Appendix 9). The electronic portal enabled user-friendly programming of patient and clinical data with all fixed scale and computer adaptive PRO measures into one outcome measurement package.

3.2.3 Outcome Measures

Outcome measures utilised in this and subsequent chapters are fully described at first introduction from this point on in this thesis. PRO measurement questionnaires (sample versions) and licensing details are catalogued in an indexed section in the appendix for ease of reference (Appendix 10).

In this study, patients completed the PROMIS Physical function (v1.0) and QuickDASH to assess physical function and arm-specific disability. PROMIS Pain interference (v1.0) and PROMIS Depression (v1.0) were also completed. Pain intensity at the time of enrolment was measured with an 11-point ordinal measure (0-10, Numerical Rating Scale) (Table 14).

All PROMIS measures were administered via CAT which administers relevant questions using a dynamic item selection algorithm, based on the participant's previous response (198). The overall score of each PROMIS instrument ranges from 0 (minimum) to 100 (maximum) points, with a score of 50 points representing the mean and 10 the standard deviation for a general population in the U.S. All PROMIS measures include response options on a 5-point Likert scale: (1 = not at all; 2 = a little bit; 3 = somewhat; 4 = quite a bit; or 5 = very much) (199). Higher scores reflect greater levels of the measured construct. For instance, higher PROMIS PF implies greater physical function and greater PROMIS Depression reflects higher levels of depression (50)(47).

The PROMIS PF (v1.0) assesses the ability to accomplish physical activities ranging from low-intensity tasks (e.g. dressing) to vigorous physical activities (e.g. strenuous sports). Questions are indicative of health status at the time of completion (51)(52)(195). Lower scores indicate higher levels of disability.

PROMIS Depression CAT (v1.0) assesses the level of depressive symptoms by measuring negative mood (sadness, guilt), views of self (worthlessness, self-criticism) & diminished positive affect and engagement (loss of interest) within the previous week (200)(201)(202). The test administers questions regarding symptom severity in relation to depression within the past 7 days using a 28-item question bank (202)(201).

The PROMIS Pain Interference CAT (v1.0) assesses the impact of pain on common activities of daily life including social, cognitive, emotional, physical, and recreational aspects using a 41-item question bank (203).

QuickDASH is an abbreviated version of the full 30-item DASH consisting of 11 items related to physical functioning (e.g. daily tasks, social activities, work and sleep) and arm symptoms (e.g. pain, tingling) answered on a 5-point Likert scale (206)(207)(208)(209). Participants need to answer at least 10 items to generate a total score, scaled from 0 to 100 with higher scores representing greater disability (204).

The NRS for pain is an 11-point ordinal scale of pain intensity anchored by opposite statements i.e. “no pain” (zero) versus “worst possible pain” (ten) (208)(209).

3.2.4 Statistical Analysis

An a priori power analysis indicated that a minimum sample size of 84 patients was needed to detect a 0.4 (moderate) correlation between the QuickDASH and PROMIS PF with 80% power (alpha 0.05). Thus, a total of 93 patients was required, factoring in a 10% incomplete data level.

Bivariate and multivariable analyses were conducted to assess the objectives. A Pearson correlation was conducted to assess normally distributed variables. Spearman's rank correlation was conducted for non-parametric data. The strength of correlations between PRO measures were classified as high (>0.7), high-moderate (0.61-0.69), moderate (0.4 to 0.6), moderate-weak (0.31 to 0.39), or weak (<0.3) (210). The association between dichotomous variables and continuous variables was analysed using the Student t-test in case of normally distributed data and the Wilcoxon rank-sum test in case of non-normally distributed data. The association between categorical variables (e.g. marital status, work status) and continuous variables were analysed by use of the one-way analysis of variance test in case of normally distributed data and the Kruskal-Wallis test for non-normally distributed data.

To determine the factors that were independently and most strongly associated with PROMIS PF and QuickDASH score, a backward, stepwise, multivariable linear regression analysis was performed. Explanatory variables that met the $p<0.10$ significance criteria in bivariate factor analysis were entered into multivariable linear regression. An adjusted R-squared (R^2) was calculated to assess the collective influence of the factors in the final multivariable regression model on the variability associated with PROMIS PF and QuickDASH scores. Mean imputation was used for one missing pain intensity score and the marital status of one patient was retrieved from the medical records. All statistical analysis including power estimations were performed using STATA 14.0 (StataCorp LP, College Station, TX, USA).

3.3 Results

The mean QuickDASH score was 34 [23 (SD), 0-95 (Range)] and the mean PROMIS PF score was 46 [9.5 (SD), 20-66 (Range)] (Table 14). There was a moderate correlation between the PROMIS PF and QuickDASH ($r = - 0.55$; $p< 0.001$) (Table 15).

Higher PROMIS PF correlated with lower PROMIS Depression ($r= -0.35$; $p<0.001$) and PROMIS PI ($r= -0.51$; $p<0.001$). Similarly, higher disability on the QuickDASH correlated with PROMIS Depression ($r= 0.34$; $p<0.001$) and PROMIS PI ($r= 0.74$; $p<0.001$) (Table 15). Other correlates of greater disability in bivariate analysis included older age, work status and prior surgery (Table 15).

After controlling for likely confounding variables in multivariable analysis, pain interference had the strongest influence on physical function (Beta=-0.57, partial $R^2 =0.25$; $p<0.001$). Together with male sex, presence of other pain conditions, prior surgery, retired patients, unemployed patients who were unable to work, and patients on workers' compensation the full model accounted for 49% of the variance in PROMIS PF (Table 16).

After controlling for likely confounding variables, PROMIS PI had the strongest influence on QuickDASH scores (Beta=1.9, partial $R^2 =0.48$; $p<0.001$). Together with older age, being a homemaker, being unemployed but able to work and unemployed and unable to work, and being on workers' compensation, the full model accounted for 61% of the variance in QuickDASH scores (Table 16).

Table 13. Patient Demographics

Demographic	Mean	SD	Range
Age (years)	50	18	21-94
Education (years)	15	2.3	12-20
Sex	**Number**	**Percent**	
Women	52	56	
Men	41	44	
Work status			
Working full-time	41	44	
Working part-time	11	12	
Homemaker	1	1.1	
Retired	21	23	
Unemployed, able to work	6	6.5	
Unemployed, unable to work	11	12	
Workers compensation	1	1.1	
Currently on sick leave	1	1.1	
Marital status			
Single	35	38	
Living with partner	2	2.2	
Married	41	44	
Separated/divorced	12	13	
Widowed	3	3.2	
Diagnosis			
Non-Traumatic	46	49	
Carpal tunnel syndrome	11	12	
Trigger finger/thumb	10	11	
Cubital tunnel syndrome	7	8	
Wrist pain nos	4	4	
Hand Osteoarthritis	4	4	
Dupuytren's contracture	4	4	
Heterotopic ossification elbow	3	3	
Hand infection	3	3	
Traumatic	47	51	
Distal radius fracture	9	10	
Trauma nos	7	8	
Hand fracture nos	7	8	
Soft tissue injury	7	8	
Elbow fracture	5	5	
Nerve injury	4	4	
Mallett finger	4	4	
Tendon laceration	4	4	
Prior surgery			
Yes	10	11	
No	83	89	
Sought treatment before			
Yes	37	40	
No	56	60	
Other pain conditions			
Yes	27	29	
No	66	71	

Table 14. Health-related Outcomes

Health-related outcomes	Mean	SD	Range
QuickDASH	34	23	0-95
PROMIS PF	46	9.5	20-66
PROMIS PI	57	7.5	39-75
PROMIS Depression	47	9.1	34-65
NRS	3.9	2.8	0-10

Table 15. Bivariate Analysis

	PROMIS PF		QuickDASH	
Sex	Mean (SD)	p value	Mean (SD)	p value
Men	48 (9.4)	0.034	31 (21)	0.21
Women	44 (9.2)		37 (24)	
Marital status				
Single	46 (9.3)		33 (23)	
Living with partner	40 (7.1)		28 (11)	
Married	47 (9.3)	0.26	33 (22)	0.44
Separated/divorced	42 (11)		38 (27)	
Widowed	37 (9.1)		58 (19)	
Work status				
Working full-time	49 (8.1)		28 (18)	
Working part-time	50 (5.2)		18 (12)	
Homemaker	50 (0)		75 (0)	
Retired	42 (8.7)	0.0014	39 (22)	0.0018
Unemployed, able to work	43 (13)		41 (21)	
Unemployed, unable to work	37 (10)		58 (26)	
Workers Compensation	37 (0)		39 (0)	
Currently on sick leave	45 (0)		36 (0)	
Traumatic condition				
Yes	43 (7.4)	0.310	38 (21)	0.350
No	50 (8.1)		31 (20)	
Other pain condition				
Yes	41 (8.3)	< 0.001	38 (22)	0.20
No	47 (9.3)		33 (23)	
Sought treatment before				
Yes	44 (9.2)	0.12	36 (24)	0.67
No	47 (9.6)		33 (22)	
Prior surgery				
Yes	39 (10)	0.014	47 (24)	0.080
No	46 (9.2)		33 (22)	

Health-related outcomes	**Coefficient**	**p value**	**Coefficient**	**p value**
QuickDASH	-0.55	< 0.001	N/A	N/A
PROMIS PF	N/A	N/A	-0.55	< 0.001
PROMIS PI	-0.51	< 0.001	0.74	< 0.001
PROMIS Depression	-0.35	< 0.001	0.34	< 0.001
Age	-0.27	0.0084	0.23	0.026
Years of education	0.17	0.10	-0.19	0.074
Pain	-0.20	0.055	0.38	< 0.001

Table 16. Multivariable analysis

PROMIS PF	Coefficient	Partial R^2	SE	p value	Adjusted R^2	95% CI	
PROMIS PI	-0.57	0.25	0.11	< 0.001		-0.78	-0.36
Sex	3.2	0.054	1.5	0.030		0.31	6.1
Other pain conditions	-3.8	0.059	1.6	0.023		-7.0	-0.53
Prior surgery	-4.3	0.039	2.3	0.066	0.49	-8.9	0.29
WS: retired	-4.7	0.080	1.7	0.0080		-8.2	-1.3
WS: unemployed, unable to work	-6.5	0.076	2.4	0.010		-11	-1.6
WS: on Workers Compensation	-19	0.083	6.9	0.0070		-33	-5.5

In model: sex, work status (WS), other pain conditions, prior surgery, age, education, PROMIS PI, PROMIS Depression.

QuickDASH	Coefficient	Partial R^2	SE	p value	Adjusted R^2	95% CI	
PROMIS PI	1.9	0.48	0.22	< 0.001		1.5	2.4
Age	0.24	0.081	0.086	0.0070		0.065	0.41
WS: homemaker	43	0.094	14	0.0040	0.61	14	71
WS: unemployed, able to work	14	0.056	6.0	0.027		1.6	26
WS: unemployed, unable to work	13	0.072	5.0	0.011		3.0	23
WS: on Workers Compensation	31	0.050	14	0.036		2.0	59

In model: work status (WS), prior surgery, age, education, PROMIS PI, PROMIS Depression.

3.4 Discussion

This pilot study successfully informed the basic methodology for experiments in this thesis and proved feasible in delivering a web-based, computerized outcomes measurement program to a population with upper extremity conditions. In terms of the scientific objectives, the study aimed to assess whether PROMIS PF, a computer adaptive general measure of physical function, could measure upper extremity disability as well as the QuickDASH, a region-specific fixed scale questionnaire. Based on the correlation between the two instruments, PROMIS PF could be utilised as a measure of disability following upper extremity conditions. One should also take into account the strong correlation with depression, as well as the strong influence of pain interference in explaining the largest proportion of variation in both disability measures.

The correlation between PROMIS PF and QuickDASH, and other generic and region-specific PRO measures can be explained in three ways (197)(211).

First, there are a growing number studies demonstrating the strong correlation between psychosocial factors and both generic and region-specific disability measures. These relationships have been well-defined in the first systematic review in Chapter 2. The strong correlation between measures of disability and psychosocial factors may suggest that measures of disability more closely assess psychological and social domains over impairment i.e. disability is not intrinsically defined by or focused on pathophysiology or anatomical regions.

Second, both general disability and region-specific disability may be influenced by general health and activity levels. In other words, an individual's general health may have a universal influence on the performance of physical functions at the level of tasks and roles irrespective of which region is predominantly involved.

Finally, general measures of health and physical function may contain sufficient numbers of upper extremity-specific items to achieve a high enough correlation during assessment. For instance, a generic PRO measure that assesses self-care may adequately capture the impact on this domain following an arm or a leg problem. In contrast, it is important to recognise that some generic measures may be less responsive when investigating specific conditions and be prone to floor-ceiling effects (197)(211). This may be due to these instruments measuring domains that aren't wholly relevant to the condition being assessed.

In relation to the secondary objectives, both disability measures correlated with symptoms of depression and pain interference. This is consistent with prior research (52)(88). Pain interference is also considered under the aspect of ineffective coping (131). This factor showed a stronger influence on disability in multivariable analysis despite the strong correlation of both depression and pain interference with disability in bivariate analysis. Secondary gain (i.e. worker's compensation) also demonstrated a strong correlation with both measures of disability, which is again consistent with prior work and shown to have a sociological influence on illness [38]. In terms of pain, 'other pain conditions' explained some of the variation in general disability (PROMIS PF), however, the influence was lower compared to psychosocial factors. Interestingly, upper limb diagnoses classified by traumatic and non-traumatic conditions did not correlate with either disability measure, providing further indications that pathophysiology may play less of a role compared to psychosocial factors.

3.4.1 Limitations

Firstly, although correlational analysis provides a form of validity assessment, more sophisticated statistical approaches, such as factor analysis and principal component analysis, offer greater empirical support in understanding the dimensionality and construct validity of PRO measures (40). In other words, these methods provide a more comprehensive means of establishing the underlying constructs being measured by such instruments.

Considering this, the next chapter performs factor analysis on a range of upper extremity disability measures. Secondly, this study assessed a heterogenous selection of patients from a general hand and upper extremity clinic. Findings may have differed by diagnoses, patient backgrounds, levels of psychological distress, specific traumatic or non-traumatic conditions, certain anatomic locations, time point along the recovery process and capacity to cope in response to pain. Finally, although it wasn't within the scope of this study, it would have been useful to assess acceptability (i.e. test completion times) and precision (i.e. floor-ceiling effects) to further compare fixed scale and computer adaptive PRO measures. Chapter 4 also assesses floor-ceiling effects related to a range of disability PRO measures utilised in upper extremity conditions

3.4.2 Conclusion

This study observes the correlation between a general measure of disability, the PROMIS PF, and a region-specific measure, the QuickDASH, in patients with upper extremity illness. This relationship may be due to both measures being strongly affected by psychosocial factors. In this study, pain interference, which reflects coping strategies, was the dominant factor explaining most of the variation in disability. These and other factors are assessed in further detail in the chapters 5,6 and 7 which examine the influential factors predicting disability after proximal humerus, elbow and distal radius fractures respectively. The next chapter expands on the findings of this study and assesses the underlying constructs between disability measures of general health, general physical function, arm specific function and joint specific function using factor analysis alongside their floor-ceiling effects.

Chapter 4

4. Performance of PRO Measures of Disability and Patient Experience following Upper Extremity Fractures

4.1 Background

In Chapter 3, a web-based, computerized platform, programmed with a set of PRO measures was successfully administered in patients with a range of upper extremity conditions and the data showed a correlation between PROMIF PF and QuickDASH as well as the dominant influence of psychosocial factors, such as pain interference on both these measures of disability. This chapter formed an expansion of this work and assessed the correlation between different types of disability measure and satisfaction scales applied to an upper extremity fracture population over the course of recovery. It also aimed to define the underlying constructs being measured by these instruments alongside their floor and ceiling effects.

The overarching goal was to identify the extent to which disability measures that differed by type i.e. generic or region-specific, and mode of administration i.e. fixed scale or computer adaptive, correlated with one another and with patient experience. Furthermore, the study aimed to understand whether these measures of disability were addressing similar or different underlying constructs, and how they performed at extreme ends of the scale.

A patient-centered, biopsychosocial approach to health care requires musculoskeletal HCPs to respond to the needs, preferences and values of individuals (35)(62)(212)(213)(214). In a broader sense, when considering 'population health', appreciating these needs is integral to the growing trend toward value-based models of health care focused on patients and outcomes, over volume-driven systems built around clinicians (215). From both perspectives, it has become important to gauge patient perceptions on the limitations they face following a condition (i.e. disability) and the quality of care received in managing these conditions (i.e. experience).

This thesis accepts the definition and conceptual framework of disability developed by the WHO ICF (19). The term represents the subjective impact of health conditions on meaningful physical functions required for life, work and recreation, which can be assessed by PRO measures. These measures are frequently selected to assess disability without necessarily appreciating the health domains or underlying constructs being measured (21).

Patient experience is quantified by a variety PREMs that gauge aspects of health care delivery and quality within health care systems (216)(217). In practice, these include a range of scales that measure aspects such as satisfaction, confidence, education, support, recommendation and expectation management by HCPs and services along the pathway of care (56).

In orthopaedic surgery, there is substantial interest in the measurement of PROs and patient reported experience following musculoskeletal conditions (31). Musculoskeletal PRO measures can be classified by type i.e. region-specific, condition-specific and generic health measures, and mode of administration i.e. fixed scale or CAT (218). Fixed scales developed using classical test theory are well-established but require completion of most if not all items to generate a valid total score, which can be time-consuming (52)(202). Furthermore, as the range of questions are often limited, they may be subject to floor and ceiling effects (52)(202). All this runs the risk of increased responder burden, questionnaire fatigue, distraction and altered responses leading to an inaccurate or incomplete final dataset (31)(219).

In 2004, the US National Institute of Health developed PROMIS in response to these limitations (47)(41). PROMIS aims to provide dynamic and personalized PRO measurement using CATs developed using extensive question (or item) banks and IRT (50)(46)(45)(54). Health domains are theoretically assessed with greater precision and efficiency using targeted, adaptive questioning based on a participant's prior response (45)(46)(50)(54)(55). These measures are described in detail in Chapter 2.

PROMIS measures are the most commonly used CATs in clinical research and PROMIS PF one of the most widely utilized in orthopedics (51)(218). These measures have been tested in a range of musculoskeletal conditions (41)(166)(218)(220). In its original form, PROMIS PF assesses disability in both upper and lower extremities, and based on initial field tests showed little difference between conditions from either region (54)(51)(195)(196). However, further studies demonstrated differential functioning of items in specific populations and suggested that the validity of PROMIS PF could be compromised in assessing upper extremity function (221)(51). This led to the development of PROMIS upper extremity (UE) PF. PROMIS PF and PROMIS UE PF demonstrate strong correlations with QuickDASH in general upper limb conditions (113)(165)(222). However, potential ceiling effects of PROMIS UE PF in high demand younger adults have been highlighted (221).

Considering the relationship between disability and patient experience, some studies have proven the assumption that patients with fewer limitations tend to be more satisfied with care (223). Threshold values in QuickDASH scores were shown to be highly predictive of patient satisfaction following open carpal tunnel decompression (223). Similar findings have been observed in rotator cuff surgery (224). Interestingly, this interaction is somewhat mixed in studies involving lower limb arthroplasty (225)(226). Despite total hip and knee replacements being recognized as two of the most successful procedures in orthopaedic surgery to date, studies have demonstrated weak correlations between post-operative satisfaction and disability (217)(225)(226)(227)(228)(229). It appears that patients with improved health-related outcomes and fewer limitations are not necessarily more satisfied, even after undergoing well-established quality of life improving operations (230)(229). The interactions between disability measures and disability and patient experience have rarely been assessed in fracture populations (218).

In the drive to validate PRO measures and understand what they are measuring, this study was interested in assessing the correlation between commonly utilized PRO measures of arm-specific disability during recovery after proximal humerus, elbow and distal radius fractures. It also aimed to assess the correlation between these measures of disability and patient experience, represented by satisfaction with clinical aspects of care and overall satisfaction with health services. Furthermore, a definition of the underlying constructs being measured during recovery at different time points was also performed and examined for any differences by fracture location. Whilst an assessment of common underlying traits between measures of coping strategy has been performed using factor analysis, to the best knowledge, this has not been evaluated amongst popularly used measures of arm-specific disability (131). Floor-ceiling effects of disability measures were also assessed in this study as markers of measurement precision and based on evidence to suggest the presence of these effects in certain generic health measures in assessing arm-specific disability (54).

The systematic reviews in Chapter 2 informed the choice of instruments in this and upcoming studies with selection based on the most popular, validated measures of disability from each type and mode of administration (218). These included the PROMIS PF (a computer adaptive generic measure of physical function), PROMIS UE PF (a computer adaptive region-specific measure of physical function), QuickDASH (a fixed scale region-specific measure of arm-specific disability), European Quality of Life Index-3L (EQ-5D-3L, a fixed scale measure of general health), and the Oxford Shoulder Score (OSS), Oxford Elbow Score (OES) and Patient Rated Wrist Evaluation (PRWE) (fixed scale measures of joint-specific disability). Both PROMIS PF and PROMIS UE PF are designed to assess physical function alone whilst QuickDASH, EQ-5D-3L, OSS, OES and PRWE assess physical function alongside other health domains.

4.1.1 Objectives

The primary objective was to assess the correlation between measures of physical function (PROMIS PF, PROMIS UE PF) with measures of physical function combined with other health domains (QuickDASH, OSS, OES, PRWE, EQ-5D-3L) within a week (t=0), 2-4 weeks (t=1) and 6-9 months (t=2) following proximal humerus, elbow and distal radius fracture. The secondary objective was to assess the correlation between all PRO measures of disability and patient experience (NRS for satisfaction with clinical care and NRS for satisfaction with health services). The final objective was to assess the underlying constructs being measured by PRO measures of disability and satisfaction scales using factor analysis and ascertain instrument precision and coverage by evaluating floor and ceiling effects.

4.2 Methods

4.2.1 Study Design

A consecutive series of 775 adult patients with isolated proximal humerus, elbow and distal radius fractures attending new patient fracture clinics between 1st January 2016 and 31st August 2016 were enrolled in a research and ethics committee approved study at a level I trauma centre (IRAS No. 16/YH/0017) (Appendix 11-15). This was a prospective cohort study (Level 1b/2b).

Inclusion criteria were that patients should be fluent in English and aged eighteen years or over at the time of injury. Those unable to provide informed consent, including patients with diagnosed mental health problems or cognitive dysfunction, and sustaining concurrent injuries involving the same arm or any other region were excluded. Shoulder, elbow or wrist fractures as part of complex polytrauma, re-fracture during recovery from a previous injury, re-fracture involving a previous malunion, fracture-dislocations of the shoulder, elbow and wrist, and peri-prosthetic fracture around a previous fixation or joint replacement, were also considered ineligible.

31 patients (4%) declined participation due to time constraints leaving 744 patients providing full informed consent and data protection approvals. All 744 patients completed a digital proforma for demographic information, and the secure, encrypted, web-based PRO measurement administration and data collection tool used in the pilot study (Assessment Center℠, Northwestern University) on a tablet computer or laptop (231). Pilot test runs completed by clinical colleagues on the digital platform resulted in acceptable response times (mean, 11.5 ± 3.7mins).

Data was captured at baseline (t=0, initial orthopaedic review in new patient fracture clinic following acute management in the emergency department), early follow-up (t=1, subsequent clinic review at 2-4 weeks post-injury) and final assessment (t=2, 6-9 months post-injury). t=1 was selected to account for any potential change in influential factors, patient's condition and circumstances during the initial weeks following injury. All patient demographics were captured at t=0 and only unique patient identifiers at t=1 and t=2 enabling data linkage. Most assessments were conducted face-to-face (70%; n=1,551/2,222), with others completed by phone (25%; n=556/2,222) or electronically by patients, directly on the digital platform (5%; n=115/2,222).

4.2.2 Patient Characteristics

A cohort of 498 women and 246 men with a mean age of 58.5 years ± 20.4 (range, 16–97 years) composed the study population (Table 17). All tables in this and subsequent studies are presented after the relevant results sections. Four patients died of unrelated illness before they could complete the final part at t=2 and a total of 6 patients were lost to follow-up.

Education level, marital status, social status and work status, as well as arm dominance and any previous arm injuries, including side, were acquired from the demographic proforma. The age-adjusted Charlson comorbidity index (CACI) (232), Index of multiple deprivation 2015 (IMD)

factor (233), any neurovascular compromise, open versus closed fracture, surgical intervention and complications were gathered from information held in clinical records. The CACI is a validated scoring tool to evaluate patient's overall health and is predictive of one-year mortality accounting for a range of comorbidities (232) (Appendix 16). The IMD combines information from national administrative datasets to form a relative ranking of social deprivation based on the patient's location (postal codes) out of a total of 32,844 neighborhoods across England, defined by the UK Office for National Statistics (233). This ranking was converted to a % and named the 'IMD factor' with lower % signifying greater deprivation (Appendix 17).

Complications were defined as any adverse event specifically related to injury and its management e.g. post-operative wound infection or prolonged joint stiffness requiring manipulation were included but development of a chest infection during the course of recovery was not.

Injuries were independently classified [PJ; SG] by energy [e.g. high speed road traffic accident (high); fall from standing height (low)] and categorized by region i.e. any proximal humerus, elbow (including radial head, distal humerus and proximal ulna fractures) and distal radius fractures. Use of opioid analgesia was defined as regular use of any opiates beyond a 2-week period post-injury. This was based on an observation that most patients rarely required a prescription for additional pain relief beyond this period or any more than the initial 7-day course of compound analgesics provided in the emergency department. Patients using opiate analgesia prior to injury were only included if there was an increase in opioid analgesic requirements secondary to their fracture. Anti-depressant use was defined as any earlier use i.e. for pre-existing depression, or a new diagnosis of depression in the acute recovery phase i.e. within the first month following injury.

4.2.3 Outcome Measures

PRO measures of disability included i) PROMIS PF (170), ii) PROMIS UE PF (170), iii) QuickDASH (204,205,207) and iv) EQ-5D-3L (234,235), and either v) OSS (236), OES (237) or PRWE (238) depending on the injured joint (Appendix 10). Measures of patient experience included vi) an ordinal numerical rating scale of patient satisfaction with any clinical aspect of care e.g. peri-operative inpatient experience, HCP-patient clinical interactions (NRS Satisfaction with Clinical care), and vii) an ordinal numerical rating scale of patient satisfaction with any other general aspect of the health service e.g. access to the hospital, cleanliness of ward areas (NRS Satisfaction with Health service).

All PROMIS measures were administered via CATs, which are described in detail in Chapter 2 and applied in the form of PROMIS PF, PROMIS Depression and PROMIS PI in Chapter 3. Participants were given reminders via telephone for incomplete or partially completed assessments, as approved by our research and ethics committee.

Both PROMIS PF and QuickDASH are previously described in Chapter 3.
PROMIS Upper Extremity Physical Function (v1.0) assesses disability related to physical activities involving the arm and hand (e.g. writing, closing buttons, lifting heavy objects) (170)(52). Lower scores indicate higher levels of upper-extremity disability.

EQ-5D-3L comprises five domains i.e. mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each requiring 3 response levels that provide a five-digit number that can be converted to a total index score. Higher scores represent greater overall health state (234).

OSS assesses the impact on pain, function and activities of daily life pertaining to the shoulder in the previous 4 weeks (236). 12 items each with five response categories form a total score ranging from 0 to 48 with lower scores representing greater disability (236).

OES assesses the impact on pain, function and activities of daily life pertaining to the elbow in the previous 4 weeks (236). 12 items each with five response categories form a total score ranging from 0 to 48 with lower scores representing greater disability (236).

PRWE is a 15-item scale (including 5 pain, 6 specific activity and 4 usual activity items) allowing patients to self-report pain and disability related to their wrist condition using questions scaled from 1 to 10 (238). A total score ranges from 0 to 100, equally rating pain and disability with higher scores representing greater disability (238).

4.2.4 Statistical analysis

Descriptive statistics included frequencies and percentages for discrete variables, and mean, standard deviation and range for continuous variables. Bivariate analysis included Pearson correlation for continuous variables. The strength of the correlations between the PRO measures of disability and satisfaction were classified as high (>0.7), high-moderate (0.61 to 0.69), moderate (0.4 to 0.6), moderate-weak (0.31 to 0.39), or weak (<0.3) (210).

Factor analysis was used to describe the variability among observed, correlated variables in terms of a potentially lower number of unobserved variables called factors. This form of evaluation assumes there are factors within a PRO measurement dataset that measure the same constructs (i.e. load onto specific factors). For example, QuickDASH and PROMIS UE both claim to measure upper extremity disability and are therefore expected to load onto the same factor. Promax rotation was utilized for optimal factor loading, except for proximal humerus fractures after 4 weeks (t=1), where Varimax rotation resulted in a less complex model. All relevant factors (i.e. factors with variable loading ≥0.30) were selected. Of the initial 744 patients, 30 patients had missing data (i.e. 4%) and were omitted from factor analysis.

Floor and ceiling effects influence analysis as they reduce the amount of variation in a questionnaire. These were measured by calculating the percentage of respondents who obtained the absolute lowest (worse) and highest (best) possible scores on a given PRO measure (239).

An a priori power analysis indicated that a minimum sample size of 165 patients would provide 90% power to detect a correlation of 0.25 for each diagnosis specific disability measure, with alpha set at 0.05. All statistical analysis was performed using STATA 14.0 (StataCorp LP, College Station, TX, USA).

4.3 Results

Health related outcomes improved in all five types of disability measure during the course of recovery (Table 18). Correlations between PRO measures of physical function (PROMIS PF, PROMIS UE PF) and disability measures combining physical function with other health domains ranged from 'weak' to 'moderate-high' levels at t=0 (Table 19a) [i.e. PROMIS PF: QuickDASH (r=-0.56), OSS (r=0.47), OES (r=0.63), PRWE (r=-0.45), EQ-5D-3L (r=0.44); PROMIS UE PF: QuickDASH (r=-0.47), OSS (r=0.48), OES (0.64), EQ-5D-3L (r=0.17), $p<0.0001$ in all displayed correlations].

The strength of these correlations generally increased over the course of recovery from t=1 [PROMIS PF: QuickDASH (r=-0.75), OSS (r=0.71), OES (r=0.76), PRWE (r=-0.53), EQ-5D-3L (r=0.65); PROMIS UE PF: QuickDASH (r=-0.78), OSS (r=0.78), OES (0.68), PRWE (r=-0.67), EQ-5D-3L (r=0.64)] (Table 19b) to t=2 [PROMIS PF: QuickDASH (r=-0.78), OSS (r=0.86), OES (r=0.75), PRWE (r=-0.73), EQ-5D-3L (r=0.61); PROMIS UE PF: QuickDASH (r=-0.83), OSS (r=0.87), OES (0.84), PRWE (r=-0.80), EQ-5D-3L (r=0.67)] (Table 19c). P-values were less than 0.001 in all aforementioned correlations. The strength of correlations between PROMIS UE PF and other region-specific measures (QuickDASH, OSS, OES, PRWE) was generally higher than PROMIS PF at t=1 and t=2 (Table 19b) (Table 19c).

The correlations between all PRO measures of disability with both satisfaction with clinical care and overall satisfaction with health services also increased during recovery with the highest correlations at t=2 [NRS Satisfaction Clinical Care: PROMIS PF (r=0.51), PROMIS UE PF (r=0.56), QuickDASH (r=-0.69), OSS (r=0.62), OES (r=0.83), PRWE (r=-0.63), EQ-5D-3L (r=0.64); [NRS Satisfaction Health Service: PROMIS PF (r=0.52), PROMIS UE PF (r=0.59), QuickDASH (r=-0.74), OSS (r=0.60), OES (r=0.87), PRWE (r=-0.71), EQ-5D-3L (r=0.68)] (Table 19c).

Factor analysis including all fractures combined, demonstrated the underlying construct of physical function was separate from general health and quality of life at t=0 and t=2 whilst at t=1, a common underlying construct was being measured by PROMIS PF, PROMIS UE PF, QuickDASH and EQ-5D-3L (Table 20). At t=0, factor analysis by fracture type demonstrated QuickDASH was associated with the relevant joint specific measure of disability and EQ-5D-3L rather than the physical function trait in all three fractures. This relationship was maintained at t=1 and t=2 in elbow fractures only. At t=1 and t=2, all PRO measures generally assessed the same underlying trait in shoulder and wrist fractures (Table 20).

PROMIS PF, PROMIS UE PF and QuickDASH had no floor or ceiling effects throughout recovery (Table 21). Joint specific measures (OSS, OES, PRWE) showed no floor effects at any stage but ceiling effects at t=2 [OSS (12.4%), OES (12%), PRWE (12%)]. General health measured by EQ-5D-3L also showed no floor effects but increasing ceiling effects during the recovery process [t=0 (1.08%), t=1 (3.63%), t=2 (56.05%)].

Table 17. Patient Demographics

Demographic	Value	
Subjects enrolled (t=0)	744	
Subjects (t=1)	744	
Subjects (t=2)	734	
Age (years)	58.5 ± 20.4	(16 - 97)
Female	68%	(498)
Charlson Comorbidity Index	1.9 ± 1.7	(0 - 6)
Marital status		
Single	23%	(166)
Partner / Married	50%	(365)
Separated / Divorced / Widowed	27%	(203)
Social status		
Alone	21%	(153)
Partner / Friend(s) / Family	70%	(514)
Full / Part-time care	9%	(67)
Education (years)	13.7 ± 3	(6 - 23)
Work status		
Working	44%	(326)
Homemaker	45%	(328)
Retired	6%	(46)
Unemployed / Work compensation / Litigation	5%	(34)
IMD factor	70.4 ± 23.6	(0 - 99.8)
Fracture Location		
Proximal humerus	24%	(173)
Elbow	25%	(183)
Distal radius	51%	(378)
Broad Injury Classification Ω		
Category 1	51%	(377)
Category 2	18%	(131)
Category 3	31%	(226)
Dominant side injured	50%	(363)
High energy injury	16%	(119)
Neurovascular compromise	5%	(38)
Open injury	2%	(13)
Surgery	16%	(118)
Complication	25%	(182)
Prior fracture to dominant arm	19%	(137)
Prior fracture to non-dominant arm	11%	(79)
Opioid use	34%	(252)
Anti-depressant use	24%	(174)

Continuous variables as mean + standard deviation (range)

Discrete variables as percentage (number)

Ω Broad Injury Classification Categories by Region

Broad Classification	Proximal Humerus Fracture	Elbow Fracture	Distal Radius Fracture
Category 1	Greater tuberosity	Radial head/neck	AO Type A
Category 2	2-part	Extra-articular	AO Type B
Category 3	> 2-part	Intr-articular	AO Type C

Table 18. Health-related Outcomes and Patient Experience

PRO Measures	**t=0**			**t=1**			**t=2**		
	n	Mean (SD)	Range	n	Mean (SD)	Range	n	Mean (SD)	Range
PROMIS PF	744	32.4 ± 6.1	(23.5 - 55.8)	744	36.4 ± 8.4	(23.5 - 51.4)	734	51.7 ± 12.8	(23.5 - 73.3)
PROMIS UE PF	744	24.2 ± 6.2	(14.7 - 56.4)	744	29.2 ± 5.9	(15.6 - 45.7)	734	43.2 ± 10.7	(19.5 - 56.4)
QuickDASH	744	70.2 ± 12.1	(36.4 - 93.2)	744	63.3 ± 18.5	(15.9 - 90.9)	734	24.5 ± 24.5	(0 - 88.6)
OSS	177	7.9 ± 5.5	(0 - 24)	177	12 ± 7.1	(3 - 34)	173	34.8 ± 11.4	(14 - 48)
OES	183	16.7 ± 7.8	(3 - 30)	183	25.9 ± 9.4	(8 - 41)	183	39.8 ± 10.5	(11 - 48)
PRWE	384	81.8 ± 6.7	(59 - 94.5)	384	70.9 ± 12.3	(27 - 91.5)	378	23.7 ± 25	(0 - 82.5)
EQ-5D-3L	739	0.274 ± 0.355	(-0.594 - 1)	744	0.325 ± 0.407	(-0.349 - 1)	734	0.795 ± 0.329	(-0.181 - 1)
NRS Satisfaction (Clinical care)	742	8.2 ± 1.6	(1 - 10)	742	8.2 ± 1.7	(1 - 10)	737	8.4 ± 2	(0 - 10)
NRS Satisfaction (Health service)	742	7.4 ± 2	(1 - 10)	742	7.5 ± 2.1	(0 - 10)	737	8 ± 2.4	(0 - 10)

Table 19. Correlation Matrices

Table 19a. Correlation Matrix of Health-outcome measures and Satisfaction ratings at t=0

Health-related outcomes	PROMIS PF	PROMIS UE PF	QuickDASH	OSS	OES	PRWE	EQ-5D-3L	NRS Satisfaction (Clinical Care)	NRS Satisfaction (Health Service)
PROMIS PF	1.0000								
PROMIS UE PF	0.6807	1.0000							
QuickDASH	-0.5629	-0.4665	1.0000						
OSS	0.4689	0.4771	-0.7996	1.0000					
OES	0.6335	0.6410	-0.8428	n/a	1.0000				
PRWE	-0.4511	-0.1556*	0.4543	n/a	n/a	1.0000			
EQ-5D-3L	0.4371	0.1711	-0.5936	0.5964	0.7549	-0.5901	1.0000		
NRS Satisfaction (Clinical Care)	0.1993	0.1797	-0.3808	0.2987	0.5613	-0.0321**	0.2847	1.0000	
NRS Satisfaction (Health Service)	0.2200	0.1644	-0.3874	0.2223***	0.5653	-0.0825****	0.2759	0.7196	1.0000

p values were below 0.001 for all variables unless specified. P-values *0.0022 **0.5308 ***0.0030 ****0.1072

Table 19b. Correlation Matrix of Health-outcome measures and Satisfaction ratings at t=1

Health-related outcomes	PROMIS PF	PROMIS UE PF	QuickDASH	OSS	OES	PRWE	EQ-5D-3L	NRS Satisfaction (Clinical Care)	NRS Satisfaction (Health Service)
PROMIS PF	1.0000								
PROMIS UE PF	0.7311	1.0000							
QuickDASH	-0.7530	-0.7763	1.0000						
OSS	0.7119	0.7758	-0.9155	1.0000					
OES	0.7643	0.6802	-0.8360	n/a	1.0000				
PRWE	-0.5335	-0.6688	0.6411	n/a	n/a	1.0000			
EQ-5D-3L	0.6539	0.6434	-0.6559	0.8119	0.7878	-0.4144	1.0000		
NRS Satisfaction (Clinical Care)	0.4365	0.3438	-0.4298	0.3510	0.7071	-0.2508	0.4354	1.0000	
NRS Satisfaction (Health Service)	0.4325	0.3598	-0.4491	0.2905*	0.7205	-0.2927	0.4094	0.7545	1.0000

p values were below 0.001 for all variables unless specified. * 0.0001

Table 19c. Correlation Matrix of Health-outcome measures and Satisfaction ratings at t=2

Health-related outcomes	PROMIS Physical Function	PROMIS UE Physical Function	QuickDASH	OSS	OES	PRWE	EQ-5D-3L	NRS Satisfaction (Clinical Care)	NRS Satisfaction (Health Service)
PROMIS PF	1.0000								
PROMIS UE PF	0.8356	1.0000							
QuickDASH	-0.7796	-0.8326	1.0000						
OSS	0.8595	0.8703	-0.9644	1.0000					
OES	0.7498	0.8432	-0.9402	n/a	1.0000				
PRWE	-0.7302	-0.8000	0.9442	n/a	n/a	1.0000			
EQ-5D-3L	0.6077	0.6734	-0.8196	0.8808	0.9099	-0.8412	1.0000		
NRS Satisfaction (Clinical Care)	0.5141	0.5575	-0.6856	0.6159	0.8277	-0.6348	0.6431	1.0000	
NRS Satisfaction (Health Service)	0.5203	0.5906	-0.7398	0.6028	0.8684	-0.7050	0.6795	0.8724	1.0000

p values were below 0.001 for all variables unless specified

Table 20. Factor Analysis

PRO Measures	t=0 Factor 1	t=0 Factor 2	t=0 Factor 3	t=1 Factor 1	t=1 Factor 2	t=1 Factor 3	t=2 Factor 1	t=2 Factor 2	t=2 Factor 3
PROMIS PF		0.6241		0.8015			0.8838		
PROMIS UE		0.748		0.8949			0.8498		
QuickDASH	-0.5077	-0.3285		-0.8418			-0.5462		-0.3307
EQ-5D-3L	0.7008			0.6777					0.4516
Satisfaction clinic			0.7855		0.8156			0.8807	
Satisfaction overall			0.7834		0.8066			0.8534	
Proximal Humerus Fracture									
PROMIS PF			0.5149	0.7331			0.9145		
PROMIS UE			0.6117	0.7615			0.887		
QuickDASH	-0.8073			-0.9043			-0.9037		
OSS	0.78			0.959			0.9394		
EQ-5D-3L	0.7683			0.7664	0.3174		0.7654		
NRS Satisfaction (Clinical care)		0.8455			0.8502			0.9216	
NRS Satisfaction (Health service)		0.8655			0.8411			0.93	
Elbow Fracture									
PROMIS PF			0.7265			0.5225		0.792	
PROMIS UE			0.8364			0.611		0.695	
QuickDASH	-0.8649			-0.7407					-0.5326
OES	0.8149			0.6487					0.5418
EQ-5D-3L	0.7332			0.5718					0.5093
NRS Satisfaction (Clinical care)		0.8342			0.8231		0.8309		
NRS Satisfaction (Health service)		0.8118			0.7334		0.7785		
Distal Radius Fracture									
PROMIS PF	-0.3745	0.4971		0.7765				0.8603	
PROMIS UE		0.5818		0.9244				0.8071	
QuickDASH	0.4313	-0.3096	-0.3225	-0.7901			0.539	-0.3181	
PRWE	0.7039			-0.7226			0.6681	-0.3096	
EQ-5D-3L	-0.766			0.6161			-0.7624		
NRS Satisfaction (Clinical care)			0.677		0.6886				0.7495
NRS Satisfaction (Health service)			0.6917		0.691				0.7472

Variables p<0.10 in bivariate analysis with 0.30 or more loading

Table 21. Floor-ceiling Effects

PRO Measure	Floor Effects	Ceiling Effects
t=0		
PROMIS PF	0 (0.0%)	0 (0.0%)
PROMIS UE PF	0 (0.0%)	0 (0.0%)
QuickDASH	0 (0.0%)	0 (0.0%)
OSS	2 (1.13%)	0 (0.0%)
OES	0 (0.0%)	0 (0.0%)
PRWE	0 (0.0%)	0 (0.0%)
EQ-5D-3L	0 (0.0%)	8 (1.08%)
t=1		
PROMIS PF	0 (0.0%)	0 (0.0%)
PROMIS UE PF	0 (0.0%)	0 (0.0%)
QuickDASH	0 (0.0%)	0 (0.0%)
OSS	0 (0.0%)	0 (0.0%)
OES	0 (0.0%)	0 (0.0%)
PRWE	0 (0.0%)	0 (0.0%)
EQ-5D-3L	0 (0.0%)	27 (3.63%)
t=2		
PROMIS PF	0 (0.0%)	0 (0.0%)
PROMIS UE PF	0 (0.0%)	0 (0.0%)
QuickDASH	0 (0.0%)	0 (0.0%)
OSS	0 (0.0%)	22 (12.43%)
OES	0 (0.0%)	22 (12.02%)
PRWE	0 (0.0%)	46 (11.98%)
EQ-5D-3L	0 (0.0%)	417 (56.05%)

Values are given as the number and percentage of patients with the lowest score (floor effect) or highest score (ceiling effect)

4.4 Discussion

PRO measures of physical function and physical function combined with other health domains generally correlate with one another irrespective of instrument type and mode of administration i.e. generic versus region-specific or fixed scale versus CAT. However, the strength of this correlation increased over time with highest correlations at the final assessment.

The most compelling reason for this correlation may be the growing body of evidence for psychosocial factors being the dominant and underlying mediators of both general and region-specific disability (68)(97)(116). This is similar to the observations in chapter 3 and the correlation between PROMIS PF and QuickDASH. Other reasons may be that these instruments are predominantly influenced by overall health and activity, or simply that general measures of physical function e.g. PROMIS PF, contain sufficient numbers of upper extremity focused items to adequately measure disability in this region. However, in this longitudinal study, the increase in correlation strength over time is somewhat more difficult to explain. It is possible that region-specific measures are more discriminant during the acute injury episode and both region-specific and general disability are less differentiated with recovery time. For instance, an individual may be completely unable to open a tight jar of jam in the initial phase of a painful shoulder fracture, but have no issues walking long distances.

PROMIS UE PF had a strong correlation with PROMIS PF and demonstrated stronger correlations with other region-specific measures than PROMIS PF. Another recent study involving more than 5000 adults from a general upper extremity outpatient clinic demonstrated a strong correlation between PROMIS UE PF and PROMIS PF (240). Strong correlations are also observed between these measures in rotator cuff pathology (241). Other studies show moderate-high correlations between PROMIS PF and QuickDASH (165)(166) and high correlations between PROMIS UE PF and QuickDASH (113) in mostly non-traumatic upper extremity conditions. Both PROMIS PF and PROMIS UE PF have shown strong correlations

with the EQ-5D general health measure in shoulder instability and rotator cuff pathology (241)(242). We were unable to find any studies assessing the performance of PROMIS CATs against the OSS, OES or PRWE, making this the first study to investigate the relationship between these measures. Whilst all of these disability measures are popular and well-validated instruments, few studies have assessed their measurement credentials in focused upper limb fracture populations (116)(204)(205)(218).

In terms of the relationship between disability and experience, the strength of correlations between the limitations faced by patients after fractures and how satisfied they were with their clinical care and overall health service experience also *increased* with time during recovery. Perhaps this is intuitive given that individuals with fewer limitations and restrictions are more likely to be satisfied and vice versa. Again, this is the first study investigating this relationship in an upper extremity fracture population. The interaction between disability and satisfaction has been investigated in the field of elective spine surgery but the findings are conflicting (243)(244).

Interestingly, the strength of correlations between all PRO measures of disability and satisfaction with clinical care and health services were similar. Satisfaction perceived by patients related to their clinical care may not be that different from their experience with hospital systems.

Factor analysis demonstrated that these measures of disability either measured the common underlying construct of physical function or general health. Region specific measures such as the QuickDASH associated with either physical function or general health depending on stage of recovery or type of fracture. Region specific and generic health measures appeared distinct from measures of physical function throughout recovery following elbow fractures whilst this distinction only existed within a few days following proximal humerus and distal radius fractures. At first follow-up and final assessment, all forms of PRO measure appeared to assess the same underlying construct after fractures of the shoulder and wrist. Whilst this observations

are difficult to rationalise, it may in part be explained by differences in demographic profiles of patients between elbow versus shoulder and wrist fractures i.e. younger, active, working populations versus generally older, lower-demand individuals.

In terms, of floor-ceiling effects, PROMIS PF, PROMIS UE PF and QuickDASH showed no floor and ceiling effects throughout recovery. In contrast, from this perspective, joint specific measures and measures of generic health did and should therefore likely be avoided, especially when assessing longer term disability and performance at the higher end of the scale. The potential for floor and ceiling effects with generic health measures is well recognized (44). This work also demonstrated that region-specific measures not originally designed for trauma conditions may also be prone to such effects. Prior studies highlight ceiling effects of both PROMIS PF and PROMIS UE PF in higher functioning patients with shoulder instability, as well those with a range of upper extremity conditions (240)(242)(245). Others demonstrate minimal or zero ceiling effects (166)(241). Whilst further item development may be required for specific subpopulations, this work demonstrated the capability of PROMIS UE PF, PROMIS PF and QuickDASH in avoiding such effects during fracture recovery in a wide range of patients.

4.4.1 Limitations

These findings should be considered in light of some limitations. Firstly, the generalisability of this study may be challenged despite the wide range in patient demographics and indices of multiple deprivation as it was performed at a single institution (a level I trauma center in the UK). Second, there may be a variety of other factors playing a role in how patients judge limitations, experience clinical care and engage with their health care services. These range from level of expectation with health services to quality of doctor-patient interactions. Such aspects may not have been captured in their entirety using the satisfaction ratings in this study, yet may have had a substantial influence on health-related and experiential outcomes.

Third, due to logistical and practical issues, patients completed PRO measures via telephone, online or in person. Although most evaluations were conducted in person, each mode of questionnaire administration introduces varying levels of procedural, measurement and responder bias. Fourth, this study aimed to assess disability and satisfaction using a test battery that was not too burdensome to complete. However, the process may still have felt laborious to some, especially when similar sounding items were administered in quick succession. Full item randomisation may have minimised this but would have made programming the digital platform more complicated. Fifth, some items are administered in the context of specific time-frames (e.g. Oxford scores assess status within the previous four weeks) causing a few participants to question how they should respond e.g. "Should I answer this based on how I feel now or how I felt before the accident?". In these rare instances, it was difficult not to advise patients to consider their current perceptions of health status and their overall propensity to perform certain tasks or exhibit specific traits. Sixth, floor to ceiling effects were assessed in a broad group and sub-group analysis, especially in higher performing individuals, may have revealed different results. This requires further investigation. Seventh, although few patient experience measures have been fully validated in fracture populations and trauma settings, more sophisticated instruments could have been applied in this population. One option is the recently developed Quality of Trauma Care-PREM (QTAC-PREM), the first measure to assess patient and family perspectives of quality in overall injury care (246)(247). Finally, we were unable to accurately record test completion times most commonly due to test interruptions following aspects of clinical care or patient choice e.g going off for investigations, cast-changes, patients wishing to complete the test at a later stage etc. This would have been a useful metric to assess the 'acceptability' of these measures in the context of PRO measures properties.

4.4.2 Conclusion

The restoration of physical function is a fundamental principle in orthopaedic trauma (248). PRO measures of disability commonly assess physical function alone or in combination with other health domains. The key finding of this study was that disability measures appeared to correlate with one another irrespective of instrument type or mode of administration when assessing arm-specific disability following fractures of shoulder, elbow and wrist. This may be explained by numerous studies that demonstrate psychosocial factors as having a dominant underlying influence on both general and region-specific disability (68)(97)(116).

Interestingly, the strength of these correlations increased over time during recovery suggesting the possibility of other mediators of this relationship in the initial days and weeks post-fracture. Similarly, disability correlated with satisfaction with clinical care and health services, and the strength of this correlation also increased over time. Potential synergy between these components intimates a joint approach to minimizing limitations and maximizing experience in orthopaedic trauma care.

The longitudinal study design also highlighted the importance of accounting for recovery stage and region of injury when considering the underlying constructs being measured and any potential floor-ceiling effects. This may impact both study development and the investigator's choice of PROM. For instance, the QuickDASH may be a more appropriate choice than EQ-5D-3L in assessing generic health outcomes without generating any ceiling effects at 6-9 months following elbow fractures.

Minimising floor-ceiling effects is especially important following trauma where there is a potential for wide variations in scores during recovery. Notably, joint-specific and general health measures appeared to generate substantial ceiling effects compared to CATs for physical function and the QuickDASH at around 6-9 months post injury. Large scale controlled trials

have utilized joint-specific measures such as the OSS for assessing long-term disability following proximal humeral fractures (249). It may be prudent to assess the ceiling effects in these data sets. In this study, PROMIS UE PF had the strongest correlations and alongside PROMIS PF and QuickDASH showed no floor or ceiling effects. PROMIS UE PF may be the instrument of choice in measuring physical function following upper extremity fractures. However, clinical, cultural and technological barriers may need to be overcome before universal adoption of these measures outside the U.S (218). Whilst further psychometric evaluation and testing in different sub-populations is recommended, PROMIS UE PF as a computer adaptive measure of upper extremity disability was taken forward to the experimental studies in this thesis (23).

International expert groups recommend using both a disease-specific PRO measure of physical function *and* a generic health measure to assess patients with specific chronic conditions (21)(52)(54)(155)(250)(251). No such consensus has been reached in fracture populations. Based on these findings, a single, carefully selected PRO measure of arm–specific disability following upper extremity fractures delivered at appropriate time-points may suffice.

Understanding and minimising the limitations faced by patients following health conditions and optimising the experience of how these conditions are managed within their health care services, is the basis of patient-centred care. Furthermore, psychometric evaluation of popular PRO measures of disability, comparing their properties with one another and comparing their relationship with satisfaction may benefit the future design of quality metrics for assessing value in health care and informing health policy (252)(65). The current use of PRO measures of general health (e.g. EQ-5D) to assess overall disease burden and health adjusted life years [i.e. Disability Adjusted Life Years (DALYs), and Quality Adjusted Life Years (QALYs)] in capturing what really matters to patients has been recently questioned (253). There is a requirement for further research to continue defining the optimal measurement of arm-specific disability within upper extremity fracture populations (253).

Chapter 5

5 Influential Factors of Disability following Proximal Humerus Fractures

5.1 Background

In chapter 4, the construct validity and precision of different types of disability measure were tested, demonstrating correlations with one another irrespective of instrument type or mode of administration. Further information was also gained around the underlying traits being measured by these instruments. Informed by the work conducted so far, Chapters 5, 6 and 7 take the opportunity to address the primary objective of this thesis, namely to identify the influential factors predictive of disability after proximal humerus, elbow and distal radius fractures respectively. Utilizing the WHO ICF framework, this study incorporated multiple variables, including psychosocial factors that may play a dominant underlying role in a population with proximal humerus fractures (Figure 15). Utilising this framework also enables a conceptualization of disability in relation to profiles of individuals sustaining these injuries (Figure 16).

The aim of this chapter was to identify the influential factors predictive of future disability following proximal humerus fractures, using a comprehensive selection of outcome measures. This line of investigation could enhance treatment decision-making and inform future patient-centered management strategies to improve longer term health-related outcomes.

Figure 20. The WHO ICF Framework applied to evaluating disability after Proximal Humerus Fractures

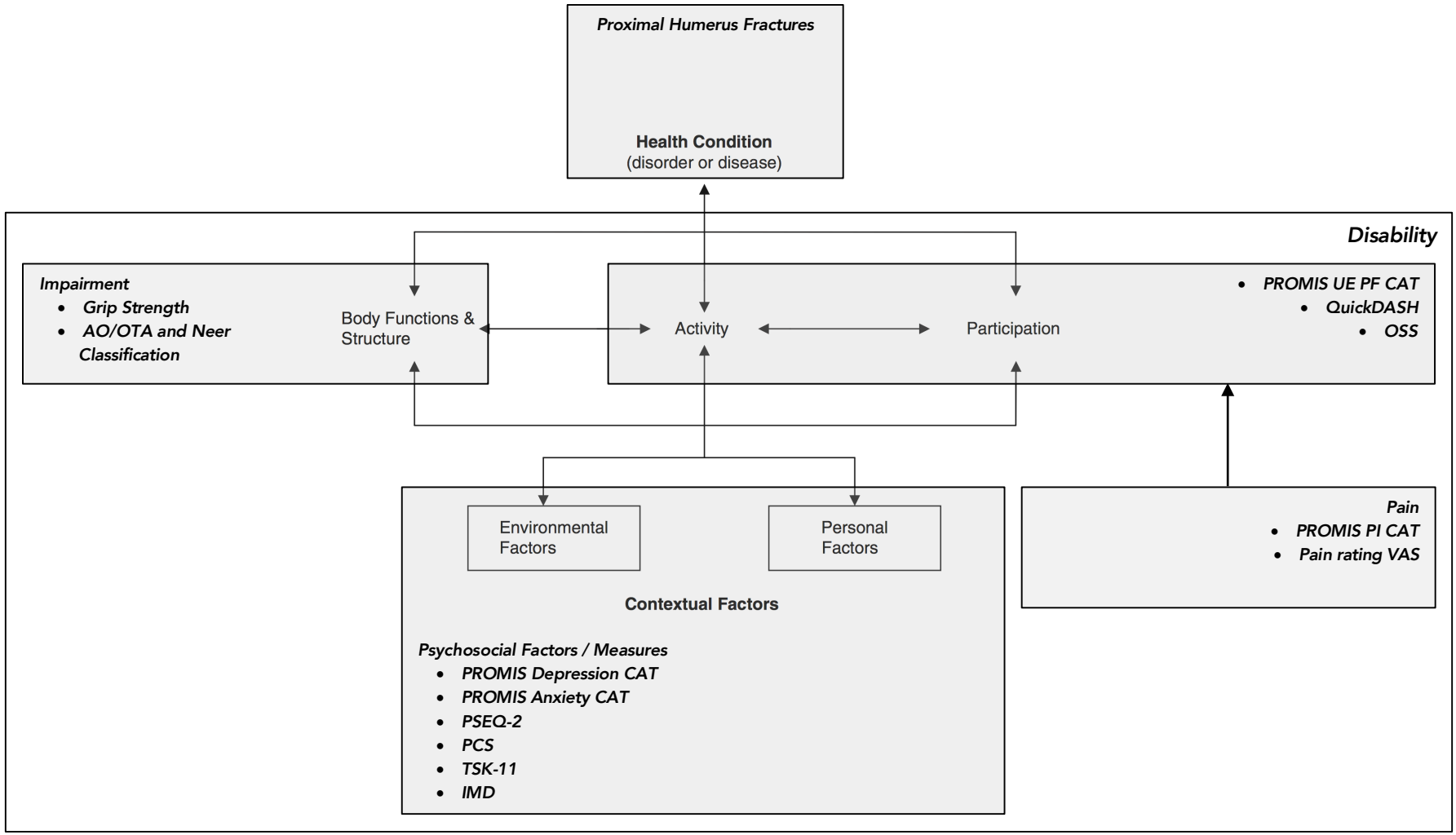
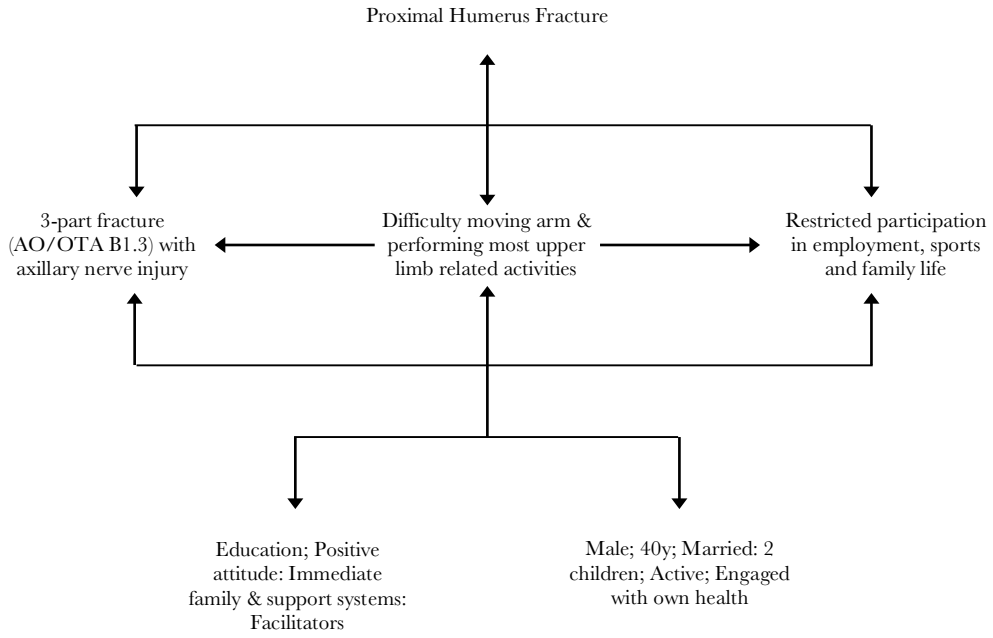
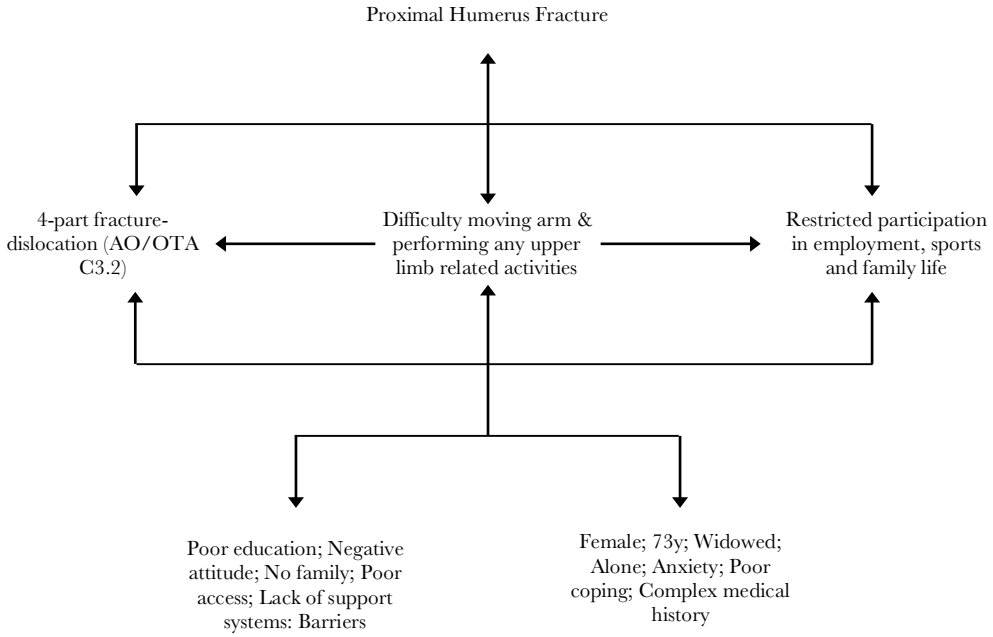


Figure 21. The WHO ICF Framework adapted to profiles of individuals with Proximal Humerus Fractures





§ The examples represent a few domains of each component related to the health condition and are not intended to represent a complete overview of impairments, activity limitations, participation restrictions, environmental and personal factors.

‡ Direction or magnitude of arrows may differ for specific situations and/or individuals. Two-directional arrows represent a multi-directional influence

The incidence of proximal humerus fractures is increasing rapidly, largely due to osteoporotic fractures in the elderly (1)(255)(256)(257)(258)(259)(262)(263)(264). The impact on quality of life following these injuries remains substantial with shoulder fractures in particular demonstrating lower HrQoL indices and slower recovery compared to fractures in other anatomical regions (13)(254)(257)(265). Despite a rising trend in the operative management of these injuries, and an expansion in the number of surgical options available, there continues to be some inconsistency in deciding when to operate and if so, what operation to perform (91)(266)(267). This is reflected in systematic reviews showing moderate to high quality evidence for non-superior patient outcomes following operative intervention for displaced fractures of the humeral neck (268). A UK-based multi-centre, randomized controlled trial demonstrated surgical treatment to be neither clinically-effective nor cost-effective in managing the majority of proximal humeral fractures (91)(249)(269). Whilst valuable information is gained from such large-scale, pragmatic trials, the debate around optimal management continues as authors highlight the limitations of these studies (275)(276). These include issues around potential selection bias, shortcomings of generalising findings in highly heterogeneous cohorts, and the inaccuracies of outcome measures that may not be universally appropriate for all patients (270)(271)(272).

Evidence is also lacking on the optimal management of fractures in the young, in high energy trauma, two-part tuberosity fractures, and less common injuries, such as fracture-dislocations and head split configurations (268). Ultimately, there appears to be insufficient evidence to inform treatment choice and determine which interventions produce consistently better outcomes (267)(268). Due to the heterogeneity of injury, it seems unlikely that evidence-based practice for surgical intervention of each possible configuration is likely to be achieved soon. A shift toward a patient-centered, biopsychosocial approach that aims to understand the influential factors of disability may be a more productive way of improving outcomes than focusing on injury pathophysiology and treatment alone (259).

The WHO ICF framework enables consideration of the impact of proximal humerus fractures at the individual level and provides a schema for linking outcome measures to perform structured disability research in these populations (Figure 15)(Figure 16) (19)(20)(25). Considering this model, studies have shown that psychosocial factors predominantly influence disability over objective measures of pathophysiology (i.e. impairment) related to the various condition in the arm (273)(274). Such factors are also shown to play a significant role in recovery, effectively predicting surgical outcomes, even after accounting for relevant clinical factors (275). Depression, anxiety, somatization, catastrophic-thinking, lower self-efficacy and overall mental health have all been associated with greater disability and poor outcomes following chronic or sub-acute shoulder pathologies such as rotator cuff tears and chronic shoulder pain (273)(274)(276)(277)(278)(279)(280). While psychosocial factors strongly influence patient-to-patient variations in disability related to non-traumatic shoulder pathologies, the factors prognostic of medium-term disability following proximal humerus fractures remain unclear. Furthermore, most studies in the field to date have been cross-sectional, involving heterogeneous populations with a mixture of traumatic and non-traumatic conditions. This has indicated a requirement for longitudinal studies involving populations with specific fractures of the upper extremities (96)(259).

5.1.1 Objectives

The primary objective was to assess the association between the magnitude of disability at 6 to 9 months after a proximal humerus fracture and psychosocial factors and grip strength within a week after fracture, along with injury or demographic factors. The secondary objective was to assess the same associations but with psychosocial factors and grip strength at 2 to 4 weeks after injury. The final objective was to observe any similarities and differences in the correlation between explanatory variables and upper extremity disability i.e. generic fixed scale (EQ-5D-3L), region-specific (QuickDASH), joint-specific (OSS) and region-specific computer adaptive (PROMIS UE PF) measures, at baseline and early follow-up after injury.

5.2 Methods

5.2.1 Study Design

A consecutive series of 185 adult patients sustaining isolated proximal humerus fractures attending new patient fracture clinics between 1st January 2016 and 31st August 2016 were enrolled in a research and ethics committee approved study (IRAS No. 16/YH/0017) (Appendix 11-15). This was a prospective cohort study at a level I trauma center in the UK (Level 1b/2b). Inclusion criteria were that patients should be fluent in English and aged eighteen years or over at the time of injury. Those unable to provide informed consent, including patients with diagnosed mental health problems or cognitive dysfunction, and sustaining concurrent injuries involving the same arm or any other region were excluded. Proximal humerus fractures as part of complex polytrauma, refracture of the shoulder during recovery from a previous injury, fracture in a malunited shoulder and peri-prosthetic fracture around a previous fixation or joint replacement, were also considered ineligible. Eight patients (4.3%) declined participation due to time constraints leaving 177 patients in the study. Informed consent and data protection approvals were obtained from each participant prior to enrollment.

All 177 patients completed a digital proforma for demographic information, and the secure, encrypted, web-based PRO measurement administration and data collection tool used throughout this thesis (Assessment Center℠, Northwestern University) (231). The pilot test runs completed by clinical colleagues on the digital platform resulted in acceptable response times (mean, 12.1 $\pm$ 4.8mins).

Data was captured at baseline (t=0, initial orthopaedic review in new patient fracture clinic following acute management in the emergency department), early follow-up (t=1, subsequent clinic review at 2-4 weeks post-injury) and final assessment (t=2, 6-9 months post-injury). Most assessments were conducted face-to-face (71%; n=373/527), with others completed by phone (24%; n=129/527) or electronically by patients, directly on the digital platform (5%; n=25/527).

5.2.2 Patient Characteristics

A cohort of 128 women and 49 men with a mean age of 66 years ± 16.3 (range, 18-95) composed the study population (Table 22). 4 patients died of unrelated illness before they could complete the final part at t=2. No patients were lost to follow-up.

Education level, marital status, social status and work status, as well as arm dominance and any previous arm injuries, including side of injury, were acquired from the demographic proforma. The CACI (232), IMD (233), any neurovascular compromise, open versus closed fracture, surgical intervention and complications were gathered from information held in clinical records. The CACI and IMD factor are described previously in Chapter 4. Complications were defined as any adverse event specifically related to injury and its management e.g. post-operative wound infection or prolonged shoulder stiffness requiring manipulation were included, but development of a chest infection during the course of recovery was not.

Injuries were independently classified [PJ; SG] by energy [e.g. high speed road traffic accident (high); fall from standing height (low)] and the AO (Appendix 18) (281) and Neer classification systems (Appendix 19) (282) prior to further classification into three fracture types (i.e. greater tuberosity, 2-part, more than 2-part). Defining the overall distribution of fracture patterns using well-established classification systems was felt necessary, prior to re-classification into three broad categories to enable more practical analysis and clinically relevant translation. Full agreement was achieved following consensus meetings between two investigators [PJ; SG].

Use of opioid analgesia was defined as regular use of any opiates beyond a 2-week period post-injury. This was based on observations that most patients rarely required a prescription for additional pain relief beyond this period or any more than the initial 7-day course of compound analgesics provided in the emergency department. Any patients already using opioids for other conditions were only included if there was any change or increase in their analgesic requirements secondary to the fracture. Anti-depressant use was defined as any earlier use i.e. for pre-existing depression, or a new diagnosis of depression in the acute recovery phase i.e. within the first month following injury.

5.2.3 Outcome Measures

PRO measures were delivered in the following order: i) PROMIS UE PF (170), ii) PROMIS PI (203), iii) PROMIS Depression (200,201), iv) PROMIS Anxiety (201), v) PROMIS Emotional support (PROMIS ES) (283), vi) PROMIS Instrumental support (PROMIS IS) (283), vii) QuickDASH (204,205,207), viii) OSS (236), ix) EQ-5D-3L (234,235), x) Pain Catastrophizing Scale (PCS) (284), xi) Pain Self-efficacy Questionnaire-2 (PSEQ-2) (285,286), xii) Tampa Scale for Kinesiophobia-11 (TSK-11) (287) (Appendix 10).

The PROMIS measurement system is described in Chapter 4. All PRO measures were administered at t=0, t=1 and t=2 except for PROMIS ES and PROMIS IS which were deployed at t=1 and t=2 only. Participants were given reminders via telephone for incomplete or partially completed assessments, as approved by our research and ethics committee.

PROMIS UE PF, OSS and EQ-5D-3L are described previously in Chapter 4, and QuickDASH, PROMIS Depression and PROMIS PI are described in Chapter 3.

PROMIS Anxiety (v1.0) assesses levels of anxiety through measuring aspects of fear (e.g. fearfulness, feelings of panic), anxious misery (e.g. worry, dread), hyperarousal (e.g. tension, nervousness, restless) and some somatic symptoms related to arousal (e.g. dizziness) (50)(201). Higher scores represent greater pain interference, depression and anxiety, respectively.

PROMIS Emotional support (v1.0) assesses patient perceived feelings of being cared for and being valued as a person whilst PROMIS Instrumental support (v1.0) assesses the perceived availability of support from others in fulfilling specific functions e.g. help with chores, assistance getting to an appointment (283).

PCS measures the cognitive responses to pain that exacerbate fearful aspects of pain experiences (e.g. rumination, magnification, helplessness) (284). 13 items are scored from 1 ("not at all") to 4 ("all the time") and total scores range from 13 to 52 with higher scores reflecting greater catastrophizing.

PSEQ-2, a shortened version of the full PSEQ, assesses coping and level of confidence in achieving one's goals despite pain (285,286). Items are scored on a 7-point Likert scale from 0 ("not at all confident") to 6 ("completely confident") and added to form a total score ranging from 0 to 12, with higher scores indicating stronger self-efficacy (285,286).

TSK-11, a shortened version of the full TSK, assesses pain-related fear beliefs, somatization and fear of movement or injury (287). 11 items are rated on a 4-point scale and added to form a total score ranging from 11 to 44 with higher scores indicating greater kinesiophobia (287).

Grip strength (isometric grip force in kg) was measured using a Jamar digital dynamometer (Asimov Engineering, Los Angeles, CA) in injured and non-injured arms at t=0, t=1 and t=2, with an average of two measurements on each side taken as the final absolute measure. The percentage of injured side relative to the non-injured side was calculated. Hand grip was placed at the second or third station depending on hand size, and the shoulder adducted and kept in neutral rotation, with the elbow at 90^{o} flexion, and forearm and wrist in neutral position (288). Participants were asked to grip as hard as they could within limits of pain and sustain the contraction for as long as it took to achieve a stable reading.

5.2.4 Statistical analysis

Descriptive statistics included frequencies and percentages for discrete variables, and mean, standard deviation and range for normally distributed continuous variables. Bivariate analysis involved unpaired Student's t-test or analysis of variance for comparing continuous and discrete variables and Pearson correlation for continuous variables. Strength of correlations were classified as high (>0.70), high-moderate (0.61-0.69), moderate (0.40-0.60), moderate-weak (0.31-0.39) and weak (<0.30) (210).

Multi-collinearity (the phenomenon in which two or more predictor variables in a multiple regression model are highly correlated, meaning that one can be linearly predicted from the others with a substantial degree of accuracy) can be indicated by high beta, high standard error and wide 95% confidence intervals, and assessed with partial R^2, correlation matrices at t=0 and t=1, and variance inflation factor (VIF). Multicollinearity does not reduce the reliability of the model, but may influence the beta-coefficients and standard errors. A correlation greater than 0.80 was considered an indication of multicollinearity and led to omission of one of the two variables with this high correlation. The variable causing the lowest change in the model's adjusted R^2 was omitted. In other words, the analysis aimed for the lowest reduction in the model's overall ability to explain variability in the dependent variable.

VIF is an index measuring the extent to which variance of estimated regression coefficients and independent variables increase due to collinearity. A VIF between 5 and 10 is potentially too high, while a VIF greater than 10 clearly indicates multicollinearity. At t=0, no psychological variables had correlations greater than 0.80 (Table 23a) and VIF was lower than 5 for all variables. At t=1, several variables had correlations greater than 0.80 (Table 23b). Thus, PROMIS depression, PROMIS anxiety, PROMIS Emotional support, PCS and TSK were excluded from multivariable analysis at t=1, resulting in VIFs lower than 5. Sensitivity analysis demonstrated that omission of variables did not reduce the models' adjusted R^2 i.e. the overall ability to predict the outcome variable.

VIF analysis also indicated multicollinearity between age and CACI (correlation=0.90) (Table 23c). Although CACI incorporates more information than age, several parameters are required to calculate a total score, making it less practical to use in daily practice. Thus, CACI was omitted from multivariable analysis, if both age and CACI had a p-value < 0.10 in bivariate analysis.

After adjusting for multicollinearity, the remaining psychological measures and each independent variable associated with disability at t=0 and t=1, with $p<0.10$ in bivariate analysis, was entered into multivariable regression. Eight multivariable models were created in total i.e. one for each disability PRO measure with independent variables at t=0 and t=1. $p<0.05$ was considered statistically significant in multivariable analysis. Partial R^2 indicated how much each variable accounted for the total variance, which in turn was reflected by the Adjusted R^2 is a measure of the percentage of the overall variability in the response variable that could be explained by all the variables included in the model.

Multiple linear imputation was used for missing values (i.e. number of imputations set to 40): IMD factor (1), percentage grip strength of the non-injured side at t=0 (7), percentage grip strength of the non-injured side at t=1 (3), PSEQ-2 at t=0 (1) and TSK-11 at t=0 (1). This method maintains the overall variability in the data while preserving relationships with other variables.

An a-priori power analysis indicated that a minimum sample size of 160 would provide 80% statistical power with alpha set at 0.05. This was based on a regression with ten predictors and an assumption that an independent variable would account for 3.5% or more of the variability in disability and the complete model would account for at least 30% variability. All statistical analysis was performed using STATA 14.0 (StataCorp LP, College Station, TX, USA).

5.3 Results

Health related outcomes improved overall during the course of recovery (Table 24). The magnitude of disability reflected by each of the four PRO measures (QuickDASH, OSS, EQ-5D and PROMIS UE PF) at 6 to 9 months after a proximal humerus fracture was associated with older age, greater comorbidity (CACI), marital status (being separated, widowed or divorced), social support status (not having a partner, family or friends for support), fewer years of education, work status (being unemployed, on workers compensation or involved in litigation claims), greater deprivation (IMD factor), experience of a treatment complication, opioid and anti-depressant use, as well as weaker grip strength and a number of psychological factors (greater pain interference, depression, anxiety, pain catastrophizing, or kinesiophobia, and less self-efficacy) at baseline (t=0) in bivariate analysis (Table 25).

The best multivariable models included kinesiophobia which consistently explained a large proportion of the variability in all disability measures at t=0 [QuickDASH (Partial R^2=0.09, p=0.001; OSS (Partial R^2=0.115, p=0.000; EQ-5D (Partial R^2=0.098, p=0.006); PROMIS UE PF (Partial R^2=0.14, p=0.000)] (Table 26). A relatively high proportion of the overall variability in disability measures was explained by the combination of significant factors in multivariable analysis [Adjusted R^2: QuickDASH (77%); OSS (73%); EQ-5D (63%); PROMIS UE PF (66%)].

At early follow-up (t=1), a similar set of variables were associated with disability in bivariate analysis (Table 27). However, pain self-efficacy (PSEQ-2) was the strongest predictor with all measures of disability in multivariable analysis [QuickDASH (Partial R^2=0.124; p<0.001); OSS (Partial R^2=0.249, p<0.001); EQ-5D-3L (Partial R^2=0.377, p<0.001); PROMIS UE PF (Partial R^2=0.266, p<0.001)] (Table 28). Other factors that explained a proportion of the variance included being on worker's compensation or involved in a litigation claim, social support from partners, friends and a family, anti-depressant use, instrumental support, and pain interference but these were not consistent across disability measures. Multivariable analysis accounted for a

substantial level of multi-collinearity amongst psychosocial variables at t=1. The statistically significant variables at t=1 in each model explained even higher proportions of variance in disability compared to variables at t=0 [Adjusted R^2: QuickDASH (81%); OSS (77%); EQ-5D-3L (71%); PROMIS UE PF (70%)] (Table 28).

Broad injury classification correlated with OSS (p=0.0443) and PROMIS UE PF (p=0.0260), and neurovascular compromise correlated with QuickDASH (p=0.0587) and EQ-5D (p=0.0885). However, these variables, along with other injury-related factors and grip strength did not explain any of the variability in disability in multivariable analysis.

Table 22. Patient Demographics

Demographic	Value	
Subjects enrolled (t=0)	177	
Subjects (t=1)	177	
Subjects (t=2)	173	
Age (years)	66 ± 16	(18 - 95)
Female	72%	(128)
Charlson Comorbidity Index	2.6 ± 1.8	(0 - 6)
Marital status		
Single	15%	(26)
Partner / Married	48%	(86)
Separated / Divorced / Widowed	27%	(65)
Social status		
Alone	29%	(52)
Partner / Friend(s) /Family	62%	(109)
Full / Part-time care	9%	(16)
Education (years)	13.7 ± 2.8	(7 - 22)
Work status		
Working	27%	(48)
Homemaker	5%	(8)
Retired	55%	(99)
Unemployed	5%	(8)
Workers comp / Litigation	8%	(14)
IMD factor	71.7 ± 23.2	(2.7 - 99.8)
Broad injury classification		
Greater tuberosity	21%	(38)
2-Part	40%	(70)
>2-Part	39%	(69)
Dominant side injured	53%	(93)
High energy injury	12%	(22)
Neurovascular compromise	3%	(5)
Open injury	0%	(0)
Surgery	10%	(17)
Complication	25%	(44)
Prior fracture to dominant arm	16%	(28)
Prior fracture to non-dominant arm	12%	(22)
Opioid use	48%	(85)
Anti-depressant use	34%	(60)

Continuous variables as mean + standard deviation (range)
Discrete variables as percentage (number)

Table 23. Correlation Matrices

Table 23a. Correlation Matrix of Psychological variables at t=0

	PROMIS PI	PROMIS depression	PROMIS anxiety	PCS	PSEQ-2	TSK-11
PROMIS PI	1.0					
PROMIS depression	0.27	1.0				
PROMIS anxiety	0.072	0.57	1.0			
PCS	0.36	0.56	0.40	1.0		
PSEQ-2	-0.27	-0.50	-0.18	-0.39	1.0	
TSK-11	0.37	0.31	0.11	0.54	-0.50	1.0

Table 23b. Correlation Matrix of Psychological variables after t=1

	PROMIS PI	PROMIS depression	PROMIS anxiety	PCS	PSEQ-2	TSK-11	PROMIS ES	PROMIS IS
PROMIS PI	1.0							
PROMIS depression	0.65	1.0						
PROMIS anxiety	0.49	0.73	1.0					
PCS	0.48	0.74	**0.80**	1.0				
PSEQ-2	-0.57	**-0.81**	-0.77	**-0.82**	1.0			
TSK-11	0.55	**0.85**	0.79	**0.83**	**-0.90**	1.0		
PROMIS ES	-0.39	-0.62	-0.64	-0.65	0.66	-0.74	1.0	
PROMIS IS	-0.28	-0.56	-0.70	-0.68	0.67	-0.73	**0.84**	1.0

Table 23c. Correlation Matrix age & CACI

	CACI
Age	**0.88**

Table 24. Health Related Outcomes

Variables	Value t=0			Value t=1			Value t=2		
Performance-based outcomes	n	Mean (SD)	Range	n	Mean (SD)	Range	n	Mean (SD)	Range
Grip strength (% of non-injured side)	170	39.9 ± 10.7	(11.4 - 67.3)	174	47 ± 10.2	(20.6 - 69.7)	172	73.9 ± 13.8	(31.3 - 113.3)
Health-related outcomes	n	Mean (SD)	Range	n	Mean (SD)	Range	n	Mean (SD)	Range
QuickDASH	177	74.7 ± 11.7	(36.4 - 93.2)	177	71.7 ± 15.7	(15.9 - 90.9)	173	31.9 ± 25	(0 - 79.5)
OSS	177	7.9 ± 5.5	(0 - 24)	177	12 ± 7.1	(3 - 34)	173	34.8 ± 11.3	(14 - 48)
EQ5D Index	177	0.317 ± 0.184	(0.038 - 0.667)	177	0.377 ± 0.227	(0.038 - 1)	173	0.749 ± 0.249	(0.14 - 1)
PROMIS UE PF	177	21.9 ± 5.5	(14.7 - 40.7)	177	27.1 ± 5.4	(15.6 - 41)	173	40.5 ± 9.9	(26.2 - 56.4)
PROMIS PI	177	68 ± 6.8	(38.1 - 76.9)	177	66.9 ± 5.9	(46.1 - 74.1)	173	52.8 ± 11.2	(38.7 - 70.3)
PROMIS Depression	177	50.7 ± 9.5	(34.2 - 75.6)	177	50.2 ± 9.6	(34.2 - 69.2)	172	45.1 ± 11.5	(34.2 - 68)
PROMIS Anxiety	177	52.2 ± 11.6	32.9 - 76.2	177	47 ± 10.4	(32.9 - 69.6)	173	44.2 ± 11.2	(32.9 - 63.3)
PROMIS ES	n/m	n/m	n/m	177	51.6 ± 12.1	(32.6 - 66.2)	172	51.3 ± 11.4	(31.5 - 66.2)
PROMIS IS	n/m	n/m	n/m	177	55 ± 9.5	(38.8 - 66.2)	172	53.5 ± 9.1	(38.8 - 66.2)
PCS	177	20 ± 6.8	(13 - 45)	177	19.1 ± 7	(13 - 44)	173	17.8 ± 6.8	(13 - 40)
PSEQ-2	176	8.6 ± 2.4	(3 - 12)	177	7.4 ± 2.6	(1 - 12)	173	8.6 ± 3.3	(2 - 12)
TSK-11	176	28.6 ± 6.3	(15 - 40)	177	24.9 ± 8.1	(11 - 40)	173	20.7 ± 10.2	(11 - 44)

Variables as mean + standard deviation (range)
n/m, Not measured

Table 25. Bivariate at Analysis t=0

	QuickDASH		OSS		EQ-5D-3L		PROMIS UE PF	
	Value	**p value**	**Value**	**p value**	**Value**	**p value**	**Value**	**p value**
Age	0.2497	**<0.001**	-0.3061	**<0.001**	-0.1433	**0.0599**	-0.3052	**<0.001**
Sex								
Women	33.8 ± 24.1	0.1068	33.9 ± 11.5	0.1000	0.743 ± 0.279	0.2987	40.2 ± 9.5	0.4500
Men	26.8 ± 27.1		37.2 ± 10.8		0.793 ± 0.275		41.5 ± 10.9	
Charlson Comorbidity Index	0.3751	**<0.001**	-0.4111	**<0.001**	-0.2484	**0.0010**	-0.3840	**<0.001**
Marital status								
Single	41 ± 26.1		31.2 ± 11.5		0.632 ± 0.331		38.2 ± 10.9	
Partner / Married	15.7 ± 16.7	**0.0000**	42.2 ± 7.2	**0.0000**	0.917 ± 0.145	**0.0000**	46 ± 8.7	**0.0000**
Separated / Divorced / Widowed	51 ± 18.1		25.8 ± 8.6		0.583 ± 0.264		33.9 ± 6	
Social support status								
Alone	55.7 ± 18.8		25.6 ± 8.6		0.503 ± 0.299		32.8 ± 6.6	
Partner / Friend(s) / Family	18.9 ± 18.7	**0.0000**	40.4 ± 8.9	**0.0000**	0.891 ± 0.166	**0.0000**	44.9 ± 9	**0.0000**
Full / Part-time care	48.9 ± 12.4		23.9 ± 7.2		0.604 ± 0.200		34.2 ± 4.7	
Education	-0.2997	**0.0001**	0.3129	**0.0000**	0.1741	**0.0220**	0.2713	**0.0003**
Work status								
Working	9.9 ± 11.1		44.4 ± 4.7		0.952 ± 0.102		48.1 ± 7.9	
Homemaker	35.8 ± 31.3		33.1 ± 14.4		0.601 ± 0.516		39.8 ± 12.8	
Retired	37.4 ± 22.9	**0.0000**	32.1 ± 11	**0.0000**	0.719 ± 0.264	**0.0000**	38.4 ± 8.7	**0.0000**
Unemployed	52.8 ± 21.6		25.7 ± 8.8		0.553 ± 0.275		34.4 ± 9.2	
Workers compensation / Litigation	56.3 ± 18.5		25.8 ± 8.4		0.545 ± 0.240		33.2 ± 6.9	

IMD Factor	-0.1967	**0.0097**	0.1588	**0.0374**	0.1689	**0.0267**	0.2002	**0.0084**
Broad injury classification								
Greater tuberosity	25.1 ± 26.2		38.7 ± 11.3		0.813 ± 0.303		44.4 ± 11	
2-Part	32.4 ± 24.4	0.1391	34.4 ± 11.1	**0.0443**	0.756 ± 0.267	0.3222	39.5 ± 9.1	**0.0260**
>2-Part	35.1 ± 24.7		33 ± 11.4		0.728 ± 0.274		39.5 ± 9.6	
Dominant side injured								
Yes	34.3 ± 25.7	0.1902	33.7 ± 11.8	0.1926	0.726 ± 0.302	0.1346	39.9 ± 10.1	0.3515
No	29.3 ± 24.1		35.9 ± 10.8		0.790 ± 0.246		41.3 ± 9.7	
High energy injury								
Yes	36.9 ± 27.3	0.3209	33.1 ± 13	0.4646	0.699 ± 0.327	0.3027	40.3 ± 11.4	0.9224
No	31.2 ± 24.7		35 ± 11.1		0.765 ± 0.270		40.6 ± 9.7	
Neurovascular compromise								
Yes	52.7 ± 27.5	**0.0587**	26.6 ± 11.2	0.1036	0.548 ± 0.363	**0.0885**	35.6 ± 11.9	0.2582
No	31.3 ± 24.7		35 ± 11.3		0.763 ± 0.274		40.7 ± 9.8	
Open injury								
Yes	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
No	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Surgery								
Yes	39.3 ± 26.5	0.2007	31.3 ± 11.8	0.1871	0.671 ± 0.294	0.1805	37.4 ± 8.4	0.1728
No	31.1 ± 24.8		35.1 ± 11.3		0.766 ± 0.275		40.9 ± 10	
Complication								
Yes	51.2 ± 19.8	**0.0000**	26.2 ± 8.5	**0.0000**	0.546 ± 0.291	**0.0000**	33.5 ± 5.8	**0.0000**
No	25.5 ± 23.3		37.6 ± 10.8		0.826 ± 0.236		42.9 ± 9.9	

Prior dominant side fracture								
Yes	36.6 ± 28.1	0.2801	32.8 ± 12	0.3275	0.666 ± 0.371	0.9695	39.1 ± 10.8	0.3996
No	31 ± 24.4		35.1 ± 11.2		0.774 ± 0.254		40.8 ± 9.7	
Prior non-dominant side fracture								
Yes	37.6 ± 24.4	0.2989	32.6 ± 11.3	0.3784	0.686 ± 0.333	0.2402	37.8 ± 9.9	0.2068
No	31.2 ± 25.1		35 ± 11.4		0.765 ± 0.270		40.9 ± 9.9	
Opioid use								
Yes	44.2 ± 23.9	**0.0000**	29.9 ± 10.5	**0.0000**	0.620 ± 0.302	**0.0000**	35.9 ± 8.4	**0.0000**
No	20.9 ± 20.5		39.2 ± 10.3		0.879 ± 0.183		44.7 ± 9.3	
Anti-depressant use								
Yes	54.8 ± 15.3	**0.0000**	25.5 ± 6.8	**0.0000**	0.523 ± 0.257	**0.0000**	32.9 ± 5.9	**0.0000**
No	21 ± 21		39.2 ± 10.4		0.868 ± 0.211		44.2 ± 9.3	
Performance-based outcomes at t=0	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
Grip strength (% non-injured side)	-0.3364	**0.0000**	0.3717	**0.0000**	0.3546	**0.0000**	0.3103	**0.0000**
Health-related outcomes at t=0	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
PROMIS Pain Interference	0.2905	**0.0001**	-0.3167	**0.0000**	-0.1236	**0.0105**	-0.2109	**0.0054**
PROMIS Depression	0.3518	**0.0000**	-0.2953	**0.0001**	-0.3447	**0.0000**	-0.2125	**0.0050**
PROMIS Anxiety	0.1377	**0.0708**	-0.0864	**0.0001**	-0.2447	**0.0012**	0.0009	**0.0026**
PCS	0.4095	**0.0000**	-0.3756	**0.0000**	-0.3307	**0.0000**	-0.3023	**0.0001**
PSEQ-2	-0.4662	**0.0000**	0.4409	**0.0000**	0.3415	**0.0000**	0.4084	**0.0000**
TSK-11	0.5451	**0.0000**	-0.5799	**0.0000**	-0.4505	**0.0000**	-0.5188	**0.0000**

Pearson correlation indicated by r; **bold** indicates statistically significant difference; continuous variables as mean (±standard deviation).

Table 26. Multivariable Analysis of Predictive Factors at t=0 for Disability at t=2

QuickDASH	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	0.27	0.03	0.50	0.12	0.029	4.39	0.03	
MS: Separated / Widowed / Divorced	11.42	3.60	19.24	3.96	0.004	4.11	0.05	
SS: Partner / Friend(s) / Family	-12.35	-19.75	-4.96	3.74	0.001	3.86	0.06	
WS: Unemployed	18.87	7.47	30.26	5.77	0.001	1.77	0.07	
WS: Workers compensation	14.67	5.16	24.18	4.81	0.003	2.05	0.06	0.77
Complications	9.75	4.69	14.81	2.56	0.000	1.46	0.11	
Opioid use	5.52	0.69	10.36	2.45	0.025	1.76	0.02	
Antidepressant use	13.28	7.42	19.13	2.96	0.000	2.22	0.11	
TSK-11	0.74	0.31	1.18	0.22	0.001	2.38	0.09	

In model: age, marital status (MS), social status (SS), education, work status (WS), IMD, neurovascular status, complications, opioid use, antidepressant use, grip strength %, PROMIS PI, PROMIS depression, PROMIS anxiety, PCS, PSEQ-2, TSK-11

OSS	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	-0.14	-0.25	-0.02	0.06	0.021	4.30	0.057	
MS: Separated / Widowed / Divorced	-5.04	-8.98	-1.10	1.99	0.013	4.42	0.037	
SS: Partner / Friend(s) / Family	3.64	0.01	7.27	1.84	0.049	3.88	0.02	
WS: Unemployed	-8.28	-13.77	-2.78	2.78	0.003	1.76	0.059	
WS: Workers compensation	-4.56	-9.16	0.03	2.32	0.032	2.01	0.029	0.73
Complications	-5.21	-7.64	-2.79	1.23	0.000	1.42	0.124	
Antidepressant use	-5.16	-8.01	-2.32	1.44	0.000	2.26	0.108	
TSK-11	-0.40	-0.62	-0.19	0.11	0.000	2.48	0.115	

In model: age, marital status (MS), social status (SS), education, work status (WS), IMD, complications, opioid use, antidepressant use, broad classification grip strength %, PROMIS PI, PROMIS depression, PCS, PSEQ-2, TSK-11

EQ-5D-3L	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
SS: Partners / Friend(s) / Family	0.18	0.08	0.28	0.05	0.001	3.80	0.331	
WS: Homemaker	-0.17	-0.31	-0.03	0.07	0.020	1.47	0.045	
Complications	-0.14	-0.21	-0.07	0.04	0.000	1.46	0.106	
Opioid use	-0.07	-0.15	0.01	0.03	0.030	1.74	0.026	0.63
Antidepressant use	-0.10	-0.18	-0.02	0.04	0.020	2.22	0.030	
PROMIS PI	0.01	0.00	0.01	0.00	0.012	1.70	0.051	
TSK-11	-0.01	-0.01	0.00	0.00	0.006	2.37	0.098	

In model: age, marital status (MS), social status (SS), education, work status (WS), IMD, neurovascular status, complications, opioid use, antidepressant use, grip strength %, PROMIS PI, PROMIS depression, PCS, PSEQ, TSK

PROMIS UE PF	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	-0.15	-0.26	-0.04	0.06	0.009	4.61	0.06	
MS: Separated / Divorced / Widowed	-4.13	-8.01	-0.24	1.97	0.037	4.43	0.02	
SS: Partner / Friend(s) / Family	4.80	1.22	8.38	1.81	0.009	3.94	0.04	
WS: Unemployed	-5.87	-11.29	-0.45	2.74	0.034	1.76	0.03	
WS: Workers Compensation	-4.41	-8.94	0.12	2.29	0.050	2.03	0.03	
Complications	-4.09	-6.48	-1.70	1.21	0.001	1.42	0.07	0.66
Opioid use	-3.89	-6.21	-1.57	1.17	0.001	1.80	0.06	
Anti-depressant	-4.30	-7.10	-1.50	1.42	0.003	2.26	0.05	
PROMIS PI	0.23	0.07	0.40	0.083	0.005	1.77	0.07	
PROMIS Anxiety	0.13	0.02	0.24	0.06	0.026	2.24	0.07	
TSK-11	-0.44	-0.66	-0.23	0.11	0.000	2.49	0.14	

In model: age, marital status (MS), social status (SS), education, work status (WS), IMD, complications, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PROMIS depression, PROMIS anxiety, PCS, PSEQ-2, TSK-11

Partial R^2 only shown for variables with $p < 0.05$

Table 27. Bivariate Analysis at t=1

	QuickDASH		OSS		EQ5D Index Score		PROMIS UE PF	
	Value	**p-value**	**Value**	**p-value**	**Value**	**p-value**	**Value**	**p-value**
Age	0.2497	**<0.001**	-0.3061	**<0.001**	-0.1433	**0.0599**	-0.3052	**<0.001**
Sex								
Women	33.8 ± 24.1	0.1068	33.9 ± 11.5	0.1000	0.743 ± 0.279	0.2987	40.2 ± 9.5	0.4500
Men	26.8 ± 27.1		37.2 ± 10.8		0.793 ± 0.275		41.5 ± 10.9	
Charlson Comorbidity Index	0.3751	**<0.001**	-0.4111	**<0.001**	-0.2484	**0.0010**	-0.3840	**<0.001**
Marital status								
Single	41 ± 26.1		31.2 ± 11.5		0.632 ± 0.331		38.2 ± 10.9	
Partner / Married	15.7 ± 16.7	**0.0000**	42.2 ± 7.2	**0.0000**	0.917 ± 0.145	**0.0000**	46 ± 8.7	**0.0000**
Separated / Divorced / Widowed	51 ± 18.1		25.8 ± 8.6		0.583 ± 0.264		33.9 ± 6	
Education	-0.2997	**0.0001**	0.3129	**0.0000**	0.1741	**0.0220**	0.2713	**0.0003**
Social support status								
Alone	55.7 ± 18.8		25.6 ± 8.6		0.503 ± 0.299		32.8 ± 6.6	
Partner / Friend(s) / Family	18.9 ± 18.7	**0.0000**	40.4 ± 8.9	**0.0000**	0.891 ± 0.166	**0.0000**	44.9 ± 9	**0.0000**
Full / Part-time care	48.9 ± 12.4		23.9 ± 7.2		0.604 ± 0.200		34.2 ± 4.7	
Work status								
Working	9.9 ± 11.1		44.4 + 4.7		0.952 ± 0.102		48.1 ± 7.9	
Homemaker	35.8 ± 31.3		33.1 + 14.4		0.601 ± 0.516		39.8 ± 12.8	
Retired	37.4 ± 22.9	**0.0000**	32.1 + 11	**0.0000**	0.719 ± 0.264	**0.0000**	38.4 ± 8.7	**0.0000**
Unemployed	52.8 ± 21.6		25.7 + 8.8		0.553 ± 0.275		34.4 ± 9.2	
Workers compensation	56.3 ± 18.5		25.8 + 8.4		0.545 ± 0.240		33.2 ± 6.9	
IMD Factor	-0.1967	**0.0097**	0.1588	**0.0374**	0.1689	**0.0267**	0.2002	**0.0084**
Broad injury classification								
Greater tuberosity	25.1 ± 26.2		38.7 ± 11.3		0.813 ± 0.303		44.4 ± 11	
2-Part	32.4 ± 24.4	0.1391	34.4 ± 11.1	**0.0443**	0.756 ± 0.267	0.3222	39.5 ± 9.1	**0.0260**
>2-Part	35.1 ± 24.7		33 ± 11.4		0.728 ± 0.274		39.5 ± 9.6	

Dominant side injured								
Yes	34.3 ± 25.7	0.1902	33.7 ± 11.8	0.1926	0.726 ± 0.302	0.1346	39.9 ± 10.1	0.3515
No	29.3 ± 24.1		35.9 ± 10.8		0.790 ± 0.246		41.3 ± 9.7	
High energy injury								
Yes	36.9 ± 27.3	0.3209	33.1 ± 13	0.4646	0.699 ± 0.327	0.3027	40.3 ± 11.4	0.9224
No	31.2 ± 24.7		35 ± 11.1		0.765 ± 0.270		40.6 ± 9.7	
Neurovascular compromise								
Yes	52.7 ± 27.5	**0.0587**	26.6 ± 11.2	0.1036	0.548 ± 0.363	**0.0885**	35.6 ± 11.9	0.2582
No	31.3 ± 24.7		35 ± 11.3		0.763 ± 0.274		40.7 ± 9.8	
Open injury								
Yes	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
No	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Surgery								
Yes	39.3 ± 26.5	0.2007	31.3 ± 11.8	0.1871	0.671 ± 0.294	0.1805	37.4 ± 8.4	0.1728
No	31.1 ± 24.8		35.1 ± 11.3		0.766 ± 0.275		40.9 ± 10	
Complication								
Yes	51.2 ± 19.8	**0.0000**	26.2 ± 8.5	**0.0000**	0.546 ± 0.291	**0.0000**	33.5 ± 5.8	**0.0000**
No	25.5 ± 23.3		37.6 ± 10.8		0.826 ± 0.236		42.9 ± 9.9	
Prior dominant side fracture								
Yes	36.6 ± 28.1	0.2801	32.8 ± 12	0.3275	0.666 ± 0.371	0.2436	39.1 ± 10.8	0.3996
No	31 ± 24.4		35.1 ± 11.2		0.774 ± 0.254		40.8 ± 9.7	
Prior non-dominant side fracture								
Yes	37.6 ± 24.4	0.2989	32.6 ± 11.3	0.3784	0.686 ± 0.333	0.2402	37.8 ± 9.9	0.2068
No	31.2 ± 25.1		35 ± 11.4		0.765 ± 0.270		40.9 ± 9.9	
Opioid use								
Yes	44.2 ± 23.9	**0.0000**	29.9 ± 10.5	**0.0000**	0.620 ± 0.302	**0.0000**	35.9 ± 8.4	**0.0000**
No	20.9 ± 20.5		39.2 ± 10.3		0.879 ± 0.183		44.7 ± 9.3	
Anti-depressant use								
Yes	54.8 ± 15.3	**0.0000**	25.5 ± 6.8	**0.0000**	0.523 ± 0.257	**0.0000**	32.9 ± 5.9	**0.0000**
No	21 ± 21		39.2 ± 10.4		0.868 ± 0.211		44.2 ± 9.3	

Performance-based outcomes at t=1	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
Grip strength (% non-injured side)	-0.3534	**0.0000**	0.3635	**0.0000**	0.3260	**0.0000**	0.3061	**0.0000**
Health-related outcomes at t=1	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
PROMIS Pain Interference	0.5950	**0.0000**	-0.5606	**0.0000**	-0.4996	**0.0000**	-0.6858	**0.0000**
PROMIS Depression	0.7116	**0.0000**	-0.6398	**0.0000**	-0.7090	**0.0000**	-0.6886	**0.0000**
PROMIS Anxiety	0.5366	**0.0000**	-0.4329	**0.0000**	-0.5460	**0.0000**	-0.5513	**0.0000**
PROMIS Emotional Support at t=1	-0.7091	**0.0000**	0.6308	**0.0000**	0.6644	**0.0000**	0.6707	**0.0000**
PROMIS Instrumental Support at t=1	-0.5739	**0.0000**	0.4718	**0.0000**	0.5690	**0.0000**	0.4885	**0.0000**
PCS	0.6615	**0.0000**	-0.5703	**0.0000**	-0.6838	**0.0000**	-0.5825	**0.0000**
PSEQ-2	-0.7345	**0.0000**	0.6922	**0.0000**	0.7776	**0.0000**	0.6975	**0.0000**
TSK-11	0.7451	**0.0000**	-0.6742	**0.0000**	-0.7439	**0.0000**	-0.7107	**0.0000**

Pearson correlation indicated by r; **bold** indicates statistically significant difference; continuous variables as mean (±standard deviation)

Table 28. Multivariable Analysis of Predictive Factors at t=1 for Disability at t=2

QuickDASH	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
MS: Separated / Widowed / Divorced	10.21	3.38	17.03	3.45	0.004	3.73	0.073	
SS: Partner / Friend(s) / Family	-7.59788	-14.31	-0.88	3.40	0.027	3.88	0.036	
WS: Unemployed	13.53	2.88	24.19	5.39	0.013	1.81	0.052	
WS: Workers compensation	16.14	7.47	24.80	4.38	0.000	2.01	0.088	
Complications	6.86	2.04	11.67	2.44	0.006	1.52	0.056	0.81
Antidepressant use	11.37	5.37	17.36	3.03	0.000	2.83	0.092	
PROMIS PI	0.64	0.22	1.07	0.22	0.003	2.31	0.058	
PROMIS IS	0.44	0.12	0.77	0.17	0.008	3.49	0.035	
PSEQ-2	-2.94	-4.19	-1.69	0.63	0.000	3.78	0.124	

In model: age, marital status (MS), social status (SS), education, work status (WS), IMD, neurovascular status, complications, opioid use, antidepressant use, grip strength %, PROMIS PI, PROMIS IS, PSEQ-2

OSS	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
MS: Partner / Married	5.14	1.56	8.72	1.81	0.005	4.89	0.032	
MS: Separated / Widowed / Divorced	-3.89	-7.27	-0.50	1.71	0.025	4.00	0.072	
SS: Full / Part-time care	-4.93	-8.80	-1.06	1.96	0.013	1.83	0.067	
WS: Unemployed	-7.31	-12.39	-2.23	2.57	0.005	1.79	0.063	
WS: Workers compensation	-7.72	-11.87	-3.56	2.10	0.000	2.02	0.104	0.77
Complications	-3.99	-6.29	-1.69	1.16	0.001	1.51	0.089	
Antidepressant use	-5.23	-8.12	-2.34	1.46	0.000	2.83	0.079	
PROMIS IS	-0.38	-0.54	-0.22	0.08	0.000	2.31	0.134	
PSEQ-2	1.73	1.13	2.33	0.31	0.000	3.84	0.249	

In model: age, marital status (MS), social status (SS), education, work status (WS), IMD, complications, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PROMIS IS, PSEQ-2

EQ-5D-3L	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
SS: Partner / Friend(s) / Family	0.10	0.02	0.19	0.04	0.021	3.88	0.110	0.71
WS: Homemaker	-0.15	-0.27	-0.02	0.06	0.023	1.41	0.025	
Complications	-0.09	-0.15	-0.02	0.03	0.009	1.52	0.039	
PSEQ-2	0.06	0.05	0.08	0.01	0.000	3.78	0.377	

In model: age, marital status (MS), social status (SS), education, work status (WS), IMD, neurovascular status, complications, opioid use, antidepressant use, grip strength %, PROMIS PI, PROMIS IS, PSEQ-2

PROMIS UE PF	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
PROMIS PI	-0.59	-0.79	-0.38	0.11	0.000	2.31	0.242	0.70
PSEQ-2	1.15	0.54	1.76	0.31	0.000	3.84	0.266	

In model: age, marital status (MS), social status (SS), education, work status (WS), IMD, complications, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PROMIS IS, PSEQ-2

Only partial R^2 of significant values is displayed (i.e. $p<0.05$)

5.4 Discussion

The *fear of movement* or further injury appeared to be the dominant psychological predictor of future disability outcomes within a few days of injury (t=0) whilst confidence and *coping* with the fracture and its associated symptoms was a stronger determinant after a few weeks of recovery (t=1). These observations make sense in the clinical context; it is understandable that within days of the acute event, patients may be most concerned about causing further injury with any inadvertent movements. The concept of kinesiophobia encompasses a focus on pain (i.e. pain-related fear beliefs), a somatic focus (i.e. perception of a serious underlying medical condition) and activity-avoidance focus (i.e. fear of movement resulting in further injury) (76)(287)(289). All three aspects may play a role in the patient's experience post-injury and lead to a heightened protective response with the potential for over-cautious behavior. The impact of pain during this early stage was also substantial and reflected by opioid use explaining a significant amount of variation in disability at t=0.

In most cases, symptoms often decrease within the first few weeks of sustaining a shoulder fracture; patients get used to immobilization or protected movement, they manage to achieve optimal pain control, and have time to contend with their situation and tend to daily life with a restricted arm. As this occurs, there may be a shift in mindset toward increasing resilience and adapting to their current situation in order to achieve life, work and recreational goals moving forward. Conversely, those with less confidence in their ability to cope with pain and their fracture, may have greater self-perceived disability than would be expected for their physical condition (131).

Pain self-efficacy, pain interference and pain catastrophizing are all shown to measure the same underlying construct of human illness behavior i.e. effective coping, and demonstrate a strong correlation with disability in previous studies (96)(131). In our study, pain self-efficacy at early follow-up consistently predicted disability in all measures at 6-9 months after injury. PROMIS

Pain interference was a significant correlate of QuickDASH and PROMIS UE PF at t=1 only. Pain catastrophizing was a strong correlate of disability but displayed substantial collinearity with other measures. The influence of effective coping in experiencing pain and perceiving disability is well established in non-traumatic conditions (88)(96)(115)(135)(164)(131). It now appears that coping strategies are predictive of health-related outcomes following proximal humerus fractures within a few weeks of injury.

Notably, pain intensity itself was not included as an explanatory variable based on the strong association it has with disability and the consequent risk of preventing other factors from being identified in regression analysis. However, pain interference was included and provides a useful assessment of the effect of pain on limitations. This has been shown to be related to greater catastrophic thinking and lower pain self-efficacy (87)(140)(131)(290)(291).

In this study, the interactions between psychosocial factors and disability were not the same throughout the recovery process. Specifically, multiple psychosocial variables (i.e. depression, anxiety, pain catastrophizing and emotional support) exhibited a substantial degree of shared correlation with disability (multi-collinearity) at t=1, a finding that was not present at t=0. The omission of these variables from regression analysis allowed further statistical definition of factors that explained a greater proportion of the overall variance in disability. It is important to recognise depression, anxiety, pain catastrophizing and emotional support demonstrated a significant correlation with disability in bivariate analysis and may still play a dominant role in influencing it. Depression and anxiety demonstrate strong correlations with disability following non-traumatic upper extremity conditions in many studies (88)(140)(164)(165)(292)(293). In this study, anti-depressant use during the early recovery phase for pre-existing or newly diagnosed depression consistently predicted ongoing disability.

Social factors, such as marital status (i.e. being married or having a partner, being separated, widowed or divorced), social status (i.e. being supported by partners, family and friends, and receiving full or part-time care) and work status (i.e. being unemployed, involved in worker's compensation or litigation claims) explained a substantial proportion of the variation in disability when combined with other factors, at baseline and early follow-up. Instrumental and emotional support both correlated with disability but the latter was excluded from further analysis due to collinearity and weaker effects on overall variance after sensitivity analysis. In essence, the perception of tangible and practical help at hand *and* feeling cared for by family, partners and friends in the face of stressful situations e.g. a painful shoulder fracture, are both prognostic of longer-term disability. These aspects may also contribute to coping and resilience in buffering stress (96). Alternatively, those without anyone to provide this supportive function e.g. widowers, divorcees, may experience the opposite effect. Practical ways of maximising facets of social support have been considered in fracture care and recognising the fracture itself as only one part of the overall condition is important (11)(86)(294)(295). Quality of support and social dependence is shown to be a strong predictor of outcomes following proximal humerus fractures in the elderly, independent of age and fracture severity (21)(86)(96)(301)(296). In terms of work status, being out of work and involved in compensation and litigation claims during early recovery also negatively impacted outcomes. Further investigations involving occupational stressors of disability are warranted (297).

Fracture classification, which often forms the basis of clinical decision-making, was not associated with self-reported disability after proximal humerus fractures. This is consistent with a growing number of studies demonstrating objective pathophysiology is a less significant contributor of disability compared to psychosocial factors (71)(298). Interestingly, the presence of complications following shoulder fractures, such as adhesive capsulitis, appeared to be strongly associated with disability and in theory, may involve a variety of aspects, such as morbidity-induced distress and fear, that go beyond impairment alone.

A greater proportion of variability in disability was explained by the factors in this study compared to other investigations observed in the first systematic review in Chapter 2. This may be a consequence of evaluating a specific condition rather than a heterogeneous group of diagnoses. This work also included some important, pragmatic observations in performing patient outcomes research following shoulder fractures: (i) delivering multiple PRO measures during recovery from trauma, as early as day 0 post-injury was feasible, (ii) administration of PRO measures, including CATs, via an electronic portal was user-friendly and efficient, and (iii) low levels of missing data and participant attrition during follow-up were achievable, reflecting the benefits of a full-time investigator and point of contact (47)(54)(113)(166).

Notably, some of the outcome measures used in this study were originally developed for chronic conditions (e.g. OSS, TSK, PROMIS measures). This study also demonstrated a level of content (face) validity and feasibility in applying them in trauma patients. The OSS, for instance, was originally developed for elderly patients with shoulder osteoarthritis (236). Although, it has been applied in several studies evaluating outcomes following proximal humerus fractures, its use in measuring outcomes in young, active populations has been questioned (236)(271). The OSS seemed to perform effectively in all patients and was associated with a similar correlational profile compared to other measures. Further psychometric evaluation and resolving ceiling effects as observed in Chapter 4, is required before widespread endorsement in trauma. Amongst the PRO measures of disability, identical correlation profiles between the QuickDASH and EQ-5D-3L, and PROMIS UE PF and OSS, could be explained by the fact they were all related to a similar set of psychosocial variables.

5.4.1 Limitations

These findings must be considered in light of some limitations. Firstly, despite the wide range within demographic factors and the IMD, the study population may not have been entirely representative given that it was based at a single specialist institution. Second, although a large proportion of the variance is explained by the multivariable models, there are other factors that could have potentially influenced measurement during the management of these patients. Clinical factors such as fracture displacement, re-injury, development of stiffness and pain in other joints, and changes to the management plan, may have created some additional stress and diminished coping. Also, management decisions are often made by surgeons with a wide range of experiences and backgrounds. Neither the level of experience and sub-specialty, nor the precise course of mobilization, rehabilitation or the timing of surgery was defined. In the same way, logistical factors, such as delays to investigation and operation, and timing of test administration around the clinical encounter could have influenced responses. A patient's mindset and outcomes are shown to be influenced by clinician-patient interaction (126). Specifically, the clinical encounter may have been a source of positive or negative reinforcement for responses depending on whether patients completed their assessment before or after seeing the surgeon. In practice, such factors were challenging to quantify. Third, the broad three-part classification system could be questioned as it may not have been detailed enough to capture injury severity. A pragmatic approach was taken based on relatively small numbers within certain AO/OTA or Neer classifications which could potentially compromise analysis, compared to improved numbers when distributed across three surgically relevant categories. Large-scale studies may be required to further delineate the relationship between disability and specific fracture sub-types but evidence to date suggest this is unlikely to yield any further important insights. Fourth, due to the logistics of follow-up, patients completed outcome measures at t=2 via telephone, online or in person. Each mode of assessment is associated with varying levels of procedural, measurement, interviewer and responder bias. These biases may have also been introduced with patients recruiting family and friends to assist them with

questionnaire completion. Certain friends and family members couldn't help getting involved despite receiving an explanation of the importance of capturing the patient's true response. Proxy responses were often unavoidable, difficult to quantify but rare overall. Fifth, this study aimed to achieve a balance between comprehensive outcome assessment and limiting responder burden through use of abbreviated fixed scales and CATs. Regardless, some patients may have still found this measurement process laborious. Furthermore, although PRO items were carefully ordered during programming, the administration of similar sounding items could have posed an additional source of frustration and led to inaccurate responses. Randomisation of individual questions could minimise this but would have added significant complexity to programming measures onto the digital platform. From another perspective, despite only using abbreviated measures with acceptable psychometric credentials, the study may be criticized for not incorporating full-versions of certain measures e.g. PSEQ, that are considered by some to better capture the substantive components related to a specific construct. Sixth, certain outcome measures involve items related to health status within a specific time-frame (e.g. OSS, the past 4 weeks). Although we were interested in capturing health status and impact in the present, the items were delivered in their original form and not modified in any way in order to avoid introducing bias and invalidating measures. Most patients responded according to their current status, assuming this was indeed the point of interest, whilst some queried the time frame they should relate their responses toward e.g. "Should I answer this based on what I can do now?", "Is this based on how I feel now or how I felt when I injured my arm?". Despite aiming to avoid interference with the measurement process, it was difficult not to advise patients to consider their current health status and health perceptions and overall ability to perform a task. These instances were rare overall. Finally, PROMIS ES and PROMIS IS were not assessed at baseline due to a programming error. Although this may have influenced the analysis it is unlikely to have led to any significant effect on the overall interpretation of findings.

5.4.2 Conclusion

Anatomical restoration is the goal of most surgical interventions in orthopaedic trauma, but should be considered alongside other factors if we are to improve upon the 'status quo' in terms of patient outcomes (70). Operative decisions based purely on fracture configuration, surgical trends and clinical culture, are less likely to consistently restore function and alleviate disability.

Disability following proximal humerus fractures is strongly predicted by the fear of movement in the immediate stage, and the confidence and capabilities of maintaining one's activities in life despite fracture-related pain within the first 6 weeks. Musculoskeletal HCPs should also be cognizant of specific social factors, complications, use of anti-depressants and opioids as indicators prognostic of poor health-related outcomes (265). As these interactions seem to differ during the initial phases of recovery, HCPs and researchers should be mindful of which factors predominate and when.

This work complements the expanding body of evidence demonstrating the magnitude of upper extremity disability is predominantly influenced by psychological factors. These factors, whether they are positive or negative responses to injury, movement and pain, should not be considered as binary phenomena but more as dynamic, normal and modifiable aspects of human illness behavior (138)(128). In other words, they are part of a continuum that extends from the maladaptive end of the spectrum, to a normal protective response, toward resilience and adaptive capabilities. HCPs should understand where patients are positioned on this continuum and, if necessary, how this position can be improved. Novel management strategies may be required to achieve this. These include screening and identifying those in need, delivering coaching and mind-body skills-based training, HCP education in effective communication and promoting coping strategies and more formal psychological therapies such as CBT. These strategies are discussed in Chapter 9.

Ultimately, coping reflects the propensity for adaptation and resilience required to contend with stressful situations like a painful fracture. Providing patients with the ability to enhance adaptive capabilities and bolster resilience during a time of need may be the most effective means of improving outcomes following proximal humerus fractures. Incorporating these tactics alongside the treatment of pathophysiology may lead to more informed treatment choices and positive patient outcomes regardless of injury severity and treatment modality after proximal humerus fractures (270). This certainly merits further study.

Chapter 6

6. Influential Factors of Disability following Elbow Fractures

6.1 Background

In chapter 5, disability following proximal humerus fractures were shown to be strongly predicted by the fear of movement in the initial stage, and the confidence and capabilities of maintaining one's activities in life despite fracture-related pain within the first month. In a similar fashion, Chapter 6 assesses the influential factors of disability following elbow fractures, and also approaches this using the WHO ICF framework (Figure 15).

The overarching goal was to identify the influential factors predicting future disability following elbow fractures, using a comprehensive selection of outcome measures relevant to the elbow, as well as arm-specific disability and health in general. This information could enhance decision-making and inform future patient-centered management strategies to improve long-term health related outcomes.

Figure 22. The WHO ICF Framework applied to evaluating disability after Elbow Fractures

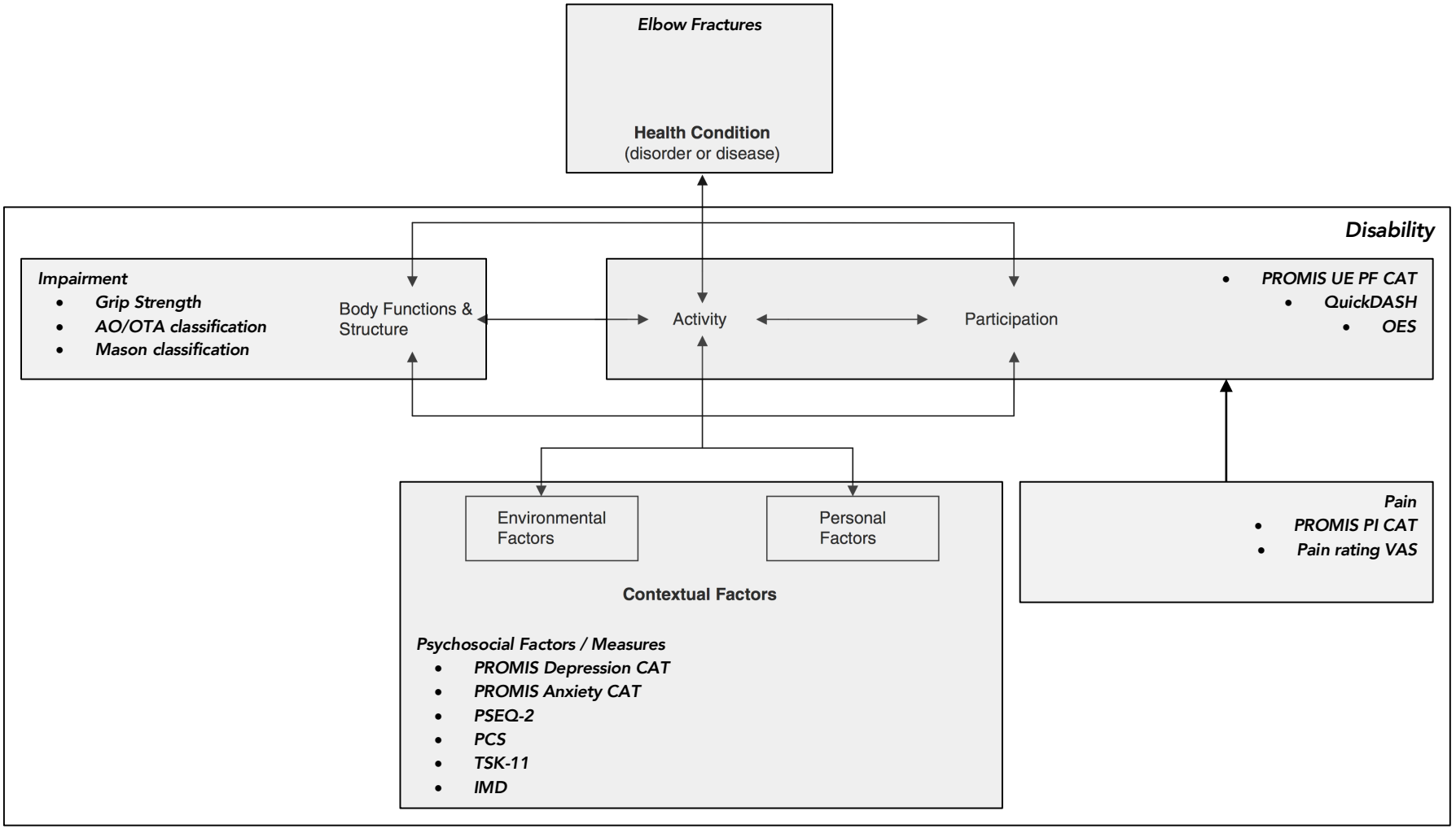
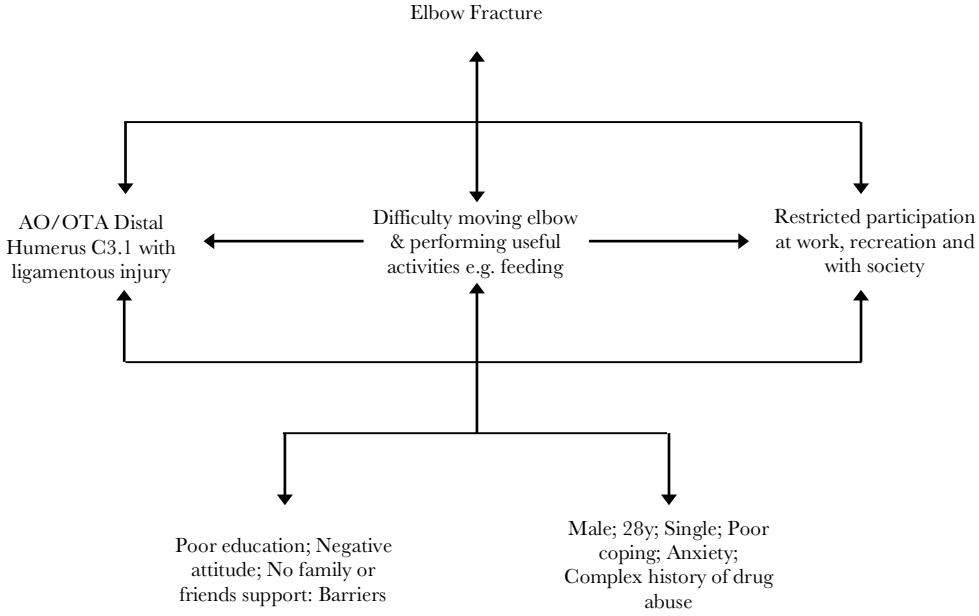
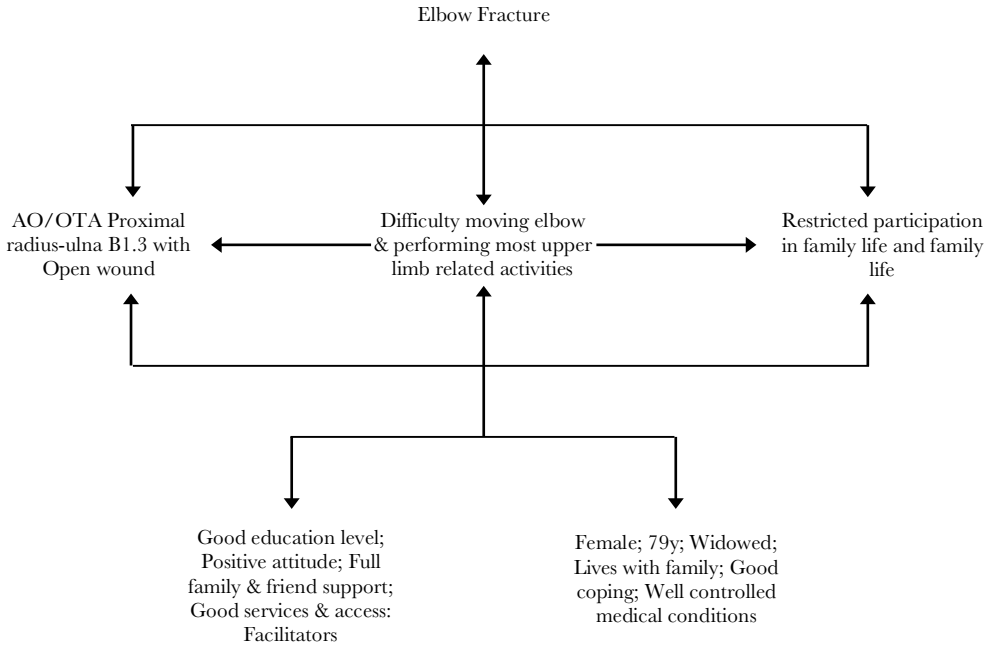


Figure 23. The WHO ICF Framework adapted to profiles of individuals with Elbow Fractures





§ The examples represent a few domains of each component related to the health condition and are not intended to represent a complete overview of impairments, activity limitations, participation restrictions, environmental and personal factors.

‡ Direction or magnitude of arrows may differ for specific situations and/or individuals. Two-directional arrows represent a multi-directional influence

Fractures of the elbow account for almost 5% of all fractures and range from relatively simple, undisplaced fractures of the radial head and neck, to complex fracture dislocations involving adjacent soft tissue and neurovascular structures (299)(300)(301)(302). These injuries can compromise the biomechanical function of the elbow which acts as a fulcrum for levering the forearm and positioning the hand in space (299)(300)(301)(302). The ensuing fracture-related pain and post-traumatic complications, including stiffness at one end of the spectrum and instability at the other, may substantially impact a patient's HrQoL (13)(302)(299)(303). The resultant limitations in performing specific activities that require a functional elbow, such as feeding and grooming, can be extremely disabling (304).

Linking outcome measures to components of the WHO ICF framework, relevant to disability following elbow fractures and it's contributing factors, may allow the identification of modifiable components to improve outcomes following such injuries (19)(26). Disability associated with chronic and often self-remitting elbow conditions e.g. lateral epicondylosis and lateral elbow pain, is shown to be better predicted by psychological factors, such as depression, pain anxiety, kinesiophobia and catastrophic thinking, than objective measures of pathophysiology (76)(88). This relationship is also evident in studies concerning disability following elbow trauma (128)(305).

Total elbow arthroplasty performed for fractures of the elbow demonstrated poorer scores within psychosocial domains of the OES compared to rheumatoid arthritis (305). A further study involving radial head fractures, demonstrated symptoms of depression and catastrophic thinking were significantly associated with post-traumatic disability (128). Both depression and post-traumatic stress disorder are shown to have a greater impact on HrQoL in patients with traumatic injuries of the arm, including elbow fractures, compared to those with general orthopaedic conditions of the upper extremity (13). Studies involving patients with various types of elbow fracture in cohorts combined with non-traumatic conditions also demonstrate a strong

correlation between pain-related factors (e.g. pain behavior, pain interference, as well as other non-fracture-related pain conditions) and disability (108)(111)(132)(293)(306). One study shows pain as the dominant measure of elbow disability at least 6 months on from an intra-articular fracture of the elbow (87). Measures of pain may in turn be strongly influenced by psychosocial aspects of illness and illness behaviour (87)(128).

Whilst psychosocial factors and pain appear to be strong correlates of disability, impairment, represented by objective measures of pathophysiology, seems to have less of an influence (128)(307). For instance, a study involving long-term outcomes of AO-Type C, intra-articular fractures of the distal humerus fractures treated by open reduction internal fixation, demonstrated sustained benefits of surgical management with self-perceived disability predicted by pain over measures of impairment (e.g. radiographic classification, imaging features of arthrosis) (307). Similarly, tension band wiring of transverse, displaced olecranon fractures also demonstrate good clinical results over time, but without any correlation between patient-rated disability and arthrosis or loss of extension (308).

Most studies in this specific area have been cross-sectional, involving elbow fracture patients in highly variable numbers within heterogeneous cohorts combining traumatic and non-traumatic conditions. Studies have also observed the expected change in influential factors of disability over time (128). Essentially, there is a need for prospective, longitudinal investigations that consider disability in elbow fracture populations accounting for the course of recovery (259)(96). This is again evidenced in the first systematic review in Chapter 2. Identifying factors that are modifiable and predictive of disability early in the recovery process may empower HCPs to provide coaching, institute cognitive therapies, facilitate decision-making and enhance rehabilitation. These strategies may be the most effective way of improving patient outcomes following such injuries (249)(259)(275).

6.1.1 Objectives

The primary objective was to assess the association between magnitude of disability at 6 to 9 months after an elbow fracture, and psychosocial factors and grip strength within a week after fracture, along with injury and demographic factors. The secondary objective was to assess the same associations but with psychosocial factors and grip strength at 2 to 4 weeks after injury. The final objective was to observe any similarities and differences in the correlation between explanatory variables and measures of upper extremity disability i.e. generic fixed scale (EQ-5D-3L), region-specific (QuickDASH), joint-specific (OES) and generic computer adaptive (PROMIS UE PF) measures, at baseline and early follow-up after injury.

6.2 Methods

6.2.1 Study Design

A consecutive series of 191 adult patients sustaining isolated elbow fractures attending new patient fracture clinics between 1st January 2016 and 31st August 2016 were enrolled in a research and ethics committee approved study (IRAS No. 16/YH/0017) (Appendix 11-15). This was a prospective cohort study at a level I trauma center in the UK (Level 1b/2b).

Inclusion criteria were that patients should be fluent in English and aged eighteen years or over at the time of injury. Those unable to provide informed consent, including patients with diagnosed mental health problems or cognitive dysfunction, and sustaining concurrent injuries involving the same arm or any other region were excluded. Any elbow fracture as part of complex polytrauma, re-fracture of the elbow during recovery from a previous injury, fracture in a malunited elbow after a prior fracture, and peri-prosthetic fracture around a previous fixation or joint replacement, were also considered ineligible. Eight patients (4.2%) declined participation due to time constraints leaving 183 patients in the study. Informed consent and data protection approvals were obtained from each participant prior to enrollment.

All 183 patients completed a web-based proforma of demographic information followed by electronic versions of PRO measures of disability and psychosocial factors on a tablet device or laptop. This was conducted using the Assessment Center^{SM} (Northwestern University) system as previously described (231). Pilot tests involving the online outcome measurement package were conducted on clinical colleagues and response times were considered acceptable (13.1$\pm$4.2 mins).

Data was captured at baseline (t=0, initial orthopaedic review in new patient fracture clinic following acute management in the emergency department), early follow-up (t=1, subsequent clinic review at 2-4 weeks post-injury) and final assessment (t=2, 6-9 months post-injury). Most assessments were conducted face-to-face (58%; n=318/549), with others completed by phone (34%; n=187/549) or electronically by patients, directly on the digital platform (8%; n=44/549). All data was captured by a single investigator.

6.2.2 Patient Characteristics

The cohort comprised 91 women and 92 men with a mean age of 48.2 years $\pm$ 20.2 (range, 18-93) (Table 29). No patients were lost to follow-up. Education level, marital status, social status and work status, as well as arm dominance and any previous arm injuries, including side, were acquired from the demographic proforma. CACI (232) and the IMD factor (233), described previously, were also assessed, along with any neurovascular compromise, open versus closed fracture, joint aspiration in clinic, surgical intervention and complications. These details were all gathered from information held in clinical records.

Complications were defined as any adverse event specifically related to the injury and its management e.g. post-operative wound infection and prolonged elbow stiffness requiring manipulation were included, whilst generic complications e.g. chest infection, were not.

Injuries were independently classified [PJ; SG] by energy [e.g. high speed road traffic accident (high); fall from standing height (low)] and the AO (Appendix 20) (281) and modified Mason (Appendix 21) (309)(310)(311) classification systems prior to further categorization into three fracture types (i.e. radial head / neck, intra-articular and extra-articular fracture). This allowed an appreciation of the distribution of fracture patterns using more detailed classification systems prior to re-classification into a system that enabled more practical interpretation. It also provided a pragmatic way of accounting for multi-focal injuries e.g. terrible triad elbow injuries, where the fractures were classified by the worst injury which was invariably intra-articular. Any isolated radial head / neck fracture was classified as such irrespective of whether they were intra- or extra-articular. Full agreement was achieved after consensus meetings between two investigators [PJ; SG] with input from a senior attending-level clinical colleague when there was disagreement. Use of opioid analgesia was defined as regular use of any opiates beyond a 2-week period post-injury. Any patients already using opioids for other conditions pre-injury were only included if there was a change or increase in their opiate analgesic requirement secondary to the fracture. Most patients rarely required a prescription for additional pain relief beyond this period or any more than the initial 7-day course of compound analgesics prescribed in the emergency department. Anti-depressant use was defined as any earlier use i.e. for pre-existing depression or a new diagnosis of depression in the acute recovery phase i.e. within the first month following injury.

6.2.3 Outcome Measures

PRO measures were delivered in the following order time points: i) PROMIS UE PF (170), ii) PROMIS PI (203), iii) PROMIS Depression (200,201), iv) PROMIS Anxiety (201), v) PROMIS ES (283), vi) PROMIS IS (283), vii) QuickDASH (204,205,207), viii) OES (237), ix) EQ-5D-3L (234,235), x) PCS (284), xi) PSEQ-2 (285,286), xii) TSK-11 (287) (Appendix 10).

Chapter 4 describes the PROMIS measurement system is detail. All PRO measures were administered at t=0, t=1 and t=2 except for PROMIS ES and PROMIS IS which were deployed at t=1 and t=2 only. Grip strength was recorded using a technique described in Chapter 5. Participants were given reminders via telephone for incomplete or partially completed assessments, as approved by the research and ethics committee. QuickDASH, PROMIS Depression and PROMIS PI are previously described in Chapter 3, PROMIS UE PF, OES and EQ-5D-3L in Chapter 4, and PROMIS Anxiety, PROMIS ES and PROMIS IS, PCS, PSEQ-2 and TSK-11 in Chapter 5.

6.2.4 Statistical analysis

Descriptive statistics included frequencies and percentages for discrete variables, and mean, standard deviation and range for normally distributed continuous variables. Bivariate analysis involved unpaired Student's t-test or analysis of variance for comparing continuous and discrete variables and Pearson correlation for continuous variables. Strength of correlations were classified as high (>0.70), high-moderate (0.61-0.69), moderate (0.40-0.60), moderate-weak (0.31-0.39) and weak (<0.30) (210).

As previously described, multicollinearity is the phenomenon in which two or more predictor variables in a multiple regression model are highly correlated, meaning that one can be linearly predicted from the other with a substantial degree of accuracy. This may be indicated by high beta, high standard error and wide 95% confidence intervals, and assessed with partial R^2, correlation matrices at t=0 and t=1, and VIF. Multicollinearity does not reduce the reliability of the model, but may influence the beta-coefficients and standard errors. A correlation greater than 0.80 was considered an indication of multicollinearity and led to omission of one of the two variables with this high correlation. The variable causing the lowest change in the model's adjusted R^2 was omitted. In other words, the analysis aimed to provide the lowest reduction in the model's overall ability to explain variability in the dependent variable.

VIF was again taken as an index measuring the extent to which variance of estimated regression coefficients and independent variables increased due to collinearity. A VIF between 5 and 10 was considered as high, while a VIF greater than 10 clearly indicating multicollinearity. At t=0, only PCS had a correlation greater than 0.80 and thus was excluded from multivariable analysis at t=0 (Table 30a). At t=1, several variables had correlations greater than 0.80 (Table 30b). Thus, PROMIS depression, PROMIS anxiety, PROMIS Emotional support, PCS and TSK-11 were excluded from multivariable analysis at t=1, resulting in VIFs lower than 5. Sensitivity analysis demonstrated that omission of variables did not reduce the models' adjusted R^2 i.e. the overall ability to predict the outcome variable.

VIF analysis also indicated multicollinearity between age and CACI (correlation=0.90) (Table 30c). Although CACI incorporates more information than age, several parameters are required to calculate a total score, making it less practical to use in daily practice. Thus, CACI was omitted from multivariable analysis, if both age and CACI had a p-value < 0.10 in bivariate analysis.

After adjusting for multicollinearity, the remaining psychosocial measures and each independent variable correlating with disability at t=0 and t=1, with $p<0.10$ in bivariate analysis, was entered into multivariable regression. Eight multivariable models were created in total i.e. one for each disability PRO measure with independent variables at t=0 and t=1. $p<0.05$ was considered statistically significant in multivariable analysis. Partial R^2 indicated how much each variable accounted for the total variance, which in turn was reflected by the Adjusted R^2. This represented a percentage of the overall variability in the response variable i.e. disability measure, that could be explained by all the variables included in the model. Mean imputation was used to address missing values (5 values missing for EQ-5D-3L at t=0; 3 values missing for percentage grip strength of non-injured side at t=0) as this level of missing data was felt to compromise only a small proportion of the total data set.

An a-priori power analysis indicated that a minimum sample size of 160 would provide 80% statistical power with alpha set at 0.05. This was based on a regression with ten predictors and an assumption that an independent variable would account for 3.5% or more of the variability in disability and the complete model would account for at least 30% variability. All statistical analysis was performed using STATA 14.0 (StataCorp LP, College Station, TX, USA).

6.3 Results

Health related outcomes following elbow fractures increased overall during the course of recovery (Table 31). The magnitude of disability reflected by each of the four measures (QuickDASH, OES, EQ-5D-3L and PROMIS UE PF) at 6 to 9 months after an elbow fracture was associated with greater comorbidity (CACI), marital status (being single, separated, divorced or widowed), social support status (being without a partner, friends, family or not having full-time or part-time care), work status (being retired, unemployed, on worker's compensation or involved in litigation claims), broad injury classification (extra-articular, intra-articular fracture), high energy injury, undergoing surgery, experience of a treatment complication, having a prior non-dominant arm fracture, opioid and anti-depressant use, as well as weaker % grip strength and a number of psychological factors (greater pain interference, depression, anxiety, pain catastrophizing, and kinesiophobia, and less self-efficacy) at baseline (t=0) in bivariate analysis (Table 32). The best multivariable models included kinesiophobia which consistently explained a large proportion of the variability in all disability measures at t=0 [QuickDASH (Partial R^2=0.08, p=0.005); OES (Partial R^2=0.122, p<0.001); EQ-5D-3L (Partial R^2=0.069, p=0.001); PROMIS UE PF (Partial R^2=0.14, p=0.005)] and anxiety with the EQ-5D-3L only (Partial R^2=0.119, p<0.001) (Table 33). Other factors that explained a substantial proportion of the variance included antidepressant use, older age and being retired but these were not consistent across disability measures. A relatively high proportion of the overall variability in disability measures was explained by the combination of significant factors in multivariable analysis [Adjusted R^2: QuickDASH (86%); OES (83%); EQ-5D-3L (74%); PROMIS UE Physical function (77%)].

At early follow-up (t=1), an identical set of variables along with (lower emotional and instrumental support) were associated with disability in bivariate analysis at t=1 (Table 34). In addition, older age, being female, fewer years of education and having a joint aspiration correlated with three measures of disability (QuickDASH, OES, PROMIS UE Physical function only), in bivariate analysis at t=0 and t=1 (Table 32) (Table 34).

Pain self-efficacy [QuickDASH (Partial R^2=0.136; p=0.004); OES (Partial R^2=0.195, p=0.002); EQ-5D-3L (Partial R^2=0.125, p<0.001); PROMIS UE Physical Function (Partial R^2=0.123, p=0.003)] and instrumental support [QuickDASH (Partial R^2=0.273; p<0.001); OES (Partial R^2=0.256, p<0.002); EQ-5D-3L (Partial R^2=0.166, p<0.001); PROMIS UE Physical Function (Partial R^2=0.075, p=0.001)] consistently accounted for a substantial proportion of the variability in all measures of disability in multivariable analysis (Table 35). Other significant factors that also explained substantial if not greater proportion of the variance included antidepressant use and being retired but these were not consistent across disability measures. Multivariable analysis accounted for a substantial level of multi-collinearity amongst psychosocial variables at t=1. The statistically significant variables at t=1 in each model explained the same or marginally higher proportions of variance in disability compared to variables at t=0 [Adjusted R^2: QuickDASH (88%); OES (83%); EQ-5D-3L (76%); PROMIS UE PF (78%)]. No injury-related correlates of disability at either stage of recovery were selected in multivariable analysis.

Table 29. Patient Demographics

Demographic	Value	
Subjects enrolled (t=0)	183	
Subjects (t=1)	183	
Subjects (t=2)	183	
Age (years)	48.2 ± 20.2	(18 - 93)
Female	50%	(91)
Charlson Comorbidity Index	1.2 ± 1.6	(0 - 6)
Marital status		
Single	32%	(59)
Partner / Married	51%	(93)
Separated / Divorced / Widowed	17%	(31)
Social status		
Alone	16%	(30)
Partner / Friend(s) / Family	81%	(148)
Full / Part-time care	3%	(5)
Education (years)	14.6 ± 2.7	(8 - 21)
Work status		
Working	57%	(105)
Homemaker	3%	(5)
Retired	26%	(48)
Unemployed	7%	(13)
Workers compensation / Litigation	7%	(12)
IMD factor	66.3 ± 27	(0 - 99.5)
Broad injury classification		
Radial head / neck fracture	66%	(122)
Extra-articular fracture	9%	(16)
Intra-articular fracture	25%	(45)
Dominant side injured	45%	(83)
High energy injury	19%	(34)
Neurovascular compromise	4%	(7)
Open injury	4%	(7)
Joint aspiration	7%	(13)
Surgery	21%	(39)
Complication	26%	(47)
Prior fracture to dominant arm	16%	(30)
Prior fracture to non-dominant arm	11%	(20)
Opioid use	31%	(56)
Anti-depressant use	26%	(47)

Continuous variables as mean + standard deviation (range)
Discrete variables as percentage (number)

Table 30. Correlation Matrices

Table 30a. Correlation Matrix for Psychological variables at t=0

	PROMIS PI	PROMIS depression	PROMIS anxiety	PCS	PSEQ-2	TSK-11
PROMIS PI	1					
PROMIS depression	0.4	1				
PROMIS anxiety	0.56	0.74	1			
PCS	0.5	0.71	0.78	1		
PSEQ-2	-0.47	-0.68	-0.64	-0.71	1	
TSK-11	0.44	0.62	0.72	**0.83**	-0.6	1

Table 30b. Correlation Matrix for Psychological variables at t=1

	PROMIS PI	PROMIS depression	PROMIS anxiety	PCS	PSEQ-2	TSK-11	PROMIS ES	PROMIS IS
PROMIS PI	1							
PROMIS depression	0.096	1						
PROMIS anxiety	0.29	**0.82**	1					
PCS	0.32	**0.84**	**0.89**	1				
PSEQ-2	-0.3	**-0.81**	**-0.85**	**-0.89**	1			
TSK-11	0.34	**0.86**	**0.9**	**0.93**	**-0.86**	1		
PROMIS ES	-0.17	-0.65	0.67	-0.61	0.69	-0.66	1	
PROMIS IS	-0.25	-0.7	-0.74	-0.79	0.71	-0.74	0.52	1

Table 30c. Correlation Matrix for age and CACI

	CACI
Age	0.91

Table 31. Health-related Outcomes and Performance-based Measures

Variables	Value t=0			Value t=1			Value t=2		
Performance-based outcomes	n	Mean (SD)	Range	n	Mean (SD)	Range	n	Mean (SD)	Range
Grip strength (% non-injured side)	180	42.2 ± 8.3	21 - 61.3	183	55.1 ± 11.5	30.3 - 77.8	183	81.7 ± 15.5	51.9 - 112.3
Health-related outcomes	n	Mean (SD)	Range	n	Mean (SD)	Range	n	Mean (SD)	Range
QuickDASH	183	65.3 ± 12.5	(43.2 - 90.9)	183	49.1 ± 18.8	(25 - 88.6)	183	20.2 ± 21.7	(0 - 72.7)
OES	183	16.7 ± 7.8	(3 - 30)	183	25.9 ± 9.4	(8 - 41)	183	39.8 ± 10.5	(11 - 48)
EQ-5D-3L	178	0.243 ± 0.377	(-0.349 - 1)	183	0.477 ± 0.389	(-0.349 - 1)	183	0.774 ± 0.369	(-0.181 - 1)
PROMIS UE PF	183	30.1 ± 6.4	(15.7 - 56.4)	183	34.3 ± 6	(21 - 45.7)	183	46.5 ± 10.1	(22.5 - 56.4)
PROMIS PI	183	63.6 ± 7.3	(36.3 - 78.9)	183	57 ± 11.9	0 - 71.6	183	47.8 ± 10.7	(34.8 - 74.1)
PROMIS Depression	183	51.9 ± 13.2	(34.2 - 76.4)	183	47.6 ± 12.7	34.2 - 76.3	182	41.9 ± 10.8	(34.2 - 66.7)
PROMIS Anxiety	183	49.1 ± 9.2	(32.9 - 69.1)	183	44.9 ± 10.8	32.9 - 69.4	182	40.8 ± 11.3	(32.7 - 67.1)
PROMIS ES	n/m	n/m	n/m	183	54.7 ± 9.3	31.5 - 66.9	181	54.2 ± 9	(33.6 - 66.2)
PROMIS IS	n/m	n/m	n/m	183	54.8 ± 7.4	35.1 - 66.1	183	54.7 ± 6.6	(41.2 - 62.1)
PCS	183	19 ± 6.5	(13 - 39)	183	17.2 ± 5.8	13 - 32	183	16.6 ± 7	(12 - 39)
PSEQ-2	183	8.1 ± 3.4	(0 - 12)	183	8.3 ± 3.1	1 - 12	183	9.8 ± 3.1	(2 - 12)
TSK-11	183	24.3 ± 8.6	(12 - 42)	183	20.2 ± 8.5	11 - 40	183	17 ± 9.6	(11 - 39)

Variables as Mean ± Standard deviation (range); n/m, not measured

Table 32. Bivariate Analysis at t=0

	QuickDASH		OES		EQ-5D-3L		PROMIS UE PF	
	Value	**p value**	**Value**	**p value**	**Value**	**p value**	**Value**	**p value**
Age	0.2854	**0.0001**	-0.1553	**0.0358**	-0.0745	0.3163	-0.3228	**0.0000**
Sex								
Women	24.6 ± 22.2	**0.0056**	38.4 ± 11.9	**0.0614**	0.754 ± 0.381	0.4466	43 ± 9	**0.0000**
Men	15.8 ± 20.2		41.3 ± 8.8		0.795 ± 0.356		50 ± 10.1	
Charlson Comorbidity Index	0.3427	**0.0000**	-0.2508	**0.0006**	-0.1335	**0.0717**	-0.3563	**0.0000**
Marital status								
Single	23.8 ± 25.1	**0.0000**	37.3 ± 11.9	**0.0000**	0.670 ± 0.458	**0.0014**	45.8 ± 11.5	**0.0000**
Partner / Married	13.6 ± 16		43.3 ± 7.3		0.870 ± 0.275		49.1 ± 8	
Separated / Divorced / Widowed	33.1 ± 22.6		34.4 ± 12.4		0.684 ± 0.358		39.7 ± 10.1	
Social support status								
Alone	50.5 ± 21.8	**0.0000**	25.6 ± 11	**0.0000**	0.303 ± 0.427	**0.0000**	34 ± 8.9	**0.0000**
Partner / Friend(s) / Family	13 ± 14.5		43.3 ± 6.8		0.886 ± 0.248		49.5 ± 7.9	
Full / Part-time care	51.8 ± 11.7		22.2 ± 9		0.2884 ± 0.420		31.1 ± 1.4	
Education	-0.2518	**0.0006**	0.1909	**0.0097**	0.1135	0.1262	0.2974	**0.0000**
Work status								
Working	7.4 ± 8.7	**0.0000**	45.1 ± 4	**0.0000**	0.938 ± 0.171	**0.0000**	52.4 ± 5.9	**0.0000**
Homemaker	43.6 ± 33.6		26.8 ± 18.9		0.340 ± 0.605		40.7 ± 14.9	
Retired	28.2 ± 19.4		37.6 ± 11.2		0.768 ± 0.324		41.6 ± 8	
Unemployed	52.8 ± 12.6		21.2 ± 5.1		0.037 ± 0.252		29.8 ± 2.9	
Workers compensation / Litigation	54.5 ± 15.1		27.8 ± 6.5		0.346 ± 0.375		34.3 ± 8	
IMD Factor	-0.0298	0.6889	0.0647	0.3842	0.0630	0.3970	0.0128	0.8631

Broad injury classification								
Radial head / neck fracture	17.7 ± 20.7		40.7 + 9.8		0.799 ± 0.347		47.6 ± 10.1	
Extra-articular fracture	14.8 ± 12.3	**0.0059**	43.8 + 6.4	**0.0130**	0.899 ± 0.257	**0.0361**	47.9 ± 7.5	**0.0239**
Intra-articular fracture	29 ± 24.5		36.2 + 12.6		0.662 ± 0.435		42.9 ± 10.5	
Dominant side injured								
Yes	21.1 ± 22.8		39.5 ± 10.9		0.752 ± 0.401		46.1 ± 10.2	
No	19.4 ± 20.8	0.6029	40.1 ± 10.9	0.6896	0.793 ± 0.340	0.4637	46.8 ± 10.1	0.6582
High energy injury								
Yes	35.6 ± 25.1		31.8 ± 12.3		0.482 ± 0.476		40.4 ± 11.9	
No	16.7 ± 19.2	**0.0000**	41.7 ± 9.2	**0.0000**	0.841 ± 0.305	**0.0000**	47.8 ± 9.2	**0.0001**
Neurovascular compromise								
Yes	39.6 ± 22		35 ± 7.9		0.635 ± 0.394		35.7 ± 7.3	
No	19.4 ± 21.4	**0.0152**	40 ± 10.6	0.2156	0.780 ± 0.368	0.3104	46.9 ± 10	**0.0039**
Open injury								
Yes	30.2 ± 29.7		34.4 ± 13.5		0.580 ± 0.427		43.2 ± 12.5	
No	19.8 ± 21.3	0.2139	40.1 ± 10.4	0.1659	0.782 ± 0.365	0.1566	46.6 ± 10.1	0.3917
Joint aspiration								
Yes	5.2 ± 3		45.8 ± 1.6		1 ± 0		53.7 ± 4.2	
No	21.3 ± 22.1	**0.0095**	39.4 ± 10.8	**0.0344**	0.757 ± 0.377	0.0216	45.9 ± 10.3	**0.0070**
Surgery								
Yes	28.6 ± 25.5		36.4 ± 12.4		0.666 ± 0.448		43.9 ± 11.2	
No	17.9 ± 20	**0.0063**	40.8 ± 9.8	**0.0195**	0.804 ± 0.340	**0.0381**	47.2 ± 9.8	**0.0794**
Complication								
Yes	46.1 ± 21.2		27.7 ± 11.8		0.369 ± 0.464		35.4 ± 9.1	
No	11.2 ± 12.9	**0.0000**	44 ± 5.7	**0.0000**	0.914 ± 0.182	**0.0000**	50.3 ± 7.3	**0.0000**

Prior dominant side fracture								
Yes	17.2 ± 20.8	0.4088	40.8 ± 10.1	0.5974	0.835 ± 0.305	0.3261	48.7 ± 9.8	0.1951
No	20.8 ± 21.8		39.7 ± 10.6		0.762 ± 0.380		46 ± 10.2	
Prior non-dominant side fracture								
Yes	35.2 ± 25.4	**0.0009**	33.2 ± 13.3	**0.0024**	0.563 ± 0.453	**0.0059**	39.8 ± 9.4	**0.0017**
No	18.3 ± 20.5		40.7 ± 9.9		0.800 ± 0.350		47.3 ± 9.9	
Opioid use								
Yes	44.3 ± 22.1	**0.0000**	28.5 ± 11.5	**0.0000**	0.412 ± 0.450	**0.0000**	36.7 ± 10.1	**0.0000**
No	9.6 ± 9.6		44.8 ± 4.5		0.934 ± 0.155		50.8 ± 6.5	
Anti-depressant use								
Yes	51.3 ± 17.4	**0.0000**	25.2 ± 10	**0.0000**	0.303 ± 0.418	**0.0000**	34.1 ± 8.4	**0.0000**
No	9.4 ± 8.7		44.9 ± 3.9		0.937 ± 0.141		50.8 ± 6.5	

Performance-based outcomes at t=0	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
Grip strength (% of non-injured side)	-0.4904	**0.0000**	0.4687	**0.0000**	0.4100	**0.0000**	0.4944	**0.0000**
Health-related outcomes at t=0	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
PROMIS Pain Interference	0.4132	**0.0000**	-0.3935	**0.0000**	-0.3892	**0.0000**	-0.3941	**0.0000**
PROMIS Depression	0.6506	**0.0000**	-0.6136	**0.0001**	-0.5665	**0.0000**	-0.6539	**0.0000**
PROMIS Anxiety	0.6661	**0.0000**	-0.7209	**0.0001**	-0.7047	**0.0000**	-0.6555	**0.0000**
PCS	0.8065	**0.0000**	-0.8177	**0.0000**	-0.7620	**0.0000**	-0.7741	**0.0000**
PSEQ-2	-0.6417	**0.0000**	0.6525	**0.0000**	0.5886	**0.0000**	0.6789	**0.0000**
TSK-11	0.6823	**0.0000**	-0.7431	**0.0000**	-0.6889	**0.0000**	-0.6627	**0.0000**

Pearson correlation indicated by r; **bold** indicates statistically significant difference; continuous variables as mean (±standard deviation)

Table 33. Multivariable Analysis of Predictive Factors at t=0 for Disability at t=2

QuickDASH	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	0.28	0.16	0.41	0.07	0.000	4.49	0.10	0.86
Female	3.96	0.73	7.18	1.63	0.017	1.79	0.05	
MS: Partner / Married	-4.59	-8.33	-0.86	1.89	0.016	2.39	0.07	
WS: Retired	9.45	2.36	16.55	3.59	0.009	3.29	0.05	
WS: Unemployed	12.24	5.37	19.11	3.48	0.001	2.32	0.07	
Complications	6.69	2.01	11.37	2.37	0.005	2.86	0.07	
Opioid use	8.91	4.59	13.22	2.19	0.000	2.72	0.09	
Antidepressant use	20.60	14.98	26.22	2.84	0.000	4.07	0.24	
PROMIS PI	-0.26	-0.48	-0.05	0.11	0.015	1.62	0.01	
TSK-11	0.34	0.11	0.57	0.12	0.005	2.72	0.08	

In model: age, sex, marital status (MS), social status (SS), education, work status (WS), energy of injury, neurovascular status, joint aspiration, surgery, complications, prior non-dominant arm fracture, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PROMIS depression, PROMIS anxiety, PSEQ-2, TSK-11

OES	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	-0.08	-0.14	-0.01	0.03	0.028	4.49	0.354	0.83
MS: Partner / Married	2.15	0.19	4.10	0.99	0.032	2.39	0.058	
WS: Retired	-4.04	-7.75	-0.33	1.88	0.033	3.27	0.02	
Opioid use	-2.92	-5.18	-0.66	1.14	0.012	2.71	0.061	
Antidepressant use	-10.27	-13.18	-7.37	1.47	0.000	3.96	0.328	
PROMIS PI	0.23	0.11	0.34	0.06	0.000	1.62	0.070	
PROMIS Depression	0.18	0.08	0.27	0.05	0.000	3.90	0.104	
PROMIS Anxiety	-0.27	-0.41	-0.14	0.07	0.000	3.91	0.108	
PSEQ-2	0.38	0.06	0.69	0.16	0.019	2.79	0.065	
TSK-11	-0.29	-0.41	-0.16	0.06	0.000	2.72	0.122	

In model: age, female sex, marital status (MS), social status (SS), education, work status (WS), high energy injury, joint aspiration, surgery, complications, prior non-dominant arm fracture, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PROMIS depression, PROMIS anxiety, PSEQ-2, TSK-11

EQ-5D-3L	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
CCI	-0.05	-0.08	-0.02	0.17	0.004	3.60	0.059	0.74
MS: Separated / Divorced / Widowed	0.14	0.03	0.25	0.06	0.016	2.21	0.033	
WS: Retired	-0.34	-0.50	-0.18	0.08	0.000	3.24	0.103	
Antidepressant use	-0.25	-0.37	-0.12	0.06	0.000	3.78	0.183	
PROMIS PI	0.01	0.00	0.01	0.00	0.023	1.58	0.019	
PROMIS Depression	0.00	0.00	0.01	0.00	0.029	3.42	0.032	
PROMIS Anxiety	-0.01	-0.02	-0.01	0.00	0.000	3.75	0.119	
TSK-11	-0.01	-0.01	0.00	0.00	0.001	2.67	0.069	

In model: CCI, marital status (MS), social status (SS), work status (WS), high energy injury, joint aspiration, surgery, complications, prior non-dominant arm fracture, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PROMIS depression, PROMIS anxiety, PSEQ-2, TSK-11

PROMIS UE PF	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Female	-4.93	-6.85	-3.01	0.04	0.113	1.79	0.15	0.77
WS: Retired	-9.26	-13.48	-5.03	2.14	0.000	3.29	0.21	
WS: Unemployed	-7.83	-11.92	-3.73	2.07	0.000	2.32	0.18	
Complications	-3.32	-6.11	-0.53	1.41	0.020	2.86	0.11	
PROMIS PI	0.14	0.02	0.27	0.064	0.028	1.62	0.01	
PSEQ-2	0.41	0.05	0.77	0.18	0.026	2.79	0.05	
TSK-11	-0.20	-0.34	-0.06	0.07	0.005	2.72	0.14	

In model: age, sex, marital status (MS), social status (SS), education, work status (WS), energy of injury, neurovascular status, complications, joint aspiration, surgery, prior non-dominant arm fracture, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PROMIS depression, PROMIS anxiety, PSEQ-2, TSK-11

Partial R^2 only shown for variables with $p<0.05$

Table 34. Bivariate Analysis at t=1

	QuickDASH		OES		EQ-5D-3L		PROMIS UE PF	
	Value	**p-value**	**Value**	**p-value**	**Value**	**p-value**	**Value**	**p-value**
Age	0.2854	**0.0001**	-0.1553	**0.0358**	-0.0745	0.3163	-0.3228	**0.0000**
Sex								
Women	24.6 ± 22.2	**0.0056**	38.4 ± 11.9	**0.0614**	0.754 ± 0.381	0.4466	43 ± 9	**0.0000**
Men	15.8 ± 20.2		41.3 ± 8.8		0.795 ± 0.356		50 ± 10.1	
Charlson Comorbidity Index	0.3427	**0.0000**	-0.2508	**0.0006**	-0.1335	**0.0717**	-0.3563	**0.0000**
Marital status								
Single	23.8 ± 25.1	**0.0000**	37.3 ± 11.9	**0.0000**	0.670 ± 0.458	**0.0014**	45.8 ± 11.5	**0.0000**
Partner / Married	13.6 ± 16		43.3 ± 7.3		0.870 ± 0.275		49.1 ± 8	
Separated / Divorced / Widowed	33.1 ± 22.6		34.4 ± 12.4		0.684 ± 0.358		39.7 ± 10.1	
Social support status								
Alone	50.5 ± 21.8	**0.0000**	25.6 ± 11	**0.0000**	0.303 ± 0.427	**0.0000**	34 ± 8.9	**0.0000**
Partner / Friend(s) / Family	13 ± 14.5		43.3 ± 6.8		0.886 ± 0.248		49.5 ± 7.9	
Full / Part-time care	51.8 ± 11.7		22.2 ± 9		0.2884 ± 0.420		31.1 ± 1.4	
Education	-0.2518	**0.0006**	0.1909	**0.0097**	0.1135	0.1262	0.2974	**0.0000**
Work status								
Working	7.4 ± 8.7	**0.0000**	45.1 ± 4	**0.0000**	0.938 ± 0.171	**0.0000**	52.4 ± 5.9	**0.0000**
Homemaker	43.6 ± 33.6		26.8 ± 18.9		0.340 ± 0.605		40.7 ± 14.9	
Retired	28.2 ± 19.4		37.6 ± 11.2		0.768 ± 0.324		41.6 ± 8	
Unemployed	52.8 ± 12.6		21.2 ± 5.1		0.037 ± 0.252		29.8 ± 2.9	
Workers compensation	54.5 ± 15.1		27.8 ± 6.5		0.346 ± 0.375		34.3 ± 8	
IMD Factor	-0.0298	0.6889	0.0647	0.3842	0.0630	0.3970	0.0128	0.8631
Broad injury classification								
Radial head / neck fracture	17.7 ± 20.7	**0.0059**	40.7 + 9.8	**0.0130**	0.799 ± 0.347	**0.0361**	47.6 ± 10.1	**0.0239**
Extra-articular fracture	14.8 ± 12.3		43.8 + 6.4		0.899 ± 0.257		47.9 ± 7.5	
Intra-articular fracture	29 ± 24.5		36.2 + 12.6		0.662 ± 0.435		42.9 ± 10.5	

Dominant side injured								
Yes	21.1 ± 22.8	0.6029	39.5 ± 10.9	0.6896	0.752 ± 0.401	0.4637	46.1 ± 10.2	0.6582
No	19.4 ± 20.8		40.1 ± 10.9		0.793 ± 0.340		46.8 ± 10.1	
High energy injury								
Yes	35.6 ± 25.1	**0.0000**	31.8 ± 12.3	**0.0000**	0.482 ± 0.476	**0.0000**	40.4 ± 11.9	**0.0001**
No	16.7 ± 19.2		41.7 ± 9.2		0.841 ± 0.305		47.8 ± 9.2	
Neurovascular compromise								
Yes	39.6 ± 22	**0.0152**	35 ± 7.9	0.2156	0.635 ± 0.394	0.3104	35.7 ± 7.3	**0.0039**
No	19.4 ± 21.4		40 ± 10.6		0.780 ± 0.368		46.9 ± 10	
Open injury								
Yes	30.2 ± 29.7	0.2139	34.4 ± 13.5	0.1659	0.580 ± 0.427	0.1566	43.2 ± 12.5	0.3917
No	19.8 ± 21.3		40.1 ± 10.4		0.782 ± 0.365		46.6 ± 10.1	
Joint aspiration								
Yes	5.2 ± 3	**0.0095**	45.8 ± 1.6	**0.0344**	1 ± 0	0.0216	53.7 ± 4.2	**0.0070**
No	21.3 ± 22.1		39.4 ± 10.8		0.757 ± 0.377		45.9 ± 10.3	
Surgery								
Yes	28.6 ± 25.5	**0.0063**	36.4 ± 12.4	**0.0195**	0.666 ± 0.448	**0.0381**	43.9 ± 11.2	**0.0794**
No	17.9 ± 20		40.8 ± 9.8		0.804 ± 0.340		47.2 ± 9.8	
Complication								
Yes	46.1 ± 21.2	**0.0000**	27.7 ± 11.8	**0.0000**	0.369 ± 0.464	**0.0000**	35.4 ± 9.1	**0.0000**
No	11.2 ± 12.9		44 ± 5.7		0.914 ± 0.182		50.3 ± 7.3	
Prior dominant side fracture								
Yes	17.2 ± 20.8	0.4088	40.8 ± 10.1	0.5974	0.835 ± 0.305	0.3261	48.7 ± 9.8	0.1951
No	20.8 ± 21.8		39.7 ± 10.6		0.762 ± 0.380		46 ± 10.2	
Prior non-dominant side fracture								
Yes	35.2 ± 25.4	**0.0009**	33.2 ± 13.3	**0.0024**	0.563 ± 0.453	**0.0059**	39.8 ± 9.4	**0.0017**
No	18.3 ± 20.5		40.7 ± 9.9		0.800 ± 0.350		47.3 ± 9.9	

Opioid use								
Yes	44.3 ± 22.1	**0.0000**	28.5 ± 11.5	**0.0000**	0.412 ± 0.450	**0.0000**	36.7 ± 10.1	**0.0000**
No	9.6 ± 9.6		44.8 ± 4.5		0.934 ± 0.155		50.8 ± 6.5	
Anti-depressant use								
Yes	51.3 ± 17.4	**0.0000**	25.2 ± 10	**0.0000**	0.303 ± 0.418	**0.0000**	34.1 ± 8.4	**0.0000**
No	9.4 ± 8.7		44.9 ± 3.9		0.937 ± 0.141		50.8 ± 6.5	
Performance-based outcomes at t=1	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
Grip strength (% non-injured side)	-0.6584	**0.0000**	0.5874	**0.0000**	0.5735	**0.0000**	0.6261	**0.0000**
Health-related outcomes at t=1	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
PROMIS Pain Interference	0.3012	**0.0000**	-0.3410	**0.0000**	-0.2908	**0.0000**	-0.3355	**0.0000**
PROMIS Depression	0.8398	**0.0000**	-0.7890	**0.0000**	-0.7096	**0.0000**	-0.7228	**0.0000**
PROMIS Anxiety	0.8488	**0.0000**	-0.8446	**0.0000**	-0.7829	**0.0000**	-0.6653	**0.0000**
PROMIS ES t=1	-0.6789	**0.0000**	0.6000	**0.0000**	0.5358	**0.0000**	0.5455	**0.0000**
PROMIS IS t=1	-0.7799	**0.0000**	0.8145	**0.0000**	0.7508	**0.0000**	0.6852	**0.0000**
PCS	0.8655	**0.0000**	-0.8813	**0.0000**	-0.8537	**0.0000**	-0.7796	**0.0000**
PSEQ-2	-0.8712	**0.0000**	0.8363	**0.0000**	0.8106	**0.0000**	0.8152	**0.0000**
TSK-11	0.9083	**0.0000**	-0.9138	**0.0000**	-0.8621	**0.0000**	-0.7781	**0.0000**

Pearson correlation indicated by r; **bold** indicates statistically significant difference; continuous variables as mean (±standard deviation).

Table 35. Multivariable Analysis of Predictive Factors at t=1 for Disability at t=2

QuickDASH	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	0.18	0.06	0.30	0.06	0.003	4.91	0.078	
MS: Partner / Married	-3.99	-7.35	-0.63	1.70	0.02	2.45	0.056	
WS: Unemployed	13.23	7.20	19.26	3.05	0.000	2.33	0.118	0.8849
Antidepressant use	11.93	6.56	17.30	2.72	0.000	4.78	0.163	
PSEQ-2	-1.36	-2.27	-0.45	0.46	0.004	3.81	0.136	
PROMIS IS	-0.83	-1.10	-0.57	0.14	0.000	3.36	0.273	

In model: age, female sex, marital status (MS), social status (SS), education, work status (WS), high energy injury, neurovascular status, joint aspiration, surgery, complications, prior fracture in non-dominant arm, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PSEQ-2, PROMIS ES, PROMIS IS

OES	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Female	1.75	0.07	3.43	0.52	0.042	1.81	0.006	
Antidepressant use	-5.80	-8.86	-2.74	1.55	0.000	4.57	0.129	
PROMIS PI	-0.08	-0.14	-0.02	0.03	0.013	1.32	0.010	0.83
PSEQ-2	0.83	0.31	1.35	0.27	0.002	3.66	0.195	
PROMIS IS	0.54	0.39	0.70	0.08	0.000	3.27	0.256	

In model: age, female sex, marital status (MS), social status (SS), education, work status (WS), high energy injury, joint aspiration, surgery, complications, prior non-dominant arm fracture, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PSEQ-2, PROMIS ES, PROMIS IS

EQ-5D-3L	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
CCI	-0.03	-0.06	0.00	0.02	0.045	3.75	0.005	
WS: Homemaker	0.13	0.01	0.24	0.06	0.027	3.36	0.011	
Grip strength %	0.47	0.07	0.87	0.20	0.022	3.00	0.021	0.76
PSEQ-2	0.04	0.02	0.06	0.01	0.000	3.08	0.125	
PROMIS IS	0.01	0.01	0.02	0.00	0.000	2.99	0.166	

In model: CCI, marital status (MS), social status (SS), work status (WS), high energy injury, joint aspiration, surgery, complications, prior non-dominant arm fracture, opioid use, antidepressant use, broad classification, grip strength %, PROMIS PI, PSEQ-2, PROMIS ES, PROMIS IS

PROMIS UE PF	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Female	-3.57	-5.43	-1.71	0.94	0.000	1.81	0.115	
WS: Retired	-8.21	-12.32	-4.10	2.08	0.000	3.30	0.126	
WS: Unemployed	-6.70	-10.58	-2.81	1.97	0.001	2.33	0.094	
Neurovascular status	-4.34	-8.56	-0.11	2.14	0.044	1.37	0.022	0.78
Complications	-2.79	-5.55	-0.04	1.39	0.047	3.03	0.016	
PROMIS PI	-0.11	-0.17	-0.04	0.03	0.002	1.33	0.034	
PSEQ-2	0.89	0.30	1.48	0.30	0.003	3.81	0.123	
PROMIS IS	0.30	0.13	0.47	0.09	0.001	3.36	0.075	

In model: age, sex, marital status (MS), social status (SS), education, work status (WS), energy of injury, neurovascular status, complications, joint aspiration, surgery, prior non-dominant arm fracture, opioid use, antidepressant, use, broad classification, grip strength %, PROMIS PI, PROMIS ES, PROMIS IS

Only partial R^2 of significant values is displayed (i.e. $p<0.05$)

6.4 Discussion

Kinesiophobia, the fear of movement or further injury, appeared to be a dominant predictor of disability at 6-9 months, outcomes within a few days of an elbow fracture (t=0), whilst *self-efficacy*, the confidence and resilience to cope with the fracture and its associated symptoms, and *instrumental support*, were stronger determinants after a few weeks of recovery (t=1).

The concept of kinesiophobia encompasses a fear of activities and movements that may risk further injury, pain and disruption of the underlying fracture. One could consider such fears as a normal part of the post-traumatic experience. However, they may also evoke maladaptive responses such as a heightened desire to protect their arm and become over-cautious about movement, which may slow recovery. This psychological barrier to movement could compound the biological processes involved in the development of post-traumatic stiffness, a common complication of elbow trauma (312). Despite the lack of robust evidence supporting the timing of mobilization following elbow fractures, most surgeons agree on the principle of safe, early mobilization, especially when considering the morbidity and burden related to managing a stiff painful elbow after a fracture (312)(313)(314).

Taking a closer look at the concept of kinesiophobia, a longitudinal study involving sports-related injuries of the elbow in mostly younger throwing athletes, demonstrated a strong correlation between the 'fear of injury' subscale with baseline disability, change in disability and pain (136). Further analysis of these specific subscales may be required to identify whether therapies should focus on strategies to diminish the fear of movement (i.e. activity avoidance), contend with negative thoughts around pain (i.e. pain-related fear beliefs) or educate patients further around handling their underlying injury (i.e. somatization). In a broader sense, this brings into consideration the issue of mobilisation following fractures in general. In any given fracture population, there are invariably a proportion of patients that express a lack of awareness around how much movement is permitted following injury when they return to their

usual settings. Despite guidance from pro-active MDTs working with standardized rehabilitation protocols, this area may be confounded by insufficient high quality evidence to inform practice, poor HCP-patient communication and wide variability in clinical practice (315).

The transition toward self-efficacy being the dominant factor in influencing disability at a few weeks following an elbow fracture is somewhat intuitive. Once symptoms have been controlled and there is familiarisation with the injury and process of safe mobilisation, a patient's mind-set may shift from fear-based thoughts around painful movement toward coping and adaptation in meeting their current and future goals in life, work and recreation. Conversely, those without adaptive capabilities and the resilience to cope with fractures and pain may have greater self-perceived disability than expected for their condition (131).

Effective coping is shown to have a strong correlation with disability in both proximal humerus fractures in the previous chapter and elbow fractures in this study. This factor may be scored using measures of pain self-efficacy, pain interference *and* pain catastrophizing (96)(111)(131). Although PSEQ-2 was the most dominant psychological factor contributing to disability at t=1, it also explained some of the variability in longer-term OES and PROMIS PF at t=0. In a similar fashion, PROMIS PI accounted for some of variance in all measures of disability at t=0, albeit to a lesser extent, and both OES and PROMIS PF at t=1. Pain catastrophizing was a strong correlate of disability but displayed substantial collinearity with other measures. Notably, the influence of effective coping on self-perceived disability and pain is well established in non-traumatic conditions (88)(96)(115)(135)(164)(131). This study demonstrated the predictive capacity of coping strategies following an elbow fracture on disability within a few weeks after the injury.

Other psychological factors had variable interactions with disability during the recovery process. Depression and anxiety at t=0 were predictive of disability measured by OES and EQ-5D-3L. Due to multi-collinearity, particularly at t=1, multiple psychological variables including depression, anxiety and pain catastrophizing were omitted from regression analysis. This enabled further statistical definition of factors that could explain a greater proportion of the overall variance in disability. Studies involving non-traumatic upper extremity conditions demonstrate a strong correlation between depression, anxiety and the magnitude of disability (88)(140)(164)(165)(292)(293). Such factors may still play a dominant role in influencing health-related outcomes following elbow fractures based on the significant correlation observed with all measures of disability in bivariate analysis. Notably, the use of anti-depressant explained a substantial proportion of the variation in disability represented by QuickDASH, OES and EQ-5D-3L at t=0 and QuickDASH and OES at t=1.

Social factors, such as marital status (i.e. being married or having a partner, being separated, widowed or divorced) and work status (i.e. being retired or unemployed) also explained a substantial proportion of the variation in disability when combined with other factors, although somewhat inconsistently, both at t=0 and t=1. Interestingly, social support status did not feature in multi-variable analysis despite being significantly correlated with all measures of disability in bivariate analysis. However, instrumental support, the perceived availability of support from others in fulfilling specific functions, accounted for a significant proportion of the variation in disability outcomes at t=1. The provision of tangible support from family, friends and partners to fulfil daily functions appeared to have a stronger impact on future health-related outcomes than emotional support which is the perceived feeling of being cared for and valued when faced with the stresses and strains of a painful elbow fracture. This may reflect the needs of relatively younger, more active patients with these injuries who may be faced with greater practical commitments in daily life and work. In reality, both emotional support and instrumental support are likely to make substantial contributions to buffering stress following injury.

From the injury perspective, no clinical or injury-related factors except complications explained some of the variability in disability across measures at t=0 and t=1. This was similar to the prior study involving proximal humerus fractures and consistent with the growing body of evidence for disability being influenced more by psychosocial factors than measures of impairment, pathophysiology and clinical factors (71)(298). Many complications may however, involve a degree of psychological overlay including distress and fear related to morbidity that extends beyond impairment alone. Injury classification, energy of injury, joint aspiration, surgery and prior non-dominant arm fractures were all significantly correlated with disability in bivariate analysis but not selected in multivariable models. The broad injury classification categorized elbow fractures into radial head/neck, extra-articular and intra-articular configurations, which are somewhat discrete in terms of patho-anatomy and clinical management. Despite this distinction, injury type did not explain any of the variability in disability.

A greater proportion of variability in disability was explained by the explanatory variables in this study compared to similar investigations in this field observed in Chapter 2. This may be due to investigating injuries within a specific region rather than a heterogeneous group of diagnoses. This study also demonstrated (i) the feasibility of delivering multiple PRO measures during recovery from elbow trauma, as early as day 0 post-injury, (ii) the ability to efficiently administer PRO measures, including CATs, via a web-based electronic portal, and (iii) the possibility of achieving a robust set of patient outcomes with low levels of missing data and participant attrition using a full-time investigator (47)(54)(113)(166).

All four measures of disability in this study have been utilized to variable extents in capturing health-related outcomes following elbow trauma in the literature. A level of content (face) validity and feasibility in applying such measures in patients with elbow fractures was also

demonstrated. This is important considering all these measures were originally developed without trauma populations in mind.

For instance, the OES, the only joint-specific measure, was developed using patients undergoing elbow surgery predominantly for a range of chronic conditions (237). Interestingly, the four different disability measures appeared to have similar correlational profiles which could be explained by the fact they were all related to a similar set of psychosocial factors. Further psychometric evaluation is required before their widespread endorsement in outcomes assessment following elbow trauma.

6.4.1 Limitations

These findings must be considered in light of some limitations. Firstly, it is recognized that a single-center study may not be entirely representative of the wider population despite a wide range in demographic profile and indices of deprivation. Second, the best multivariable models in this study demonstrated a large proportion of the variance in disability, however, in practice other factors could potentially influence outcome measurement. Clinical factors such as fracture displacement, re-injury, development of stiffness and pain in other joints, as well as changes to the management plan, may have acted as further stressors. Day-to-day management decisions are often made by surgeons with wide-ranging backgrounds and levels of experience. The level of seniority, sub-specialisation, course of mobilization and timing of surgery were not defined. In the same way, logistical factors, such as delays to imaging and surgical admission, as well as the timing of PRO administration were not recorded and could have affected responses. This is especially important as the patient's mindset and responses may be influenced by the clinical encounter (126). In practice, such factors were challenging to quantify. Third, it could be questioned that the broad classification system employed in this study focused on categorising injury type rather than stratifying injury severity. For instance, radial head and neck fractures range from relatively simple extra-articular fractures to complex intra-articular configurations and all these injuries were grouped into one category. Nevertheless, most radial head and neck

fractures are relatively easier to manage overall compared to other intra-articular fractures of the elbow. Essentially, a pragmatic approach was taken based on variable numbers within AO and Mason categories. We were mindful that this could both compromise analysis and potentially cloud the interpretation of findings. Further studies may be required to delineate the relationship between disability and specific fracture sub-types but the evidence to date suggests this line of investigation is unlikely to yield any unique additional insights. Fourth, due to the logistics of follow-up, patients completed outcome measures at t=2 via telephone, online or in person. In this trauma centre, most patients with radial head and neck fracture do not routinely attend for follow-up at t=2. Further investigations are required to assess whether different forms of PRO measurement administration influence responses in these populations. Each mode of delivery is associated with varying levels of procedural, measurement, interviewer and responder bias. Responder bias was a particular issue with regard to patients recruiting family and friends to assist them with questionnaire completion despite stressing the importance of obtaining the 'true' patient responses. Proxy responses were often unavoidable and difficult to quantify but mostly rare. Fifth, the aim was to achieve a balance between comprehensive PRO measurement and limiting the burden on responders. Despite using abbreviated fixed scales and CATs, a minority of patients expressed a level of questionnaire fatigue by wishing to complete tests at a later stage of requesting a call back. Furthermore, regardless of PRO measurement items being selectively programmed onto the electronic platform, the administration of similar sounding items could have posed a source of frustration triggering inaccurate or inappropriate responses. Full questionnaire randomization could have minimised this issue but was not performed due to programming complexity. On the other hand, some investigators may criticise this work for not incorporating full versions of instruments which may more accurately assess a specific domain. Only abbreviated counterparts with acceptable psychometric credentials e.g. PSEQ-2, were utilized as a trade-off but it is accepted that these may not have been validated in specific trauma populations. Sixth, certain outcome measures involve items related to health status within a specific time-frame (e.g. OES, the past 4 weeks). Whilst we were interested in capturing

health status and impact in the present, this was not at the detriment of introducing bias and invalidating measures through modifying or changing the questions to suit study needs. Most patients assumed present health state was the point of interest and responded accordingly, whilst others queried the timeframe and circumstances in which to relate responses e.g. "Should I answer this based on what I can do now or what I could do before the injury?", "Is this based on my current or future goals in life?", "Is this with my sling on or off?", "Is this based on how I feel now or how I felt when I just injured my elbow?". On these rare occasions, it was difficult not to advise patients to consider self-perceived health in the present and reflect on the overall ability to perform a task. Finally, PROMIS ES and PROMIS IS were not assessed at baseline due to a programming error which may have influenced the analysis but is unlikely to have altered the final interpretations of this study.

6.4.2 Conclusion

Disability following elbow fractures is strongly predicted by kinesiophobia within the first week of injury, and self-efficacy and instrumental support within the first month. The fear of movement and further injury, fear of pain and fear of disrupting the underlying fracture are all perceptions that can prolong the course of recovery, compound the loss of motion and herald the onset of a stiff elbow. This is particularly relevant in elbow fractures where post-traumatic stiffness is a common, potentially adverse sequela of injury and source of disability. Coping strategies and the propensity to adapt to a painful elbow fracture may enable patients to successfully navigate the course of recovery. Conversely, a lack of confidence and resilience in maintaining one's activities in life may result in poor long-term health-related outcomes. The presence of instrumental support during this time is just as, if not more important, and may reflect the practical needs, higher demands and societal commitments of relatively younger, more active patients experiencing these injuries (11)(86)(294)(295).

Whilst common elbow injuries, such as undisplaced or minimally displaced radial head and neck fractures are safely managed non-operatively, displaced and unstable injuries frequently undergo fixation or replacement (316)(317)(318)(319). Debate still, surrounds best practice in managing certain configurations such as isolated, displaced and stable partial articular configurations where outcomes following fixation versus non-operative treatment are equivocal (320)(321). Other areas of contention include technical aspects in the operative management of distal humerus and proximal ulnar fractures (322)(323).

Building on the findings of Chapter 5, orthopaedic surgeons and musculoskeletal HCPs should be cognizant of the influential factors of disability during specific stages of recovery whilst advancing the understanding of clinical factors associated with these injuries. Modifiable, psychosocial factors should be considered alongside surgical goals of anatomical restoration in certain elbow fractures as they appear to dominate the prediction of longer-term disability (128)(138). This approach may be particularly important as these injuries depend on proactive patients, motivated to mobilize during rehabilitation. In keeping with the previous chapter concerning proximal humerus fractures, these findings may translate toward better identification of those at risk of greater than expected disability considering the injury and point in time, coaching strategies using optimistic language (especially contending with the fear of movement) and bolstering adaptation and resilience through close engagement either musculoskeletal HCP-led or psychology specialist-led behavioural therapies (70). This is discussed in further detail in Chapter 9.

Chapter 7

7. Influential Factors of Disability following Distal Radius Fractures

7.1 Background

Chapters 5 and 6 demonstrated similar findings in terms of the influential factors of disability in proximal humerus and elbow fractures respectively. Specifically fear of movement in the initial stages of recovery and coping abilities in the intermediate phase around a month post-fracture appeared to be dominant predictors of longer-term disability in these injuries. This chapter presents the findings of a similar methodology in assessing the influential and predictive factors of disability following distal radius fractures, in alignment with the WHO ICF framework (Figure 32) (Figure 33).

The overarching goal was to identify the influential factors predictive of disability following distal radius fractures, using a comprehensive selection of outcome measures relevant to wrist injuries, arm-specific disability and health in general health. The aim was to enhance decision-making and inform the development of novel patient-centered management strategies to improve health related outcomes following these common upper limb fractures.

Figure 24. The WHO ICF Framework applied to evaluating disability after Distal Radius Fractures

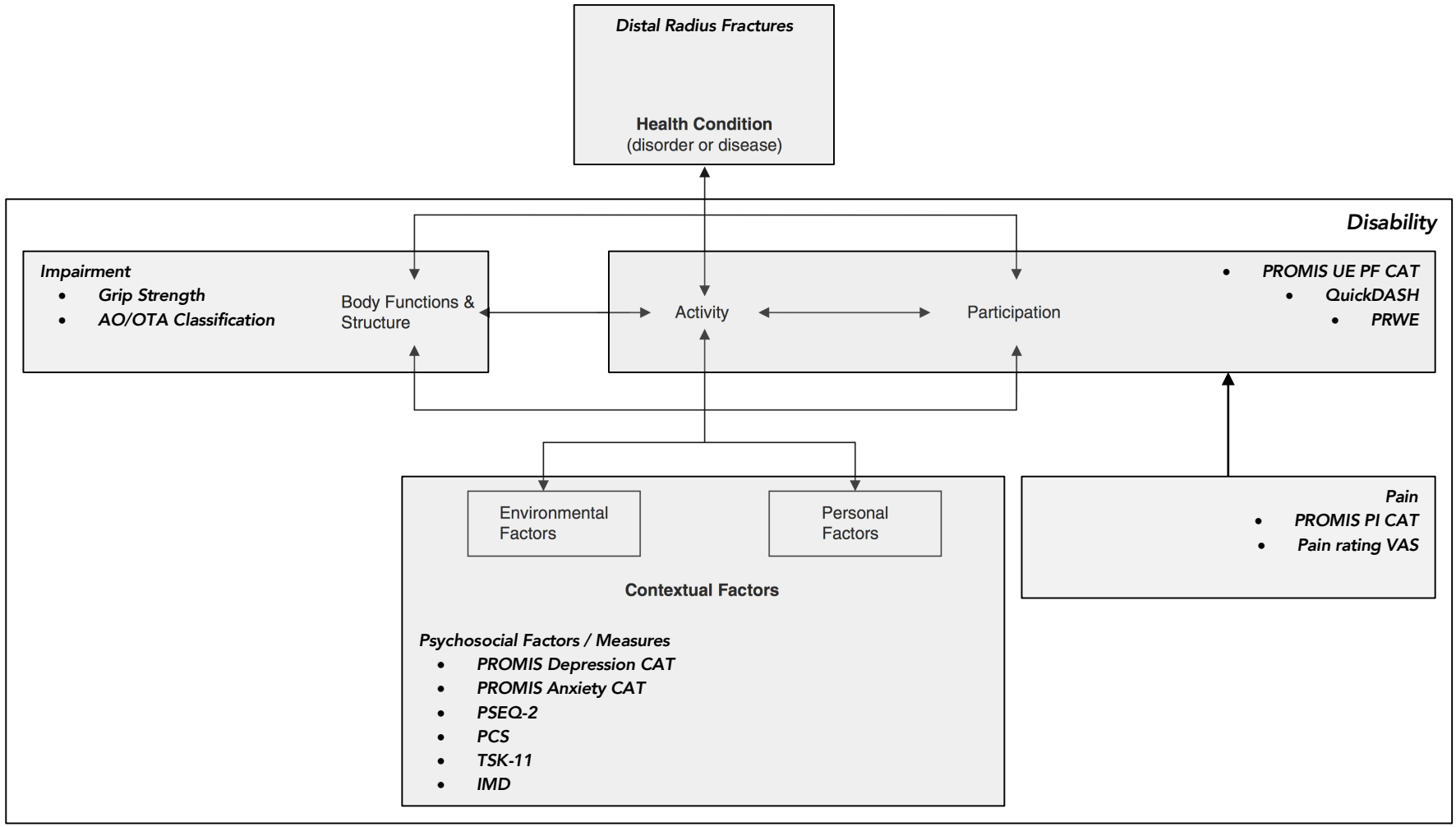
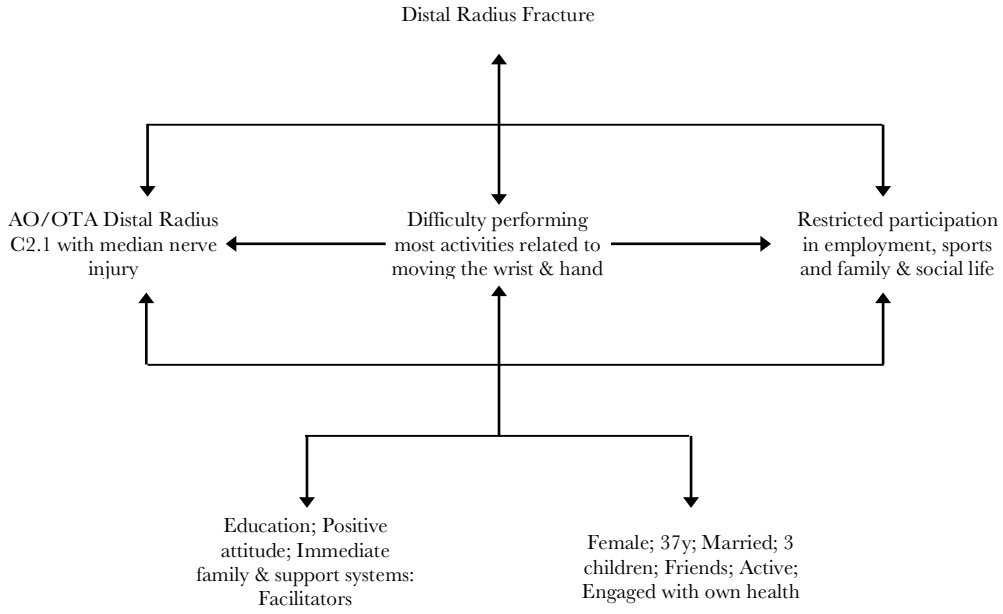
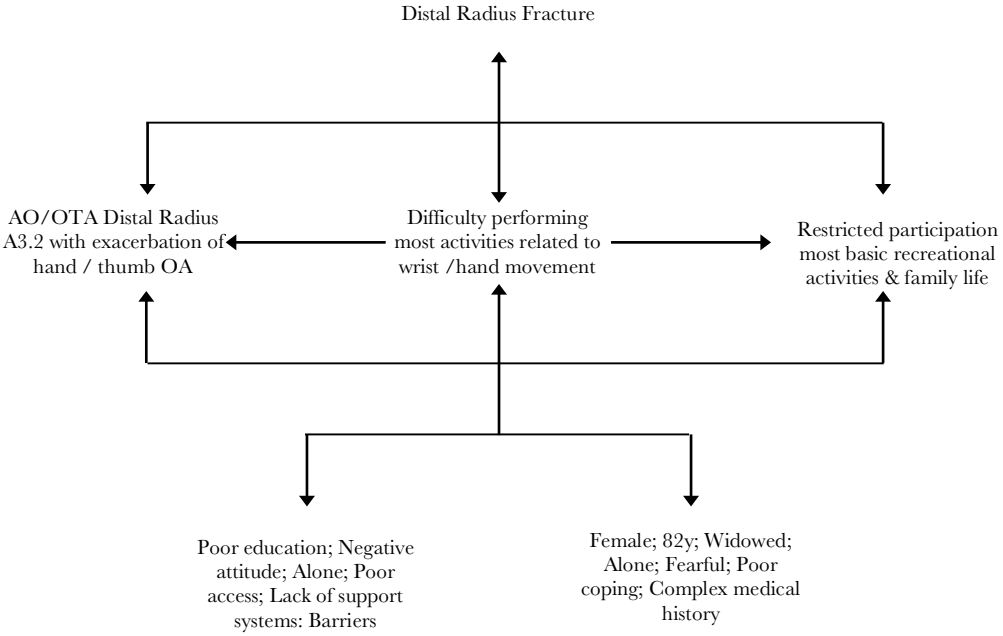


Figure 25. The WHO ICF Framework adapted to profiles of individuals with Distal Radius Fractures





§ The example represents a few domains of each component related to the health condition and is not intended to represent a complete overview of impairments, activity limitations, participation restrictions, environmental and personal factors.

‡ Direction or magnitude of arrows may differ for specific situations and/or individuals. Two-directional arrows represent a multi-directional influence

Distal radius fractures are the commonest upper extremity fractures across most age groups and occur more frequently in older females (8)(324)(325). Their incidence is bimodal and continues to rise especially in ageing populations where there is an increased risk of osteoporosis and falls (8)(324)(326)(327). Representing up to 18% of all fractures and with almost 1 in 10 females sustaining a wrist fracture by the age of 90, these injuries pose a major musculoskeletal health concern, impacting the quality of life in a vast number of individuals (9)(13)(325)(328).

In spite of extensive scientific investigation, there is ongoing debate around how best to treat these injuries and which factors lead to consistently better long-term outcomes (78)(325)(326)(329)(330)(331). Current randomized controlled trials (RCTs) intend to cast further light where high quality systematic reviews have underlined the lack of evidence for supporting operative interventions over conservative treatment, or open surgery over percutaneous fixation (326)(328)(330)(332)(333)(334).

Ongoing RCTs from Australasia and the Netherlands aim to determine the clinical and cost-effectiveness of plating versus closed reduction and casting of displaced fractures (326)(330). A UK-based multi-center trial (DRAFFT) demonstrated no significant difference in outcomes between percutaneous wiring over locking plate fixation of dorsally displaced fractures (94)(325)(326)(335). In contrast, other prospective RCTs show improved grip strength and PRO measures after plating, albeit in fewer patients (336)(337)(338). Underlying this line of investigation is the philosophy that anatomical restoration leads to better outcomes and may best be achieved, in theory at least, by open reduction internal fixation using implants such as locking plates (339)(340)(341)(342). The concept of fragment specific plate fixation is borne from this principle and although such implants may find a place in the surgeon's toolbox for specific fracture configurations, they have yet to demonstrate superiority over other plating systems (343)(344)(345)(346).

Most surgeons believe that restoring anatomy of the articular surface and extra-articular alignment are essential technical goals in achieving good functional results (340). The correlation of post-operative radial shortening and persistent articular gaps with worse long-term PROs supports this belief (347). However, a number of studies also show that anatomical restoration, reflected by radiographic measurement, does not correlate with improved clinical or patient reported outcomes (324)(339)(348)(349).

Furthermore, malunion, a not uncommon sequelae of distal radius fractures, especially following non-operative management, is not shown to have a significant impact on functional outcomes, even in higher functioning older adults (350). If alignment only accounts for a limited portion of PROs following wrist injuries, there is a demand for identifying factors that play a more significant role (339)(348). Malunion should perhaps be considered as a loss of alignment in combination with symptoms and disability. As the majority of distal radius fractures heal with some loss of alignment, even after surgery, radiographic alignment may not be the best correlate of symptoms and disability (348). Interestingly there is some compelling evidence from paleo-anthropological data and comparative research involving other primates for the functional reserve and anatomical tolerance of the distal radius for post-fracture deformity (351).

Ultimately, a shift toward a patient-centered, biopsychosocial approach and understanding the influential factors of disability may provide alternative ways of improving patient outcomes i.e. 'questioning which factors matter to patients & how these can be modified' over 'which fractures to fix & how to fix them'. Using the WHO ICF framework of disability in a similar fashion to the last two chapters, studies have shown that upper extremity disability following distal radius fractures correlates with a variety of psychological factors (35)(36)(37)(38)(39)(40)(41)(42)(43)(44). Pain and grip strength also predict self-perceived function during the early post-operative period following such injuries (79). Both factors are influenced by psychological aspects, signifying the dominant role played by illness behaviour during recovery (78)(79).

Most of these findings are borne from cross-sectional investigations and/or studies that include distal radius fractures within heterogeneous cohorts of traumatic and non-traumatic conditions (96)(259). Furthermore, recent systematic reviews have highlighted the requirement for further high quality studies to assess the full measurement properties of the PRWE and DASH in patients sustaining distal radius fractures (352). At best, there is only moderate evidence for the responsiveness of PRWE and DASH, and reliability and validity of the PRWE in these populations to date. Identifying prognostic factors through prospective, longitudinal investigation, focused on wrist fracture populations using established arm-specific disability measures may more effectively identify modifiable predictors of longer-term disability. Integrating these factors into practice may be the most effective way of optimizing clinical and patient focused outcomes in these common injuries.

7.1.1 Objectives

The primary objective was to assess the association between magnitude of disability at 6 to 9 months after a distal radius fracture and psychosocial factors and grip strength within a week of injury along with injury and demographic factors. The secondary objective was to assess the same associations but with psychosocial factors and grip strength at 2 to 4 weeks after injury. The final objective was to observe any similarities and differences in the correlation between explanatory variables and measures of upper extremity disability i.e. generic fixed scale (EQ-5D-3L]), region-specific (QuickDASH]), joint-specific (PRWE) and generic computer adaptive (PROMIS UE PF) measures, at baseline and early follow-up after injury.

7.2 Methods

7.2.1 Study Design

A consecutive series of 399 adult patients sustaining isolated distal radius fractures attending new patient fracture clinics between 1st January 2017 and 31st August 2017 were enrolled in a research and ethics committee approved study (IRAS No. 16/YH/0017) (Appendix 11-15). This was a prospective cohort study at a level I trauma center in the UK (Level 1b/2b). Inclusion criteria were that patients should be fluent in English and aged eighteen years or over at the time of injury. Those unable to provide informed consent, including patients with diagnosed mental health problems or cognitive dysfunction, and sustaining concurrent injuries involving the same arm or any other region were excluded. Distal radius fractures as part of complex polytrauma, re-fracture of the wrist during recovery from a previous injury, fracture in a malunited wrist following a prior fracture and peri-prosthetic fracture around a previous fixation, were also considered ineligible. Fifteen patients (3.7%) declined participation due to time constraints leaving 384 patients in the study. Informed consent and data protection approvals were obtained from each participant prior to enrollment.

All 384 patients completed the web-based proforma including demographic data and electronic PRO measurement using the secure, web-based tool (Assessment Center℠, Northwestern University) on tablet computers or laptops (231). Pilot versions of the digital PRO platform tested on clinical colleagues demonstrated acceptable response times (15±3.3 mins).

Data was captured at baseline (t=0, initial orthopaedic review in new patient fracture clinic following acute management in the emergency department), early follow-up (t=1, subsequent clinic review at 2-4 weeks post-injury) and final assessment (t=2, 6-9 months post-fracture). Most assessments were conducted face-to-face (75%; n=860/1146), with others completed by phone (21%; n=240/1146) or electronically by patients, directly on the digital platform (4%; n=46/1146). All data was captured by a single investigator.

7.2.2 Patient Characteristics

The cohort comprised 284 women and 100 men with a mean age of 60.6 years ± 20.5 (range, 18-99) (Table 36). 6 patients died of unrelated illness before they could complete the final part at t=2. No patients were lost to follow-up. Education level, marital status, social status and work status, as well as arm dominance and any previous arm injuries, including side, were acquired from the demographic proforma completed electronically. CACI (232) and IMD (233) have already been defined in prior chapters and were captured using medical records and postal code information respectively. Health records were also reviewed for any neurovascular compromise, open versus closed fracture, surgical intervention and complications. Complications were defined as any adverse event specifically related to injury and its management e.g. post-operative wound infection, chronic regional pain syndrome (CRPS), or prolonged wrist or hand stiffness requiring manipulation. Generic complications e.g. chest infection, were not.

Injuries were independently classified [PJ; SG] by energy [e.g. high speed road traffic accident (high); fall from standing height (low)] and the AO classification (Appendix 16) (281) prior to further classification into two fracture categories (i.e. extra-articular or inter-articular). This allowed an appreciation of the distribution of fracture patterns using a more detailed system prior to re-classification to enable more practical interpretation. Full agreement was achieved after consensus meetings between two investigators [PJ; SG] with input from a senior attending-level clinical colleague when there was disagreement. Use of opioid analgesia was defined as regular use of any opiates beyond a 2-week period post-injury. Any patients already using opioids for other conditions prior to injury were only included if there was any change or increase in their opiate analgesic requirements secondary to the fracture. Most patients rarely required a prescription for additional pain relief beyond this period or any more than the initial 7-day course of compound analgesics prescribed in the emergency department. Anti-depressant use was defined as any earlier use i.e. for pre-existing depression, or a new diagnosis of depression in the acute recovery phase i.e. within the first month following injury.

7.2.3 Outcome Measures

PRO measures were delivered in the following order: i) PROMIS UE PF (170), ii) PROMIS PI (203), iii) PROMIS Depression (200,201), iv) PROMIS Anxiety (201), v) PROMIS ES (283), vi) PROMIS IS (283), vii) QuickDASH (204,205,207), viii) PRWE (238), ix) EQ-5D-3L (234,235), x) PCS (284), xi) PSEQ-2 (285,286), xii) TSK-11 (287) (Appendix 10).

All PROMIS measures were administered as CATs. The mathematical model and technical features of these instruments are described in detail in prior chapters (54)(198). All PRO measures were administered at t=0, t=1 and t=2 except for PROMIS ES and IS which were deployed at t=1 and t=2 only. Grip strength (isometric grip force in kg) was measured using a Jamar digital dyanometer (Asimov Engineering, Los Angeles, CA) in injured and non-injured arms with an average of two measurements on each side taken as the final absolute measure. The percentage of injured side relative to the non-injured side was calculated. Hand grip was placed at the second or third station depending on hand size, and the shoulder adducted and kept in neutral rotation, with the elbow at 90^{o} flexion, and forearm and wrist in neutral position (288). Grip strength was only assessed when the hand was free from a cast or the patient's cast was deemed not to interfere with adequate grip performance i.e. usually at t=1 and/or t=2. Participants were given reminders via telephone for incomplete or partially completed assessments, as approved by the research and ethics committee.

QuickDASH, PROMIS Depression and PROMIS PI are previously described in Chapter 3, PROMIS UE PF, PRWE and EQ-5D-3L in Chapter 4, and PROMIS Anxiety, PROMIS ES and PROMIS IS, PCS, PSEQ-2 and TSK-11 in Chapter 5.

7.2.4 Statistical analysis

Descriptive statistics included frequencies and percentages for discrete variables, and mean, standard deviation and range for normally distributed continuous variables. Bivariate analysis involved unpaired Student's t-test or analysis of variance for comparing continuous and discrete variables and Pearson correlation for continuous variables. Strength of correlations were classified as high (>0.70), high-moderate (0.61-0.69), moderate (0.40-0.60), moderate-weak (0.31-0.39) and weak (<0.30) (210).

Multi-collinearity as explained in prior chapters was assessed by observing a high beta, standard error and wide 95% confidence intervals, and assessed with partial R^2, correlation matrices at t=0 and t=1, and VIF. A correlation greater than 0.80 was considered an indication of multicollinearity and led to omission of one of the two variables with this high correlation. Again, the variable causing the lowest change in the model's adjusted R^2 was omitted i.e. aiming for the lowest reduction in the model's overall ability to explain variability in the dependent variable. VIF was again used as a gauge of the extent to which coefficients and independent variables increased due to collinearity. A VIF between 5 and 10 was potentially too high, while a VIF greater than 10 clearly indicates multicollinearity. At t=0, no psychological variables had correlations greater than 0.80 (Table 37a) and VIF was lower than 5 for all variables. At t=1, several variables had correlations greater than 0.80 (Table 37b). Thus, PROMIS depression, PROMIS anxiety, PCS, TSK-11, and PROMIS ES support were excluded from multivariable analysis at t=1, resulting in VIFs lower than 5. Sensitivity analysis demonstrated that omission of variables did not reduce the models' adjusted R^2 i.e. the overall ability to predict the outcome variable. The correlation between PROMIS ES and PROMIS IS was 0.79 i.e. just below the cut-off. Sensitivity analysis demonstrated no reduction in adjusted R^2 without PROMIS ES but with it, the VIF increased to 5, justifying its omission from models at t=1. Grip strength percentage of injured side over non-injured side also showed signs of multicollinearity (i.e. high beta, high standard error and wide 95% confidence interval) and its exclusion increased adjusted R^2, therefore it was also omitted from the final models. VIF analysis also indicated

multicollinearity between age and CACI (correlation=0.92) (Table 37c). Although CACI incorporates more information than age, several parameters are required to calculate a total score, making it less practical to use in daily practice. Thus, CACI was omitted from multivariable analysis, if both age and CACI had a p-value < 0.10 in bivariate analysis.

After adjusting for multicollinearity, the remaining psychological measures and each independent variable associated with disability at t=0 and t=1, with $p<0.10$ in bivariate analysis, was entered into multivariable regression. Eight multivariable models were created in total i.e. one for each disability PRO measure with independent variables at t=0 and t=1. $p<0.05$ was considered statistically significant in multivariable analysis. Partial R^2 indicated how much each variable accounted for the total variance, which in turn was reflected by the Adjusted R^2 as a measure of the percentage of the overall variability in the response variable that could be explained by all the variables included in the model.

We used multiple linear imputation for missing values (number of imputations set to 40): education (1), IMD factor (7), percentage grip strength of the non-injured side (15) at t=1. Multiple linear imputation maintained the overall variability in the data while preserving relationships with other variables.

An a-priori power analysis indicated that a minimum sample size of 312 subjects would provide 90% statistical power, with alpha set at 0.05. This was based on a regression with ten predictors and an assumption that an independent variable would account for 2% or more of the variability in disability and the complete model would account for at least 40% variability. All statistical analysis was performed using STATA 14.0 (StataCorp LP, College Station, TX, USA).

7.3 Results

Health related outcomes increased overall during the course of recovery following distal radius fracture (Table 38). Greater disability reflected by each of the four disability measures at 6 to 9 months after a distal radius fracture (unless otherwise specified in parentheses) was associated with older age, female sex, greater comorbidity (CACI), marital status (being single, separated, widowed or divorced), social support status (not having a partner, family or friends, full or part-time care), fewer years of education (EQ-5D-3L and PROMIS UE PF only), work status (being retired, unemployed, on workers compensation or involved in litigation claims), greater deprivation (IMD factor) (QuickDASH, PRWE, EQ-5D-3L only), high energy injuries, presence of neurovascular compromise, experiencing complications, prior fracture involving the dominant arm (QuickDASH, PRWE and PROMIS UE PF only), opioid and anti-depressant use, and a number of psychological factors (greater pain interference, depression, anxiety, pain catastrophizing, or kinesiophobia, and less self-efficacy) at baseline (t=0) in bivariate analysis (Table 39).

Factors that consistently explained a large proportion of the variability in disability at t=0, included pain self-efficacy [QuickDASH (Partial R^2=0.23, $p<0.001$); PRWE (Partial R^2=0.13, $p<0.001$); EQ-5D-3L (Partial R^2=0.16, $p<0.001$)] and the use of anti-depressants [QuickDASH (Partial R^2=0.44, $p<0.001$); PRWE (Partial R^2=0.47, $p<0.001$); EQ-5D-3L (Partial R^2=0.31, $p<0.001$); PROMIS UE PF (Partial R^2=0.14, $p<0.001$)] in multi-variable analysis (Table 40). Other factors that explained a smaller proportion of the variance included older age, being female, being retired, on worker's compensation or involved in a litigation claim, using opioids, having a prior fracture of the dominant arm, experiencing complications, depression, anxiety, pain interference, pain catastrophizing and kinesiophobia. However, these were not consistent across measures of disability. A relatively high proportion of the overall variability in disability measures was explained by the combination of significant factors in multivariable analysis [Adjusted R^2: QuickDASH (81%); OSS (82%); EQ-5D (68%); PROMIS UE PF (60%)].

At early follow-up (t=1), apart from IMD factor, an identical set of variables were associated with disability in bivariate analysis (Table 41). The strongest predictors of disability in multivariable analysis were again, pain self-efficacy [QuickDASH (Partial R^2=0.39; p<0.001); PRWE (Partial R^2=0.30, p<0.001); EQ-5D-3L (Partial R^2=0.30, p<0.001); PROMIS UE Physical Function (Partial R^2=0.52, p<0.001)] and use of anti-depressants [QuickDASH (Partial R^2=0.18; p<0.001); PRWE (Partial R^2=0.26, p<0.001); EQ-5D-3L (Partial R^2=0.12, p<0.001)] (Table 42). PROMIS IS also featured in explaining the variability in most measures of disability [QuickDASH (Partial R^2=0.18, p<0.001); PRWE (Partial R^2=0.10, p<0.001); EQ-5D-3L (Partial R^2=0.02, p<0.010)].

Other factors that explained some of the variance included experiencing complications, being retired, unemployed, on worker's compensation or involved in a litigation claim, having a prior dominant arm fracture, opioid use and pain interference but these were not consistent across disability measures. Multivariable analysis adjusted for a substantial level of multi-collinearity amongst psychosocial variables at t=1. The statistically significant variables at t=1 in each model explained even higher proportions of variance in disability compared to variables at t=0 [Adjusted R^2: QuickDASH (87%); PRWE (86%); EQ-5D-3L (72%); PROMIS UE PF (66%)].

Notably, broad injury classification and undergoing surgery did not correlate with disability at either time point in bivariate analysis, and of those injury-related factors that did (i.e. high energy injury and neurovascular compromise at t=0 and t=1), none were selected in any multivariable regression models.

Table 36. Patient Demographics

Demographic	Value	
Subjects enrolled (t=0)	384	
Subjects (t=1)	384	
Subjects (t=2)	378	
Age (years)	60.6 ± 20.5	(18 - 99)
Female	74%	(284)
Charlson Comorbidity Index	2 ± 1.7	(0 - 6)
Marital status		
Single	21%	(81)
Partner / Married	48%	(186)
Separated / Divorced / Widowed	31%	(117)
Social status		
Alone	20%	(75)
Partner / Friend(s) / Family	75%	(290)
Full / Part-time care	5%	(19)
Education (years)	13.1 ± 3.2	(6 - 23)
Work status		
Working / Homemaker	42%	(160)
Retired	50%	(191)
Unemployed	6%	(25)
Workers compensation / Litigation	2%	(8)
IMD factor	71.5 ± 21.7	(9.4 - 99.7)
Broad injury classification		
Extra-articular fracture	58%	(222)
Intra-articular fracture	42%	(162)
Dominant side injured	50%	(192)
High energy injury	16%	(63)
Neurovascular compromise	7%	(26)
Open injury	2%	(6)
Surgery	16%	(63)
Complication	24%	(92)
Prior fracture to dominant arm	21%	(82)
Prior fracture to non-dominant arm	10%	(40)
Opioid use	30%	(114)
Anti-depressant use	19%	(72)

Continuous variables as mean + standard deviation (range)
Discrete variables as percentage (number)

Table 37. Correlation Matrices

Table 37a. Correlation Matrix for psychological variables at t=0

	PROMIS PI	PROMIS depression	PROMIS anxiety	PCS	PSEQ-2	TSK-11
PROMIS PI	1					
PROMIS depression	0.36	1				
PROMIS anxiety	0.39	0.54	1			
PCS	0.58	0.59	0.62	1		
PSEQ-2	-0.37	-0.48	-0.65	-0.64	1	
TSK-11	0.45	0.41	0.54	0.62	-0.67	1

Table 37b. Correlation Matrix for psychological variables at t=1

	PROMIS PI	PROMIS depression	PROMIS anxiety	PCS	PSEQ-2	TSK-11	PROMIS ES	PROMIS IS
PROMIS PI	1							
PROMIS depression	0.63	1						
PROMIS anxiety	0.62	**0.83**	1					
PCS	0.56	0.79	**0.83**	1				
PSEQ-2	-0.67	-0.75	-0.75	**-0.81**	1			
TSK-11	0.71	**0.84**	**0.89**	**0.88**	**-0.84**	1		
PROMIS ES	-0.63	**-0.82**	**-0.84**	**-0.85**	0.75	**-0.85**	1	
PROMIS IS	-0.45	-0.71	-0.79	**-0.83**	0.66	-0.71	0.79	1

Table 37c. Correlation matrix age and CACI

	CACI
Age	0.92

Table 38. Health-related Outcomes and Performance-based Measures

Variables	Value t=0			Value t=1			Value t=2		
Performance-based outcomes	n	Mean (SD)	Range	n	Mean (SD)	Range	n	Mean (SD)	Range
Grip strength (% non-injured side)	n/m	n/m	n/m	367	16.7 ± 4.2	5.9 - 29.4	382	68.6 ± 12.9	21.9 - 108.5
Health-related outcomes	n	Mean (SD)	Range	n	Mean (SD)	Range	n	Mean (SD)	Range
QuickDASH	384	70.4 ± 11.2	(36.4 - 90.9)	384	66.2 ± 15.7	(27.3 - 90.9)	378	23.2 ± 24.8	(0 - 88.6)
PRWE	384	81.8 ± 6.7	(59 - 94.5)	384	70.9 ± 12.3	(27 - 91.5)	378	23.7 ± 25	(0 - 82.5)
EQ-5D-3L	384	0.319 + 0.346	(-0.358 - 1)	384	0.337 ± 0.403	(-0.349 - 1)	378	0.823 ± 0.329	(-0.181 - 1)
PROMIS UE PF	384	22.5 ± 4.5	(14.7 - 31.2)	384	27.8 ± 4.5	(17.7 - 37.8)	378	42.9 ± 10.9	(19.5 - 56.4)
PROMIS PI	384	63.4 ± 5.5	(57.3 - 77.8)	384	65.4 ± 4.8	(54.4 - 74.1)	378	49.1 ± 10.5	(38.7 – 72.1)
PROMIS Depression	384	52.9 ± 9.2	(34.2 - 75.6)	384	47.8 ± 10.7	(34.2 - 68.9)	378	42.8 ± 10.1	(34.2 – 66.7)
PROMIS Anxiety	384	53 ± 10.2	(36.5 - 78.4)	384	47.6 ± 13	(32.9 - 74.4)	378	43.6 ± 12.4	(32.7 – 67.2)
PROMIS ES	n/m	n/m	n/m	384	51.5 ± 9.8	(31.5 - 66.2)	378	52.1 ± 9.9	(31.5 – 66.2)
PROMIS IS	n/m	n/m	n/m	384	54.1 ± 9.1	(36.2 - 66.2)	378	54.4 ± 8.2	(34.7 – 66.2)
PCS	384	19.7 ± 6.6	(12 - 48)	384	17.4 ± 6	(13 – 36)	378	16 ± 5.9	(12 – 33)
PSEQ-2	384	9.6 ± 2.6	(2 - 12)	384	8.3 ± 2.6	(0 – 12)	378	9.7 ± 2.9	(2 – 12)
TSK-11	384	27.1 ± 6.3	(17 - 43)	384	20.9 ± 8.1	(11 – 40)	378	17.6 ± 9.2	(11 – 38)

Variables as Mean ± Standard deviation (range)

Table 39. Bivariate Analysis at t=0

	QuickDASH		PRWE		EQ5D Index Score		PROMIS UE PF	
	Value	**p value**	**Value**	**p value**	**Value**	**p value**	**Value**	**p value**
Age	0.1178	**0.0220**	0.1639	**0.0014**	-0.0275	0.5936	-0.3134	**0.0000**
Sex								
Women	26.6 ± 25	**0.0000**	26.7 ± 25	**0.0001**	0.811 ± 0.338	0.2412	41 ± 10.7	**0.0000**
Men	13.6 ± 21.5		15.2 ± 23.2		0.856 ± 0.301		48.2 ± 9.6	
CACI	0.0986	**0.0554**	0.1515	**0.0032**	-0.0267	**0.6051**	-0.2766	**0.0000**
Marital status								
Single	26.5 ± 29.2	**0.0000**	25.7 ± 31.1	**0.0001**	0.748 ± 0.386	**0.0005**	44.3 ± 12.1	**0.0000**
Partner / Married	17.2 ± 20		18.3 ± 20.1		0.889 ± 0.252		44.9 ± 10.1	
Separated / Divorced / Widowed	30.7 ± 26.2		31.2 ± 25.4		0.767 ± 0.376		38.4 ± 10	
Social support status								
Alone	51.6 ± 27.5	**0.0000**	51.8 ± 28	**0.0000**	0.490 ± 0.450	**0.0000**	33 ± 9.6	**0.0000**
Partner / Friend(s) / Family	16 ± 18.5		16.4 ± 18.5		0.906 ± 0.224		45.6 ± 9.8	
Full / Part-time care	21.1 ± 18		26.6 ± 20.7		0.867 ± 0.323		39.1 ± 7.9	
Education	0.0109	0.8324	0.0050	0.9235	-0.1235	**0.0164**	0.1192	**0.0207**

Work status							
Working / Homemaker	13.3 ± 18.8		12.4 ± 19.9		0.880 ± 0.258		48.9 ± 9.4	
Retired	25.3 ± 23.5		26.9 ± 22.7		0.829 + 0.330		39.5 ± 9.6	
Unemployed	56.7 ± 23.1	**0.0000**	56.9 ± 21.9	**0.0000**	0.516 + 0.440	**0.0000**	32.9 ± 8.6	**0.0000**
Workers compensation / Litigation	67.9 ± 9.1		68.9 ± 7		0.491 + 0.504		30.6 ± 7.4	
IMD Factor	-0.1173	**0.0238**	-0.1120	**0.0310**	0.1146	**0.0273**	0.0705	0.1754
Broad injury classification								
Extra-articular fracture	24.1 ± 25		24.7 ± 25.2		0.821 + 0.341		42.3 + 10.7	
Intra-articular fracture	22 ± 24.6	0.4136	22.3 + 24.7	0.3694	0.825 + 0.313	0.8976	43.6 + 11.1	0.2506
Dominant side injured								
Yes	23.1 ± 25.7		23.9 + 25.8		0.814 ± 0.349		43.1 ± 11.4	
No	23.3 ± 23.9	0.9363	23.4 + 24.2	0.8662	0.832 ± 0.308	0.5938	42.6 ± 10.4	0.6752
High energy injury								
Yes	38.7 ± 30.3		39.0 ± 32.3		0.603 ± 0.442		39 ± 12.5	
No	20.1 ± 22.4	**0.0000**	20.6 ± 22.1	**0.0000**	0.867 ± 0.282	**0.0000**	43.7 ± 10.4	**0.0017**
Neurovascular compromise								
Yes	36.5 ± 31.3		40.3 ± 30.3		0.637 ± 0.425		37.6 ± 11.8	
No	22.2 ± 24	**0.0046**	22.4 ± 24.1	**0.0004**	0.837 ± 0.317	**0.0027**	43.3 ± 10.7	**0.0107**
Open injury								
Yes	9.8 ± 6.8		11.3 ± 9.4		0.981 ± 0.48		46.8 ± 8.6	
No	23.4 ± 24.9	0.1851	23.9 ± 25.1	0.2234	0.820 ± 0.331	0.2375	42.8 ± 10.9	0.3790

Surgery							
Yes	25.2 ± 26.2	0.4872	23.4 ± 24.9	0.6861	0.786 ± 0.343	0.3325	41.8 ± 10.6	0.3921
No	22.8 ± 24.6		24.8 ± 25.6		0.830 ± 0.326		43.1 ± 10.9	
Complication								
Yes	47.5 ± 29.8	**0.0000**	48.5 ± 25	**0.0000**	0.525 ± 0.448	**0.0000**	35.1 ± 11.1	**0.0000**
No	15.4 ± 16.7		15.7 ± 16.8		0.919 ± 0.203		45.4 ± 9.6	
Prior dominant side fracture								
Yes	29 ± 27.4	**0.0183**	30.7 ± 27.9	**0.0050**	0.777 ± 0.369	0.1605	41 ± 10.7	**0.0918**
No	21.6 ± 23.9		21.8 ± 23.9		0.835 ± 0.317		43.4 ± 10.9	
Prior non-dominant side fracture								
Yes	22.5 ± 25.6	0.8552	22.9 ± 24.7	0.8356	0.831 ± 0.302	0.8644	43.4 ± 11.3	0.7617
No	23.3 ± 24.8		23.8 ± 25.0		0.822 ± 0.332		42.8 ± 10.8	
Opioid use								
Yes	47.8 ± 28.8	**0.0000**	47 ± 30.4	**0.0000**	0.533 ± 0.442	**0.0000**	34.5 ± 10.6	**0.0000**
No	12.5 ± 12.2		13.6 ± 12.6		0.948 ± 0.140		46.5 ± 8.9	
Anti-depressant use								
Yes	65.5 ± 18.9	**0.0000**	66.6 ± 17.1	**0.0000**	0.321 ± 0.402	**0.0000**	29.3 ± 7.5	**0.0000**
No	13.4 ± 12.8		13.7 ± 13.3		0.939 ± 0.156		46 ± 9	

Performance-based outcomes at t=0	Coefficient	p value	Coefficient	p value	Coefficient	p value	Coefficient	p value
Grip strength (% of non-injured side)	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m
Health-related outcomes at t=0	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
PROMIS Pain Interference	0.3744	**0.0000**	0.4114	**0.0000**	-0.3244	**0.0000**	-0.4715	**0.0000**
PROMIS Depression	0.4677	**0.0000**	0.5056	**0.0000**	-0.3986	**0.0000**	-0.3826	**0.0000**
PROMIS Anxiety	0.4779	**0.0000**	0.4662	**0.0000**	-0.4308	**0.0000**	-0.3671	**0.0000**
PCS	0.4823	**0.0000**	0.5447	**0.0000**	-0.5379	**0.0000**	-0.5217	**0.0000**
PSEQ-2	-0.6737	**0.0000**	-0.6562	**0.0000**	0.6710	**0.0000**	0.4334	**0.0000**
TSK-11	0.4998	**0.0000**	0.5230	**0.0000**	-0.4793	**0.0000**	-0.3657	**0.0000**

Pearson correlation indicated by r; **bold** indicates statistically significant difference; continuous variables as Mean (± Standard deviation)

Table 40. Multivariable Analysis of Predictive Factors at t=0 for Disability at t=2

QuickDASH	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	0.18	0.07	0.28	0.05	0.001	3.64	0.02	0.81
Female	3.99	1.02	6.97	1.51	0.009	1.41	0.03	
WS: Retired	5.33	1.45	9.22	1.98	0.007	3.11	0.02	
Complications	7.19	3.47	10.90	1.89	0.000	2.08	0.05	
Antidepressant use	34.05	29.23	38.88	2.45	0.000	2.94	0.44	
PROMIS PI	0.33	0.07	0.59	0.13	0.013	1.68	0.01	
PCS	-0.58	-0.87	-0.29	0.15	0.000	3.03	0.03	
PSEQ-2	-3.44	-4.19	-2.68	0.38	0.000	3.30	0.23	

In model: age, female sex, marital status (MS), social status (SS), work status (WS), IMD factor, high energy injury, neurovascular status, complications, prior dominant arm fracture, opioid use, antidepressant use, PROMIS PI, PROMIS depression, PROMIS anxiety, PCS, PSEQ-2, TSK-11

PRWE	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	0.19	0.09	0.30	0.05	0.000	3.64	0.033	0.82
WS: Retired	7.16	3.39	10.93	1.92	0.000	3.11	0.039	
Complication	6.86	-3.56	6.54	1.83	0.000	2.08	0.05	
Prior dominant arm fracture	3.64	0.94	6.33	1.37	0.008	1.05	0.016	
Antidepressant use	37.78	33.11	42.46	2.38	0.000	2.94	0.474	
PROMIS PI	0.27	0.02	0.52	0.13	0.037	1.68	0.012	
PROMIS Depression	0.18	0.03	0.34	0.08	0.021	1.83	0.016	
PSEQ-2	-2.50	-3.24	-1.77	0.37	0.000	3.30	0.129	

In model: age, female sex, marital status (MS), social status (SS), work status (WS), IMD factor, high energy injury, neurovascular status, complications, prior dominant arm fracture, opioid use, antidepressant use, PROMIS PI, PROMIS depression, PROMIS anxiety, PCS, PSEQ-2, TSK-11

EQ-5D-3L	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
WS: Retired	-0.06	-0.11	0.00	0.03	0.035	1.94	0.00	
WS: Unemployed	0.22	0.13	0.31	0.05	0.000	1.46	0.06	
WS: Workers compensation / litigation claim	0.32	0.17	0.47	0.08	0.000	1.32	0.04	
Complications	-0.19	-0.18	-0.06	0.03	0.000	2.04	0.04	
Antidepressant use	-0.43	-0.51	-0.35	0.04	0.000	2.86	0.31	0.68
PROMIS Anxiety	0.00	0.00	0.01	0.00	0.011	2.45	0.02	
PCS	-0.01	-0.01	0.00	0.00	0.002	2.89	0.03	
PSEQ-2	0.05	0.04	0.06	0.01	0.000	3.17	0.16	
TSK-11	0.01	0.00	0.01	0.00	0.027	2.19	0.01	

In model: marital status (MS), social status (SS), work status (WS), education, IMD factor, high energy injury, neurovascular status, complications, opioid use, antidepressant use, PROMIS PI, PROMIS depression, PROMIS anxiety, PCS, PSEQ-2, TSK-11

PROMIS UE PF	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
WS: Retired	-5.90	-8.39	-3.40	1.27	0.000	3.17	0.18	
Opioid use	-2.99	-5.25	-0.73	1.15	0.010	2.19	0.04	
Antidepressant use	-9.80	-12.86	-6.74	1.56	0.000	2.89	0.14	
PROMIS PI	-0.35	-0.52	-0.19	0.086	0.000	1.75	0.05	0.60
PCS	-0.31	-0.50	-0.13	0.09	0.001	3.00	0.04	
TSK-11	0.21	0.04	0.38	0.09	0.014	2.23	0.01	

In model: age, female sex, marital status (MS), social status (SS), education, work status (WS), energy of injury, neurovascular status, complications, prior dominant arm fracture, opioid use, antidepressant use, PROMIS PI, PROMIS Depression, PROMIS Anxiety, PCS, PSEQ-2, TSK-11

Partial R^2 only shown for variables with $p<0.05$

Table 41. Bivariate Analysis at t=1

	QuickDASH		PRWE		EQ-5D-3L		PROMIS UE PF	
	Value	**p-value**	**Value**	**p-value**	**Value**	**p-value**	**Value**	**p-value**
Age	0.1178	**0.0220**	0.1639	**0.0014**	-0.0275	0.5936	-0.3134	**0.0000**
Sex								
Women	26.6 ± 25	**0.0000**	26.7 ± 25	**0.0001**	0.811 ± 0.338	0.2412	41 ± 10.7	**0.0000**
Men	13.6 ± 21.5		15.2 ± 23.2		0.856 ± 0.301		48.2 ± 9.6	
CACI	0.0986	**0.0554**	0.1515	**0.0032**	-0.0267	**0.6051**	-0.2766	**0.0000**
Marital status								
Single	26.5 ± 29.2		25.7 ± 31.1		0.748 ± 0.386		44.3 ± 12.1	
Partner / Married	17.2 ± 20	**0.0000**	18.3 ± 20.1	**0.0001**	0.889 ± 0.252	**0.0005**	44.9 ± 10.1	**0.0000**
Separated / Divorced / Widowed	30.7 ± 26.2		31.2 ± 25.4		0.767 ± 0.376		38.4 ± 10	
Social support status								
Alone	51.6 ± 27.5		51.8 ± 28		0.490 ± 0.450		33 ± 9.6	
Partner / Friend(s) / Family	16 ± 18.5	**0.0000**	16.4 ± 18.5	**0.0000**	0.906 ± 0.224	**0.0000**	45.6 ± 9.8	**0.0000**
Full / Part-time care	21.1 ± 18		26.6 ± 20.7		0.867 ± 0.323		39.1 ± 7.9	
Education	0.0109	0.8324	0.0050	0.9235	-0.1235	**0.0164**	0.1192	**0.0207**
Work status								
Working / Homemaker	13.3 ± 18.8		12.4 ± 19.9		0.880 ± 0.258		48.9 ± 9.4	
Retired	25.3 ± 23.5	**0.0000**	26.9 ± 22.7	**0.0000**	0.829 + 0.330	**0.0000**	39.5 ± 9.6	**0.0000**
Unemployed	56.7 ± 23.1		56.9 ± 21.9		0.516 + 0.440		32.9 ± 8.6	
Workers compensation	67.9 ± 9.1		68.9 ± 7		0.491 + 0.504		30.6 ± 7.4	
IMD Factor	-0.1173	0.0238	-0.1120	**0.0310**	0.1146	**0.0273**	0.0705	0.1754
Broad injury classification								
Extra-articular fracture	24.1 ± 25	0.4136	24.7 ± 25.2	0.3694	0.821 + 0.341	0.8976	42.3 + 10.7	0.2506
Intra-articular fracture	22 ± 24.6		22.3 + 24.7		0.825 + 0.313		43.6 + 11.1	

Dominant side injured								
Yes	23.1 ± 25.7	0.9363	23.9 + 25.8	0.8662	0.814 ± 0.349	0.5938	43.1 ± 11.4	0.6752
No	23.3 ± 23.9		23.4 + 24.2		0.832 ± 0.308		42.6 ± 10.4	
High energy injury								
Yes	38.7 ± 30.3	**0.0000**	39.0 ± 32.3	**0.0000**	0.603 ± 0.442	**0.0000**	39 ± 12.5	**0.0017**
No	20.1 ± 22.4		20.6 ± 22.1		0.867 ± 0.282		43.7 ± 10.4	
Neurovascular compromise								
Yes	36.5 ± 31.3	**0.0046**	40.3 ± 30.3	**0.0004**	0.637 ± 0.425	**0.0027**	37.6 ± 11.8	**0.0107**
No	22.2 ± 24		22.4 ± 24.1		0.837 ± 0.317		43.3 ± 10.7	
Open injury								
Yes	9.8 ± 6.8	0.1851	11.3 ± 9.4	0.2234	0.981 ± 0.48	0.2375	46.8 ± 8.6	0.3790
No	23.4 ± 24.9		23.9 ± 25.1		0.820 ± 0.331		42.8 ± 10.9	
Surgery								
Yes	25.2 ± 26.2	0.4872	23.4 ± 24.9	0.6861	0.786 ± 0.343	0.3325	41.8 ± 10.6	0.3921
No	22.8 ± 24.6		24.8 ± 25.6		0.830 ± 0.326		43.1 ± 10.9	
Complication								
Yes	47.5 ± 29.8	**0.0000**	48.5 ± 25	**0.0000**	0.525 ± 0.448	**0.0000**	35.1 ± 11.1	**0.0000**
No	15.4 ± 16.7		15.7 ± 16.8		0.919 ± 0.203		45.4 ± 9.6	
Prior dominant side fracture								
Yes	29 ± 27.4	**0.0183**	30.7 ± 27.9	**0.0050**	0.777 ± 0.369	0.1605	41 ± 10.7	**0.0918**
No	21.6 ± 23.9		21.8 ± 23.9		0.835 ± 0.317		43.4 ± 10.9	
Prior non-dominant side fracture								
Yes	22.5 ± 25.6	0.8552	22.9 ± 24.7	0.8356	0.831 ± 0.302	0.8644	43.4 ± 11.3	0.7617
No	23.3 ± 24.8		23.8 ± 25.0		0.822 ± 0.332		42.8 ± 10.8	
Opioid use								
Yes	47.8 ± 28.8	**0.0000**	47 ± 30.4	**0.0000**	0.533 ± 0.442	**0.0000**	34.5 ± 10.6	**0.0000**
No	12.5 ± 12.2		13.6 ± 12.6		0.948 ± 0.140		46.5 ± 8.9	
Anti-depressant use								
Yes	65.5 ± 18.9	**0.0000**	66.6 ± 17.1	**0.0000**	0.321 ± 0.402	**0.0000**	29.3 ± 7.5	**0.0000**
No	13.4 ± 12.8		13.7 ± 13.3		0.939 ± 0.156		46 ± 9	

Performance-based outcomes at t=1	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
Grip strength (% of non-injured side)	-0.2207	**0.0000**	-0.2523	**0.0000**	0.1476	**0.0048**	0.3245	**0.0000**
Health-related outcomes at t=1	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
PROMIS Pain Interference	0.5957	**0.0000**	0.5870	**0.0000**	-0.4472	**0.0000**	-0.5673	**0.0000**
PROMIS Depression	0.7641	**0.0000**	0.7581	**0.0000**	-0.6412	**0.0000**	-0.6827	**0.0000**
PROMIS Anxiety	0.7627	**0.0000**	0.7116	**0.0000**	-0.6581	**0.0000**	-0.6170	**0.0000**
PROMIS ES at t=1	-0.8136	**0.0000**	-0.8102	**0.0000**	0.7068	**0.0000**	0.6597	**0.0000**
PROMIS IS at t=1	-0.7868	**0.0000**	-0.7575	**0.0000**	0.6556	**0.0000**	0.5915	**0.0000**
PCS	0.8689	**0.0000**	0.8625	**0.0000**	-0.7514	**0.0000**	-0.7225	**0.0000**
PSEQ-2	-0.8622	**0.0000**	-0.8390	**0.0000**	0.8006	**0.0000**	0.7442	**0.0000**
TSK-11	0.8621	**0.0000**	0.8266	**0.0000**	-0.7332	**0.0000**	-0.7527	**0.0000**

Pearson correlation indicated by r; **bold** indicates statistically significant difference; continuous variables as mean (±standard deviation).

Table 42. Multivariate Analysis of Predictive Factors at t=1 for Disability at t=2

QuickDASH	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Complications	3.29	0.21	6.36	1.57	0.037	2.09	0.00	0.87
Antidepressant use	18.68	14.26	23.09	2.25	0.000	3.57	0.18	
PSEQ-2	-4.21	-4.876704	-3.55	0.34	0.000	3.44	0.39	
PROMIS IS	-0.64	-0.8057465	-0.48	0.08	0.000	2.56	0.18	

In model: age, female sex, marital status (MS), social status (SS), work status (WS), IMD factor, high energy injury, neurovascular status, complications, prior dominant arm fracture, opioid use, antidepressant use, PROMIS PI, PSEQ-2, PROMIS Instrumental support

PRWE	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
Age	0.14	0.05	0.23	0.05	0.002	3.60	0.03	0.86
WS: Retired	4.47	1.10	7.85	1.72	0.010	3.13	0.02	
Complications	4.07	0.84	7.29	1.64	0.014	2.09	0.02	
Prior dominant-arm fracture	3.52	1.13	5.92	1.22	0.004	1.05	0.02	
Opioid use	-3.85	-6.95	-0.75	1.58	0.015	2.28	0.01	
Antidepressant use	25.38	20.75	30.00	2.35	0.000	3.57	0.26	
PSEQ-2	-3.74	-4.43	-3.05	0.35	0.000	3.44	0.30	
PROMIS IS	-0.55	-0.72	-0.38	0.09	0.000	2.56	0.10	

In model: age, female sex, marital status (MS), social status (SS), work status (WS), IMD factor, high energy injury, neurovascular status, complications, prior dominant arm fracture, opioid use, antidepressant use, PROMIS PI, PSEQ-2, PROMIS Instrumental support

EQ-5D-3L	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
WS: Unemployed	0.17	0.09	0.26	0.04	0.000	1.45	0.04	
WS: Workers comp / Litigation claim	0.29	0.15	0.43	0.07	0.000	1.29	0.04	
Complications	-0.07	-0.13	-0.01	0.03	0.026	2.06	0.01	
Antidepressant use	-0.26	-0.34	-0.17	0.04	0.000	3.46	0.12	0.72
PROMIS PI	0.01	0.01	0.02	0.00	0.000	1.88	0.05	
PSEQ-2	0.08	0.66	0.09	0.01	0.000	3.40	0.30	
PROMIS IS	0.00	0.00	0.01	0.00	0.010	2.41	0.02	

In model: marital status (MS), social status (SS), education, work status (WS), IMD factor, high energy injury, neurovascular status, complications, opioid use, antidepressant use, PROMIS PI, PSEQ-2, PROMIS Instrumental support

PROMIS UE PF	Regression Coefficient	95% Confidence Interval		Standard Error	p-value	VIF	Partial R^2	Adjusted R^2
Variables								
WS: Retired	-4.66	-6.97	-2.35	1.18	0.000	2.68	0.20	0.66
PSEQ-2	2.07	1.60	2.54	0.24	0.000	3.47	0.52	

In model: age, female sex, marital status (MS), social status (SS), education, work status (WS), high energy injury, neurovascular status, complications, prior dominant arm fracture, opioid use, antidepressant use, PROMIS PI, PSEQ-2, PROMIS Instrumental support

Only partial R^2 of significant values is displayed (i.e. $p<0.05$)

7.4 Discussion

Self-efficacy, the confidence in one's ability to succeed and accomplish tasks, despite experiencing a wrist fracture was a dominant predictor of future disability within the early phases of recovery. The use of anti-depressants during this time also appeared to be a strong correlate of worse health-related outcomes. Depression, anxiety, pain interference, pain catastrophizing and kinesiophobia during the initial specialist review (t=0) were also predictive of longer-term disability whereas injury-related factors at either stage of early recovery (i.e. t=0 or t=1) were not. These findings were consistent across the four PRO measures of disability and similar to the findings in prior chapters involving proximal humerus and elbow fractures.

Confidence, the ability to adapt and be resilient in the face of painful upper extremity conditions are shown to have a strong correlation with disability (96)(131). To the best knowledge, this is the first-time coping strategies (e.g. PSEQ-2), over the initial weeks post-injury, have been shown to predict future disability in a distal radius fracture population. Kortlever et al., demonstrated PSEQ and other measures of coping strategy in response to pain i.e. pain interference (PROMIS PI), pain catastrophizing (PCS) and Psychosocial Inflexibility in Pain Scale (PIPS), all assessed a common underlying aspect of human illness behavior and strongly correlated with upper extremity disability (131). Interestingly, PROMIS PI and PCS also accounted for the variability in some measures of disability in our study, consistent with the current literature (76)(77)(84)(111)(113)(116)(130)(306).

Other psychological factors associated with disability following wrist fractures include depression, anxiety and kinesiophobia (76)(77)(88)(103)(105)(109)(108)(116). A longitudinal investigation by Yeoh et al., demonstrated baseline depression as the strongest predictor of worse disability outcomes 1 year after low energy distal radius fractures in patients over 55 years (109). A striking observation was the seemingly high levels of depression affecting up to 1 in 3 injured patients (109). In this study, PROMIS depression explained some of the variability in PRWE at t=0 only

(Partial R^2=0.016, p<0.021). Whilst no attempt was made to screen for or diagnose depression clinically, almost 1 in 5 in the cohort were using anti-depressant medications during early recovery, a factor that consistently predicted disability throughout this and prior studies involving shoulder and elbow fractures. The level of depression was shown to naturally improve over time, signifying the importance of accounting for disease phase during measurement (128). Interventions to alleviate depression within the first month of a wrist fracture or wrist fracture fixation have been advocated in reducing pain-related disability (103).

Anxiety is another psychological construct that correlates with disability and mediates its relationship with pain following fractures of the wrist (116)(132)(88)(77)(103). In this study, PROMIS anxiety accounted for a small amount of variability in disability measured by EQ-5D-3L at t=0. Recovery-related anxiety is shown to have a stronger association with disability than measures of pain, state, trait and general anxiety in less severe arm injuries (132). This may explain why PROMIS anxiety, which can be regarded as a generic measure of anxiety, didn't have more of an influence. Pre-operative pain anxiety (and levels of pain catastrophizing) were significantly associated with delayed recovery in another study following wrist fracture surgery (77). The authors advocate assessment in the first 12 weeks post-surgery, when pain and disability may potentially worsen.

Kinesiophobia explained very small proportions of the variability in disability measured by EQ-5D-3L (Partial R^2=0.01, p<0.027) and PROMIS UE PF (Partial R^2=0.01, p<0.014) at t=0 (127). This concept is shown to encompass pain-related fear, somatization (i.e. perception of a serious underlying medical condition) and activity-avoidance (i.e. fear of movement and re-injury) (76)(287)(289). While all three sub-domains of this concept may play a role in the early experiences post-wrist fracture, the sense of protection received by initial cast immobilization could mitigate the risk of developing one or more of these perceptions. This may explain the relatively low levels of interaction between kinesiophobia and disability in this study. In contrast,

the studies involving proximal humerus fractures in Chapter 5 and elbow fractures in Chapter 6 observed kinesiophobia to be the strongest predictor at the initial review (t=0). In these cases, most patients are initially supported by a sling or brace, both comparatively less rigid and leaving patients potentially more prone to such fears.

PROMIS IS accounted for a significant proportion of the variance in disability at t=1 in all measures of disability except PROMIS UE PF. The prognostic significance of instrumental support at this stage of recovery can be explained. By t=1, most patients likely achieve control of fracture-related pain, manage to cope with immobilization and contend with activities of daily life with a restricted wrist and hand. At this point, the focus may be turned toward managing tasks and functions despite an immobilised wrist, and looking toward family and friends for practical support in buffering the stresses and strains of the fracture and fracture-related pain. Social support, whether emotional or instrumental, is shown to contribute a small but significant part of long-term self-reported pain and disability outcomes following distal radius fractures in other studies (96)(114). Optimizing aspects of support during early fracture management could aide coping and resilience when faced with this injury (11)(86)(96)(114)(294)(295).

Notably, the interactions between psychosocial factors and disability were not the same across our assessment points. Multiple psychosocial variables (i.e. depression, anxiety, pain catastrophizing, kinesiophobia and emotional support) exhibited a substantial degree of shared correlation (multi-collinearity) at t=1, a finding not present at t=0. Omission of these variables from regression analysis at t=1 allowed further statistical definition of other factors that explained a greater proportion of the overall variance. However, it should be recognized that the collinear variables were significant correlates of disability in bivariate analysis, and thus, may still play a dominant role in influencing it.

Work status and being retired, unemployed, on worker's compensation or involved in a litigation claims were the only social status variables that explained some portion of the variability in disability. Of these, only being retired was consistently selected in all models and measures of disability at t=0. Those who do not have a regular commitment or requirement to work, such as the elderly retiree or the unemployed individual, may be prone to poorer physical functioning in the longer term. For those involved in compensation or litigation claims, greater self-perceived disability may be related to aspects of secondary gain i.e. conscious or unconscious use of illness and symptom expression for personal advantage (80). A more detailed assessment of the influence of occupational stressors on post-traumatic disability following wrist fractures is required (297).

In terms of injury-related factors, fracture classification did not correlate with medium-term health-related outcomes after a wrist fracture, however, complications related to the injury and the experience of a prior upper limb fracture explained portions of the variability in most measures of disability at t=0 and t=1.

A relatively high proportion of variability in disability was explained by the factors in this study compared to other investigations in this field, a feature that can be observed by comparing studies identified in the first systematic review in Chapter 2. This could be as a consequence of evaluating a specific condition rather than a heterogeneous group of diagnoses. This work also demonstrated that (i) delivering multiple PRO measures to assess distal radius fracture outcomes as early as day 0 post-injury is feasible, (ii) administering PRO measures, including CATs, via an electronic portal that was user-friendly and efficient, and (iii) that low levels of missing data and participant attrition during follow-up were achievable and may reflect the benefits of a full-time investigator and point of contact for patients (47)(113)(166)(54).

7.4.1 Limitations

The limitations of these findings must be considered. Firstly, the generalizability of this study may be challenged as it was performed at a single institution (a level I trauma center in the UK). However, the demographic factors and indices of social deprivation within our cohort had a wide range. Second, a variety of clinical and logistical factors could have potentially influenced outcomes. Clinical factors such as fracture displacement, re-injury, development of stiffness and pain in other joints, and changes to the management plan, may have been sources of additional stress and frustration. Most patients are also placed in an incomplete plaster of paris cast during the initial emergency department attendance. In clinical practice, the cast may be completed, modified or replaced with or without the use of traction systems and the decision to operate may occur at any early stage. These choices are made by senior surgeons with substantial experience as well as relatively junior staff in busy clinical settings. Neither the level of experience, sub-specialty nor the precise course of immobilization or the timing of surgery was defined. Furthermore, other factors such as logistical delays to management and timing of test administration around the clinical encounter could have influenced responses. This is important considering clinician-patient interactions are shown to influence mindset and patient outcomes (126). In practical terms, these variations could have had a significant impact in the face of unexpected changes or failure to meet the expectations of patients. Third, it could be argued that the 2-part classification system was not detailed enough to account for injury severity. A pragmatic approach was taken based on classification using the AO/OTA system, revealing numbers in some categories were insufficient for analysis whereas the number of patients categorized by intra- and extra-articular fracture configurations were evenly distributed. Further studies may be required to assess specific fracture subtypes. Fourth, due to the logistics of follow-up, patients completed outcome measures at t=2 via telephone, online or in person. Each mode of assessment is prone to varying levels of procedural, measurement, interviewer and responder bias. Bias may also have been introduced with patients recruiting family and friends to assist in questionnaire completion. Interviewer bias may have also occurred and presents a risk whenever

a single investigator is involved. At times, interference from friends and family members couldn't be helped despite stressing the importance of gaining true patient responses. However, proxy responses were rare overall. Fifth, this study aimed to comprehensively assess outcomes without the measurement set being too burdensome to complete. Despite incorporating abbreviated fixed scales and CATs to limit this burden, some patients may have still found this process laborious. Also, the administration of similar sounding items between measures could have posed an additional source of frustration. Full randomization of all questions may have minimized this but would have added significant complexity to programming the digital platform. From another perspective, although the psychometric credentials of abbreviated measures in this study were deemed acceptable, some outcome experts may still recommend full versions be used to better capture the substantive components of a tested domain. Sixth, certain outcome measures assess items in the context of specific time-frames (e.g. PRWE and status within the past week). Although capturing health status in the present was the point of interest, questions were not altered in order to avoid the introduction of bias and invalidating measures. Most patients responded according to their current status, whilst others queried the time frame and circumstances in which to relate their response e.g. "Should I answer this based on what I can do now or what I could do before the fracture?", "Is this based on how I feel now or how I felt straight after the injury?", "Do I answer this as if my cast is on or off?". In these rare instances, it was difficult not to advise patients to consider current health status and overall ability to perform a task. Seventh, PROMIS ES and IS support were not assessed at baseline due to a programming error. Although this may have influenced the analysis, it is unlikely to have changed the final interpretation. Finally, this chapter and the studies presented in the prior two chapters aimed to assess a comprehensive range of outcome measures. It is recognised that other influential factors may exist for a specific condition. One such factor is the appearance of deformity. This aspect is particularly relevant after distal radius fractures and fracture malunion. For instance, patients may mention being bothered by a 'bent', 'crooked' or unsightly wrist. This can be distressing in itself, and have physical, psychological and social implications. Whilst PRO

measures such as the Michigan Hand Questionnaire assesses this feature, there is no standardised measure for assessing patient-perceived wrist appearance following a fracture of the distal radius. Not surprisingly, there no studies identified to date assessing the impact of appearance on limitations.

7.4.2 Conclusion

Current evidence on the management of distal radius fractures is extremely conflicting. High quality RCTs aim to advance our understanding of treatment options and despite their limitations demonstrate the capacity to promote widespread change in clinical practice (329)(353). In the UK, there has been a substantial increase in wire fixation, from 12% to 42%, with a concurrent decline in plating, from 75% to 48%, following publication of the DRAFFT trial (353). In contrast, there appears to be an overall rise in surgical treatment predominantly using locking plate fixation in other high income countries (94)(325)(326)(335)(348)(354)(355)(356). Ultimately, there is a considerable amount of variation in how these injuries are managed due to equivocal evidence and it appears that treatment choice is still based on subjective factors such as personal experience, personal preference and treatment trends (331)(357)(358). The pursuit of anatomical restoration will always remain the goal of most orthopaedic surgeons but a patient-focused approach may be the best way to achieve a step change in improving disability following these injuries (70).

Disability following distal radius fractures is strongly predicted by confidence and coping strategies maintaining one's activities in life despite wrist fracture-related pain within the first month of injury. Clinicians should also be cognizant of specific social factors, complications, use of anti-depressants and opioids as indicators prognostic of poor outcomes (265). As these interactions seem to differ during the initial phases of recovery, musculoskeletal HCPs should be mindful of which factors predominate and when. This may allow them to better identify patients who may be at risk of a maladaptive response to injury and pain.

From the injury perspective, no clinical or injury-related factors explained any variability in disability across measures at t=0 and t=1. This is consistent with the growing body of evidence for disability being influenced more by psychosocial factors and pain than measures of impairment, pathophysiology and clinical factors (71)(298). Adverse complications such as post-traumatic stiffness, complex regional pain syndrome (CRPS), secondary elbow stiffness or frozen shoulder are popularly recognised as distinct clinical diagnoses with specific pathophysiology but may themselves be mediated by psychosocial factors (359)(360)(361). One can appreciate feelings of anxiety, depression, distress and fear as part of the morbidity associated with the development of such conditions and treatment complications (359). Larger scale studies may be able to define the specific psychosocial factors associated with these sequelae in the context of wrist fractures.

Identifying those with greater than expected symptoms and disability following a wrist fracture at a specific point in time, is the first step. Following this with close patient engagement, HCP lead coaching on coping strategies followed by behavioural therapies may be required in some cases. All this should be delivered using optimistic and reassuring language, avoiding over-emphasis on maladaptive aspects that could lead to over-cautious activity. The concluding chapter of this thesis discusses these potential strategies in greater detail but the next and final experimental chapter aims to provide a more complete view on patient perspectives by investigating the relationship between disability, patient experience and patient activation.

Chapter 8

8. The Impact of Patient Engagement on Disability and Patient Experience following Upper Extremity Fractures

8.1 Background

Chapters 1 and 2 built the foundations for this thesis and defined the health constructs that influence upper extremity disability, the developmental origins of existing upper extremity PRO measures, and the performance of CATs versus fixed length scales in a range of upper extremity conditions. Collectively, these reviews also generated a set of candidate PRO measures for this thesis. Chapter 3 is a pilot study that applied some of the methods and PRO measures planned for the core experiments using a secure, online platform. Aside from assessing the methodological and technical feasibility of performing this type of research, it identified the correlation between a computer adaptive, general measure of physical function (PROMIS PF) with a widely used region-specific, fixed-scale (QuickDASH), and considered psychosocial factors as the common underlying trait behind this relationship. Chapter 4 expanded on this by assessing the correlation between four types of disability measure, the underlying constructs being measured using factor analysis and the correlation between disability and satisfaction. The findings up to this point fueled the core experimental studies in Chapters 5, 6, 7 and this final Chapter 8 in achieving the overarching goals of this thesis. This was to identify the most influential factors predicting longer-term disability after proximal humerus, elbow and distal radius fractures *and* to define the relationship between disability, experience and activation to inform a patient-centered approach to managing these challenging injuries. In this chapter, gauging the impact of activation on medium-term disability and satisfaction may provide another means of improving health and experiential outcomes in upper extremity trauma populations.

Health care is in the midst of a paradigm shift toward patient centered care and personalising the delivery of health to benefit the individual (35)(214). This requires an understanding of the preferences, values and perspectives of individuals on their health and health care (35)(214). Patient focused outcomes data allows us to achieve this understanding by quantifying disability, patient experiences and patient engagement (also known as activation) (35)(214).

Disability has been well-defined by the WHO ICF as a "multi-dimensional construct involving a dynamic interaction between impairment, activity limitations and participation restrictions, that are influenced by contextual factors" (19). In effect, this represents the self-reported subjective impact of various health domains and is best gauged by PRO measures (PROMs) that measure the factors influencing disability and disability itself. *Patient experience* is quantified by a range of PREMs that assess one or more facets of health care delivery and quality within health care systems (216)(217). A commonly measured feature is the satisfaction patients experience during interactions with the health care system and pathways of health care (56). *Patient engagement or activation* is defined as the propensity of individuals to engage in adaptive health behaviors and reflects how pro-active patients are in managing their health and interacting with their health care services (2)(230). This has been quantified using PAMs (362). Scientific reporting of health outcomes alongside patient experience is common-place, however, relatively few studies have investigated the relationship between how activated patients are in relation to their limitations and experiences.

Threshold values in post-operative QuickDASH and change in QuickDASH scores are shown to be highly predictive of patient satisfaction following open carpal tunnel decompression (223). A further study involving this intervention highlighted the significant influence of psychological factors, such as depression and pain catastrophizing, on dissatisfaction and self-perceived disability (363). Similar findings have been observed in the management of rotator cuff tears (224). The field of lower limb arthroplasty offers some interesting insights in this area.

Total hip (THR) and knee (TKR) replacements are two of the most successful procedures in modern medicine demonstrating significant gains in HrQoL, yet the interaction between measures of disability and patient experience appears mixed (225)(226)(227)(228)(229). Post-operative satisfaction measured by a quality of care indicator (Patient Judgement of Hospital Quality Index) is shown to predict HrQoL (Medical Outcomes Study 36-item Short Form) following these procedures (228). However, a large-scale national study based in the UK demonstrated only a weak positive correlation between experience and disability outcomes following THR and TKR (217). A further study shows overall patient satisfaction is predicted more by expectation management, satisfaction with pain relief and satisfaction with hospital experience, than Oxford Hip Score, Oxford Knee Score and Medical Outcomes Study 12-item Short Form after these procedures (229). It appears that patients with improved health-related outcomes and fewer limitations are not necessarily more satisfied following even the most established orthopaedic surgical interventions (229)(230).

Ultimately, there is an interest in the role of patient engagement on future self-perceived limitations and patient experience, and understanding whether any relationships could translate to improving clinical care in upper extremity fracture populations. Individuals with higher pre-operative PAM scores are shown to experience improved pain and symptom relief, mental health and satisfaction following primary THR and TKR (230).

Patient engagement is also shown to correlate with disability, pain intensity, and satisfaction with treatment in individuals with a range of acute and chronic upper extremity conditions (115). Interestingly, the level of activation was only retained in the multivariable model for pain intensity in this study, whilst pain self-efficacy best accounted for the variability in disability, level of pain and treatment satisfaction (115).

There is a call for testing the assumption that the more engaged a patient is with their health, the more likely they are to achieve improved health-related outcomes post-injury. Furthermore, if patients are more engaged early on, they may be more satisfied with their clinical care and health care services in the longer term. If this holds true, strategies to promote patient engagement and activation could be developed to enhance both experiential and health-related outcomes.

The overarching goal of this study was to assess the impact of the level of patient activation on future disability and satisfaction with clinical care and satisfaction with health care services overall in patients with orthopaedic trauma to the upper extremity.

8.1.1 Objectives

The primary objective was to assess the correlation between patient engagement [Patient Activation Measure (PAM-13) and Effective Consumer Scale (ECS-17)] within a month of injury, with medium-term disability (PROMIS UE PF) at 6 to 9 months after fractures of the upper extremity (accounting for demographic, clinical and psychosocial factors). The secondary objective was to evaluate this relationship with disability measured by QuickDASH at 6 to 9 months. Finally, the predictive ability of PAM-13 and ECS-17 for patient experience (NRS satisfaction with clinical care and NRS satisfaction with overall experience of health care services) at 6 to 9 months following injury was also assessed.

8.2 Methods

8.2.1 Study design

A consecutive series of 775 adult patients sustaining isolated proximal humerus, elbow and distal radius fractures attending new patient fracture clinics between 1st January 2016 and 31st August 2016 were enrolled in a research and ethics committee approved study (IRAS No. 16/YH/0017) (Appendix 11-15). This was a secondary analysis of a prospective cohort study at a level I trauma center in the UK (Level 1b/2b). Inclusion criteria were that patients should be fluent in English and aged eighteen years or over at the time of injury. Those unable to provide informed consent, including patients with diagnosed mental health problems or cognitive dysfunction, and sustaining concurrent injuries involving the same arm or any other region were excluded. Shoulder, elbow or wrist fractures as part of complex polytrauma, re-fracture during recovery from a previous injury, fracture in a malunited bone, fracture-dislocations of the shoulder, elbow and wrist, and peri-prosthetic fractures around a previous fixation or joint replacement, were also considered ineligible. 31 patients (4%) declined participation due to time constraints leaving 744 patients in the study providing informed consent and data protection approvals.

All 744 patients completed a digital demographic proforma and initial PRO measurement collection on the secure, encrypted web-based data collection tool (Assessment Center℠, Northwestern University) used extensively in this thesis (231). Pilot tests using this system were completed by colleagues demonstrating acceptable response times (13.9 $\pm$ 3.3 mins).
Data was captured at baseline (t=0, initial orthopaedic review in new patient fracture clinic following acute management in the emergency department), early follow-up (t=1, subsequent clinic review at 2-4 weeks post-injury) and final assessment (t=2, 6-9 months post-injury). Most assessments were conducted face-to-face (70%; n=1,551/2,222), with others completed by phone (25%; n=556/2,222) or electronically by patients, directly on the digital platform (5%; n=115/2,222).

8.2.2 Patient Characteristics

The cohort comprised 498 women and 246 men with a mean age of 58.5 ± 20.4 years (range, 16–97 years) (Table 43). 4 patients in total died of unrelated illness before they could complete the final part at t=2 and a total of 6 patients were lost to follow-up.

Education level, marital status, social status and work status, as well as arm dominance and any previous arm injuries, including side, were acquired from the demographic proforma. CACI (232) and IMD factor were recorded as previously described (233). Clinical records were also assessed for any neurovascular compromise, open versus closed fracture, surgical intervention and complications. Complications were defined as any adverse event specifically related to injury and its management e.g. post-operative wound infection or prolonged joint stiffness requiring manipulation. General complications e.g. urinary tract infections, during recovery were not.

Injuries were independently classified [PJ; SG] by energy [e.g. high speed road traffic accident (high); fall from standing height (low)] and categorized by region i.e. any proximal humerus, elbow (including radial head, distal humerus and proximal ulna fractures) and distal radius fractures. Use of opioid analgesia was defined as regular use of any opiates beyond a 2-week period post-injury. Any patients already using opioids for other conditions were only included if there was any change or increase in their analgesic requirement secondary to the fracture. This was based on an observation that most patients rarely required a prescription for additional pain relief beyond this period or any more than the initial 7-day course of compound analgesics provided in the emergency department. Any patients already using opioids for other conditions were only included if there was any change or increase in their opiate analgesic requirement secondary to the fracture. Anti-depressant use was defined as any earlier use i.e. for pre-existing depression, or a new diagnosis of depression in the acute recovery phase i.e. within the first month following injury.

8.2.3 Outcome Measures

PRO measures delivered in order included: i) PAM-13, ii) ECS-17, iii) PROMIS UE PF (170), iv) PROMIS PI (203), v) PROMIS Depression (200,201), vi) PROMIS Anxiety (201), vii) PROMIS ES (283), viii) PROMIS IS (283), ix) QuickDASH (204,205,207), x) PCS (284), xi) PSEQ-2 (285,286), xii) TSK-11 (287), xiii) NRS satisfaction with clinical care and ix) NRS satisfaction with the overall health service (Appendix 10).

The PAM-13 and ECS-17 were identified as established, validated measures that framed the concept of patient activation in different ways. The Patient Activation Measure (PAM-13) assesses activation and the personal and psychological competencies (e.g. knowledge, skills, confidence) required to manage one's health and health services (364)(362). These can be categorized into 4 item categories: i) baseline roles and responsibilities of individuals with their health, ii) their confidence with health and health care services, iii) the ability to maintain health and prevent ill health, and iv) the propensity for adaptive health behaviours and level of resilience. It was originally developed and tested in several chronic conditions (2)(365). 13 items are rated to generate a total score ranging from 0 (no activation) to 100 (high activation).
The Effective Consumer Scale (ECS-17) is designed to measure an individual's skills, behaviors and effectiveness in dealing with their condition and making decisions to effectively manage their health (365)(366). It was originally designed for musculoskeletal patients with rheumatoid arthritis using 17 items covering five domains i) how I use my health information, ii) how I clarify my priorities, iii) how I communicate with others, iv) how I work with the health team to control my disease, v) how I decide and act on decisions. Each item is rated from 0 (never) to 4 (always), providing a score out of 68 which is converted to a total score out of 100. The index is not scored if more than 1 item is missing on a subscale or if 3 items are missing from the total scale (365)(366).

The PROMIS measurement suite used throughout this thesis is described previously and all PRO measures were administered at t=0, t=1 and t=2 except for PROMIS ES and PROMIS IS which were deployed at t=1 and t=2 only.

QuickDASH, PROMIS Depression and PROMIS PI are previously described in Chapter 3. PROMIS UE PF in Chapter 4 and PROMIS Anxiety, PROMIS ES, PROMIS IS, PCS, PSEQ-2 and TSK-11 in Chapter 5.

NRS Satisfaction was assessed using a rating from 0 to 10 denoting low to high satisfaction respectively. NRS Satisfaction with clinical care included any aspects specifically related to the fracture and its management e.g. interactions with the surgeon or therapist about the injury, the operative experience, features of rehabilitation. NRS Satisfaction with health service experiences included more generic aspects of care at the trauma centre e.g. access to hospital services, quality of hospital facilities. This approach was borne from the observation that patients frequently expressed positive or negative experiences related either of these aspects e.g. "…all the doctors were great but there was such a delay to getting my scans and a hospital bed for my operation", or "the facilities at the hospital were good but the clinical staff didn't really take time to explain anything / tell me about the operation".
Finally, grip strength was assessed using the technique described previously and the percentage of injured side relative to the non-injured side was calculated. (288).

8.2.4 Statistical analysis

Descriptive statistics included frequencies and percentages for discrete variables, and mean with standard deviation for continuous variables. Bivariate analysis involved unpaired Student t-test or analysis of variance for continuous and discrete variables and Pearson correlation for continuous variables. The initial aim was to include variables with $p<0.10$ in bivariate analysis

in multivariable models. Levels of correlational strength were set as high (>0.7), high-moderate (0.61 to 0.69), moderate (0.4 to 0.6), moderate-weak (0.31 to 0.39), or weak (<0.3)(210).
It was evident from preliminary analysis that several measures correlated with one another risking multi-collinearity and potentially preventing a 'true' understanding of inter-relations between variables. For example, PAM-13 and ECS-17 can be considered to measure the same underlying construct, thereby exhibiting a strong correlation with one another. Inclusion of these measures in the same multivariable model could lead to multi-collinearity. This was confirmed using VIF analysis, considering values higher than 5 indicating a high risk of multi-collinearity. Furthermore, there were a few instances where beta coefficients had reverse correlations to what would be expected clinically in bivariate analysis (e.g. greater depression correlated with greater function in preliminary analysis).

Taking all this into consideration, decision was made to proceed with factor analysis. Factor analysis works on the assumption that there are multiple underlying factors or common constructs within a dataset. For instance, since PAM-13 and ECS-17 measure the same construct, they should make up (i.e. load) onto the same factor. This also goes for other questionnaires measuring similar constructs that again, may load onto a common factor. Varimax rotation was utilized for optimal factor loading based on this dataset.

The first step was to select all factors with an Eigen value above 1.0 before plotting the values and omitting factors after the curve plateaued. This resulted in four factors for variables with $p<0.10$ on bivariate analysis for i) PROMIS UE, ii) QuickDASH, iii) NRS satisfaction with clinic care, and iv) NRS satisfaction with overall health services (Table 8.4 – Factor analysis variables with $p<0.10$ in bivariate analysis and loading ≥ 0.30 i.e. 'relevant' factors). The Kaiser-Meyer-Olkin (KMO) measure was then performed to indicate the extent to which variables associated with one another. A measure ≥0.50 indicates an appropriate level in factor analysis. KMO was ≥0.80 for all 4 factor models.

Multivariable analysis was subsequently performed with 4 relevant factors for each outcome measure. Power analysis indicated that a minimum sample size of 630 patients would provide 90% statistical power with alpha set at 0.05. This was based on a regression with five predictors and the assumption that an independent variable would account for 1% or more of the variability in disability and the complete model would account for at least 40% variability. Of the initial 734 patients, 30 (i.e. 4% of full dataset) had missing data and were omitted completely from the factor analysis d subsequent multivariable analysis. All statistical analysis was performed using STATA 14.0 (StataCorp LP, College Station, TX, USA).

8.3 Results

Health-related outcomes improved overall during the course of recovery (Table 44). Patient engagement measured by PAM-13 and ECS-17 had moderate to moderate-high correlations with PROMIS UE PF (PAM-13: r=0.55; ECS-17: r=0.60) and QuickDASH (PAM-13: r=-0.65; ECS-17: r=-0.67) at 6-9 months after upper extremity fractures in bivariate analysis (Table 45). PAM-13 and ECS-17 also demonstrate moderate correlations with NRS for satisfaction with clinical care (PAM-13: r=0.53; ECS-17: r=0.57) and NRS for satisfaction with overall health services (PAM-13: r=0.55; ECS-17: r=0.58) in bivariate analysis. $p<0.001$ for all displayed correlations (Table 45).

Four underlying factor sets were identified in this study, predominantly representing 1) psychosocial factors and patient engagement, 2) patient socio-demographics and patient engagement, 3) pathophysiology including physical performance, and 4) social support (Table 46). Factor 1 (Psychosocial factors and patient engagement) accounted for most of the variation in disability (PROMIS UE PF, Semi-partial R^2=0.45; QuickDASH, Semi-partial R^2=0.63). Factor 1 also accounted for most of the variation in patient experience (NRS Satisfaction with clinical care, Semi-partial R^2=0.56; NRS Satisfaction with health services, Semi-partial R^2=0.64). The most dominant factors influencing both measures of disability and both ratings of patient experience within this factor set were psychosocial (i.e. pain catastrophizing, pain self-efficacy, emotional support and instrumental support as well as opioid and anti-depressant use). This superseded patient engagement (Table 47).

All four factor sets accounted for a substantial amount of the overall variance in both disability (PROMIS UE PF, Adj R^2=0.59; QuickDASH, Adj R^2=0.72) and patient experience (NRS Satisfaction with clinical care, Adj R^2=0.59; NRS Satisfaction with health services, Adj R^2=0.66) (Table 47).

Table 43. Patient Demographics

Demographic	Value	
Subjects enrolled (t=0)	744	
Subjects (t=1)	744	
Subjects (t=2)	734	
Age (years)	58.5 ± 20.4	(16 - 97)
Female	68%	(498)
CACI	1.9 ± 1.7	(0 - 6)
Marital status		
Single	23%	(166)
Partner / Married	50%	(365)
Separated / Divorced / Widowed	27%	(203)
Social status		
Alone	21%	(153)
Partner / Friend(s) / Family	70%	(514)
Full / Part-time care	9%	(67)
Education (years)	13.7 ± 3	(6 - 23)
Work status		
Working	44%	(326)
Homemaker	45%	(328)
Retired	6%	(46)
Unemployed / Workers compensation / Litigation	5%	(34)
IMD factor	70.4 ± 23.6	(0 - 99.8)
Fracture Location		
Proximal humerus	24%	(173)
Elbow	25%	(183)
Distal radius	51%	(378)
Broad Classification Ω		
Category 1	51%	(377)
Category 2	18%	(131)
Category 3	31%	(226)
Dominant side injured	50%	(363)
High energy injury	16%	(119)
Neurovascular compromise	5%	(38)
Open injury	2%	(13)
Surgery	16%	(118)
Complication	25%	(182)
Prior fracture to dominant arm	19%	(137)
Prior fracture to non-dominant arm	11%	(79)
Opioid use	34%	(252)
Anti-depressant use	24%	(174)

Continuous variables as mean + standard deviation (range)
Discrete variables as percentage (number)

Ω Broad Injury Classification Categories by Region

Broad Classification	Proximal Humerus Fracture	Elbow Fracture	Distal Radius Fracture
Category 1	Greater tuberosity	Radial head/neck	AO Type A
Category 2	2-part	Extra-articular	AO Type B
Category 3	> 2-part	Intr-articular	AO Type C

Table 44. Health-related Outcome and Performance Based Measures

Variables	Value t=0		Value t=1		Value t=2	
Health-related outcomes	**Mean (SD)**	**Range**	**Mean (SD)**	**Range**	**Mean**	**Range**
PROMIS UE PF	24.2 ± 6.2	(14.7 – 56.4)	29.2 ± 5.9	(15.6 – 45.7)	43.2 ± 10.7	(19.5 - 56.4)
QuickDASH	70.2 ± 12.1	36.4 – 93.2	63.3 ± 18.5	15.9 – 90.9	24.5 ± 24.5	(0 - 88.6)
Satisfaction clinical	8.2 ± 1.6	(1 – 10)	8.2 ± 1.7	(1 – 10)	8.4 ± 2.0	(0 - 10)
Satisfaction overall	7.4 ± 2.0	(1 – 10)	7.5 ± 2.1	(0 – 10)	8 ± 2.4	(0 - 10)
PROMIS PI	67.1 ± 6.6	(36.3 - 78.9)	63.7 ± 8.3	(0 – 74.1)	49.6 ± 10.9	(34.8 – 74.1)
PROMIS Depression	52.0 ± 10.5	(34.2 - 76.4)	48.3 ± 11.0	(34.2 – 76.3)	43.1 ± 10.6	(34.2 – 68)
PROMIS Anxiety	51.8 ± 10.5	(32.9 - 78.4)	46.8 ± 11.9	(32.9 – 74.4)	43.1 ± 12	(32.7 – 67.2)
PROMIS ES	n/m	n/m	54.7 ± 9.3	31.5 - 66.9	52.4 ± 10.1	(31.5 – 66.2)
PROMIS IS	n/m	n/m	54.8 ± 7.4	35.1 - 66.1	54.2 ± 8.3	(0 – 66.2)
PCS	19.6 ± 6.7	(0 - 48)	17.2 ± 6.8	(13 – 32)	16.6 ± 6.2	(12 – 39)
PSEQ-2	9.0 ± 2.8	(0 - 12)	8.3 ± 3.1	(1 -12)	9.8 ± 2.0	(2 – 12)
TSK-11	26.7 ± 7.1	(12 - 43)	20.2 ± 6.7	(11 – 40)	17 ± 5.1	(11 – 39)
PAM-13	n/m	n/m	68.6 ± 13.3	(22.6 - 83.9)	n/m	n/m
ECS-17	n/m	n/m	76.8 ± 18.8	(4.4 - 100)	n/m	n/m
Performance-based outcomes	**Mean (SD)**	**Range**	**Mean (SD)**	**Range**	**Mean**	**Range**
Grip strength (% of non-injured side)	n/a	n/a	33.8 ± 19.4	5.9 - 77.8	n/a	n/a

Table 45. Bivariate Analysis at t=0

	QuickDASH		PROMIS UE PF		Satisfaction (Clinical-Level)		Satisfaction (Service-Level)	
	Value	**p value**	**Value**	**p value**	**Value**	**p value**	**Value**	**p value**
Age	0.2161	**0.0000**	-0.3528	**0.0000**	0.0002	0.9949	-0.0014	0.9702
Sex								
Women	28 ± 24.5	**0.0000**	41.2 ± 10.1	**0.0000**	8.3 ± 2	**0.0810**	7.8 ± 2.4	**0.0209**
Men	17 ± 22.7		47.6 ± 10.5		8.6 ± 2.1		8.3 ± 2.3	
Charlson Comorbidity Index	0.2549	**0.0000**	-0.3550	**0.0000**	-0.0483	0.1922	-0.0402	0.2775
Marital status								
Single	27.8 ± 27.8	**0.0000**	43.9 ± 11.9	**0.0000**	7.9 ± 2.4	**0.0000**	7.3 ± 2.7	**0.0000**
Partner / Married	15.9 ± 18.3		46.2 ± 9.4		9 ± 1.6		8.6 ± 1.9	
Separated / Divorced / Widowed	37.2 ± 25.1		37.2 ± 9.2		7.9 ± 2.2		7.4 ± 2.6	
Social support status								
Alone	52.7 ± 23.8	**0.0000**	33.1 ± 8.6	**0.0000**	6.4 ± 2.3	**0.0000**	5.5 ± 2.4	**0.0000**
Partner / Friend(s) / Family	16.3 ± 18		46.1 ± 9.4		9 ± 1.6		8.6 ± 1.9	
Full / Part-time care	22.9 ± 21.2		44.3 ± 10.4		8.9 ± 1.8		8.7 ± 2	
Education	-0.1166	**0.0016**	0.2067	**0.0000**	0.0100	0.7872	-0.0095	0.7976
Work status								
Working	11.9 ± 17	**0.0000**	49.6 ± 8.7	**0.0000**	9 ± 1.5	**0.0000**	8.8 ± 1.8	**0.0000**
Homemaker	29.2 ± 23.3		39.5 ± 9.1		8.4 ± 1.9		8 ± 2.2	
Retired	54.9 ± 20.1		32.3 ± 7.6		6.1 ± 2.2		4.6 ± 1.9	
Unemployed / Workers comp / Litigation	58.4 ± 16		33 ± 7.3		5.7 ± 2.6		4.4 ± 2	

IMD Factor	-0.0995	**0.0073**	0.0624	**0.0929**	0.1450	**0.0001**	0.1323	**0.0004**
Fracture Location								
Proximal humerus	31.9 ± 25		40.5 ± 9.9		7.9 ± 2.6		7.6 + 2.8	
Elbow	20.2 ± 21.7	**0.0000**	46.5 ± 10.1	**0.0000**	8.5 ± 2.2	**0.0001**	8.1 + 2.6	**0.0676**
Distal radius	23.2 ± 24.8		32.9 ± 10.9		8.7 ± 1.5		8.1 + 2	
Broad Injury Classification Ω								
Category 1	22.1 + 23.9		44.2 ± 10.8		8.6 ± 1.9		8.2 ± 2.3	
Category 2	22.5 + 24	**0.0185**	42.6 ± 10.2	**0.0273**	8.4 ± 2.2	**0.0630**	8 ± 2.5	**0.0449**
Category 3	27.8 + 25.3		41.9 ± 10.6		8.2 ± 2.1		7.7 ± 2.4	
Dominant side injured								
Yes	25.4 ± 25.5	0.3019	43 ± 11	0.5505	8.3 ± 2.2	0.1520	7.9 ± 2.5	0.2085
No	23.6 ± 23.4		43.5 ± 10.3		8.5 ± 1.9		8.1 ± 2.2	
High energy injury								
Yes	37.5 ± 28.2	**0.0000**	39.6 ± 12.1	**0.0001**	7 ± 2.5	**0.0000**	6.3 ± 2.6	**0.0000**
No	22 ± 22.9		43.9 ± 10.2		8.7 ± 1.8		8.3 ± 2.2	
Neurovascular compromise								
Yes	39.2 ± 29.2		37 ± 10.9		7.2 ± 2.2		6.1 ± 2.4	
No	23.7 ± 23.9	**0.0001**	43.6 ± 10.6	**0.0002**	8.5 ± 2	**0.0001**	8.1 ± 2.3	**0.0000**
Open injury								
Yes	20.8 ± 23.9		44.9 ± 10.6		8.6 ± 1.7		7.9 ± 3	
No	24.6 ± 24.5	0.5834	43.2 ± 10.7	0.5753	8.4 ± 2	0.7384	8 ± 2.4	0.9248

Surgery								
Yes	24.5 ± 24.5	**0.0629**	41.9 ± 10.6	0.1347	8.1 ± 2	**0.0931**	7.4 ± 2.5	**0.0073**
No	23.8 ± 24.1		43.5 ± 10.7		8.5 ± 2		8.1 ± 2.3	
Complication								
Yes	48 ± 25.6	**0.0000**	34.8 ± 9.6	**0.0000**	6.7 ± 2.4	**<0.0001**	5.8 ± 2.5	**0.0000**
No	16.7 ± 18.4		46 ± 9.5		9 ± 1.5		8.7 ± 1.9	
Prior dominant side fracture								
Yes	28 ± 26.9	**0.0640**	42.3 ± 11	0.2690	8.1 ± 2.3	**0.0307**	7.8 ± 2.5	0.2188
No	23.7 ± 23.8		43.4 ± 10.6		8.5 ± 2		8 ± 2.3	
Prior non-dominant side fracture								
Yes	29.3 ± 25.9	**0.0621**	41.1 ± 10.7	**0.0667**	7.9 ± 2.2	**0.0237**	7.3 ± 2.6	**0.0052**
No	23.9 ± 24.2		43.5 ± 10.6		8.5 ± 2		8 ± 2.3	
Opioid use								
Yes	45.9 ± 25.9	**0.0000**	35.4 ± 9.8	**0.0000**	6.6 ± 2.3	**0.0000**	5.7 ± 2.4	**0.0000**
No	13.3 ± 14.1		47.3 ± 8.7		9.4 ± 1		9.2 ± 1.3	
Anti-depressant use								
Yes	58.2 ± 18.4	**0.0000**	31.7 ± 7.5	**0.0000**	5.9 ± 2.2	**0.0000**	4.8 ± 2	**0.0000**
No	14 ± 14.7		46.8 ± 8.8		9.2 ± 1.2		9 ± 1.5	

Performance-based outcomes at t=0	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
Grip strength (% of non-injured side)	-0.1204	**0.0013**	0.2175	**0.0000**	0.0489	0.1919	0.0995	**0.0078**
Health-related outcomes at t=0 or t=1	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**	**Coefficient**	**p value**
PROMIS Pain Interference	0.3623	**<0.001**	-0.4071	**<0.001**	-0.2763	**<0.001**	-0.2986	**<0.001**
PROMIS Depression	0.4603	**<0.001**	-0.4081	**<0.001**	-0.3990	**<0.001**	-0.4595	**<0.001**
PROMIS Anxiety	0.4203	**<0.001**	-0.3480	**<0.001**	-0.4487	**<0.001**	-0.5120	**<0.001**
PROMIS Emotional Support	-0.7464	**<0.001**	0.6361	**<0.001**	0.6460	**<0.001**	0.6962	**<0.001**
PROMIS Instrumental Support	-0.7102	**<0.001**	0.5697	**<0.001**	0.6292	**<0.001**	0.6937	**<0.001**
PCS	0.5334	**<0.001**	-0.5297	**<0.001**	-0.4432	**<0.001**	-0.5232	**<0.001**
PSEQ-2	-0.5838	**<0.001**	0.4507	**<0.001**	0.4926	**<0.001**	0.5655	**<0.001**
TSK-11	0.5621	**<0.001**	-0.5020	**<0.001**	-0.4680	**<0.001**	-0.5190	**<0.001**
PAM-13	-0.6459	**<0.001**	0.5452	**<0.001**	0.5266	**<0.001**	0.5501	**<0.001**
ECS-17	-0.6747	**<0.001**	0.5968	**<0.001**	0.5685	**<0.001**	0.5764	**<0.001**

Pearson correlation indicated by r; **bold** indicates statistically significant difference; continuous variables as mean (±standard deviation).

Table 46. Factor Analysis

	QuickDASH				PROMIS UE PF				Satisfaction (Clinical-Level)				Satisfaction (Service-level)			
Variables	**Factor 1**	**Factor 2**	**Factor 3**	**Factor 4**	**Factor 1**	**Factor 2**	**Factor 3**	**Factor 4**	**Factor 1**	**Factor 2**	**Factor 3**	**Factor 4**	**Factor 1**	**Factor 2**	**Factor 3**	**Factor 4**
Age		0.9291				0.9283										
Female		0.4269				0.4277				-0.3716						0.4219
CACI		0.4269				0.9334										
Marital status																
Single																
Partner/Married				0.7443				0.7519	-0.3252	0.4844					0.7197	
Separated/Divorced/ Widowed		0.5137		-0.5159		0.5093		-0.5269							-0.5148	0.5064
Social support																
Alone																
Partner/Friend(s)/Family	-0.4086			0.7308	-0.4199			0.7198	-0.5029	0.3772	0.4476		-0.4046		0.7471	
Full/Part-time care				-0.5227				-0.5289		-0.3512	-0.4408				-0.534	
Education (years)		-0.519				-0.5209										
Work status																
Working / Homemaker																
Retired		0.8423				0.8419				-0.6662						0.7493
Unemployed	0.3815				0.3791				0.419				0.389			-0.3123
Workers comp/Litigation	0.3066				0.316				0.3179				0.3001			
IMD factor																
Fracture location																
Proximal Humerus																
Elbow			-0.668				-0.6674				-0.6834			-0.6801		
Distal Radius			0.937				0.9341				0.6334			0.935		

Broad Injury Classification															
Category 1															
Category 2															
Category 3												0.4741			
Dominant side injured															
High energy injury	0.3089	-0.3256			0.3232	-0.3285			0.3416				0.3105		-0.3474
Neurovascular compromise												0.3047			
Open injury															
Surgery												0.3321			
Complication	0.5605				0.5987				0.6022			0.3064	0.5589		
Prior fracture dominant arm															
Prior fracture non-dominant arm															
Opioid use	0.6997				0.7168				0.7197						
Anti-depressant use	0.7661				0.7913				0.7943				0.7632		
Grip strength (% non-injured side)			-0.9186				-0.9154							-0.9279	
PROMIS PI	0.431				0.4058				0.4158		0.3638		0.4383		
PROMIS Depression	0.6676				0.6449				0.6363				0.6723		
PROMIS Anxiety	0.6876				0.6616				0.6537				0.6883		
PROMIS ES	-0.7531				-0.771				-0.7891				-0.75		
PROMIS IS	-0.7474				-0.7637				-0.785				-0.7446		
PCS	0.7563				0.7212				0.7276				0.7626		
PSEQ-2	-0.7272				-0.7116				-0.7122				-0.7301		
TSK-11	0.6855				0.6625				0.6719				0.6904		
PAM	-0.6099	-0.3577			-0.6315	-0.3583			-0.6027	0.391			-0.6082		-0.3973
ECS	-0.6251	-0.3939			-0.6443	-0.3949			-0.6287	0.4423			-0.6264		-0.4227

Pearson correlation indicated by r; **bold** indicates statistically significant difference; continuous variables as mean (±standard deviation)
Variables p<0.10 in bivariate analysis with 0.30 or more loading.

Table 47. Multivariable Analysis of Predictive factors at t=0 associated with dependent variables

Variables	Regression coefficient	(95% confidence interval)		Standard error	p value	Semi-Partial R^2	Adjusted R^2
QuickDASH							
Factor 1	19.84	18.87	20.81	0.49	0.00	0.632	
Factor 2	4.74	3.78	5.71	0.49	0.00	0.037	0.72
Factor 3	-0.15	-1.12	0.82	0.49	0.76	0.000	
Factor 4	-5.32	-6.36	-4.28	0.53	0.00	0.040	
PROMIS UE PF							
Factor 1	-7.38	-7.90	-0.69	0.27	0.00	0.454	
Factor 2	-3.47	-3.99	-2.96	0.26	0.00	0.102	0.59
Factor 3	-0.11	-1.58	-0.53	0.27	0.00	0.009	
Factor 4	1.38	0.82	1.94	0.28	0.00	0.014	
NRS Satisfaction (Clinical Care)							
Factor 1	-1.57	-1.67	-0.15	0.05	0.00	0.562	
Factor 2	0.06	-0.04	0.17	0.05	0.25	0.001	0.59
Factor 3	0.20	0.09	0.31	0.05	0.00	0.008	
Factor 4	-0.33	-0.45	-0.21	0.06	0.00	0.018	
NRS Satisfaction (Health Service)							
Factor 1	-1.96	-2.07	-1.85	0.05	0.00	0.641	
Factor 2	-0.02	-0.12	0.09	0.05	0.78	0.000	0.66
Factor 3	0.29	0.18	0.41	0.06	0.00	0.012	
Factor 4	0.15	0.03	0.26	0.06	0.01	0.003	

Only the partial R^2 of significant values is displayed. **Bold** indicates statistical significance, $P < 0.05$.

8.4 Discussion

Greater patient engagement measured using the PAM-13 and ECS-17 was associated with less arm-specific disability (PROMIS UE PF and QuickDASH) following upper extremity fractures. Similarly, patient engagement also appeared to be associated with greater satisfaction with clinical care and experience of health services. Whilst this was intuitive and expected, to the best knowledge, it has not been previously demonstrated in the context of upper extremity fractures.

What was more interesting was the factor loading characteristics of patient engagement with psychosocial factors (Factor 1), and to a lesser extent, patient socio-demographic factors (Factor 2). Psychosocial factors, such as less pain catastrophizing and greater pain self-efficacy, emotional support and instrumental support, appeared to be the dominant predictors of positive health-related and experiential outcomes after these injuries. This was consistent with prior studies where coping strategies, represented by pain self-efficacy, pain catastrophizing and pain interference were shown to be the most dominant predictors of disability over other psychosocial, patient and injury-related factors (115)(364). Most of these investigations were performed in patients with non-traumatic conditions of the upper extremity.

Whilst psychosocial factors and patient engagement were dominant predictors of disability and patient experience, it was somewhat more difficult to differentiate between the other factor sets and differentiate between variables within each factor set based on loading values. This was also complicated by a degree of overlap in variables between the four factor sets. Nevertheless, if minimising patient limitations and optimizing patient experience are considered basic principles of patient-centered care, enhancing patient activation i.e. the knowledge, skills and confidence to manage health *and* bolstering coping strategies may be the best means of achieving these goals. Translating this into clinical practice requires some careful clinical, technical and practical considerations. This may be made more challenging in special situations where patients have a potentially reduced capacity to engage e.g. individuals with lower levels of education, delirium, dementia and diminished senses such as hearing or visual loss.

Further studies are required to assess the influential factors of patient activation. In elective lumbar spine surgery, psychometric evaluation of the PAM-13 demonstrates the positive correlation of activation with optimism, hope and self-efficacy (367). Other factors associated with patient activation include the extent of patient education, level of patient expectations and how well these expectations are met. Greater pre-operative expectations of surgery predict greater improvement in PROs, greater satisfaction and fulfilment of expectations in THR and TKR surgery (225)(368). The importance of clear communication and trust between professionals and patients in this interaction is well recognised (217).

Similar findings between the level of pre-operative expectations and post-operative satisfaction are observed following rotator cuff and carpal tunnel surgery (224)(369)(370). There does not appear to be any evidence in the peer-reviewed literature assessing this relationship in trauma surgery. Interestingly, pre-operative met expectations but not overall level of expectation, correlated with post-operative satisfaction in a study involving different types of hand surgery (369). Psychosocial factors appear to mediate these interactions with higher pre-visit expectations and low to moderate met expectations associated with greater symptoms of depression and lower pain self-efficacy (369). Most of the variance in post-operative satisfaction remains unexplained in many of these studies.

Activating patients to improve health-related outcomes may also drive the process of shared decision-making. This concept combines the expertise, evidence-based best practices, and preferences of both patients and surgeons in making decisions about a patient's health (371)(372). In prostate cancer management the synergy between patient activation and physician education is reflected by significant improvements in levels of diagnostic screening and ratings for shared-decision-making (373).

Notably, psychological factors are also shown to be the strongest determinants of informed shared decision-making, alongside patient satisfaction and upper extremity disability in a study involving non-traumatic upper extremity conditions (213). Health anxiety was shown to be a strong predictor of patient satisfaction and ratings of shared decision-making, whilst depression and catastrophizing predicted disability (213). A study involving a non-specific range of fractures showed depression appeared to correlate less with patient satisfaction and more with patient activation (374). Hageman et al., demonstrate patients with trauma conditions have the same preferences as those with non-traumatic conditions and are just as capable of participating in decision-making (371). These findings are particularly relevant in the context of post-traumatic recovery where early engagement of patients may improve adherence to physical therapy and mobilization. This relationship has been demonstrated in elective spinal surgery and requires further investigation in upper extremity populations, including those experiencing trauma (367).

8.4.1 Limitations

The findings of this study must be considered in light of some limitations. Firstly, despite the wide range of patient demographics, the generalisability of this study may be challenged as it was performed at a single institution. Although there was a wide range in indices of deprivation reflecting a varied social background, the metric may not adequately reflect level of literacy and aptitude for gaining knowledge and displaying skills. A variety of factors may have influenced the extent to which patients related to their health conditions and engaged with their health services. This may not have been entirely captured by the outcome measures in this study. For instance, education level may not fully reflect the aptitude to understand, assimilate and act on information to adopt positive health behaviors. Quantifying these factors may require more novel PRO measurement. Second, from the perspective of injury classification, the system used to categorise fractures in three different regions may not have accurately represented injury severity as broad fracture configurations in one region were compared to AO classifications in another. In spite of this, injury classifications loaded onto a separate factor. Third, a variety of

clinical factors e.g. change in management plans, clinician-patient interactions, and service-level factors e.g. delays or cancellations to treatment, could have potentially influenced both health-related and experiential outcomes. It was challenging to quantify these factors. Fourth, due to logistical issues, patients completed the PAM-13 and ECS-17 at t=1, and outcome measures at t=2 via telephone, online or in person. Each mode of assessment is prone to varying levels of procedural, measurement, interviewer and responder bias. Interference from friends and family members in completing outcomes measures may have also introduced some bias, however, the rate of proxy responses was low overall. Fifth, this study aimed to assess activation, limitations and experience without burdening patients. Abbreviated fixed scales (e.g. PAM-13 versus PAM-22) and CATs were incorporated with this in mind. However, some may have still found the process laborious, especially if similar sounding items were administered in quick succession. The ECS-17 and PAM-13 for instance, assess similar health-related concepts, such as knowledge, responsibility, confidence, control, adaptation and interactions in relation to their health care, but deliver these in different ways. Full randomization of all questions may have minimised this but added significant complexity to programming. Further formal psychometric evaluation of PAM-13 and ECS-17, including reliability statistics and factor analysis, may be required for fully validating these measures in this population. Finally, although ordinal scales such as those used to assess satisfaction are commonly used, more sophisticated methods of capturing experience are available. Most of these are targeted at patients in stable situations, however, a recently validated measure of experience targets patient and family perspectives on quality and performance of injury care in the acute setting known as the QTAC-PREM (246)(247).

8.4.2 Conclusion

Individuals who are more engaged with their health and the health care systems that surround them may be associated with better health-related and experiential outcomes following fractures to the upper extremity. Thus, actively engaging patients early in the recovery pathway following an upper extremity fracture may not only minimize their future perception of limitations, but lead to improved perceptions of their clinical care and trauma service experiences. However, it is important to account for psychosocial factors, such as self-efficacy, which may supersede patient engagement in predicting these longer term outcomes. In practical terms, a combined approach in improving the knowledge, skills and confidence in dealing with an upper extremity fracture and providing specific coping strategies may be required to achieve a substantial improvement in patient focused outcomes. Further research is required to identify those patients in most need of these interventions in parallel with field testing of these strategies. To the best knowledge, this is the first time the relationship between patient limitations, patient experience and patient engagement has been studied in the context of upper extremity fractures (1)(67)(230)(252). Musculoskeletal HCPs should consider integration of approaches to enhance activation and optimize coping in daily orthopaedic practice.

Chapter 9

9 Final Conclusion

Understanding the impact of health conditions from the patient's perspective requires both a definition of disability and the outcome measures used to assess it. In a practical sense, this represents knowing what to measure and how best to achieve this in the population of interest (15)(375). This thesis aims to investigate both these aspects in patients experiencing fractures of the proximal humerus, elbow and distal radius.

The overarching goal was to identify the influential factors predictive of future disability following these injuries using a range of PRO measures. This thesis also aimed to establish a more complete overview of patient perspectives by defining the relationship between disability, patient experience and patient activation. The collective findings were targeted at advancing patient-centered management and improving longer term outcomes in these challenging populations.

The following section is a summary of each chapter including the objectives and key findings from experimental studies. This summary is then combined with recommendations from global initiatives, the current evidence base and expert opinion in the field to form the final section of this thesis, entitled 'Future Research: Advancing Musculoskeletal Health care through Patient Outcomes'. This provides an overview of the language of disability and future research opportunities in musculoskeletal care before providing a closing synopsis of the combined work.

9.1 Chapter Summary

Chapter 1 established a background to this work and set some key foundations to support the research objectives. It highlighted the growing impact of musculoskeletal conditions in general on global health and the substantial burden posed by upper extremity extremity fractures. The multi-dimensional nature of disability is recognised and the WHO ICF established as a global standard and framework on which to construct experimental activity and inform scientific discussion. This model provides a clear definition and welcome taxonomy in a field where terminology is often used interchangeably and not infrequently misunderstood. An overview of outcome measurement in orthopaedics is also detailed, including a description of fixed scale and computer adaptive PRO measures and their measurement properties. Early work highlighting the dominant influence of psychosocial factors on disability is described.

Chapter 2 (Systematic Review I) highlighted the psychosocial factors that have a predominant influence on disability over impairment following upper extremity conditions. Identified studies were mostly cross-sectional and observational, involving heterogeneous cohorts with few performed on specific fracture populations. Furthermore, although psychological factors accounted for a substantial proportion of the variation in disability, much of the variance remained unexplained. The need for longitudinal investigations assessing the influential factors predictive of longer-term disability in upper extremity fracture populations was identified. Chapter 2 (Systematic Review II) demonstrated the lack of PRO measures specifically designed for upper extremity trauma and the variable quality of studies incorporating orthopaedic trauma populations in their original development. Outcome measures popularly utilized in orthopaedic upper extremity trauma are considered 'fit for purpose' i.e. there is a general acceptance that the substantive components of arm-specific disability in these patients are being captured by these instruments. Nevertheless, it is recommended that such outcome measures should be put to the test in specific fractures over the course of recovery to comprehensively validate their use in these populations over time.

Chapter 2 (Systematic Review III) compared the psychometric properties of CATs with fixed length scales in upper extremity trauma. The NIH PROMIS was the most commonly utilised set of CATs and shown to be valid and reliable in many orthopaedic conditions. CATs performed as well, if not better than validated fixed scales, especially in terms of acceptability (i.e. administration time) and precision (i.e. floor-ceiling effects). The review identified the requirement for longitudinal studies involving CATs in orthopaedic trauma populations outside the U.S.

Chapter 3 was performed as a pilot study to establish a methodology for performing the experimental work in this thesis. It also provided technical experience in programming a web-based, computerized PRO measurement platform and assessed the feasibility of applying this in an upper extremity fracture population at a UK trauma centre. The study showed PROMIS PF, a generic computer adaptive measure of physical function, correlated with QuickDASH, a region-specific fixed scale, a finding that could be explained by the dominant influence of psychosocial factors on both these instruments.

Chapter 4 demonstrated the strong correlation between different PRO measures of disability in the main upper extremity fracture cohort in this thesis. The strength of these correlations increased over time suggesting the possibility of change in the discriminatory potential of region-specific versus generic measures at different stages of recovery. Factor analysis demonstrated the common underlying constructs measured by these instruments. Floor-ceiling effects supported region-specific measures and measures of physical function over those of general health and joint-specific disability. The correlation between greater disability and poor patient experience was also demonstrated and shown to strengthen over time, supporting a combined approach to minimizing future limitations through optimizing patient experience in trauma care. Based on these findings, region-specific CATs (e.g. PROMIS UE PF) may be the instruments of choice in measuring disability following upper extremity fractures. Further psychometric evaluation involving these measures are required outside the U.S, accounting for potential clinical, cultural and technological issues, prior to their universal adoption.

Chapters 5, 6 and 7 targeted the primary objective of this thesis, namely to identify the influential factors predictive of disability following shoulder, elbow and wrist fractures. Chapter 5 demonstrated longer-term disability following proximal humerus fractures is strongly predicted by kinesiophobia (i.e. fear of movement or re-injury) within the first 2 weeks after injury, and self-efficacy (i.e. coping ability) within the first 4-6 weeks. Complications, social factors, anti-depressant and opioid use were also prognostic indicators of poor health-related outcomes. Chapter 6 showed similar findings with disability following elbow fractures being strongly predicted by kinesiophobia within the first 2 weeks post-injury, and self-efficacy and instrumental support (i.e. perceived availability of support from others in fulfilling specific functions) within the first 4-6 weeks post-injury. Chapter 7 demonstrated disability following distal radius fractures is strongly predicted by self-efficacy within the first 4-6 weeks of injury. Social factors, complications, use of anti-depressants and opioids were also prognostic indicators of poor health-related outcomes (265). The dominance of various psychological factors during the early phases of recovery in predicting disability following shoulder, elbow and wrist fractures necessitates their consideration in future patient-centered management strategies. A further consideration is the requirement for social support, especially that which is pragmatic in nature, during the early phases of a painful upper extremity fracture.

Chapter 8 targeted the secondary goal of this thesis, and demonstrated that patients who were more engaged with their health and health care systems achieved better health-related and experiential outcomes following fractures to the upper extremity. However, psychosocial factors appeared to supersede patient engagement in predicting medium-term disability and satisfaction. Translating this into clinical practice, initiatives that actively improve patient activation early in the recovery pathway following an upper extremity fracture may not only minimize their future perception of limitations, but lead to improved experience of clinical care and trauma services. A combined approach to improving knowledge, skills and coping strategies may enable patients to adapt and generate resilience in dealing with upper extremity fractures.

9.2 Future Research: Advancing Musculoskeletal Health care through Patient Outcomes

9.2.1 Toward a Common Language of Disability

Defining disability is integral to patient-centered care (i.e. care responsive to the preferences, needs and values of individuals) and population health (i.e. health outcomes and distribution of these outcomes amongst groups of individuals) (376). Establishing a common language in this field is challenging as the concept of disability continues to evolve and assumes different forms based on the context in which it is utilized (23).

Disability and related concepts have been defined by a variety of models including the Disablement Model developed by Nagi (377), the International Classification of Impairments, Disabilities and Handicaps (378), and the most recent version, the WHO ICF (19)(379). Despite differences in terminology, each model incorporates a biopsychosocial view of health and represents disability as a series of inter-related concepts describing health impact at the level of an individual's daily physical tasks, broader acts and wider participation in society (17)(23)(19).

Nagi defines disability as the 'limitations faced by individuals in performing socially defined roles and tasks within their physical environment and spheres of life' (377). The WHO ICF, on which this thesis is focused, builds on these previous models and classifies disability as 'a multi-dimensional construct involving a dynamic interaction between impairment, activity limitations and participation restrictions that are influenced by contextual factors'. Based on its systematic development through a global consensus-building process, involvement of patients and professional stakeholders, and the organization's vast experience in creating internationally accepted classifications, it may form the best guide to date for inter-disciplinary communication and advancing research in this field. As a reflection, the WHO ICF is well-endorsed by health experts and both national and international organizations such as the World Health Assembly (2001) and US Institute of Medicine (2007) (7)(19)(212).

Disability, from the perspective of legislation around equality and social security is defined in the UK and U.S as 'the physical or mental impairment(s) that have a substantial or long-term negative impact on normal or major functions and activities of daily life and work' (380)(381). At first glance, there appear to be similarities with health-related definitions, however on closer inspection there are noteworthy differences in terminology (23). Disability is the subjective impact of health from the patient's perspective whilst impairment represents objective pathophysiology and decrements to body functions and structures (19)(71)(370). According to the WHO ICF and based on current evidence, impairment forms but one component of a broader picture of disability, which also encompasses restrictions, limitations and contextual factors. Despite this, both the term and concept of are well-embedded in social policy, legislation and even clinical practice (382)(381). Given the strong influence of psychosocial factors on disability over impairment, it may be more relevant to consider aspects of mindset and circumstance than focus on pathophysiology alone (380)(383)(384)(385).

A broader consideration relates to the perception of 'disability' itself, a term many still regard as synonymous with inability and negative connotations of poor access to services, mobility restrictions and societal discrimination. This perception may be shifting with groups and institutions promoting disability as a force for empowering individuals with a positive identity and bringing them together with others facing similar challenges (17)(386). In this regard, considering disability as the 'limitations' faced by an individual in achieving activities of life may offer softer language that promotes more widespread acceptance.

Taking all this into consideration, it may be some time before we achieve a language for disability that is universally accepted across disciplines. Till then, high quality patient outcomes research is likely to remain the best way of understanding disability and advancing this field.

To this end, global initiatives and academic bodies have undertaken extensive consensus-building work around patient outcomes, including the 2017 Montreal Accord, 2015 Guidelines International Network for PRO Measures, 2011 Good Practice Guidelines for PRO Measurement by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the joint Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT)/Outcome Measures in Rheumatology (OMERACT) (21)(33). Governmental organizations such as the U.S. FDA and European Medicines Agency have developed stringent regulations around the commercial use of PRO measures (34), and groups such as the Core Outcome Measures in Effectiveness Trials (COMET) and the International Consortium for Health Outcomes Measurement (ICHOM) have made substantial advances in standardizing outcome measurement sets in a variety of health conditions (387)(388)(389)(390).

9.2 Future opportunities in patient outcomes research

Patient outcomes research is central to advancing modern health care and is reflected by the growing number of research mandates for involving patient champions in the development of clinical trials (39). Further research can be organized into a) disability, PRO measures and the WHO ICF, and b) advancing acute musculoskeletal care through non-surgical interventions (216).

9.2.1 Disability, PRO measures and the WHO ICF framework

The WHO ICF provides a strong conceptual and pragmatic framework for approaching disability and patient outcomes research. A principle characteristic of this model is the consideration of disability on a dynamic continuum rather than a binary entity differentiating individuals from being healthy or disabled. For example, kinesiophobia should be considered a normal aspect of human illness behavior and not something some patients experience and others not (127). Thus, the response to health conditions, including upper extremity fractures, may extend from the maladaptive end of the spectrum, to normal protective and modifiable

responses, toward adaptation and resilience (128)(391). PRO measures provide a means of coding these responses and positioning patients on the continuum.

Based on current evidence, self-reported psychosocial measures appear to be the strongest predictors of disability in both non-traumatic and traumatic upper extremity conditions over measures of objective pathophysiology (70)(76)(116)(292)(370). Dominant factors that predict arm-specific disability following upper extremity fractures include self-efficacy, kinesiophobia and instrumental support. Further translational work is required prior to implementing these into clinical practice. For instance, physiotherapists and occupational therapists devote a substantial amount of time working with patients and dealing with constructs such as fear of movement and building confidence and coping ability (392). These professions may be well placed to actively monitor disability along the recovery trajectory. Greater investment has been recommended in developing allied HCP resources, capabilities and involvement in disability research (392).

The WHO ICF framework should also be considered in light of its limitations, which may in fact provide some further research opportunities (20)(6). Investigators have questioned the ability to differentiate between 'activities' and 'participation' and whether these components are truly distinct (23). The WHO also actively encourages investigation of the broad range of qualifiers within 'environmental' and 'personal' subdomains of 'contextual factors' in relation to specific health conditions (26). In this thesis, the use of the PAM-13, ECS-17 and NRS satisfaction with clinical care and health services aimed to represent some elements of the contextual factors domain and environmental and personal subdomains. Qualitative research, mapping exercises and use of more sophisticated experience measures could more accurately identify environmental qualifiers relevant to upper extremity fracture patients (393).

In terms of the 'personal' component, the experimental studies in this thesis incorporate some basic demographics, social profiles e.g. marital, social support and work status, and psychological assets e.g. self-efficacy. More detailed investigation may be required e.g. the role of marriage and marital satisfaction, the size, quality and components of social networks, the impact of voluntary, part-time or flexible working, and activity limitations, absenteeism and productivity in the workplace (394)(395).

Psychological assets including coping styles and behavioural patterns are evidently important qualifiers within this subdomain. This thesis identified self-efficacy i.e. coping strategies, despite a painful shoulder, elbow or wrist fracture as a dominant predictor of disability. Further research could delineate how coping ability relates to human personality within these populations. One approach to studying the complex field of personality psychology involves understanding trait theory, where traits are defined as habitual patterns of behaviours, thoughts and emotions (396). Traits may be stable over time, differ across individuals and influence behavior (396). Identifying the influential and predictive factors of disability, accounting for patient personality traits and profiles may provide a further way of delivering targeted patient-centered care that improves outcomes at the individual level.

This thesis also demonstrates the strong association between patient activation and psychosocial factors, as well as the strong correlation between patient activation, disability and satisfaction in Chapters 4 and Chapter 8. Other psychological aspects related to coping styles and illness behavior investigated in upper extremity conditions include sense of coherence (using SOC-13) (60)(397), cognitive flexibility (using the CFS) (59)(398)(399) and positive psychosocial illness impact (using PROMIS PIIP CAT v1.0) (96).

Sense of coherence is defined as a 'sense of optimism, control, confidence and feeling that things will work out as well as can be expected following an illness' (400)(60)(401). Cognitive flexibility

is defined as the 'ability to restructure one's knowledge, incorporate new facts, widen perspectives, and adapt to the demands of new and unexpected conditions' (59)(398). Positive psychosocial illness impact is the 'perception and focus on the positive side of being confronted with an illness e.g. improving relationships, finding benefits, appreciating life' (96). There are clearly some common themes amongst these concepts which may all influence disability to varying extents. The attributes underlying most if not all these concepts could be adaptation and resilience (399).

Adaptation is defined as 'a process of social cognition during which one becomes aware of options, adopts some flexibility and experiences greater self-efficacy' (399). Those unable to adapt and demonstrate resilience in the face of injury may firmly hold onto their intuitions and negative ideations despite specialist advice, leading to greater disability and slower recovery (59)(402)(68). Psychological interventions targeted at modulating thought processes (e.g. intuitive versus analytical thought) and assimilating information could enhance adaptive capabilities and lead to more successful navigation through the recovery process.

Further investigations should delineate the focus placed on enhancing coping strategies in response to pain versus building confidence, flexibility and enabling patients to view their injury through an adaptive and resilient lens. Convincing fracture patients to work safely through pain and engage in potentially painful activities can be challenging. Generating an environment that promotes both positive communication, engagement and confidence alongside the development of coping strategies may form the basis of limiting fracture-related disability in future.

The 'personal' factors subdomain of the WHO ICF framework appears to contain the most influential factors of disability and aspects that matter most to patients following upper extremity fractures. This was reflected within the core experiment of this thesis by patients expressing their deepest concerns around reliance on social support, fear of isolation, coping with injury, loss of

income and not being able to care for others. Paradoxically, it is also this subdomain within the WHO ICF that is the least well understood. Further studies accounting for contextual factors in certain patient subgroups e.g. older patients with fragility fractures living alone, are required.

In terms of PRO measurement, ongoing evaluation of CATs is required, including further item development and cultural translation e.g. changing 'yard work' (US) to 'gardening' (UK) in PROMIS PF. These may become the PRO measures of choice in an increasingly data-driven health environment, demanding more precise and efficient outcome measurement.

Finally, further large scale longitudinal data is required to evaluate the recovery trajectory of health domains and perform more sophisticated analysis e.g. second-generation multivariate methods such as structural equation modelling (SEM) can simultaneously assess a greater number of inter-relations between variables compared to first generation multiple regression. SEM utilizes latent variables where multiple indicators of the same construct are designed to be handled within the model compared to regression models where multiple indicators may cause collinearity accounting for smaller increments in variance (403). Such second-generation models may yield more accurate and clinically translatable results.

Threshold analysis could also facilitate screening of patients heading toward poor outcomes and trigger the requirement for specific interventions (77)(138). Threshold values may serve as pragmatic guides for clinical decision-making in acute settings as long as they are not treated as substitutes for clinical acumen (404). Such cut-offs may also inadvertently expose vulnerabilities and be detrimental to patients. Displaying trajectories to patients and feeding back PRO scores may generate positive (or negative) reinforcement during recovery. This may also offer opportunities for discussion, rapport-building and enhance HCP-patient interactions. Clinical recommendations based on this line of investigation should be carefully communicated.

9.2.2 Advancing acute musculoskeletal care through non-surgical interventions

Musculoskeletal HCPs should be aware of the influential factors of disability during the initial phases of recovery as these can predict long term health-related outcomes. Questioning around pain-inducing activities and early measurement of aspects such as kinesiophobia, self-efficacy and instrumental support may facilitate *identification* of patients that go onto to have greater than expected disability for the stage of recovery. These individuals may be at risk of maladaptive responses to injury and pain. Identification should be followed by *close engagement* with patients to establish whether they could benefit from evidence-based interventions such as *coaching* and *coping strategies.*

Patient engagement during the early recovery phase requires clear communication that incorporates positive, optimistic and reassuring language, avoiding over-emphasis of phrases leading to over-cautious activity, mal-adaptation and negative ideation. Approaching fracture patients in this way may avert the need for referral to a psychologist, which could itself be associated with certain stigmas. On one hand, this can pose a minor annoyance to patients, whilst on the other, prove to have detrimental effects on management and HCP-patient relations if not handled correctly. Nevertheless, a formal psychology or psychotherapy review and evidence-based therapies, such as *mind-body-skills coaching* or *behavioral therapy* (e.g. CBT, Behavioural Activation), may eventually be required.

Allied musculoskeletal HCPs such as physiotherapists and occupational therapists are often well-placed to actively engage with patients and gain a more holistic sense of their recovery beyond the routine clinical encounters with orthopaedic surgeons. Communication skills training for physiotherapists is shown to optimize patient adherence, patient engagement and clinical outcomes in some patients following home-based rehabilitation for chronic low back pain (405). Furthermore, an emergent understanding of psychosocial aspects by these HCPs is reflected in the growing number of therapist-led combined approaches to care that integrate behavioural

therapy techniques (406). Physiotherapists have been shown to successfully deliver cognitive behavioural interventions for low back pain with additional training (406). More recently, a pragmatic RCT demonstrated behavioural activation, a form of behavior therapy for treating depression, delivered by NHS junior mental health workers with no professional training, was shown to be as clinically effective and more cost-effective than CBT conducted by psychotherapists (407). Behavioural interventions have been investigated in treating depression and fear of falling after hip fractures in the eldery (408)(409)(410). However, such treatment modalities are rarely accessed let alone utilised in patients with extremity fractures (138). Based on the findings in this thesis, there is a need for RCTs assessing the impact of coaching and behavioural interventions on long-term outcomes following upper extremity fractures (138).

Initiatives targeted at HCPs could include advanced communication skills training in acute settings, instructional courses in performing rapid, pragmatic psychosocial assessments along with training in novel behavioural therapies such as behavioural activation. From the clinician's perspective, a recent study demonstrated that whilst surgeons are likely to have an awareness of psychological factors, they are less likely to undertake formal screening of patients, opting to refer them on for formal psychological assessment (411). Communication skills training specifically directed at surgeons and other musculoskeletal HCPs may enable the consideration of psychosocial and emotional factors in the decision-making process. This could also provide an early opportunity to bolster coping strategies alongside forming a gateway for more formal psychosocial review (411). Overall, high quality evidence in supporting these non-surgical, non-pharmacological interventions may be the best means of integrating them into routine orthopaedic practice and transforming the way acute musculoskeletal care is delivered.

Another approach to enhancing musculoskeletal care through a patient-centered approach involves the concept of shared decision-making (259)(371). This combines the expertise, best available evidence and preferences of patients and surgeons in coming to a treatment decision.

Hageman et al., have shown that patients sustaining upper extremity trauma have the same preferences for shared decision-making as those with non-traumatic conditions (371). Further studies are required to determine whether active patient involvement in the decision-making process following an arm fracture can improve long term outcomes and experience (35)(62)(212)(213).

Patient outcomes research may also provide a fresh approach to an orthopedic specialty where there are several contentious issues and substantial variations in clinical and operative practices. For instance, there is an overall rise in operative interventions for specific shoulder and wrist fractures despite equivocal and often conflicting patient outcomes data. Examining the status quo, it appears that a considerable number of treatment decisions are still based on personal experience, personal preference, clinical culture and surgical trends over scientific evidence. From a broader perspective, this discussion highlights the expanding role of PRO measures from tools built for research that capture individual outcomes, to instruments guiding clinical decision-making, toward measures of performance informing health care policy (63)(65)(66)(67). Health care is moving from a volume-based supply driven culture focused on clinicians, to one based on value and outcomes with patients at the centre. Data and outcomes driven models of health care reimbursement may soon become reality where provider systems are accountable for ensuring meaningful improvements in health-related outcomes, experience and quality of care (63).

In closing, the pursuit of anatomical restoration is one of the fundamental principles in orthopaedic surgery and will remain the goal of most surgeons faced with an upper extremity fracture (248). However, the best way to consistently achieve optimal health-related outcomes following upper extremity fractures may be to adopt a patient-centered approach (70)(270). The consideration of modifiable psychosocial factors and their integration into non-surgical treatment assets may help patients adapt to injury, bolster resilience, acquire coping strategies and optimise patient focused outcomes.

9.3 Synopsis

This thesis aimed to identify the influential factors predictive of long-term disability following proximal humerus, elbow and distal radius fractures *and* define the relationship between disability, patient experience and activation in these injuries using validated fixed scale and computer adaptive PRO measures. The experimental work structured around the WHO ICF framework, demonstrated the dominance of self-efficacy, kinesiophobia and instrumental support amongst other factors in predicting medium-term disability. This is consistent with a growing body of evidence demonstrating the greater influence of psychosocial factors on arm-specific disability compared with impairment and pathophysiology (97)(140)(275)(291)(363)(402). Disability also demonstrated a strong correlation with satisfaction, a relationship which strengthened during the course of recovery, and patient activation demonstrated a strong correlation with both disability and patient experience. These patient perspectives of health have not been investigated to this extent in focused populations with shoulder, elbow and wrist fractures based on the literature to date.

The findings of this thesis suggest greater focus should be placed on psychosocial factors and coping strategies in contending with a painful fracture. This should be in conjunction with initiatives that enhance patient activation early on following injury. Further work is required to better identify patients with greater than expected disability for a given stage of recovery; promote communication skills amongst HCPs to generate an environment of positivity and confidence in daily orthopedic practice; and deliver coaching and behavioural techniques that may be initiated by musculoskeletal HCPs alongside referral processes to specialists in psychology. There is a need for high quality RCTs to assess the impact of behavioural therapies on clinical and patient-focused outcomes. These strategies may foster the core attributes of adaptation and resilience that likely underpin coping ability in successfully navigating patients through recovery following an upper extremity fracture. Collectively, these strategies may be the best way of improving their long-term health-related and experiential outcomes.

Patient focused outcome measures provide the language for guiding these strategies and capturing patient perspectives of their health conditions and health services. CATs may form the optimal mode of PRO measurement based on their speed and precision in an increasingly data-driven healthcare environment. Further clinical translational work is clearly required not to mention the resolution of a range of operational, technological, regulatory and ethical issues (65). As per the Montreal Accord 2017, the successful integration of PRO measures in modern health care requires defining "the right information for the right person in the right format through the right channels at the right time in the workflow". Achieving this in musculoskeletal care of upper extremity fracture patients is paramount in understanding disability and improving health-related outcomes in these populations (33).

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Appendices



Appendix 1. Systematic Review I: Search strategy

#1 Upper extremity anatomical terms
"upper extremity disability"[tw] OR "upper extremity disabilities"[tw] OR "arm disabilities" OR "arm disability"[tw] OR "upper limb disabilities"[tw] OR "upper limb disability"[tw] OR "shoulder disabilities"[tw] OR "shoulder disability"[tw] OR "elbow disability"[tw] OR "forearm disabilities"[tw] OR "forearm disability"[tw] OR "hand disabilities"[tw] OR "hand disability"[tw] OR "wrist disability"[tw] OR "finger disability"[tw] OR (("Upper Extremity"[majr] OR "arm"[ti] OR "upper extremity"[ti] OR "upper extremities"[ti] OR "upper limb"[ti] OR "upper limbs"[ti] OR clavicul*[ti] OR subclavicul*[ti] OR scapul*[ti] OR "brachial plexus"[ti] OR brachial*[ti] OR "rotator cuff"[ti] OR "shoulder"[ti] OR "shoulders"[ti] OR "acromion"[ti] OR Coraco*[ti] OR "subacromial"[ti] OR "subdeltoid"[ti] OR "supraspinatus"[ti] OR "infraspinatus"[ti] OR subscapular*[ti] OR "teres minor"[ti] OR "tuberosity"[ti] OR "acromioclavicular"[ti] OR "scapulothoracic"[ti] OR pectoral*[ti] OR "Suprascapular"[ti] OR coracoclavicula*[ti] OR "ACJ"[ti] OR "CCJ"[ti] OR glenoid*[ti] OR "glenohumeral"[ti] OR "upper arm"[ti] OR "Latissimus dorsi"[ti] OR "thoracodorsal"[ti] OR humer*[ti] OR "biceps"[ti] OR Bicipit*[ti] OR "triceps"[ti] OR "deltoid"[ti] OR "axillary nerve"[ti] OR "elbow"[ti] OR "Elbows"[ti] OR "olecranon"[ti] OR epicond*[ti] OR "coronoid"[ti] OR "forearm"[ti] OR "forearms"[ti] OR "Extensor Carpi"[ti] OR "Flexor Carpi"[ti] OR Extensor digit*[ti] OR Flexor digit*[ti] OR "Extensor pollicis"[ti] OR "Flexor pollicis"[ti] OR "Extensor retinaculum"[ti] OR "Flexor retinaculum"[ti] OR "Abductor pollicis"[ti] OR "Adductor pollicis"[ti] OR "anconeus"[ti] OR "Pronator"[ti] OR "Supinator"[ti] OR "median nerve"[ti] OR "ulnar nerve"[ti] OR "radial nerve"[ti] OR "Musculocutaneous"[ti] OR "radius"[ti] OR ulna*[ti] OR "radio-ulnar"[ti] OR ("hand"[ti] NOT "other hand"[ti]) OR "hands"[ti] OR "wrist"[ti] OR "wrists"[ti] OR "TFCC"[ti] OR triangul*[ti] OR carp*[ti] OR scaph*[ti] OR "lunatum"[ti] OR triquet*[ti] OR "pisiform"[ti] OR trapez*[ti] OR "capitatum"[ti] OR capitolu*[ti] OR "hamate"[ti] OR palmari*[ti] OR "Opponens pollicis"[ti] OR "finger"[ti] OR "fingers"[ti] OR metacarp*[ti] OR lumbrical-interosse*[ti] OR interphalan*[ti] OR phalan*[ti] OR "digit"[ti] OR "digits"[ti] OR "digitorum"[ti] OR "thumb"[ti] OR "thumbs"[ti] OR "fingertip"[ti] OR "nailbed"[ti] OR "subungual"[ti])

AND

#2 Outcome Measurement terms
("Disabled Persons"[majr:noexp] OR "disabled"[ti] OR "Disability Evaluation"[majr:noexp] OR "disability"[ti] OR "disabilities"[ti] OR Disab*[ti] OR "DASH"[tw] OR "QuickDash"[tw] OR "Quick-DASH"[tw] OR "MFA"[tw] OR "SMFA"[tw] OR musculoskeletal function*[tw] OR "SF 12"[tw] OR "SF 36"[tw] OR "EuroQol"[tw] OR "EQ 5D"[tw] OR "NHP"[tw] OR "Nottingham Health Profile"[tw] OR "QWB"[tw] OR "quality of well being"[tw] OR "quality of wellbeing scale"[tw] OR "OSS"[tw] OR "Oxford Shoulder Score"[tw] OR "SIP"[tw] OR "Sickness Impact Profile"[tw] OR "OES"[tw] OR "Oxford Elbow Score"[tw] OR "ASES"[tw] OR American Shoulder Elbow*[tw] OR Oxford Instability*[tw] OR "OSIS"[tw] OR "WOOS"[tw] OR "western ontario osteoarthritis"[tw] OR "WOSI"[tw] OR "Western Ontario Shoulder Instability Index"[tw] OR "PRWE"[tw] OR "Patient Reported Wrist Evaluation"[tw] OR "Michigan Hand Outcome"[tw] OR "MHQ"[tw] OR "PROMIS Physical Function"[tw] OR "shoulder pain and disability index"[tw] OR "shoulder pain and disability scale"[tw] OR "SPADI"[tw] OR "Dutch Shoulder Disability Questionnaire"[tw] OR "SDQ-NL"[tw] OR "Rowe Shoulder Score"[tw] OR "Shoulder Function Assessment Scale"[tw] OR "SFA"[tw] OR "UCLA Shoulder"[tw] OR "shoulder disability questionnaire"[tw] OR "shoulder disability questionnaires"[tw] OR "SDQ-UK"[tw] OR "Elbow Functional Assessment"[tw] OR "EFA"[tw] OR "Patient-rated Elbow Evaluation"[tw] OR "PREE"[tw] OR "Upper Extremity Functional Scale"[tw] OR "Hand Function Score"[tw] OR "Boston Questionnaire"[tw] OR ("Wrist"[tw] AND "Outcome Measure"[tw]) OR "WOM"[tw]))

AND

#3 Other impairment, psychological, social and symptomatic terms
("Psychological"[tw] OR "psychosocial"[tw] OR psycho-social*[tw] OR "Sociological Factors"[Mesh] OR "Sociology"[mesh] OR "psychology"[subheading] OR "Psychology"[mesh] OR Depress*[tw] OR "Coping"[tw] OR Catastrophi*[tw] OR "Self Efficacy"[tw] OR Neuroti* [tw] OR Inflexib*[tw] OR "PROMIS Pain Interference"[tw] OR "Pain"[mesh] OR "pain"[tw] OR Predict*[tw] OR "Kinesiophobia"[tw] OR Distress*[tw] OR "Mental"[tw] OR "ROM"[tw] OR "Range of Motion"[tw] OR "motion"[tw] OR "sensory"[tw] OR "sensation"[tw] OR "power"[tw] OR weak*[tw] OR grade*[tw] OR "radiograph"[tw] OR "xray"[tw] OR "x-ray"[tw] OR roentgen*[tw] OR "Radiography"[Mesh] OR "radiography"[Subheading] OR stiff*[tw] OR "Anxiety"[tw] OR "Injury severity"[tw] OR Work*[tw] OR social*[tw] OR "societal"[tw] OR socio*[tw] OR econom*[tw] OR "Economics"[mesh] OR "economics"[subheading] OR occupa*[tw] OR workers comp*[tw] OR "work"[mesh])

AND

("2000/01/01"[PDAT] : "3000/12/31"[PDAT]) NOT ("Animals"[mesh] NOT "Humans"[mesh]) NOT (("Child"[mesh] OR "Infant"[mesh]) NOT ("Adolescent"[mesh] OR "Adult"[mesh])) NOT (("Case Reports"[publication type] OR "case report"[ti] OR systematic[sb] OR "Review"[publication type]) NOT ("Clinical Conference"[publication type] OR "Clinical Trial"[publication type] OR "Comparative Study"[publication type] OR "Evaluation Studies"[publication type] OR "Multicenter Study"[publication type] OR "Scientific Integrity Review"[publication type] OR "Twin Study"[publication type] OR "Validation Studies"[publication type])) AND english[la])

Appendix 2. Systematic Review I: Definition of Reporting Classifications

Category	Sub-Category	Definition
Upper Extremity Regions	n/a	Classification by Shoulder (inc shoulder girdle, clavicle, brachial plexus) or Humeral Shaft or Elbow (Distal humerus, olecranon, proximal ulna, radial head-neck) or Forearm or Wrist-Hand or combinations thereof
Aetiology	Non-Trauma	Upper extremity musculoskeletal conditions not associated with an index traumatic event e.g. OA, RA, Trigger finger, carpal tunnel syndrome, Dupuytren's contracture
	Trauma	Upper extremity musculoskeletal conditions associated with index traumatic event e.g. Fracture, dislocation, subluxation, ligament / tendon rupture
	Post-Trauma	Upper extremity musculoskeletal conditions associated with complication or sequelae of index traumatic event in a delayed setting e.g. corrective surgery for malunion, nonunion surgery, stabilisation procedure
	Combination	Combined traumatic and non-traumatic conditions
Outcome Measures	Disability (PRO measure)	Subjective, patient-reported generic or specific measures reflecting disability e.g. DASH
	Clinician-based (CBO measure)	Objective, partial or fully a clinician-based measure e.g. Constant Murely Score
	Impairment (Objective metrics plus performance-based measures)	Objective metrics reported by the clinician forming part of clinical management +/- performance-based measures i.e. Clinical assessment e.g. ROM, grip strength, special tests e.g. Tinel's sign i.e. Clinical investigations e.g. MRI, radiograph, imaging classifications e.g. Anderson criteria nb. Process level features e.g. Length of stay, Complications and imaging findings excluded
	Psychological	Psychological measure, measuring mental health domain only e.g PCS, not a psychological domain within a generic e.g. EQ5D, or specific PRO measure e.g. DASH, unless included as a specific variable in analysis e.g. SF-36 MCS
	Social	Social metric, measuring social aspect only e.g. work status, worker's compensation, marital status, return to work, not social domain within a generic e.g. EQ5D, or specific PRO measure e.g. DASH, unless included as a specific variable in analysis e.g. DASH-Work module
	Pain	Pain and symptom measure, measuring symptomatic aspect only e.g Pain VAS, not a pain measure within a generic e.g. EQ5D, or specific PRO measure e.g. DASH, unless included as a specific variable in analysis e.g. PRWE pain subscale
	Other	Any other measure or metric not conforming to aforementioned categories e.g. aesthetics / cosmetic / experience / activation scores, measures, scales

Appendix 3. Systematic Review I: Screening and Exclusion Criteria

Category	Exclusion Criteria	Exclusion Type
Participant	Study is not available in English; is an Animal study; has no available abstract	Type 0
	Paediatric or adolescent patients	Type I
	Study involving non-musculoskeletal upper extremity conditions e.g. neuromuscular, vascular	Type II
	Study not involving upper extremity condition or group of conditions	Type III
Intervention Comparator Outcome	Study involving only objective, patho-anatomical, clinical, process-level metrics e.g. range of motion, radiographic classification, lab data, operative blood loss, length of stay, complications (basic science, biomedical, pure clinical) and/or no patient reported outcome measures	Type IV
	Study involving development and / or psychometric evaluation of patient reported outcome measure only	Type V
Study	Study is a technical report; protocol; case report; commentary; normative data (reference range) investigation; erratum; healthcare management; health economic evaluation	Type VI

Appendix 4. Systematic Review I: Quality assessment. 10-item checklist

I	Socio-demographic and medical data described (e.g., age, race, employment, education, diagnosis)
II	Process of data collection clearly described (e.g., interviews, questionnaires)
III	Diagnosis described
IV	Results are compared between 2 or more groups (e.g., healthy populations, between patient group, etc)
V	Participation and response rate reported and more than 75%
VI	Differences between responders/non-responders are presented when they exist.
VII	Results are described also for physical, psychological and social domains when the QoL measure captures that.
VIII	Standard statistics (mean, median, ranges, SD) are present for the main study variables.
IX	Patients signed an informed consent prior to study participation, and this was explicitly stated in the manuscript.
X	Selection of participants is adequately described.

Each item in the selected study that meets criteria is assigned one point. If an item does not meet criteria or was described insufficiently, zero points are assigned. The highest possible score is 10. Studies scoring 70% or more of the maximum attainable score (e.g., score ≥7) are arbitrarily considered to be of "high quality". Studies scoring between 50%-70% are rated as "moderate quality" (score 5-7). Studies scoring lower than 50% are considered "low quality" (score ≤4).

Appendix 5. Systematic Review II: Search strategy (PubMed)

'Upper extremity anatomy'

#1 ("Upper Extremity"[Mesh] OR "arm"[tw] OR "upper extremity"[tw] OR "upper extremities"[tw] OR "upper limb"[tw] OR "upper limbs"[tw] OR clavicul*[tw] OR subclavicul*[tw] OR scapul*[tw] OR "brachial plexus"[tw] OR brachial*[tw] OR "rotator cuff"[tw] OR "shoulder"[tw] OR "shoulders"[tw] OR "acromion"[tw] OR Coraco*[tw] OR "subacromial"[tw] OR "subdeltoid"[tw] OR "supraspinatus"[tw] OR "infraspinatus"[tw] OR subscapular*[tw] OR "teres minor"[tw] OR "tuberosity"[tw] OR "acromioclavicular"[tw] OR "scapulothoracic"[tw] OR pectoral*[tw] OR "Suprascapular"[tw] OR coracoclavicula*[tw] OR "ACJ"[tw] OR "CCJ"[tw] OR glenoid*[tw] OR "glenohumeral"[tw] OR "upper arm"[tw] OR "Latissimus dorsi"[tw] OR "thoracodorsal"[tw] OR humer*[tw] OR "biceps"[tw] OR Bicipit*[tw] OR "triceps"[tw] OR "deltoid"[tw] OR "axillary nerve"[tw] OR "elbow"[tw] OR "Elbows"[tw] OR "olecranon"[tw] OR epicond*[tw] OR "coronoid"[tw] OR "forearm"[tw] OR "forearms"[tw] OR "Extensor Carpi"[tw] OR "Flexor Carpi"[tw] OR Extensor digit*[tw] OR Flexor digit*[tw] OR "Extensor pollicis"[tw] OR "Flexor pollicis"[tw] OR "Extensor retinaculum"[tw] OR "Flexor retinaculum"[tw] OR "Abductor pollicis"[tw] OR "Adductor pollicis"[tw] OR "anconeus"[tw] OR "Pronator"[tw] OR "Supinator"[tw] OR "median nerve"[tw] OR "ulnar nerve"[tw] OR "radial nerve"[tw] OR "Musculocutaneous"[tw] OR "radius"[tw] OR ulna*[tw] OR "radio-ulnar"[tw] OR ("hand"[tw] NOT "other hand"[tw]) OR "hands"[tw] OR "wrist"[tw] OR "wrists"[tw] OR "TFCC"[tw] OR triangul*[tw] OR carp*[tw] OR scaph*[tw] OR "lunat*"[tw] OR triquet*[tw] OR "pisiform"[tw] OR trapez*[tw] OR "capitate"[tw] OR capitell*[tw] OR "hamate"[tw] OR palmar*[tw] OR "Opponens pollicis"[tw] OR "finger"[tw] OR "fingers"[tw] OR metacarp*[tw] OR lumbrical-interosse*[tw] OR phalan*[tw] OR "digit"[tw] OR "digits"[tw] OR "digitorum"[tw] OR "thumb"[tw] OR "thumbs"[tw] OR "fingertip"[tw] OR "nailbed"[tw] OR "subungual"[tw])

AND

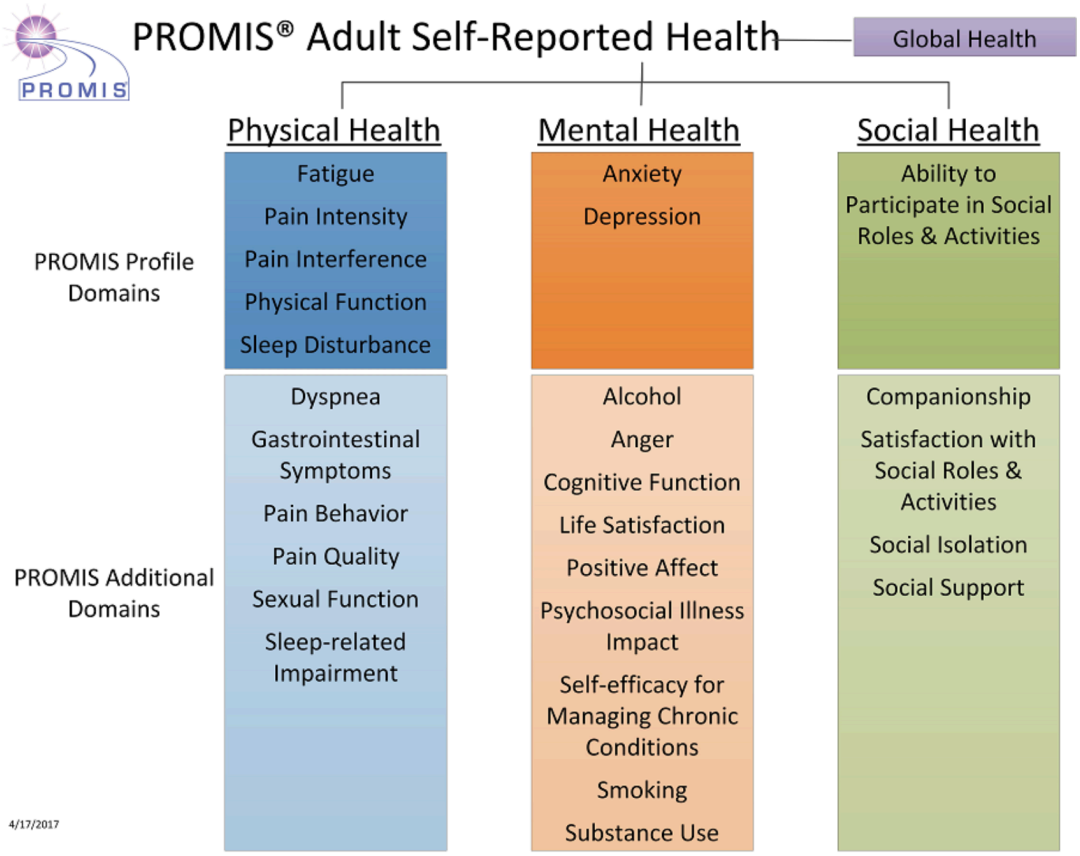
'Outcome Measurement'

#2 "Outcome Measure"[tw] OR "Outcome Measurement"[tw] OR "PROM"[tw] OR "Patient reported" [tw] OR "Patient focus*"

AND

#3 NOT ("Animals"[mesh]) NOT (("Child"[mesh] OR "Infant"[mesh]) NOT ("Adolescent"[mesh])) AND english[la])

Appendix 6. PROMIS Outcome Measurement Modules



Appendix 7. Systematic Review III: Step-wise exclusion strategy

Key		
Filter I	Study type I	Biomedical i.e. Basic Science; Biomedical engineering: Computer / mathematic modelling; Non-CAT-based Technology assessment; Performance testing; Imaging study
	Non-human	Animal, plant-based studies
	Non-English	Non-english language studies not relevant to CATs and / or trauma and orthopaedic surgery
Filter II	Study type II	Review; Technical report; Case report; Commentary; Erratum
	Study type III	Rasch analysis / IRT application in orthopaedic area but non-CAT related
	Study type IV	Rasch analysis / IRT application in non-orthopaedic area; Statistical study only
Filter III	Study type V	Study involving CATs but non-orthopaedic clinical focus
	Study type VI	Study involving orthopaedic clinical focus but non-CAT related
	Study type VII	Study involving neither orthopaedic or CAT-related clinical focus

Appendix 8. Chapter 3. Pilot Study. Institutional Review Board Approval.

PARTNERS HEALTHCARE
FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116
Tel: (617) 424-4100
Fax: (617) 424-4199

Amendment: Notification of IRB Approval/Activation
Protocol #: 2009P001019/MGH

Date: April 15, 2013

To: David C Ring, MD
MGH > Orthopedics

From: Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116

Title of Protocol:	Orthopaedic Hand Service Data Repository
Version Date:	3/10/2010
Sponsor/Funding Support:	Departmental Funds
IRB Amendment #:	204
IRB Review Type:	Expedited
Risk:	Minimal Risk
Approval Activation Date:	4/15/2013
IRB Expiration Date:	5/30/2013

This project has been reviewed by MGH IRB . During the review of this project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for obtaining and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

Please note that if an IRB member had a conflict of interest with regard to the review of this project, consistent with IRB policies and procedures, the member was required to leave the room during the discussion and vote on this project except to provide information requested by the IRB.

- ***Starting a new project: "The correlation of the PROMIS Physical Function with the QuickDASH in patients with arm and upper extremity illness." No new questionnaires added.***

As Principal Investigator, you are responsible for ensuring that this project is conducted in compliance with all applicable federal, state and local laws and regulations, institutional policies, and requirements of the IRB, which include, but are not limited to, the following:

1. Submission of any and all proposed changes to this project (e.g., protocol, recruitment materials, consent

Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116
Tel: (617) 424-4100
Fax: (617) 424-4199

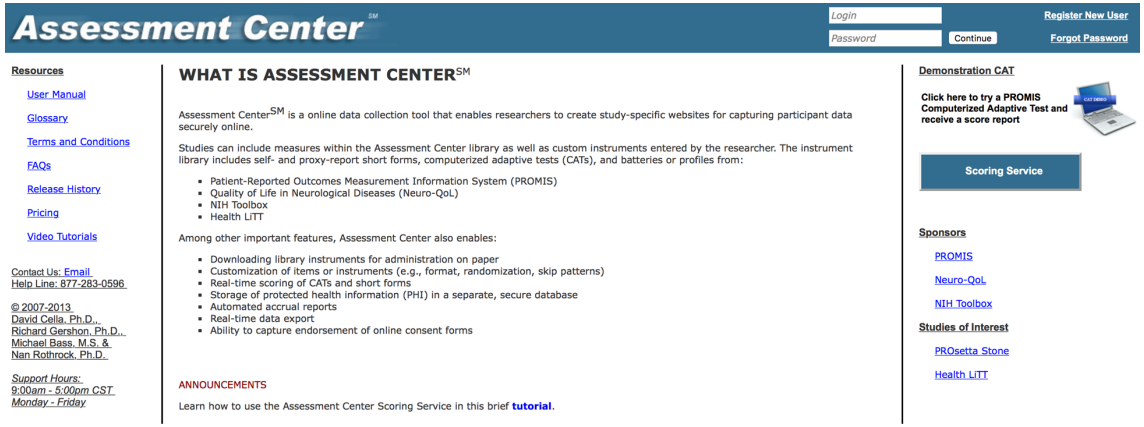
form, status of the study, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB as an unanticipated problem.

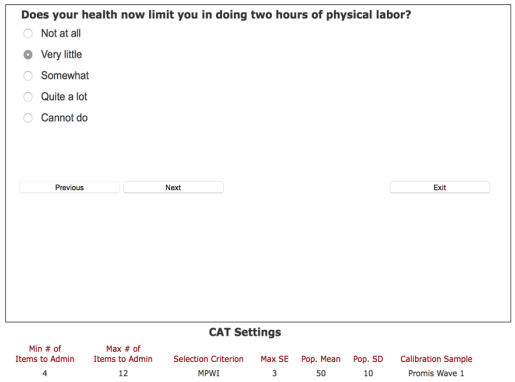
2. Submission of continuing review submissions for re-approval of the project prior to expiration of IRB approval and a final continuing review submission when the project has been completed.
3. Submission of any and all unanticipated problems, including adverse event(s) in accordance with the IRB's policy on reporting unanticipated problems including adverse events.
4. Obtaining informed consent from subjects or their legally authorized representative prior to initiation of research procedures when and as required by the IRB and, when applicable, documenting informed consent using the current IRB approved consent form(s).
5. Informing all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.
6. When investigator financial disclosure forms are required, submitting updated financial disclosure forms for yourself and for informing all site responsible investigators, co-investigators and any other members of the study staff identified by you as being responsible for the design, conduct, or reporting of this research study of their obligation to submit updated Investigator Financial Disclosure Forms for this protocol to the IRB if (a) they have acquired new financial interests related to the study and/or (b) any of their previously reported financial interests related to the study have changed.

The IRB has the authority to terminate projects that are not in compliance with these requirements.

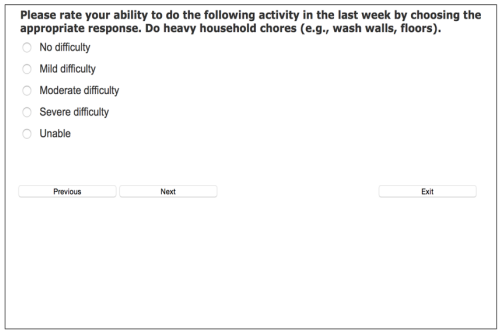
Questions related to this project may be directed to Isabel Suzarte, ISUZARTE@PARTNERS.ORG, 617-424-4115.

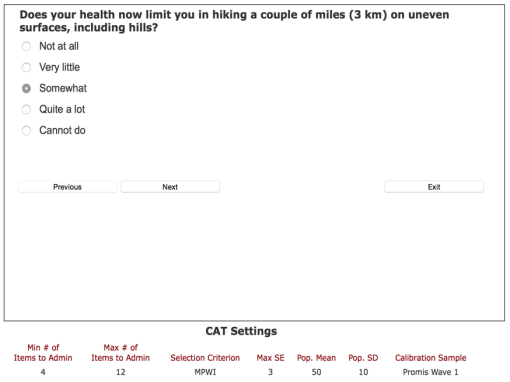
Appendix 9. Assessment Center℠ PRO Measurement Platform Screenshots



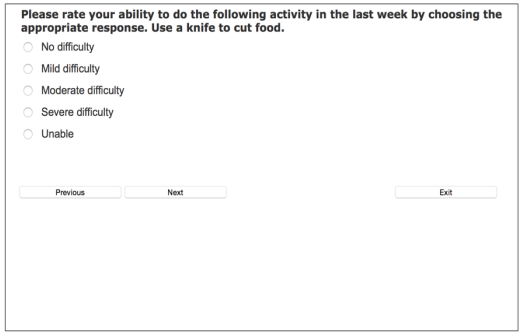


PROMIS PF v1.0





QuickDASH



Appendix 10. PRO Measurement Licensing and Registration Index

PRO Measure	Version	Licensing Organisation or Investigator (Registration details)
PROMIS Physical Function	v1.0	Northwestern University. http://www.healthmeasures.net/ (Registered 2013-2017)
PROMIS Upper Extremity Physical Function	v1.0	Northwestern University. http://www.healthmeasures.net/ (Registered 2013-2017)
PROMIS Emotional Support	v1.0	Northwestern University. http://www.healthmeasures.net/ (Registered 2013-2017)
PROMIS Instrumental Support	v1.0	Northwestern University. http://www.healthmeasures.net/ (Registered 2013-2017)
PROMIS Pain interference	v1.0	Northwestern University. http://www.healthmeasures.net/ (Registered 2013-2017)
PROMIS Depression	v1.0	Northwestern University. http://www.healthmeasures.net/ (Registered 2013-2017)
PROMIS Anxiety	v1.0	Northwestern University. http://www.healthmeasures.net/ (Registered 2013-2017)
QuickDASH	2006	Institute of Work and Health, Toronto. http://www.dash.iwh.on.ca (Registration not required)
EQ-5D-3L	2017	EQ-5D; www.euroqol.org (Registered (No. 21955), 2017)
Oxford Shoulder Score	1996	Oxford University Innovation. https://innovation.ox.ac.uk/ (Registered 2017)
Oxford Elbow Score	2008	Oxford University Innovation. https://innovation.ox.ac.uk/ (Registered 2017)
Patient Rated Wrist Evaluation	2011	MacDermid et al., 1998 (238) (Registration not required)
Pain Self Efficacy Questionnaire-2	2015	Nicholas et al., 2015 (286) (Registration not required)
Pain Catastrophizing Scale	1995	Mapi Trust. https://eprovide.mapi-trust.org/instruments/ (Registered 2017)
Tampa Scale for Kinesiophobia-11	1991	Miller et al., 1991 (287) (Registration not required)
Patient Activation Measure-13	2016	Insignia Health. https://www.insigniahealth.com/ (Registered (No.1749), 2017
Effective Consumer Scale-17	2009	Centre for Global Health. http://www.cgh.uottawa.ca/ (Registration not required)

Appendix 10.1 PROMIS PF (Example Short-form Version)

Physical Function – Short Form 8b

Please respond to each question or statement by marking one box per row.

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA11	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA53	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Not at all	**Very little**	**Somewhat**	**Quite a lot**	**Cannot do**
PFC12	Does your health now limit you in doing two hours of physical labor?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB1	Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA5	Does your health now limit you in lifting or carrying groceries?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA4	Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

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Appendix 10.2 PROMIS UE PF (Example Short-form Version)

PROMIS® Item Bank v2.0 – Physical Function – Short Form 7a

Upper Extremity – Short Form 7a

Please respond to each question or statement by marking one box per row.

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA14r1	Are you able to carry a heavy object (over 10 pounds /5 kg)?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA34	Are you able to wash your back?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA36	Are you able to put on and take off a coat or jacket?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB13	Are you able to carry a shopping bag or briefcase?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB28r1	Are you able to lift 10 pounds (5 kg) above your shoulder?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB34	Are you able to change a light bulb overhead?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFM16	Are you able to pass a 20-pound (10 kg) turkey or ham to other people at the table?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

29 November 2016

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Appendix 10.3 PROMIS ES (Example Short-form Version)

Emotional Support – Short Form 8a

Please respond to each item by marking one box per row.

		Never	Rarely	Sometimes	Usually	Always
FSE31053x2	I have someone who will listen to me when I need to talk	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FSE31059x2	I have someone to confide in or talk to about myself or my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SS12x	I have someone who makes me feel appreciated	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SSQ3x2	I have someone to talk with when I have a bad day	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FSE31069x2	I have someone who understands my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SSE-CaPS6	I have someone I trust to talk with about my feelings	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FSE31066x2	I have someone with whom to share my most private worries and fears	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SSQ4x2	I have someone I trust to talk with about my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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Appendix 10.4 PROMIS IS (Example Short-form Version)

Instrumental Support – Short Form 8a

Please respond to each item by marking one box per row.

		Never	Rarely	Sometimes	Usually	Always
CCC31052x	Do you have someone to help you if you are confined to bed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
CCC31055x	Do you have someone to take you to the doctor if you need it?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
CCC31065x	Do you have someone to help with your daily chores if you are sick?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SS6	Do you have someone to run errands if you need it?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
CCC31062x	Do you have someone to prepare your meals if you are unable to do it yourself?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SS9	Do you have someone to take over all of your responsibilities at home if you need it?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
CCC31051x3	Is someone available to help you if you need it?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
INS-CaPS2	Do you have someone to help you clean up around the home if you need it?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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Appendix 10.5 PROMIS PI (Example Short-form Version)

Pain Interference – Short Form 8a

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
PAININ9	How much did pain interfere with your day to day activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ22	How much did pain interfere with work around the home?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ31	How much did pain interfere with your ability to participate in social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ34	How much did pain interfere with your household chores?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ12	How much did pain interfere with the things you usually do for fun?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ36	How much did pain interfere with your enjoyment of social activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ3	How much did pain interfere with your enjoyment of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ13	How much did pain interfere with your family life?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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Appendix 10.6 PROMIS Depression (Example Short-form Version)

Emotional Distress - Depression – Short Form 8b

Please respond to each item by marking one box per row.

In the past 7 days....

		Never	Rarely	Sometimes	Often	Always
EDDEP04	I felt worthless……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP05	I felt that I had nothing to look forward to……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP06	I felt helpless……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP17	I felt sad……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP22	I felt like a failure…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29	I felt depressed…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP36	I felt unhappy……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP41	I felt hopeless.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2 May 2016
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Appendix 10.7 PROMIS Anxiety (Example Short-form Version)

Emotional Distress – Anxiety – Short Form 8a

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDANX01	I felt fearful.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40	I found it hard to focus on anything other than my anxiety.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41	My worries overwhelmed me.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	I felt uneasy.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX46	I felt nervous.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX07	I felt like I needed help for my anxiety.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX05	I felt anxious.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX54	I felt tense.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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Appendix 10.8 QuickDASH Questionnaire

THE QuickDASH OUTCOME MEASURE

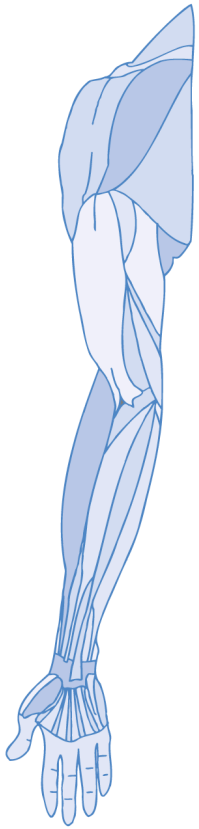
INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* of which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.



QuickDASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

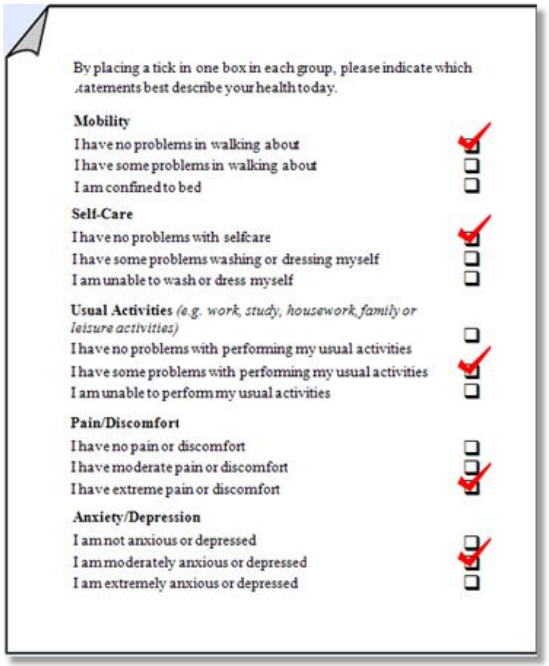
QuickDASH DISABILITY/SYMPTOM SCORE = $\left(\frac{\text{sum of n responses}}{n} - 1\right) \times 25$, where n is equal to the number of completed responses.

A QuickDASH score may not be calculated if there is greater than 1 missing item.

Appendix 10.9 EQ-5D-3L

EQ-5D

The EQ-5D-3L questionnaire



By placing a tick in one box in each group, please indicate which statements best describe your health today.

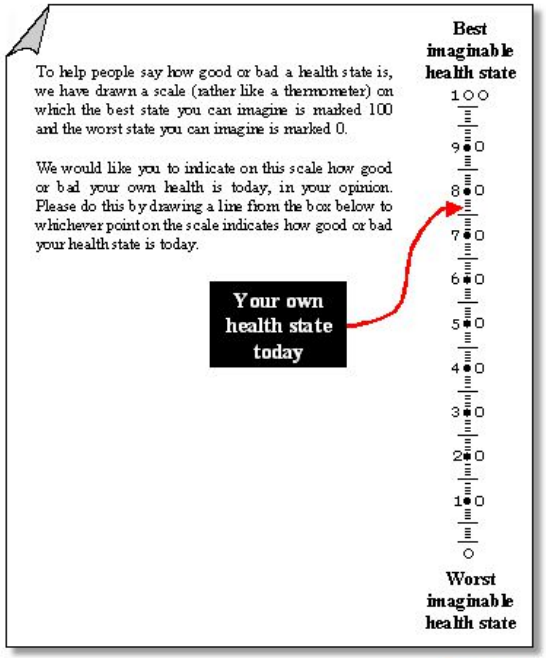
Mobility
- I have no problems in walking about
- I have some problems in walking about ☑
- I am confined to bed

Self-Care
- I have no problems with selfcare ☑
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities *(e.g. work, study, housework, family or leisure activities)*
- I have no problems with performing my usual activities
- I have some problems with performing my usual activities ☑
- I am unable to perform my usual activities

Pain/Discomfort
- I have no pain or discomfort
- I have moderate pain or discomfort ☑
- I have extreme pain or discomfort

Anxiety/Depression
- I am not anxious or depressed
- I am moderately anxious or depressed ☑
- I am extremely anxious or depressed



To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

Best imaginable health state

100
90
80
70
60
50
40
30
20
10
0

Worst imaginable health state

www.euroqol.org

Appendix 10.1.1 OSS

PROBLEMS WITH YOUR SHOULDER

Tick (✓) one box for every question.

1. During the past 4 weeks...

How would you describe the **worst** pain you had from your shoulder?

None	Mild	Moderate	Severe	Unbearable
☐	☐	☐	☐	☐

2. During the past 4 weeks...

Have you had any trouble dressing yourself because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

3. During the past 4 weeks...

Have you had any trouble getting in and out of a car or using public transport because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

4. During the past 4 weeks...

Have you been able to use a knife and fork - at the same time?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

5. During the past 4 weeks...

Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

6. During the past 4 weeks...

Could you carry a tray containing a plate of food across a room?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

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Oxford Shoulder Score (OSS)

English version for the United Kingdom

7. During the past 4 weeks…

Could you brush/comb your hair with the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

8. During the past 4 weeks…

How would you describe the pain you usually had from your shoulder?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

9. During the past 4 weeks…

Could you hang your clothes up in a wardrobe, using the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With great difficulty	No, impossible
☐	☐	☐	☐	☐

10. During the past 4 weeks…

Have you been able to wash and dry yourself under both arms?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

11. During the past 4 weeks…

How much has pain from your shoulder interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

12. During the past 4 weeks…

Have you been troubled by pain from your shoulder in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

Finally, please check back that you have answered each question.
Thank you very much.

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Oxford Shoulder Score (OSS)

English version for the United Kingdom

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Appendix 10.1.2 OES

PROBLEMS WITH YOUR ELBOW

Tick (✓) one box for every question.

1. During the past 4 weeks...

Have you had difficulty lifting things in your home, such as putting out the rubbish, because of your elbow problem?

No difficulty	A little bit of difficulty	Moderate difficulty	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

2. During the past 4 weeks...

Have you had difficulty carrying bags of shopping, because of your elbow problem?

No difficulty	A little bit of difficulty	Moderate difficulty	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

3. During the past 4 weeks...

Have you had any difficulty washing yourself all over, because of your elbow problem?

No difficulty	A little bit of difficulty	Moderate difficulty	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

4. During the past 4 weeks...

Have you had any difficulty dressing yourself, because of your elbow problem?

No difficulty	A little bit of difficulty	Moderate difficulty	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

5. During the past 4 weeks...

Have you felt that your elbow problem is "controlling your life"?

No, not at all	Occasionally	Some days	Most days	Every day
☐	☐	☐	☐	☐

6. During the past 4 weeks...

How much has your elbow problem been "on your mind"?

Not at all	A little of the time	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

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Oxford Elbow Score (OES)

English version for the United Kingdom

7. During the past 4 weeks...

Have you been troubled by pain from your elbow in bed at night**?**

Not at all	1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

8. During the past 4 weeks...

How often has your elbow pain interfered with your sleeping?

Not at all	Occasionally	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

9. During the past 4 weeks...

How much has your elbow problem interfered with your usual work or everyday activities?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

10. During the past 4 weeks...

Has your elbow problem limited your ability to take part in leisure activities that you enjoy doing?

No, not at all	Occasionally	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

11. During the past 4 weeks...

How would you describe the <u>worst pain</u> you have from your elbow?

No pain	Mild pain	Moderate pain	Severe pain	Unbearable
☐	☐	☐	☐	☐

12. During the past 4 weeks...

How would you describe the pain you <u>usually</u> have from your elbow?

No pain	Mild pain	Moderate pain	Severe pain	Unbearable
☐	☐	☐	☐	☐

Finally, please check back that you have answered each question.

Thank you very much.

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Oxford Elbow Score (OES)

English version for the United Kingdom

Appendix 10.1.3 PRWE

Name: _____ Date: _____

PATIENT RATED WRIST EVALUATION

*The questions below will help us understand how much difficulty you have had with your wrist in the past week. You will be describing your **average** wrist symptoms **over the past week** on a scale of 0-10.* Please provide an answer for **ALL** questions. If you did not perform an activity, please **ESTIMATE** the pain or difficulty you would expect. If you have **never** performed the activity, you may leave it blank.

1. PAIN

Rate the **average** amount of pain in your wrist over the past week by circling the number that best describes your pain on a scale from 0-10. A zero **(0)** means that you **did not** have any pain and a **ten (10)** means that you had the **worst pain you have ever experienced** or that **you could not do the activity because of pain.**

RATE YOUR PAIN: Sample Scale ☞	0 No Pain	1	2	3	4	5	6	7	8	9	10 Worst Ever
At rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with a repeated wrist movement	0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object	0	1	2	3	4	5	6	7	8	9	10
When it is at its worst	0	1	2	3	4	5	6	7	8	9	10
How often do you have pain?	0 Never	1	2	3	4	5	6	7	8	9	10 Always

2. FUNCTION

A. SPECIFIC ACTIVITIES

*Rate the **amount of difficulty** you experienced performing each of the items listed below - over the past week, by circling the number that describes your difficulty on a scale of 0-10. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do it at all.*

Sample scale ➞	0 No Difficulty	1	2	3	4	5	6	7	8	9	10 Unable To Do
Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Cut meat using a knife in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

B. USUAL ACTIVITIES

*Rate the **amount of difficulty** you experienced performing your **usual** activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities you performed **before** you started having a problem with your wrist. A **zero** (0) means that you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do any of your usual activities.*

Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

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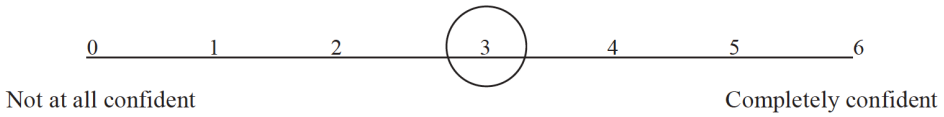
Appendix 10.1.4 PSEQ-2

Pain Self-Efficacy Questionnaire—Two-Item Short Form (PSEQ-2)

Michael K. Nicholas, PhD, Brian E. McGuire, PhD, and Ali Asghari, PhD

Please rate how **confident** you are that you can do the following things at present, **despite the pain**. To indicate your answer circle one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

For example:



Remember, this questionnaire is not asking whether or not you have been doing these things, but rather **how confident you are that you can do them at present, despite the pain.**

1. I can do some form of work, despite the pain ("work" includes housework and paid and unpaid work).	0 Not at all confident	1	2	3	4	5	6 Completely confident
2. I can live a normal lifestyle, despite the pain.	0 Not at all confident	1	2	3	4	5	6 Completely confident

Interpretation guide: A person with a score of 5 or less might be considered in need of help with their confidence in functioning in the presence of their pain. A score of 8 or higher reflects a desirable level of pain self-efficacy or confidence in functioning in the presence of pain.

Appendix 10.1.5 PCS

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Michael JL Sullivan

PCS

Client No.: _____ Age: _____ Sex: M(__) F(__) Date: _____

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0 – not at all **1** – to a slight degree **2** – to a moderate degree **3** – to a great degree **4** – all the time

When I'm in pain …

1. ☐ I worry all the time about whether the pain will end.
2. ☐ I feel I can't go on.
3. ☐ It's terrible and I think it's never going to get any better.
4. ☐ It's awful and I feel that it overwhelms me.
5. ☐ I feel I can't stand it anymore.
6. ☐ I become afraid that the pain will get worse.
7. ☐ I keep thinking of other painful events.
8. ☐ I anxiously want the pain to go away.
9. ☐ I can't seem to keep it out of my mind.
10. ☐ I keep thinking about how much it hurts.
11. ☐ I keep thinking about how badly I want the pain to stop.
12. ☐ There's nothing I can do to reduce the intensity of the pain.
13. ☐ I wonder whether something serious may happen.

… Total

Appendix 10.1.6 TSK-11

Tampa Scale for Kinesiophobia

(Miller , Kori and Todd 1991)

1 = strongly disagree
2 = disagree
3 = agree
4 = strongly agree

1. I'm afraid that I might injury myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren't taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

Reprinted from:
Pain, Fear of movement/(re) injury in chronic low back pain and its relation to behavioral performance, 62, Vlaeyen, J., Kole-Snijders A., Boeren R., van Eek H., 371.
Copyright (1995) with permission from International Association for the Study of Pain.

* Items– 4,8,9,12,14,16 are excluded from mini version.

Appendix 10.1.7 PAM-13

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say.

If the statement does not apply to you, circle N/A.

1.	When all is said and done, I am the person who is responsible for taking care of my health	Disagree strongly	Disagree	Agree	Agree strongly	N/A
2.	Taking an active role in my own health care is the most important thing that affects my health	Disagree strongly	Disagree	Agree	Agree strongly	N/A
3.	I am confident I can help prevent or reduce problems associated with my health	Disagree strongly	Disagree	Agree	Agree strongly	N/A
4.	I know what each of my prescribed medications do	Disagree strongly	Disagree	Agree	Agree strongly	N/A
5.	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself	Disagree strongly	Disagree	Agree	Agree strongly	N/A
6.	I am confident that I can tell a doctor concerns I have even when he or she does not ask	Disagree strongly	Disagree	Agree	Agree strongly	N/A
7.	I am confident that I can follow through on medical treatments I may need to do at home	Disagree strongly	Disagree	Agree	Agree strongly	N/A
8.	I understand my health problems and what causes them	Disagree strongly	Disagree	Agree	Agree strongly	N/A
9.	I know what treatments are available for my health problems	Disagree strongly	Disagree	Agree	Agree strongly	N/A
10.	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree strongly	Disagree	Agree	Agree strongly	N/A
11.	I know how to prevent problems with my health	Disagree strongly	Disagree	Agree	Agree strongly	N/A
12.	I am confident I can figure out solutions when new problems arise with my health	Disagree strongly	Disagree	Agree	Agree strongly	N/A
13.	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress	Disagree strongly	Disagree	Agree	Agree strongly	N/A

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Contact Insignia Health at www.insigniahealth.com

Appendix 10.1.8 ECS-17

EFFECTIVE CONSUMER SCALE

This survey asks you about yourself and how you manage your disease. It asks questions about the skills, attitudes and knowledge you may or may not have at this time. Your health care team are the people who provide treatment and advice to you. For example doctors, nurses, and physical therapists are all part of your health care team

Please check how much of the time each statement is true of you.

	Never	Rarely	Some-times	Usually	Always
How I Use Health Information					
1. I understand the facts I receive about my disease	☐	☐	☐	☐	☐
2. I know how to adapt general health information to my own situation	☐	☐	☐	☐	☐
3. I know who can help me judge the quality of the information I receive about my disease	☐	☐	☐	☐	☐
How I clarify my priorities					
4. When I make decisions about my disease, I am clear about what matters most in my life	☐	☐	☐	☐	☐
5. I can compare the good points and bad points of a decision about my disease	☐	☐	☐	☐	☐
6. I can set sensible goals to manage my disease	☐	☐	☐	☐	☐
How I communicate with others					
7. I feel confident in stating my concerns to my health care team	☐	☐	☐	☐	☐
8. I know how to ask good questions about my health and my disease	☐	☐	☐	☐	☐
9. I can build a good relationship with my health care team.	☐	☐	☐	☐	☐
How I work with the health team to control my disease.					
10. I am able to take part in decisions in ways I prefer with the health care team	☐	☐	☐	☐	☐
11. I know who to work with in my health care team to meet my health needs	☐	☐	☐	☐	☐
12. I can get what I need in my health team to meet my needs (for example, information and treatments)	☐	☐	☐	☐	☐
13. I feel a sense of control over the symptoms of my disease.	☐	☐	☐	☐	☐
How I decide and act on decisions					
14. I feel confident in making decisions about my health	☐	☐	☐	☐	☐
15. I can negotiate with others who are involved with my care about how we manage my disease	☐	☐	☐	☐	☐
16. I can find my way within health care services in managing my disease	☐	☐	☐	☐	☐
17. I can organise my life to carry out decisions about managing my disease	☐	☐	☐	☐	☐

Appendix 11. NHS Research Ethics Committee (REC) Approval Letter

Yorkshire & The Humber - South Yorkshire Research Ethics Committee
Unit 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0191 4283467

15 January 2016

Mr Prakash Jayakumar
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
University of Oxford, Nuffield Orthopaedic Centre
Windmill Road
OX3 7HE

Dear Mr Jayakumar

Study title:	**Patient Reported Outcome (PRO) Measurement of Disability in Trauma to the Upper Extremity**
REC reference:	**16/YH/0017**
Protocol number:	**N/A**
IRAS project ID:	**183283**

The Proportionate Review Sub-committee of the Yorkshire & The Humber - South Yorkshire Research Ethics Committee reviewed the above application on 15 January 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Gillian Mayer, nrescommittee.yorkandhumber-southyorks@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

The Sub-Committee agreed that the research summary was better written so that it could be easily understand by a lay person, given that it would be made publically available.

You provided an amended document.

The Sub-Committee was satisfied with the revised documentation.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
IRAS Checklist XML [Checklist_22122015]		22 December 2015
IRAS Checklist XML [Checklist_04012016]		04 January 2016
IRAS Checklist XML [Checklist_06012016]		06 January 2016
Letter from sponsor [Signed Sponsor Letter]	1.0	11 December 2015
Other [CV Supervisor David Ring]	1.0	24 December 2015
Other [CV Supervisor Steve Gwilym]	1.0	24 December 2015
Other [CV Supervisor Mark Williams]	1.0	25 December 2015
Other [CV Sarah Lamb]	1.0	01 January 2016
Other [Validated Questionnaire: EQ5D]	1.0	04 January 2016
Other [Validated Questionnaire: OSS]	1.0	04 January 2016
Other [Validated Questionnaire: Pain NRS]	1.0	04 January 2016
Other [Validated Questionnaire: PCS]	1.0	04 January 2016
Other [Validated Questionnaire: PRWE]	1.0	04 January 2016
Other [Validated Questionnaire: PSEQ-2]	1.0	04 January 2016
Other [Validated Questionnaire: QuickDASH]	1.0	04 January 2016
Other [Validated Questionnaire: TSK-11]	1.0	04 January 2016
Other [University of Oxford Insurance]	1.0	04 January 2016
Other [Study Summary]	5.2	13 January 2016
Participant consent form [TrUE PROMS Consent Form]	1.0	11 December 2015
Participant information sheet (PIS) [TrUE PROMS Patient Information Sheet]	1.0	11 December 2015
REC Application Form [REC_Form_04012016]		04 January 2016
Research protocol or project proposal [TrUE PROMS Protocol]	1.0	11 December 2015
Summary CV for Chief Investigator (CI) [CV]	1.0	11 December 2015

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

16/YH/0017	**Please quote this number on all correspondence**

Yours sincerely

Mr Ian Cawthorne
Chair

Email: nrescommittee.yorkandhumber-southyorks@nhs.net

Appendix 12. Patient Information Sheet

UNIVERSITY OF OXFORD

Oxford University Hospitals NHS
NHS Foundation Trust

Participant Information Sheet

'TrUE PROMS' STUDY

What are the Most Influential Factors affecting Health and Quality of Life following Shoulder, Elbow and Wrist Fractures from the Patient's Perspective?

If you are over 16 years of age and have fractured your shoulder, elbow or wrist, you may be suitable for taking part in a research study called TrUE PROMS

- Before deciding whether or not to take part in the study, it is important for you to understand the **Key Facts**, **Details** of the study, **Why** it is being done, **What** it will involve & **Next** steps

- Key Facts
  - Joining the study is entirely up to you
  - If you decide to take part, you can withdraw at any time without giving a reason
  - Whatever you decide, the standard of care you receive will not be affected in any way
  - The study team want you to be fully informed before you make your decision

- Please take a moment to read this information, especially whilst you are waiting
- Please **ask the staff** in clinic and / or a member of the **research team** if you have any questions

Contents

- Why are we carrying out this study?
- Important Information and what this study will involve?
- Do I have to take part?
- If I agree to take part: what happens next?
- If I agree to take part: what happens later?
- Confidentiality
- Are there any benefits or risks for me in joining the study?
- When did the study begin and when will it end?
- Who is organising and funding the study?
- Who has reviewed the study?
- How long will my data be stored?
- What if new information becomes available during the study?
- How do I withdraw if I want to do so?
- What if there is a problem?
- Can I have a summary of my study results?

Contact Details

Your Principal Investigator is:
Mr Prakash Jayakumar
Specialist Registrar in Trauma and Orthopaedic Surgery

Telephone:
01865 741166

Email:
trueproms@ndorms.ox.ac.uk

- Fractures of the shoulder, elbow and wrist are common in patients of all ages. These injuries have a significant impact on a patient's quality of life. Traditionally, orthopaedic surgeons have focused on fractures from the clinical perspective and used their physical examination and x-rays as a way of measuring the outcome of treatments. However, it is being increasingly recognised that these features are probably not as important as understanding the patient's mind-set (i.e psychological status), how they participate in society, at home & at work (i.e social status) and how they experience symptoms such as pain. For example, the ability to care for one-self, perform activities of daily life including return to work, and cope with pain, may be more important to the patient than the extent to which the fracture has healed on x-rays or how much one can move their arm.

- We plan to use questionnaires called patient reported outcome (PRO) instruments that provide scores in each of these areas that can then be analysed. We will be using traditional PRO instruments with a fixed number of questions and a newer system called a Computer Adaptive Test or CAT. CATs use a software program that puts forward questions based on the participant's last response, automatically 'adapting' to their answers. They aim to be shorter in duration whilst maintaining accuracy.

- Ultimately, understanding the most influential factors affecting health and quality of life after these injuries allows us to focus on these during treatment, identify patients who are in most need, and improve outcomes of care. Overall, this subject has not been studied in any great detail in upper limb trauma conditions such as shoulder, elbow and wrist fractures. CATs are also relatively new and not well studied.

- We also plan to use a relatively new questionnaire called a patient activation measure (PAM) which assesses how pro-active patients are in managing their health and healthcare. This will be compared with PRO instruments and CATs, which is another area that is not well studied.

Important information and what this study will involve?

- The TrUE PROMS Study is part of an educational project, which will be taking place in this Trust and 2 other teaching hospitals in the UK. A total of 500 patients will be invited to participate across all hospitals.
- With your permission, we aim to collect clinical and other relevant information about you and your shoulder, elbow or wrist fracture. We will provide you with questionnaires at the first presentation in fracture clinic, then at 2 weeks and around 8-12 weeks following the injury. These will be worked around times when you are due to come to clinic anyway. If this proves difficult, which it sometimes can, we can contact you by telephone or email too.
- Data collected is anonymised. A unique study number is assigned to each study participant and this number is placed in our database. This number will be used for organisational purposes and linking documents and data related to you whilst maintaining full confidentiality.
- Once follow-up information has been collected, the unique study number will allow the follow up data to be matched back to the information collected at first presentation in fracture clinic.
- How your shoulder, elbow or wrist fracture is treated will not be altered by taking part in TrUE PROMS. TrUE PROMS is collecting information and only broadly evaluating treatment type. We need your permission to collect this information, keep in touch during follow-up and potentially contact you if we can't see you in clinic at any stage.

- During your discussion with us, if you have any pain or symptomatic issues which you'd like to highlight and do not feel have been addressed satisfactorily, we will of course be able to refer you back to the clinical care team to reassess the situation.

Do I have to take part?

- No. You do not have to take part in this study. Participation is entirely voluntary.
- Should you decide not to take part, your care continues as usual with no changes. We may ask for reasons why you have declined to partake in the study in order for us to understand and improve our project, but providing reasons for not taking part is also voluntary.

If I agree to take part: what happens next?

- After an introduction to the study by the research team and once any questions have been answered, you will be invited to complete and sign the informed consent form. You will also be asked for permission to be contacted about the study and provide your contact details.
- The contact details include your home telephone, mobile and / or an email address so we can be in touch to carry out follow up which is essential to the study.
- Whilst in the department, you will be asked to complete the PRO instruments on an electronic tablet device and perform a grip strength assessment by gripping a small device within your levels of comfort. If you need assistance due to your injury or would prefer the investigator input your responses for you on the electronic tablet device, this can of course be arranged. There are multiple surveys but some of these are only a few questions long. Completing them should take no longer than a maximum of 10 minutes but this can be considerably quicker.

If I agree to take part: what happens later?

- There will be no additional visits or travel as part of this study outside your standard NHS care.
- We would like to contact you for further study follow up within 2 weeks and 8-12 weeks after your initial attendance at the fracture clinic.
- Follow up will be carried out in person using the same web-linked tablet computer in clinic or if this is not possible for any reason, by online questionnaire or telephone. This will involve responding to questions about your progress. Each follow up should take around 8 minutes.
- The table below gives an overview of what information we would like to collect about you at the various time points.

Time	Method	Information collected
New Patient Fracture Clinic	Online questionnaire	• Study Questionnaire: questions relating to your background, activity levels, thoughts and emotions, social status, symptoms, general health and how actively involved you are in your own care
At 2 weeks follow-up	Online questionnaire	• Study Questionnaire: questions relating to your background, activity levels, thoughts and emotions, social status, symptoms, general health, recovery and how actively involved you are in your own care
At 8-12 weeks follow-up	Online questionnaire	• Study Questionnaire: questions relating to your background, activity levels, thoughts and emotions, social status, symptoms, general health, recovery and how actively involved you are in your own care.

Confidentiality

All information collected about you, either from you personally or from your medical records, will be kept strictly confidential at all times. Your medical notes may be seen by authorised members of the research team so they can collect information needed for this research study. Each participant will be given a unique study number to make sure they cannot be identified outside of the study. Any information about you that is included in any reports will use only your unique study number to ensure anonymity. The contact details on the consent form and other identifying details will be kept entirely confidential in secure, locked storage at the hospital site.
The study database will be password protected and will only be used by named researchers working on this study under the direct supervision of the senior scientific investigators.

Are there any benefits or risks for me in joining the study?

- This study asks you to spend a brief amount of time completing questionnaires.
- As this research is focused on using information, some of which is already routinely collected, the risk of harm is very low.
- The study will not interfere with your fracture treatment or any later rehabilitation you might receive from your General Practitioner or Physiotherapist.
- We cannot promise the study will help you in particular, but the information we get from this study may help improve the NHS treatment for people with upper limb fractures in the future.

When did the study begin and when will it end?

- The project will start in early 2016
- The project will close at the end of 2016, with study results available shortly afterwards.
- Each participant will be in the study for a total of 8-12 weeks after their initial visit to the Fracture Clinic.

Who is organising and funding the study?

- The TrUE PROMS Study is led by researchers based at the University of Oxford.
- The study is funded by the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences.
- The clinicians and research staff involved in this study do not receive any payment other than what is required to cover the necessary expenses. The study is independent of any commercial organisation.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the South Yorkshire Research Ethics Committee

How long will my data be stored?

- Personal identifiable information (such as your name, contact details and NHS number) will be held securely and separately to the anonymised data collected in the study for up to 12 months.

- The study team do not use this data for any other purpose without further permission from the Research Ethics Committee and you.
- All centrally held study information will be disposed of responsibly in accordance with the University of Oxford guidelines.

What if new information becomes available during the study?

- This study does not change your fracture treatment or later management pathway.
- This study is largely independent of any changes to treatment guidelines.
- In the unlikely event that any changes emerge in relation to the guidelines for follow-up in the treatment of shoulder, elbow or wrist fractures, these will be implemented in the usual way by the clinical team.

How do I withdraw if I want to do so?

- Your legal rights will not be affected by agreeing to take part in or withdrawing from the study.
- You are free to withdraw from the study at any time without giving a reason.
- If you decide to withdraw from the study, this will not affect the standard of your routine care in any way. Your consulting health care professional will continue to treat you with the same level of care.
- Your anonymised data collected to the point of withdrawal will be used for analysis unless you indicate otherwise.

What if there is a problem?

- The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. In addition, NHS indemnity operates in respect of the clinical treatment with which you are provided.
  If you have any concerns or if you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact:

  Mr Prakash Jayakumar
  The TrUE PROMS Study
  University of Oxford
  Kadoorie Centre
  John Radcliffe Hospital
  Oxford OX3 9DU
  01865 228368
  trueproms@ndorms.ox.ac.uk

- Or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) Office on:
  Tel: 01865 572224 or the head of CTRG, email: ctrg@admin.ox.ac.uk

Can I have a summary of the study results?

- At the end of the study the anonymised data collected will be analysed and published in a medical journal.
- We will ask you at your final follow-up whether or not you would like to receive a summary of the results of the study. We will email the results summary to the address you provide or any updated email address you notify us of during the course of the study.
- Results will also be available on publically accessible websites. The identity of patients who took part in the study will always remain confidential.

Thank you for considering participation in this study and for taking time to read this information sheet

Appendix 13. Consent Form





Ethics Reference:

Study code: Site ID code: Participants identification number for this study

		–			–					

CONSENT FORM

Title of Project:
Patient Reported Outcome Measurement of Disability in Trauma to the Upper Extremity (TrUE PROMS Study)

Please initial boxes if you agree

Name of Local Researcher: [Please PRINT PI / CI name here]

1. I confirm that I have read the information sheet dated .....or the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Oxford (Sponsor), from relevant authorities and from the University Hospital NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree that appropriate personal identifying information will be collected, used and stored by the central research team as described in the Patient Information Sheet given to me. ☐

5. I agree to the research team contacting me with the follow-up surveys in-case we are unable to meet face to face in clinic to perform them. ☐

6. I agree to take part in the above study ☐

Ethics Reference:

Study code: | Site ID code: | Participants identification number for this study

		–			–					

In this instance, I will allow these surveys to be administered by:

Please initial boxes if you agree

	Please Tick ✓
Telephone / Mobile	☐
Email	☐
Either Tel / Mob / Email	☐

Name of Participant	Date	Signature

Name of Person taking consent	Date	Signature

Ethics Reference:

Study code:		Site ID code:		Participants identification number for this study				

When completed copy x 3:
1 for participant; 1 to study coordinating office in Oxford; 1 for medical notes;

Original: to be kept in Investigator Site File

Appendix 14. Oxford University Hospital NHS Trust R&D Approval Letter

RESEARCH SERVICES
Clinical Trials and Research Governance
Joint Research Office
Block 60
Churchill Hospital
Headington
Oxford
OX3 7LE

To whom it may concern

Date: 11/12/2015

Dear Sir/Madam,

Title: Patient Reported Outcome (PRO) Measurement of Disability in Trauma to the Upper Extremity

PID: 11761

Protocol Date/Version: 11.12.2015 Version 1.0

The above study has been designed by Mr Prakash Jayakumar and colleagues at the University of Oxford and funded by Departmental Resources (Internal Funding) . I confirm that the University will accept the role of Research Sponsor of this Study and will comply with the requirements of the Department of Health Research Governance Framework for Health and Social Care 2005, in so far as these apply in the United Kingdom.

Insurance-provided indemnity arrangements are in place for the project:
Newline Underwriting Management Ltd., at Lloyd's of London.

Sponsorship is confirmed subject to the condition that the following are sent to Clinical Trials and Research Governance for review prior to submission to the Research Ethics Committee. Failure to do so may compromise insurance cover for the project.

- Any substantial amendment
- Any extension to the study end date
- Addition of any new research site or patient identification centre

In addition, annual progress reports must be copied to Clinical Trials and Research Governance.

Any communications relating to Research Sponsorship should be directed to the undersigned, whose contact details are given in this letter.

Yours faithfully

Heather House
Head of Clinical Trials and Research Governance

Tel: +44 (0)1865 572221 · Fax: +44 (0)1865 572228 · Web: www.admin.ox.ac.uk/researchsupport/ctrg/
Email: Heather.house@admin.ox.ac.uk or Elaine.Chick@admin.ox.ac.uk

Appendix 15. Organisational Permission to Conduct Research Letter

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
OXFORD, OX3 7LD
e-mail: steve.gwilym@ndorms.ox.ac.uk

Ref: SG/lea
6th of March 2014

The London Deanery

Dear Sirs

Organisational Permission for Research: Mr Prakash Jayakumar
DPhil Project: Optimising Outcome Assessment in Upper Extremity Trauma and Upper Extremity Fragility Fractures

Mr Jayakumar has full permission to conduct this research project at the Nuffield Orthopaedic Centre, Oxford University Hospitals and the Nuffield Department of Trauma, Orthopaedics and Musculoskeletal Sciences.

Dr Jayakumar is currently pursuing a DPhil investigating the optimisation of outcome assessment in the management of upper extremity trauma, for which I am one of his supervisors. DPhil studies at Oxford have full GMC approval and fulfil all GMC requirements.

Yours sincerely

Dr Stephen Gwilym DPhil FRCS (Trauma & Orthopaedics)
Senior Research Fellow – Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences

Appendix 16. Age Adjusted Charlson Comorbidity Index (232)

Score	Condition
1	Myocardial infarction (history, not ECG changes only)
	Congestive heart failure
	Peripheral vascular disease (includes aortic aneurysm ≥6 cm)
	Cerebrovascular disease: CVA with mild or no residua or TIA
	Dementia
	Chronic pulmonary disease
	Connective tissue disease
	Peptic ulcer disease
	Mild liver disease (without portal hypertension, includes chronic hepatitis)
	Diabetes without end-organ damage (excludes diet-controlled alone)
2	Hemiplegia
	Moderate or severe renal disease
	Diabetes with end-organ damage (retinopathy, neuropathy, nephropathy, or brittle diabetes)
	Tumor without metastases (exclude if >5 y from diagnosis)
	Leukemia (acute or chronic)
	Lymphoma
3	Moderate or severe liver disease
6	Metastatic solid tumor
	AIDS (not just HIV positive)

NOTE. For each decade > 40 years of age, a score of 1 is added to the above score.

Abbreviations: ECG, electrocardiogram; CVA, cerebrovascular accident; TIA, transient ischemic attack; AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.

Appendix 17. Index of Multiple Deprivation 2015 - Definitions

Domains

Income Deprivation Domain

The Income Deprivation Domain measures the proportion of the population experiencing deprivation relating to low income. The definition of low income used includes both those people that are out-of-work, and those that are in work but who have low earnings (and who satisfy the respective means tests).

Employment Deprivation Domain

The Employment Deprivation Domain measures the proportion of the working age population in an area involuntarily excluded from the labour market. This includes people who would like to work but are unable to do so due to unemployment, sickness or disability, or caring responsibilities.

Education, Skills and Training Deprivation Domain

The Education, Skills and Training Deprivation Domain measures the lack of attainment and skills in the local population. The indicators fall into two sub-domains: one relating to children and young people and one relating to adult skills.

Health Deprivation and Disability Domain

The Health Deprivation and Disability Domain measures the risk of premature death and the impairment of quality of life through poor physical or mental health. The
domain measures morbidity, disability and premature mortality but not aspects of behaviour or environment that may be predictive of future health deprivation.

Crime Domain

The Crime Domain measures the risk of personal and material victimisation at local level.
Barriers to Housing and Services Domain

The Barriers to Housing and Services Domain measures the physical and financial accessibility of housing and local services. The indicators fall into two sub-domains: 'geographical barriers', which relate to the physical proximity of local services, and 'wider barriers' which includes issues relating to access to housing such as affordability and homelessness.

Living Environment Deprivation Domain

The Living Environment Deprivation Domain measures the quality of the local environment. The indicators fall into two sub-domains. The 'indoors' living environment measures the quality of housing; while the 'outdoors' living environment contains measures of air quality and road traffic accidents.

Lower-Layer Super Output Areas

Lower-Layer Super Output Areas (LSOAs) are small areas designed to be of a similar population size, with an average of approximately 1,500 residents or 650 households. There are 32,844 Lower-layer Super Output Areas (LSOAs) in England. They were produced by the Office for National Statistics for the reporting of small area statistics. LSOAs are referred to as 'neighbourhoods' throughout this release.

Following the 2011 Census, the geography of Lower-layer Super Output Areas was revised, and the number of areas has increased from 32,482 (as used in the 2010, 2007 and 2004 Indices of Deprivation) to 32,844 (used in the 2015 Indices of Deprivation). The boundaries of the vast majority (96 per cent) of these 32,844 areas are unchanged since the Indices of Deprivation 2010, 2007 and 2004.

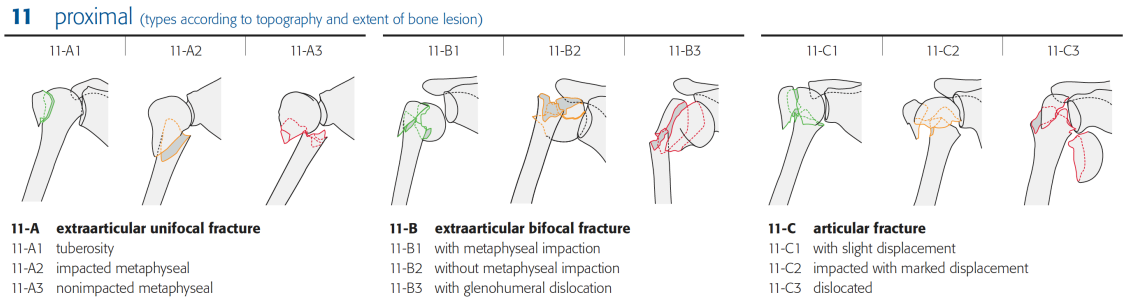
But elsewhere, some neighbourhoods have been combined or split and some new neighbourhoods have been created; this is to account for significant population change occurring in these areas between the 2001 and 2011 Censuses. This means that 31,672 areas have the same boundaries as in previous versions of the Indices, and can be used in analysis comparing relative deprivation over time (see 'understanding change over time' in the 'Further information' section below for guidance on this). (233)



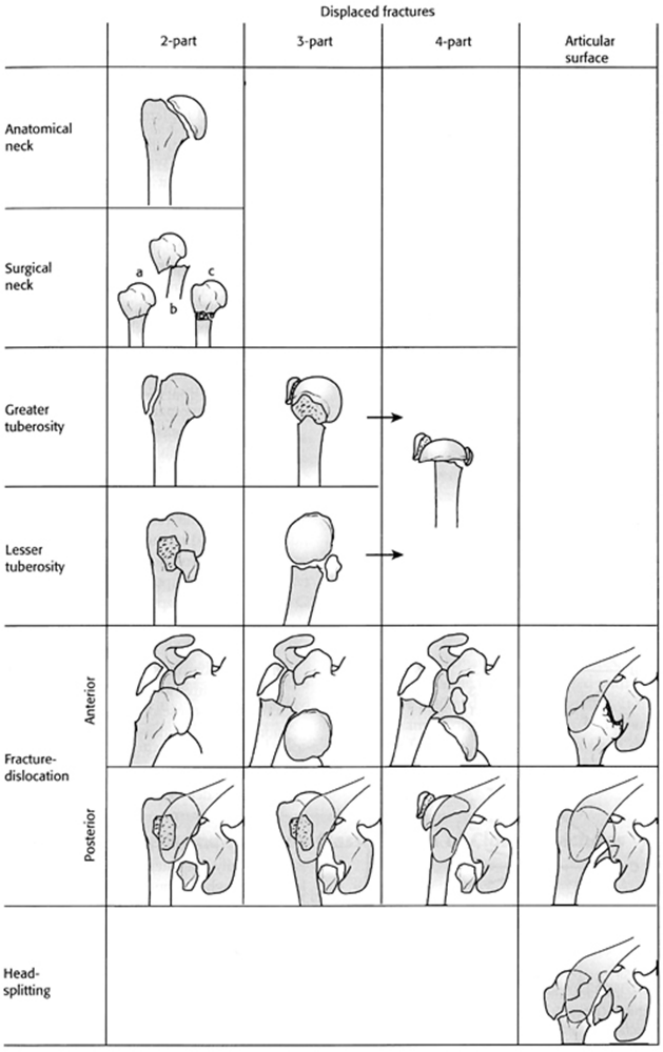
Department for
Communities and
Local Government

The English Indices of Deprivation 2015

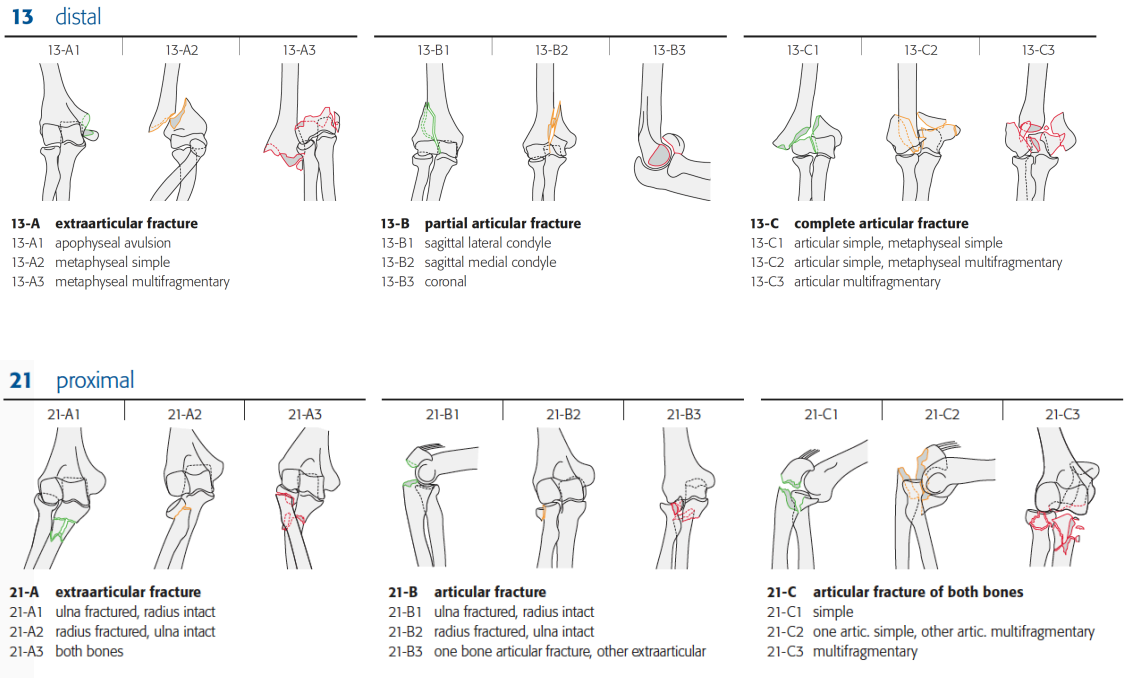
Appendix 18. AO/OTA classification of Proximal Humerus Fractures



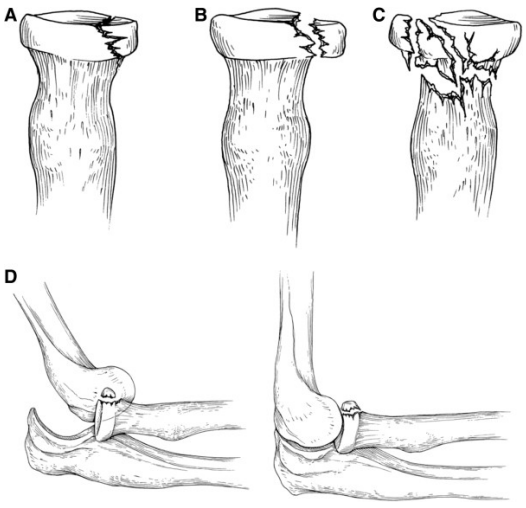
Appendix 19. Neer Classification of Proximal Humerus Fractures



Appendix 20. AO/OTA classification of Distal Humerus / Proximal Radius-Ulna Fracture

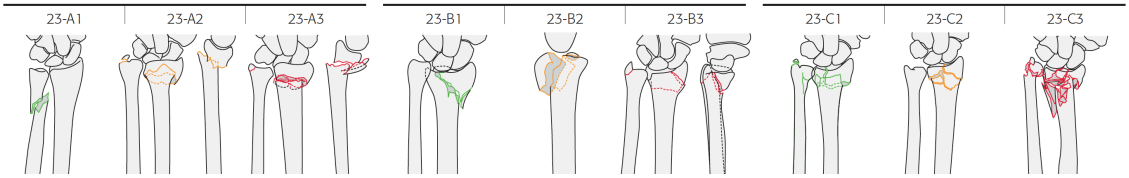


Appendix 21. Modified Mason Classification of Radial Head / Neck Fractures



Appendix 22. AO/OTA classification of Distal Radius Fracture

23 distal



23-A extraarticular fracture
23-A1 ulna fractured, radius intact
23-A2 radius, simple and impacted
23-A3 radius, multifragmentary

23-B partial articular fracture of radius
23-B1 sagittal
23-B2 coronal, dorsal rim
23-B3 coronal, palmar rim

23-C complete articular fracture of radius
23-C1 articular simple, metaphyseal simple
23-C2 articular simple, metaphyseal multifragmentary
23-C3 articular multifragmentary



‘We’ve been wrong about what our job is in medicine. We think our job is to ensure health and survival. But really it is larger than that. It is to enable health and well-being.’

Atul Gawande

American Surgeon, Writer and Public Health Researcher


UNIVERSITY · OF · OXFORD
DOMI NVS ILLV
MINA TIO MEA