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Predicting Risk for Adverse Outcomes Following Distal Radius Fracture

Saurabh Mehta PhD
Marshall University, mehtas@marshall.edu

PREDICTING RISK FOR ADVERSE OUTCOMES FOLLOWING DISTAL RADIUS FRACTURE

By SAURABH MEHTA B.PT, M.Sc. (Rehabilitation)

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AUTHOR: Saurabh Mehta B.PT (Maharaja Sayajirao University, India), M.Sc. (Rehabilitation) (University of Manitoba)

SUPERVISOR: Dr. Joy C MacDermid, PhD

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ABSTRACT

Some individuals remain at risk for adverse outcomes such as chronic wrist/hand pain, falls, and fall-related osteoporotic fractures after distal radius fracture (DRF) remain. This thesis includes five studies that were conducted to establish prediction rules for assessing the risk of these adverse outcomes following DRF.

The first manuscript outlines a theoretical framework (RACE - **R**educing pain, **A**ctivating, **C**ognitive reshaping, **E**mpowering) for managing the risk of adverse outcomes, mainly chronic pain, in individuals with DRF. The RACE is one of the first frameworks to suggest a risk-based management approach for individuals with DRF.

The Patient-Rated Wrist Evaluation (PRWE) is a condition-specific measure for DRF used in research as well as clinical practice to measure pain and functions in individuals with different wrist/hand injuries. The second manuscript contributes to the literature by providing the first systematic literature review that synthesizes the evidence regarding the psychometric properties of the PRWE. The review determined that the PRWE has excellent reliability, construct validity, and responsiveness in individuals with DRF.

The third manuscript indicates that the baseline pain intensity is an independent predictor of chronic pain in individuals with DRF. The results also suggest that the individuals who score ≥35/50 on the pain scale of the PRWE at baseline have 8 times greater risk for developing chronic wrist/hand pain compared to those who score < 35/50.

The fourth and fifth manuscripts describe results of a two step study. The fourth manuscript is a structured literature synthesis that identified suitable measures for predicting the risk of falls and fall-related osteoporotic fractures following DRF. The fifth manuscript summarizes the results of preliminary analysis of psychometric properties of selected fall risk measures identified in the fourth manuscript. The fifth manuscript also provides feasibility and sample size requirements for conducting a fall prevention trial in individuals with DRF.

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I thank my parents who have taught me to be committed and dedicated towards my work. They have given a strong and unconditional support in my pursuit of achieving life goals.

PREFACE

Below is the description of student's contribution to each of the manuscripts.

For the five manuscripts: Saurabh Mehta conceptualized the research questions, study designs, data collection and data analyses (where applicable), and writing the drafts of manuscripts.

Dr. Joy MacDermid provided required expertise throughout as Saurabh Mehta conducted these studies, assisted with refining objectives and designs for each of the studies, assisted with establishing data collection at the Hand and Upper Limb Center, London, Ontario, and editing the manuscripts.

Drs. Julie Richardson, Norma MacIntyre, Ruby Grewal assisted with reviewing the study objectives, providing their content expertise, and editing the manuscripts.

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Chapter 1. Background

Statement of Research Problem

The objectives of this thesis work were to establish clinical prediction guidelines to profile the risk for chronic pain, falls, and osteoporotic fractures following distal radius fracture (DRF). As many as 16% of individuals report ongoing pain and disability at 1 year after DRF (Moore & Leonardi-Bee, 2008; MacDermid, Roth, & Richards, 2003). At present, the rehabilitation of individuals with DRF focuses on reducing wrist pain/disability (American Academy of Orthopaedic Surgeons, 2009). This approach is based on treating presenting symptoms and does not consider screening the potential risk of chronic pain and providing rehabilitation to reduce such risk. In middle-aged individuals (between 45-65 years of age), DRF is considered to be an early sign of osteoporosis (Earnshaw, Cawte, Worley, & Hosking, 1998; Mallmin & Ljunghall, 1994). Researchers have also shown that a small subset of individuals who sustain DRF remain at risk of future falls, and osteoporotic fractures (Nordell, Kristinsdottir, Jarnlo, Magnusson, & Thorngren, 2005). Distal radius fracture is also considered to be an independent predictor of future osteoporotic fracture (Nordell et al., 2005). Therefore, it would be beneficial if all individuals with DRF undergo proper screening to profile their risk for future osteoporotic fractures which may provide insight into comprehensive management of individuals at higher risk. Current practice guidelines for DRF management focus on achieving optimal anatomic reduction, fracture healing, reducing wrist/hand pain and restoring hand functions (American Academy of Orthopaedic Surgeons, 2009). Routine assessment of the risk for chronic pain, future falls, and osteoporotic fractures is not a part of these practice guidelines. The research studies

outlined in this thesis are a part of systematic and stepwise knowledge building exercise conducted to establish evidence-based screening guidelines to profile the risk for chronic pain, falls, and osteoporotic fracture in individuals following DRF. This thesis consists of five separate manuscripts that address clinical questions related to such screening.

Falls and Burden of Fall-related Injuries

Two recent reviews summarized definitions of a fall described across randomized controlled trials (RCT) (Schwenk et al., 2012; Hauer, Lamb, Jorstad, Todd, & Becker, 2006). Falls were defined in different terms depending on the perspective taken to define falls such as medical, psychological, behavioral, or healthcare usage perspectives. "An individual coming in contact with a lower level" was a common component across these definitions (Hauer et al., 2006). Falls and fall-related injuries are one of the major health care concerns across developed countries. In older adults, falls are one of the major causes of mortality (Alamgir, Muazzam, & Nasrullah, 2012). An estimated 230 individuals per 10,000 persons were treated for fall-related injuries at the emergency departments (ED) across the United Kingdom in 1999 (Scuffham, Chaplin, & Legood, 2003). Similarly, 1.67 million older adults were treated at ED for similar injuries across the USA in 2002, of which 388,000 required hospital admission (Stevens, Corso, Finkelstein, & Miller, 2006). In Canada, 85% of all injury related hospital admissions are due to falls in older adults >65 years of age (Weir & Culmer, 2004). Recent estimates indicate the cost for managing fall-related injuries are high (Stevens et al., 2006; Beynon et al., 2011; Zecevic et al., 2012; Davis et al., 2010; Woolcott, Khan, Mitrovic, Anis, & Marra, 2012). The cost of falls that are managed in ED but do not require hospital

admission have been reported as $700 per person (Woolcott et al., 2012). These estimates provide immediate costs of managing fall-related injuries, however the long term personal, economic, and societal burden of these fall-related injuries are staggering (Bohl et al., 2010; Hartholt et al., 2011). In Canada, the direct costs related to fall can be as high as $39,000 for an individual who requires hospital admission due to a fall-related hip fracture (Woolcott et al., 2012). During a fall, part of the body area comes in contact with the ground and is subjected to the impact. Fracture occurs when the amount of the force of the impact exceeds the ability of the bone to withstand the force. Fractures involving hip, distal forearm, and vertebra are regarded among the most common fall-related osteoporotic fracture sites (Piscitelli et al., 2011a; Cummings & Melton, 2002). Not all vertebral fractures result from a fall. In fact, only 33% of all vertebral fractures result from a fall (Myers & Wilson, 1997). Immediate and long-term outcomes of fall-related osteoporotic fractures largely depend on the location of fracture. Individuals who sustain hip or vertebral fractures report a more severe and prolonged impairment of health-related quality of life (HRQOL) compared to those with fractures of upper extremity (Hallberg et al., 2004; Hartholt et al., 2011). In fact, the individuals who sustain fall-related hip fracture experience significant decline in the psychological, social, and environmental domains in the year following the injury (Chiu et al., 2012).

Osteoporosis

Osteoporosis Canada characterizes osteoporosis as a disease with loss of bone mass and deterioration of bone tissue leading to elevated risk of fracture (Osteoporosis Canada, 2011). Osteoporosis Canada further indicates that 33% of women and 20% of

men will suffer from osteoporosis in their lifetime (Osteoporosis Canada, 2011). Osteoporosis mainly results from an imbalance between bone resorption and bone formation. Some of the common mechanisms offered for this imbalance are: failure to achieve peak skeleton strength during growth, increased bone resorption resulting in loss of bone mass and disturbance of bony architecture, and impaired bone formation mechanism failing to replace lost bone (Raisz, 2005). Often, there is interplay between these mechanisms leading to impaired bone health. A fall in individuals with osteoporosis compounds their risk for sustaining fracture. Fall-related osteoporosis fractures are extremely common especially in middle-aged and older adults (Lix et al., 2012).

Distal Radius Fracture

Fracture involving the distal radius is one of the most common of all the osteoporotic fractures resulting from a fall (Cummings & Melton, 2002). Ilyas et al (2010) summarized various classification systems proposed for characterizing the DRF. The classification relevant for immediate orthopedic management is based on the stability of the fracture (stable versus unstable), displacement of fracture fragments (nondisplaced, dorsal, volar, proximal, radial, or a combination of these), number of fragments (two, three, comminuted), and associated injuries to surrounding structures. The following sections illustrate the mechanism of injury, epidemiology, and management of DRF.

Mechanism of Injury

Distal radius fracture is more common in healthy individuals mainly because they are able to outstretch their hand to break the fall and prevent injuries occurring to the body in turn exposing the wrist area to the impact from the fall. Older individuals have

slowed reflexes and speed of extending the arm to break the fall is not sufficient to prevent other body areas from coming into contact with the ground resulting in hip or shoulder fractures (Cummings, 1998). Those with relatively good bone health are able to successfully endure the impact from the fall and suffer no fractures, whereas individuals with impaired bone health suffer DRF as a result of the impact.

Epidemiology of DRF

The incidence of DRF vary greatly across the world and are known to be dependent on the geographical area with trends suggesting higher rates in countries where icy or snowy weather plays a major role in occurrence of low energy DRF (Beynon et al., 2011; Cummings & Melton, 2002; Smith & Nelson, 1998; Jacobsen, Sargent, Atkinson, O'Fallon, & Melton, III, 1999). Different studies have characterized the incidence rates of the DRF worldwide, most of which report considerable variability. Piscitelli et al (2011b) reported the incidence rate of 298 individuals per 100,000 population per year in an Italian sample. The rates of DRF in Britain were 90 individuals per 100,000 population per year for males and 368 individuals per 100,000 population per year for females (O'Neill et al., 2001). In Sweden and Finland, the reported rates were similar where 260 individuals per 100,000 population per year sustained DRF (Brogren, Petranek, & Atroshi, 2007; Flinkkila et al., 2011). In the USA, the rates have varied between 193 for females between the ages of 50-59 to 471 in females who are 80 years and older per 100,000 population per year (Orces & Martinez, 2011). Most of these studies indicate that the rates of DRF are 4 times greater in females compared to males. The most common reason cited for this is that females suffer considerable bone loss immediately before and

after menopause which exposes them to osteoporotic fractures even with minimal trauma where an age matched male typically would have been able to withstand the impact of the fall (Cummings & Melton, 2002). While the incidence of DRF and other osteoporotic fractures increases in males with age, the rates still remain lower compared to females throughout their life cycle (Riggs et al., 2006; Lapi et al., 2012; Ahmed et al., 2009).

Initial Medical Management of DRF

The orthopedic treatment for the acute stage of the DRF can be conservative or surgical fixation of the fracture. The variations in the conservative management include whether the fracture is immobilized or not, the position of the forearm in the cast, type of cast (plaster v/s synthetic material), and the duration of immobilization in the cast for optimal healing (Handoll & Madhok, 2003a). Similarly, surgical management can be in the form of external fixation or per-cutaneous pinning after closed reduction, open reduction and internal fixation, and bone graft to fill any defect in the metaphyses (Handoll & Madhok, 2003b). A recent publication summarized orthopedic management of DRF in North America and identified that conservative management of DRF is on the decline with the advent of newer surgical procedures such as volar locked plates (Yoon & Grewal, 2012).

Rehabilitation Management of DRF

Once the fracture has healed, the individuals with DRF are referred to rehabilitation. The goals of rehabilitation are to improve wrist/hand functions and alleviate pain. Prescription of customized home exercise program with no follow-up in an

outpatient rehabilitation clinic is adequate for individuals with uncomplicated DRF (Krischak et al., 2009; Wakefield & McQueen, 2000). Individuals with complications such as fracture mal-union, ongoing pain, and inability to return to work require intensive rehabilitation (Wakefield & McQueen, 2000). Rehabilitation practitioners managing the DRF population use a variety of measures to determine the level of disablement and rehabilitation needs of patients (Hoang-Kim, Pegreffi, Moroni, & Ladd, 2011). Outcome measures that are commonly used in the DRF population are divided into patient-reported outcome measures (PRO) and performance-based tests (PBT). Of the PRO used in DRF population, the Patient-Rated Wrist Evaluation (PRWE) and the Disabilities of Arm, Shoulder, and Hand (DASH) have been tested in several studies and found to have adequate psychometric properties supporting their use in the DRF population (Hoang-Kim et al., 2011; Goldhahn, Angst, & Simmen, 2008). The former was developed mainly to assess pain and functional disability in the DRF population (MacDermid, Turgeon, Richards, Beadle, & Roth, 1998), whereas the latter is a region-specific measure developed for assessing upper extremity musculoskeletal disability (MSKD) (Hudak, Amadio, & Bombardier, 1996). Wrist range of motion, grip strength, and tests for assessing hand dexterity are common PBT for assessing wrist/hand functions (American Academy of Orthopaedic Surgeons, 2009). The prognosis of most patients, especially those with uncomplicated injury, is excellent with the majority of them regaining pre-injury functional level within few weeks of hand therapy (Wakefield & McQueen, 2000).

Risk of Adverse Outcomes and Screening for this Risk

Some of the commonly characterized adverse outcomes following DRF are poor bony union, ongoing pain and disability, carpal tunnel syndrome, early osteoarthritis, and difficulty returning to work for a longer period after the injury (American Academy of Orthopaedic Surgeons, 2009). As many as 16% of individuals are at risk of chronic pain and ongoing disability following DRF (Moore & Leonardi-Bee, 2008; MacDermid et al., 2003). Approximately 7% of the individuals who report such chronic ongoing pain may fall into the category of having complex regional pain syndrome (Beerthuizen et al., 2012). Early identification of potential risk factors may allow rehabilitation practitioners to provide a focused treatment program to mitigate the risk of chronic pain following DRF. Some reports have indicated that personal and injury factors such as old age, female gender, and malunion of fracture play a small role in chronic pain in the DRF population (Grewal, MacDermid, Pope, & Chesworth, 2007; MacDermid, Donner, Richards, & Roth, 2002). However, it has also been found that older adults, specifically those with malunion, report less pain and disablement compared to younger adults (Grewal & MacDermid, 2007). This is in contrast to the findings that old age and malunion are predictors of chronic pain following DRF. Others have characterized that education level and type of job (heavy manual work versus light work) predict return to work following DRF (MacDermid, Roth, & McMurtry, 2007). These reports outlined factors that could influence chronic ongoing pain following DRF, however they have largely investigated the role of non-modifiable factors in chronic pain which are not amenable to rehabilitation interventions. Moreover, there is inconsistency amongst these reports

related to whether old age and malunion should be considered as risk factors for chronic pain across all age groups or only older adults. Lastly, these factors do not provide a reference point to the clinicians to evaluating change in the risk level or tracking the recovery of the patients. Clinicians would rather have an objective measure that they can use to predict the risk of chronic pain, to use as a reference point to track recovery, and determine the rehabilitation needs of a patient. At present, there is no such measure that can be used in individuals with DRF.

Apart from chronic pain related to DRF, there are other often neglected but potentially more severe adverse outcomes of DRF. Distal radius fracture is increasingly regarded an adverse outcome and early sign of impaired bone health. Some reports have indicated that DRF is an independent risk factor for future osteoporotic fractures (Schousboe et al., 2005; Mallmin & Ljunghall, 1994; Earnshaw et al., 1998). Nordell et al (2005) described the risk of future osteoporotic fractures in older adults with DRF and suggested that evidence-based strategies to assess risk for future falls, osteoporotic fractures, and impairment of physical functions in DRF population are needed. He suggested that a subset of individuals continue to have balance impairment which elevates the risk for future falls. A future fall can result in a fragility fracture in older adults who have underlying osteoporosis (Nordell et al., 2005). The cost of managing DRF in this patient group may not be as high as other osteoporotic fractures (Davis et al., 2010), but knowing that some individuals can sustain more severe osteoporotic fractures that have high cost of management if their fall-risk is not modified warrants a proper screening and management of fall-risk in these individuals. It might be easier for rehabilitation

practitioners to screen individuals who have established risk for falls. The use of an assistive device such as a walker or cane, history of recurrent falls, or pronounced deviations in gait are all easily identifiable markers of fall-risk. It is possible that these individuals have already received or are receiving fall-prevention interventions. However, individuals who have a low to moderate risk for falls may not exhibit these obvious signs of impairment. Individuals with DRF are mostly middle-aged and may not have an "identified" or established fall-risk. Therefore, a proper screening for fall-risk needs to be undertaken rather than deeming those with no obvious impairment as not being 'at risk'.

The current assessment and treatment approaches to managing the DRF identify the interventions for "how to manage" the injury rather than "how to screen and predict" which patient groups are at risk for wrist/hand related or other adverse outcomes (American Academy of Orthopaedic Surgeons, 2009). This clearly is a knowledge-to-practice gap that exists in DRF rehabilitation and preventing the occurrence of adverse outcomes that result from the injury. There is a need for a screening protocol to identify the risk of adverse outcomes such as chronic pain, risk for falls and balance impairment, and risk for osteoporotic fractures in individuals following DRF. Such screening can be done in conjunction with current assessment practices that incorporate assessment of wrist/hand pain and functions and radiological outcomes. Clinicians can institute appropriate management strategies once they have an understanding of the risk profile of a patient.

Another issue that requires consideration is the timing of such screening. Individuals who are initially managed in ambulatory care or ED for DRF may have

varying level of pain intensity depending on the severity of injury. The pain intensity and characteristics are attributed to the acute stage of the DRF injury. Individuals who report abnormally and uncharacteristically high pain in the injured wrist/hand area at this stage may raise a "red flag" but it still maybe too early to start conceptualizing the risk of chronic pain in such individuals (MacDermid et al., 2007). The focus of treatment at this time is to stabilize the fracture using conservative or surgical approaches described earlier. Moreover, the cast applied to the forearm restricts movements of the upper extremity and may not allow the individual to make compensatory body movements required to maintain balance during such assessment. Therefore, this time period may not be appropriate for assessing risk for chronic pain or balance impairment. The cast is usually removed 6 weeks after the injury which is considered the sub-acute phase. The focus of treatment during this stage shifts to rehabilitation of wrist/hand functions. At this stage, the injury is believed to have healed and any observed pain-focused behavior should indeed be considered as a "red flag". This stage provides an opportunity to examine the pain behavior and the risk of transitioning to chronic pain. Moreover, the individuals may also be tested for balance impairment at this stage since they will not have any problems in adopting compensatory balance reactions during testing of balance. Therefore, screening can be performed in the sub-acute stage by rehabilitation practitioners such as physiotherapists or occupational therapists who are trained to conduct assessment for balance impairment and fall-risk.

Knowledge-to-action Framework

In order to address the knowledge-to-practice gap in rehabilitating the DRF, a stepwise evidence-building exercise is required. This exercise should be conceptualized such that the new knowledge has a high potential for applicability and uptake in clinical practice. Tetroe et al (2011) described the use of the knowledge-to-action (KTA) framework for successful implementation of fall prevention strategies for community-dwelling older adults. The framework identified a stepwise approach to successfully disseminate knowledge and its successful implementation to improve fall prevention outcomes. While this approach is highly dynamic in nature, it allows researchers to identify a starting point from where they can conceptualize their scientific undertakings to address the knowledge-to-practice gap. The framework has two aspects to it: one is knowledge creation and the other is the KTA cycle (Tetroe et al., 2011). Researchers can determine whether there is adequate knowledge to answer the clinical problem in which case they can start their dissemination strategies to facilitate the uptake of the knowledge by appropriate stakeholders. In instances where the knowledge regarding how to address the clinical problem is scarce, researchers design and conduct scientific inquiry to create new knowledge (Tetroe et al., 2011). The knowledge created through this inquiry is then disseminated through the KTA cycle. The need for an objective measure that can be used to profile the risk of chronic pain (low, moderate, high) following DRF was identified earlier in this chapter. Secondly, we know that no study has specifically examined how to predict the risk for falls and osteoporotic fractures following DRF. Therefore, there is a

need to create high quality knowledge that is relevant and has the potential to facilitate uptake in clinical practice to screen for the risk of adverse outcomes following DRF.

Objectives of the Thesis Work

The overall objective of this thesis work was to establish clinical prediction guidelines to profile the risk for chronic pain, falls, and osteoporotic fractures following DRF. The thesis used an iterative approach in conducting different research studies to build new knowledge to screen the risk for these adverse outcomes. The objectives of the five manuscripts which are part of this thesis were:

1) To describe the application of two common models of chronic pain in managing DRF and use the results of this discussion to develop a theoretical model for the rehabilitation of DRF;
2) To summarize the evidence regarding the psychometric properties of the Patient-Rated Wrist Evaluation (PRWE), which is a condition-specific outcome measure for the DRF population;
3) To determine whether baseline pain intensity, as measured by the PRWE, is a predictor of chronic pain following DRF and determine the cut-off score for baseline pain intensity that is strongly predictive of chronic pain;
4) To perform a structured literature synthesis to derive a battery of measures that can be used for predicting the risk for falls and osteoporotic fractures in the DRF population; and
5) To conduct a pilot study to determine feasibility aspects for conducting a future RCT aimed at reducing the rates for falls and osteoporotic fractures following

DRF; and to conduct a preliminary analysis of psychometric properties of the measures identified in the literature synthesis (Manuscript 4) in DRF population.

The following section presents a brief summary of each manuscript which highlights why the study was conducted, what study design was used, and what the key results of the study were.

A Brief Summary of Each of the Manuscripts

The title of the first manuscript (Chapter 2) is "The Implications of Chronic Pain Models for Rehabilitation of DRF". Before undertaking further research to answer the clinical problem (the lack of screening guidelines for determining the risk of adverse outcomes after DRF), the need for a theoretical model to conceptualize rehabilitation of DRF in view of early identification of risk profile for adverse outcomes was identified. The characteristics of learned helpless and cognitive-behavioral manifestations are often visible very early in some individuals during the rehabilitation of DRF. The individual beliefs and behavioral traits are often shaped by past experiences and influenced by various socio-economic and interpersonal factors. For example, learned helplessness, motivational deficits, and depression have all been associated with individuals with chronic pain (Crombez, Eccleston, Van Hamme, & De Vlieger, 2008; Molton, Jensen, Nielson, Cardenas, & Ehde, 2008). It is important that the rehabilitation practitioners managing individuals with DRF identify these beliefs and traits and use this information in determining the risk for chronic pain, designing appropriate interventions, and tracking the recovery of these individuals. The manuscript also outlines a model describing the RACE approach (**R**educing pain, **A**ctivating, **C**ognitive reshaping, **E**mpowering) for the

management of individuals following DRF. The model recommends risk-based rehabilitation interventions where individuals with low risk for chronic pain are managed based on the wrist/hand symptoms and those with higher risk of chronic pain are treated with the risk-based RACE approach.

The second manuscript (Chapter 3) is titled "A Systematic Review of the Psychometric Properties of the Patient-Rated Wrist Evaluation". The PRWE is a condition-specific measure that was conceived to measure the constructs of pain and function specifically in the DRF population. Further studies have examined the use of PRWE and assessed its psychometric properties across other wrist/hand conditions. The PRWE has two subscales of pain and function both of which have adequate psychometric properties such that they can be used as separate measures without combining them to obtain a composite score. Since its inception, several studies have examined different psychometric properties of the PRWE but there has been no systematic review that synthesized this evidence. There was a need to create such a review to provide specific recommendations for clinical practice as well as research trials where PRWE is used to assess pain and function in individuals with different wrist/hand conditions including DRF. Moreover, a better understanding of the psychometric properties of the PRWE specifically in the DRF population was essential since we had planned to examine whether baseline pain intensity measured using the pain scale of the PRWE is a predictor of chronic pain at 1 year in individuals with DRF (third manuscript). This manuscript presents the results of the systematic review of the psychometric properties of the PRWE. The study found that the PRWE and versions of PRWE translated to other languages have

very good to excellent test-retest reliability across many wrist/hand conditions. The responsiveness of the PRWE was excellent compared to other competing measures in individuals with DRF. The PRWE also showed good convergent and divergent validity with measures assessing similar or different constructs respectively. This manuscript also summarized the values for minimal detectable change (MDC) and minimal clinically important difference (MCID) for the PRWE score for specific wrist/hand conditions. Clinicians and researchers using the PRWE in their work will find these values useful in determining the change in patient status and for calculating the sample size respectively.

The third manuscript (Chapter 4) is titled "Baseline Pain Intensity is a Predictor of Chronic Pain in Individuals with Distal Radius Fracture". The work was motivated by the need for a clinically useful objective measure that rehabilitation practitioners can use to compute the relative risk of chronic pain following DRF. In this manuscript, the results of a retrospective cohort study are described. The aim of this study was to determine if a specific cut-off level for baseline pain intensity is predictive of the risk of chronic pain in individuals with DRF. Assessment of pain intensity is reliable when using validated measures and the changes in pain intensity can be examined over time to assess the altered risk of chronic pain. A multivariate regression model showed that the baseline pain intensity measured by the pain subscale of the PRWE and being female over the age of 65 years were predictive of chronic pain at 1 year after DRF. Furthermore, the study also determined that the baseline pain score of 35/50 on the pain subscale was strongly predictive of chronic pain at 1 year (sensitivity/specificity of 85/79; area under the curve 87%).

The fourth manuscript (Chapter 5) is titled "A Systematic Literature Synthesis to Identify Measures for Screening the Risk of Adverse Outcomes in Patients Following Distal Radius Fracture". Screening the risk for falls and osteoporotic fractures is not uncommon after injuries such as hip fractures, however we discussed earlier that practice guidelines for managing DRF have not considered this screening recommendations. Through this structured literature synthesis, a battery of measures to screen the risk for falls, osteoporotic fractures, impaired physical activity (PA) level, and impairment in lower extremity muscle strength in individuals with DRF were derived. Since impairment of lower extremity muscle strength and alterations of PA level are known to influence fall-risk, these variables were included as potential risk factors for falls along with balance impairment (Rikkonen et al., 2010; Brouwer, Musselman, & Culham, 2004). The results of this literature synthesis identified up to 3 measures that have potential for use in the DRF population. The selection of measures was made primarily based on administrative burden and ease of use in small private clinics where rehabilitation DRF is commonly performed. The measures identified in manuscript 4 were tested in manuscript 5.

The title of the fifth manuscript (Chapter 6) is "Reliability and Validity of Fall Risk and Balance Measures in Individuals with Distal Radius Fracture - A Pilot Study". The psychometric properties of the measures identified in manuscript 4 required a preliminary testing in the DRF population to build evidence regarding their use in this population. A secondary purpose was to obtain normative values for these measures in the DRF population and compare them against established norms in age and gender matched

individuals. Lastly, through this study the feasibility of conducting a larger RCT to examine the effectiveness of interventions to modify potential risk factors (fear of falling (FOF), balance impairment, changes in PA, and altered lower extremity muscle strength) in individuals identified as being at risk for adverse outcomes following DRF was determined. The results of this study indicated that most measures had very good test-retest reliability (Intraclass Correlation Coefficient values of 0.75) and expected convergent/ divergent relationships with each other according to the construct measured.

To summarize, this section outlined the knowledge-to-practice gap concerning the use of evidence-based strategies to profile the risk for adverse outcomes following DRF. The section also outlined the need for creating new knowledge to address this gap. A brief summary of each of the manuscript included in this thesis portfolio has been provided. This summary included the rationale for conducting the study, how it fits the overall theme of knowledge creation, and results of study. The following five chapters include the five manuscripts in a format that is consistent with the journal targeted for submission. The seventh chapter forms the discussion where the anticipated overall advancement of science and clinical practice resulting from this thesis work are discussed. This section also highlights the strengths and limitations of this thesis work as well as future directions for research.

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Chapter 2. The Implications of Chronic Pain Models for Rehabilitation of DRF

Short title: Rehabilitation of the Distal Radius Fracture

Keywords: Distal radius fracture, chronic pain, musculoskeletal disability, learned helplessness, cognitive-behavioral model

Authors:

Saurabh Mehta**, M.Sc (Rehab) [1]; Joy MacDermid*, PhD[1,2]; Late Mary Tremblay, PhD[1]

Affiliations

[1] School of Rehabilitation Science, McMaster University, Hamilton, Ontario, Canada

[2]Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, London, Ontario, Canada

Correspondence to: Saurabh Mehta, PhD Student, School of Rehabilitation Science, McMaster University, IAHS 402 - 1400 Main Street West, Hamilton, Ontario L8S 1C7, Canada Email: mehtas8@mcmaster.ca. Tel: 001 905 230 4557 Ext 26410, Fax: 001 905 524 0069

Proofs to: the corresponding author

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Abstract

Distal radius fracture (DRF) is the most common fracture and usually occurs as a result of a fall. Most patients recover following DRF with minimal residual pain or disability, however a small subset of patients continue to experience pain and disability even one year after the injury. Currently, there are no practice guidelines for early identification and treatment of patients who are potentially at greater risk of developing these adverse outcomes. As a result, hand therapy management of patients following DRF does not incorporate screening of these at-risk patients. The objective of this paper is to apply constructs from learned helplessness and cognitive-behavioural models of chronic pain in assessing psychosocial risk profile of patients following DRF. We have also integrated key findings derived from studies addressing personal and life-style factors in assessing this risk profile. This framework is proposed as a basis to categorize patients as higher or lower psychosocial risk for developing chronic pain and disability following DRF. We outline a model depicting the RACE approach (Reducing pain, Activating, Cognitive reshaping, Empowering) towards the management of patients following DRF. The model suggests that patients with minimal psychosocial risk factors are managed based on their injury profile and those with higher psychosocial risk are treated with risk-based RACE approach. Using a biopsychosocial RACE approach to prognosis and treatment, hand therapy intervention can be customized for patients recovering from DRF. In future, researchers can conduct clinical trials to compare the RACE- based treatment approach to routine hand therapy in mitigating the risk of chronic pain and disability in patients with elevated risk profile adverse outcomes following DRF.

Introduction

Chronic pain is defined as "pain which lasts beyond the expected point of tissue healing, longer than 3 months duration", [1] and is commonly associated with musculoskeletal disorders. The overall prevalence of chronic musculoskeletal pain is increasing (27% in those living independently and 38% in long-term care homes) [2, 3]. The economic burden resulting from chronic musculoskeletal pain is substantial and likely to increase with the aging population [4, 5]. Chronic pain arising from musculoskeletal conditions such as back pain and fibromyalgia is commonly studied and is known to fit with a biopsychosocial framework [6, 7]. While theoretical frameworks have been discussed in these chronic musculoskeletal conditions, application of these frameworks to managing acute hand injury like a fracture has received little attention.

The focus of this paper is on chronic musculoskeletal pain, arising following hand injury using the example of a distal radius fracture (DRF). DRF is a common injury first described by an Irish surgeon Abraham Colles in 1814, hence it is often labelled as Colles fracture [8]. In developed countries, the incidence of DRF and other wrist fractures is > 39/10000 persons/year [9, 10]. Furthermore, rates of DRF are gradually increasing in developed countries [11, 12].

Acute pain resulting from DRF serves as a warning sign indicating tissue injury. However chronic pain serves no purpose, does not necessarily reflect tissue injury, and is a liability to the body [2, 13]. Pain during fracture healing and remodelling can warn the patients when they are overly stressing the compromised fracture site. Ideally, DRF heals in anatomic position within 6 weeks and patients are able to resume motion of the

affected wrist and hand. Even allowing for bone remodelling, it can be inferred that normal resumption of pain-free activities would be expected by three months.

However, a number of immediate and long-term complications [14] and residual disability are known to occur following DRF. Chronic pain and functional difficulties are common and mostly observed in older adults who are older than 65 years of age. In fact, the incidence of these adverse outcomes is seven times greater in this patient group than those who are under 65 years [15, 16]. Our longitudinal data illustrates that 20% of individuals with a DRF still have moderate pain (and 8% severe or very severe pain) 3-months after a DRF [17]. The incidence of severe or very severe pain remains at 8% at 6-months and drops to 5% at 1-year [17]. Since those in moderate pain at 3-months may still be transitioning due to fracture healing, it seems inappropriate to classify them as having chronic pain at that time point.

A number of studies have identified predictors of poor functional status and chronic pain following DRF. These studies have determined that financial compensation [18], age, income level, and socioeconomic status [19] are the key predictors of chronic pain and functional status following DRF. Moore et al (2008) [15] found older adults were more vulnerable for developing chronic pain following DRF; whereas others report that older patients have less functional disability even when a poor reduction is achieved [20]. This inconsistency is likely because prognosis studies are usually case series or retrospective cohort in nature. The variables being examined are dependent on availability and not derived from any theoretical framework.

To date the literature has largely focused on the biomedical aspects of the problem in the assessment and treatment of patients following DRF [21, 22]. In the light of emerging evidence that the psychological factors could influence the self-reported pain and disability [23, 24], the potential role of psychological factors in development of chronic pain following DRF needs to be explored. Therefore, we selected predominant psychological models and discuss their application to DRF with an emphasis on how they might inform hand therapy management of DRF.

Prior to exploring how these psychological models might inform DRF management, the current evidence around the management of DRF needs to be explored. A systematic review of rehabilitation following DRF found weak evidence to support active therapy over exercises given by surgeon, and also for specific modalities including ultrasound, pneumatic compression devices, and continuous passive motion [25]. It has also been suggested that "in-house" (clinic-based) hand therapy exercises may not be needed for undisplaced casted DRF [26]. These reviews also highlight that the primary focus in DRF rehabilitation has been on correcting physical impairments (oedema, loss of motion/strength/hand function). Since a small subset of patients experience chronic pain and disability following DRF [15, 16, 18], there is a need to identify patients at risk early in the rehabilitation process and determine if altered rehabilitation pathways can prevent these adverse outcomes.

A discussion of all the theoretical models of chronic pain is beyond the scope of this paper. Rather, we have selected two models from psychology literature that have been used extensively in the field of chronic pain, but not discussed in relation to patients

with DRF. The main objective of selecting these models is that the concepts described in both of them (e.g. negative cognitions, helplessness behaviour, catastrophizing etc.) are frequently observed in hand therapy practice while managing patients with DRF. Knowledge regarding these behaviors and strategies to manage them within in the scope of practice of hand therapy may improve the outcomes of patients with DRF. The objective of this paper is to discuss the learned helplessness model and the cognitive-behavioural model of chronic pain and how they apply to DRF rehabilitation. Specifically, we want to identify potential predictors of chronic pain arising from these theoretical frameworks and discuss implications of these models in rehabilitation of patients who are believed to be at-risk of developing chronic pain following DRF. Related constructs from socio-economic and self-efficacy literature are also integrated in this discussion.

Learned helplessness model

The learned helplessness model was first described by Seligman (1972) [27] and then reformulated in 1978 [28]. The model argues that when individuals are unable to overcome a challenging situation, they develop helplessness behaviour. The generality and chronicity of an individuals' helplessness is influenced by the causal attribution these individuals make for the helplessness [28]. If they determine that a given situation is universally uncontrollable, i.e. nobody can change the outcome despite their efforts; then they do not blame themselves for their lack of ability to change the outcome of that situation. Conversely, if they attribute the cause of their helplessness to be their own internal factors, where others can alter the outcome with necessary efforts, the self-blame

is greater and eventually gives rise to three-fold deficits in their behaviour. Subcomponents of this helplessness have been described as below:

I. Cognitive – holding a belief that the outcomes are uncontrollable despite efforts to overcome the situation [28].

II. Motivational – decreased motivation to initiate responses to control the situation. This is because the individual believes that the adverse outcome is inevitable and his actions will not alter it [28].

III. Emotional – learning that the outcomes are uncontrollable leads to depression and lack of self-confidence [28].

Previous studies have explored the relationship between the learned helplessness and chronic musculoskeletal pain. These studies have indicated that the helplessness influences chronic pain behaviour in patients with fibromyalgia, rheumatic conditions, and certain other chronic conditions [29-34]. Samwel et al (2006) [31] also suggested that clinicians involved in the treatment of patients with chronic pain should always examine if learned helplessness is influencing this behaviour before formulating a treatment plan.

Other studies have linked helplessness behaviour to lower self-dignity and disrupted identity. Individuals suffering from helplessness behaviour tend to have poor socio-economic status and quality of life in addition to depressive behaviour [35, 36]. Thus the literature suggests that there may be both generic and (pain) specific aspects to learned helplessness.

Learned helplessness can develop during response to injury like DRF, but is also modulated by prior experiences with painful conditions. In particular, if patients were

unable to successfully manage their pain or control the outcome of a previous health problem, they may be "preset" in a mode of learned helplessness. When confronted with a new injury, such as DRF, their injury response may be governed by previously developed learned helplessness. Patients with chronic musculoskeletal pain demonstrate depressive behaviour, withdrawal, and motivational deficits [37-39]. This is congruent with the learned helplessness model and would lead to reduced engagement in rehabilitation. Since lack of adherence to hand therapy can lead to poor outcomes following DRF [40], hand therapists may need to assess learned helplessness as a potential barrier to rehabilitation and be prepared to appropriately manage it.

Cognitive-behavioral model of chronic pain

The cognitive-behavioural model of chronic pain proposes that patients' negative beliefs and poor coping behaviours are central to the development and maintenance of chronic pain [39, 41, 42]. Patients with pain are engaged in a continuous process of interpreting the information related to their pain. Their interpretation and reaction to the injury predicts the behavioural coping and emotional state of the individual [39, 41, 42]. It has been suggested that negative cognitive behaviours following an injury could lead to catastrophic pain and chronicity [39, 41, 42]. A number of factors such as reacting negatively to the physical injury, avoiding usual activities due to fear of aggravating pain, decreased self-efficacy, and lack of initiative in handling the problem can lead to psychological distress and maintenance of the painful state. It is has been believed that pain behaviours such as verbal reporting of intense pain, limping while walking, and avoiding daily activities are associated with poor coping skills [43]. In patients with hand injuries, these

behaviours might include holding the affected hand with the unaffected hand for support, avoiding movement, jerky/dyskinetic movement, and exaggerated pain complaints during therapy. Being overly reliant on protective devices and orthotics might also suggest this behaviour pattern.

The model also proposes that factors such as attention from spouse, health care providers, and financial compensation can become motivators of the pain behaviours as they reinforce the learned helplessness [42, 44, 45]. Financial compensation has already been observed as a predictor of chronic pain in patients with DRF [18]. The attention from spouse and health care providers in influencing chronic pain behaviours in patients with DRF has not been examined, but the hand therapists may be able to observe the behaviour of "overprotective" spouses/family in the clinic. It has been suggested that patients with chronic pain are afraid of causing further damage to their injury and warrant further examination and alternative treatments for relieving pain [43]. This can be particularly important following a fracture where patients may not fully understand whether the bone is healed or there is a risk of repeat fracture. Since, most wrist fractures arise from a fall this can exacerbate the fear of re-injury. Hand therapists can play an important role in reducing fear avoidance of movement by providing appropriate explanation of the injury, healing process and guidelines for safe activity [43, 46]. In some cases, fall prevention programs that include physical and cognitive elements may be needed to reduce anxiety. Graded activity programs that incorporate principles of cognitive behavioural therapy may assist patients demonstrating fear avoidance behaviours to resume more normal activity.

Negative cognitive processes can lead to a decline in self-efficacy which contributes to, and is exacerbated by passive pain coping strategies. When patients expect pain control will be accomplished by external factors, they develop inactive attitudes towards controlling their pain. Overreliance on modalities and passive mobilization may exacerbate this problem. Conversely, we also know that adequate pain control is important since uncontrolled pain can be the instigator for adverse psychological and physiological processes that becomes a vicious circle and lead to chronic pain [43]. Mitigation of negative cognitive processes can include strategies of activating patients, empowering them and using cognitive processes (contemplation) to alter their perceptions and coping skills to be more favourable for pain control. By using more active pain relief approaches and providing techniques/interventions which allow self-management of pain, it is possible to manage pain without adversely affecting self-efficacy or creating passive strategies in patients with DRF. A qualitative study indicated that compensatory behaviours are common after DRF [47]. During the healing phase of DRF, compensatory behaviours might be both necessary and appropriate to enhance function on a temporary basis. However, maintained compensation might limit full recovery if the person does not reintegrate the hand into normal activities or adopts dependent passive compensation behaviours. We know that grip strength is markedly reduced following immobilization [48]. Lack of engagement in rehabilitation and active functional use of the hand could lead to ongoing strength impairments that reinforce reduced activity levels. Previous studies indicate that graded functional activity is effective in recovery following DRF [19].

In summary, the cognitive-behavioural model suggests that pain related beliefs and behaviours held by the patient can lead to either helpful or unhelpful coping strategies. Negative perceptions can be identified by hand therapists based on the observation of patients beliefs/attitudes or behaviours and should be considered as risk for developing chronic pain. Conversely, positive attitude and thinking, viewing pain as a manageable problem, adopting a pro-active approach by patients in pain management can reduce pain intensity and should be considered as potential therapeutic agent [41-43].

Related Constructs from other Models of chronic pain

The focus of this paper is to use two psychological models as a foundation for discussing prognostic variables that need to be considered while managing DRF. However, these variables should be considered in light of evidence derived from prognostic studies about other factors that mediate the risk for developing chronic pain following an injury. Individuals who live in poor socio-economic conditions [21, 49, 50] or those who are manual labourers [51] are more likely to exhibit chronicity of pain. Self-efficacy and perceived pain control are often termed as a predictors of pain and functional status in patients with different chronic musculoskeletal conditions and should be considered while managing patients with DRF [52-54].

Physical aspects of the injury including its severity, treatment complications and pre-exisiting health are also potenial mediators. We know that the extent of initial displacement [55] and inadequate reduction [22] contribute to higher pain and disability outcomes following DRF, hence these factors should be considered while treating patients with DRF. Moreover, individuals with commorbidities experience greater chronicity of

pain in different body areas. In particular, those suffering from diabetes [56], obesity [57, 58], and hypertension [59] exhibit greater musculoskeletal pain. In addition to the physical components of comorbidity, patients may have developed health-related negative cognitions or learned helplessness behaviours as part of their psychological response to their comorbid condition and these would govern their response to an acute injury like DRF. Additionally, personal and life-style factors such as reduced physical activity and smoking are known to impact chronic pain behaviour [60, 61]. Those who suffer from other illnesses, have had sedentary life-style, and those with history of smoking are at greater risk of developing chronic pain following DRF. These factors should also be explored while assessing patients for rehabilitation following DRF.

Clinical implications for hand therapists for assessment and treatment in rehabilitation of patients with DRF

It is apparent from the existing literature that there is small but clinically relevant subset of patients who experience profound pain and disability following DRF. The incidence rate of these adverse outcomes is 5-8% even after hand therapy interventions. Current assessment and treatment practices for patients with DRF primarily focus on physical aspect of impairment [21, 22]. Based on the discussion of the some important constructs from two psychologically-based models of chronic pain and their potential application in managing patients with DRF, it is worthwhile to incorporate psychologically-based risk-reduction and management techniques into the DRF rehabilitation for a limited number of patients who present with increased risk profiles. Firstly, this risk-reduction approach should screen patients during initial assessment to

determine risk of developing chronic pain and disability based on the assessment principles outlined in this paper. Then a customized treatment program that considers elements of a biopsychosocial presentation of the patient can be developed.

In a previous commentary on hand therapy management of DRF, one of the authors of this paper (JMD) recommended that an important part of rehabilitation is to "*Assist Patients in Dealing With Their Injury Using Appropriate Coping Mechanisms and Avoidance of Patterns That Increase the Risk of developing Chronic Pain/Disability Syndromes"* [62]. However, that paper did not describe how to do so. The application of models discussed in this paper and evidence about risk factors can provide strategies on how to assess risk factors during patient assessment (interview questions listed in Table 1). At present, there are no qualitative studies defining the specific negative cognitions associated with DRF, prognostic cohort studies that specifically define the role of learned helplessness or other specific negative cognitions, or intervention studies that compare cognitive-behavioural hand therapy with standard therapy in DRF patients. However, this work has been performed in other musculoskeletal conditions like back and neck pain where use of specific cognitive approaches to enhance rehabilitation has been shown to be effective [63-66]. While high quality studies are needed to enhance the understanding of what type and extent of negative behaviours affect outcomes following DRF, it is possible to extrapolate the findings from other musculoskeletal conditions and apply the theoretically-based suggestions contained in this paper to construct an approach for assessing and treating DRF in higher risk patients versus a low-risk patients.

Assessment Implications

As outlined earlier, the purpose of the initial assessment should be to screen the patients at-risk of chronic pain following DRF. The hand therapist can determine psychosocial risk factors from an intake interview. The interview should include specific questions that would identify response to previous injuries, attitudes/beliefs about pain, and the patients' perceived control to identify potential negative cognition of 'helplessness'. Prior negative experiences can contribute to a poor outcome of long-term pain and disability [28, 30, 31]. The "Yellow flags" are reports of unexpectedly high levels of pain, inability to control pain, and experiences with healthcare professionals who were "not able to control their pain". Patients with concurrent chronic pain conditions such as fibromyalgia, low back pain, neck pain, and headaches may have established positive or negative response patterns that are "pre-wired". During the interview, the hand therapists can identify any attitudes or behaviours of helplessness and document these as being prognostic for response to the management of the DRF. Those who verbalize these helplessness behaviours during the interview can be asked to complete the helplessness subscale (HS) of the Rheumatology Attitudes Index (RAI) [67]. The HS assesses the helplessness behaviour by self-report [67]. Although not used for DRF in the past, it has been used successfully in patients with other musculoskeletal conditions [29, 68]. The discriminative scores for the HS are not available for DRF, but average scores for HS are reported to be in the ranges of 13 to 18 in other conditions [67, 68], therefore those with verbal report of helplessness and scores of 13 and over on HS should be considered at an elevated risk for chronic pain following DRF.

Negative beliefs about the cause of the injury, expectations for recovery, limited ability to cope with the injury or its symptoms, and catastrophizing of the injury/symptoms are negative cognitions that may play a role in the development of chronic pain in patients following DRF [39, 43]. These factors should be identified early in the management of DRF patients. Negative cognitions may manifest during interviews or be evident by responses on questionnaires like the Patient Rated Wrist/Hand Evaluation (PRWHE) and the revised Illness Perception Questionnaire (IPQ). The PRWHE has a pain scale that asks about pain intensity/frequency and Usual Activities Scale which asks functional impairments compared to their pre-injury activity [69]. Patients with DRF typically experience a rapid reduction in pain and disability over the first two months. Patients who fail to return to work six months following DRF exhibited higher baseline pain scores and a dampened recovery curve compared to those with successful return to work outcomes [16]. Patients whose baseline scores on the PRWHE are ≥ 80, or do not exhibit a strong reduction in pain over the first two months following injury should be considered at a high risk for chronic pain.

The IPQ was originally developed in 1996 [70] and revised in 2002 [71]. The revised IPQ offers quantitative measurement of patients' beliefs about seven domains of their injury: identity (symptoms attributed to the injury), timeline (expected course of the injury), consequences (impact of injury on individual's life), control-cure (whether the injury can be controlled by the individual or the therapy), causes (causal attribution of the injury), emotional representations (emotional response to the injury), and illness coherence (the view of the patient regarding the illness representations in young people

with the injury)[71]. Discriminative scores for negative beliefs regarding the injury are known for musculoskeletal conditions other than DRF [71] and can be used to identify patients at high risk of chronic pain following DRF. The IPQ can measure the constructs of helplessness and cognitive-behavioural response to DRF and can serve as a useful screening measure to identify these predictors of chronic pain in patients following DRF. The IPQ has been useful in assessing similar constructs in patients with rheumatoid arthritis [71], chronic fatigue syndrome [72], diabetes, [73] and chronic obstructive pulmonary disease [74].

Given the association between chronic pain and comorbidities [56-59], it is important to have an accurate medical history of the patients presenting to hand therapy for rehabilitation following DRF. Many clinics have established intake mechanisms such as existing assessment forms or linkage to medical records that address comorbid conditions. If this is not available, the Comorbidity Index (CI) can be used for this purpose [75]. Physical activity level and smoking history should also be screened, as they often predict chronic pain [60, 61]. Lastly, patients' socioeconomic status, education level, and third party compensation status should be considered in determining their risk-profile. Those patients who belong to lower income group, who did not complete postsecondary training, and those who are receiving third party compensation are at greater risk of chronic pain following DRF [18, 19].

The Patient-Specific Functional Scale (PSFS) can be used to identify the activities that are compromised as a result of the DRF and assess the level of impairment with those activities [76, 77]. This will provide insight into how impaired the person views himself and

identifies tasks that may become the focus for activity-based treatment. Hand therapy interventions can be customized to incorporate these tasks, thereby activating the use of the affected hand.

While awareness of psychological issues is important, it does not circumvent the need for accurate physical assessment. Hand therapists, however, should be cognizant about persistent pain resulting from the complications and associated injuries following DRF. Complex regional pain syndrome [78-80], tendon injuries [81, 82], infection [83], and carpal tunnel syndrome [84, 85] are common following DRF and require different management strategies. These strategies often involve medical and surgical management of the complications and require hand therapists to refer back these patients to appropriate health care professionals. Therefore, patients showing the signs of one or more of these physical complications would not respond to an isolated risk-based assessment approach that focused only on psychosocial issues. Rather, the physical and isolated risk-based assessment approaches should be intertwined during the assessment.

In summary, when hand therapists perform initial assessment of a DRF, helplessness and cognitive-behavioural components to injury should be specifically assessed in combination with the physical components of the injury. Self-report measures (HS, PRWHE, IPQ, and PSFS) can be used to quantitatively investigate these negative constructs and identify patients at high-risk of developing chronic pain following DRF. Table 1 provides examples of how prognosis questions of different domains can be incorporated into assessment in order to determine the risk profile of patients for developing chronic pain following DRF.

Treatment Implications

We know that most patients with DRF will do well on home programs and some require more intensive rehabilitation. Patients should be encouraged to have positive recovery expectations from the outset and managed based on their prognosis for recovery. All patients should be informed that DRF has a high rate of recovery and normally results in minimal permanent disablement. They should be told that the pain resulting from a DRF is transient and usually manageable with minor intervention. This will benefit both high-risk and low-risk patients by reducing their anxiety at the outset.

Some patients may not require extensive rehabilitation following a DRF. Patients who fall into a low risk group from the psychosocial perspective and the physical perspective may be do well on a home-based exercise program with advice to contact hand therapists should they have any difficulty [21]. A positive psychosocial profile is a patient with high-self efficacy, minimal fear of pain/movement (within safety parameters) and positive goals and expectations around resumption of activity. Hand therapists should consciously evaluate these attitudes and behaviours during assessment and promote them through treatment approaches. Helplessness, lack of self-efficacy/problem-solving, fear of movement, catastrophizing, or other psychosocial barriers might suggest that closer supervision and a more psychologically based approach is needed. Graded imagery, graded meaningful activity combined with cognitive evaluation of capability/response, mirror therapy, patient-centered goal setting/treatment planning and group-based activity programs are examples of treatment choices that may benefit patients who need greater integration of psychosocial and physical rehabilitation. The

main objective is to promote self-efficacy and independence in daily activities and not focus on pain. Similar approaches have been successful in patients with other musculoskeletal conditions [32, 86].

Health care providers should use consistent and clear language while communicating with their patients. This has positive impact on patients' recovery by reducing their negative cognition regarding the injury [87]. Patients' perception that their injury is unexplained contributes to catastrophizing their illness and injury [46]. Patients should be encouraged to ask questions so that unique concerns are identified and addressed. The dynamics of client-caregiver relationship can be constructively influenced by positive communication [87]. Home-based exercise programs and patient educational materials should address both physical and psychological aspects of injury recovery. Having the education materials made more personalized can also combat learned helplessness. Studies have also shown that conveying information on prognosis and treatment benefits improves exercise adherence in patients with chronic pain [88].

Focusing on specific, relevant and achievable goals allows patients to increase their self-efficacy and physical activity simultaneously. This might mean helping elderly patients' efforts to use their affected hand while eating or dressing or injured workers to strengthen their arm in carrying objects related to their work. Similarly, younger patients may have sport or endurance related goals. In a study examining personal recovery choice pathways, patients and clinicians exhibited much more divergence in preferences [89], indicating that the person's life context was a potent determinant on the perspectives of disability and not well represented by the clinicians. Therefore, patients should have the

opportunity to exert this perspective throughout the rehabilitation process. This includes allowing patients to choose important activities in therapy and at home that meet physical goals, set personal functional goals, customize their own treatment plan, share decisions about progressing treatment and reviewing their own progress though specific (patient-based and impairment-based) data can empower them to assume greater control and actively participate in their own rehabilitation. A cohort study of patients followed 1 year after rehabilitation for spinal disorders found that a personal goal achievement score provided the greatest patient satisfaction.[90] Similarly, a patient-oriented hand therapy program was shown to produce better scores on self-reported outcome, less pain, and higher patient satisfaction than a standard hand program [91].

Figure 1 illustrates an integrated rehabilitation model for patients following DRF. It incorporates a prognosis-based approach, where high-risk individuals would receive a biopsychosocial approach to rehabilitation and low risk patients would receive advice and home program. The components of the model are: 1) **R**educing pain (without encouraging helplessness), 2) **A**ctivating (graded and meaningful activity), 3) **C**ognitive reshaping techniques to facilitate positive attitudes/behaviours and mitigate negative ones during therapy/recovery), and 4) **E**mpowering (increasing self-efficacy and control to facilitate ownership and competency around self management). We have given this model a short name derived from these components - RACE. It is acknowledged that the RACE is a conceptual framework and warrants empirical validation.

Outcome Evaluation

Constant monitoring of pain and disability can facilitate early identification of pain/disability experiences that are excessive or fail to resolve. Patients may feel being in control of their injury if they can monitor their progress. Measuring their symptoms through self-report (PRWHE) and physical parameters (strength, motion, hand volume) on a shared progress flow sheet can serve as start point for setting goals and discussing what these indicators suggest about their progress. Overly aggressive activity will cause swelling and loss of motion measured through hand volume or joint range of motion. Insufficient activity will show dampened improvements in both impairment and functional measures. The PRWHE has separate scales for tracking pain, standard tasks, and usual tasks, which may allow for discrete discussions and goal setting. The use of PSFS where patient select their own problematic functional activities is a simple way to incorporate patient-based goal setting into treatment and outcome evaluation. Patients may benefit from a personal log that allows them to monitor their outcomes and opinions about therapy for ongoing reflection and discussion.

Future Directions

Rehabilitation needs after DRF may range from a home exercise program to intensive supervised in-clinic hand therapy. Clinical prediction rules that identify subgroups have not been developed. However, we know that 5 to 10% of people develop chronic pain following DRF and this is a substantial clinical problem for hand therapists. We also know that both psychosocial and physical risk factors are implicated and thus have sufficient basis to use existing theory and evidence to assessment and treatment

approaches. However, there is a need for more high quality prognostic studies that identify risk factors derived from broader theoretical models rather than a biomedical framework. Future prognostic and effectiveness research should include measures that evaluate biological, neurophysiological, and psychological variables during recovery to build more specific and evidence-based models of how to optimize recovery following DRF. Subsequently, randomized trials that compare prognosis-based treatment versus standardized treatment and trials might be conducted to provide more meaningful information on therapy roles and effects.

Conclusion

Chronic pain occurs in a small subset of patients following DRF and can lead to profound disablement. A biopsychosocial approach to rehabilitation is needed but is not currently a standard practice. This paper discussed two psychological models of chronic musculoskeletal pain: the learned helplessness model and the cognitive-behavioural model and their application in the rehabilitation of DRF. A prognosis-based (RACE) approach to DRF was suggested, where patients with minimal psychosocial risk factors are managed based on their injury profile and those with higher risk have a risk-based treatment program. This program aims to reduce the pain stimulus, engage patients in meaningful graded activities, use cognitive interaction to optimize positive thoughts and behaviours, and empower them to be in control in managing their recovery.

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Table 1 - Application of Discussed Concepts to Assess Risk Profile of Patients with Distal Radius Fracture

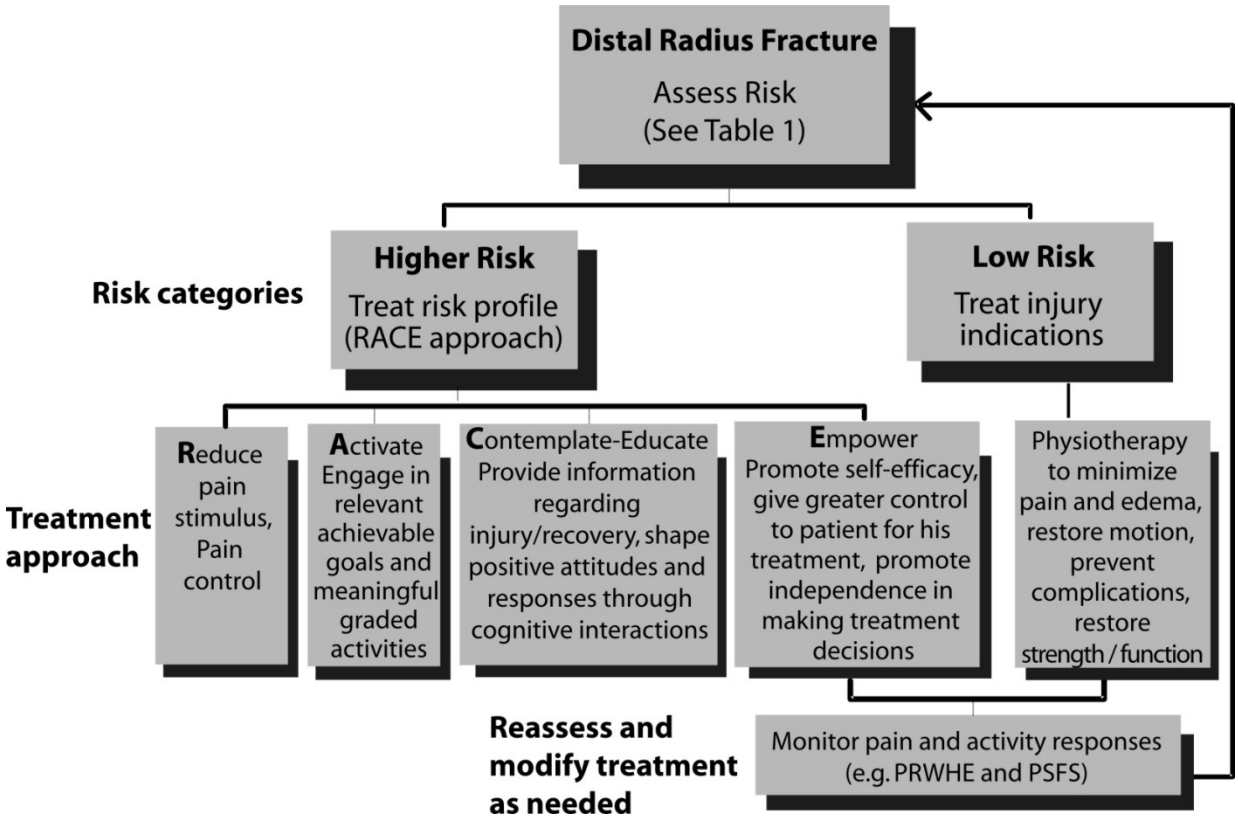
Construct assessed	Interview Questions	Self-report Measures
Learned Helplessness	• Have you had a previous injury? How well were you able to manage your pain with that injury? • In your personal view, how easy is it to manage your health?	Learned Helplessness subscale of the Rheumatology Attitudes Index. Discriminative scores for helplessness behaviour not available in patients with DRF, however in patients with fibromyalgia helplessness score was 18 [72].
Cognitive-Behavioural	Do you expect to recover completely from this injury? Do you have any concerns about how you will recover from this injury? What does the pain feel like? (looking for overly emotional or catastrophizing descriptors) Do you rely on yourself or get help for managing your health?	The Illness Perception Questionnaire (IPQ). The IPQ has been used to predict pain-related disability over a time period in patients with musculoskeletal complaints [76].
Wrist pain and functions following DRF	• What increases/decreases your wrist pain?	Patient rated wrist evaluation (PRWE). Differential scores for high pain not defined but the baseline PRWE was 48 in patients who did not take time off

	• How much does the pain affect your daily functions and your work?	from work and 68 in patients not returning to work after 17 weeks [16]. It can be obtained at http://www.srs-mcmaster.ca/ResearchResourcesnbsp/Musculoskeletal/UpperLimbNeck/tabid/2723/Default.aspx
Past medical History and Comorbidities	• Do you have other medical conditions? Do they affect your activity level and functions?	Katz comorbidity Index. The details regarding the impact of musculoskeletal conditions such as back pain and arthritis, as well as other comorbid conditions like diabetes, hypertension, and depression on patient's health can be obtained by this scale [81].
Previous musculoskeletal injuries, treatment received for the injuries, and the outcome achieved	• How long did it take to recover from your previous injury? What things helped you recover? Did medical professionals provide enough support in reducing your pain and disability?	
Chronic pain in other areas such as back pain, neck pain, arthritis, headache, fibromyalgia	• How bad is your pain in "the alternate" area? What increases or decreases your pain?	

Activity level prior to DRF	What activities did you do before your injury? • Did you stop doing those? • Do you play any sport or have any active hobbies? • Did you exercise regularly before this injury?	Patient Specific Functional Scale (PSFS). The PSFS identifies the activities that are affected by the injury and are meaningful to the patient and examines the level of difficulty experienced in those activities [82]. The minimal detectable change (MDC90) for the PSFS is 2 points, so the decrease in the PSFS score of > 2 points indicates improvement in the functional status of the patient.
Smoking habits	How many cigarettes do you smoke in a day?	

Figure 1. RACE Model

This figure illustrates the treatment approaches based on the risk profile for patients with distal radius fracture. The RACE approach is recommended for patients believed to be at higher risk of chronic pain following DRF. The patients in lower risk profile can be treated with conventional hand therapy approach.



Chapter 3. A Systematic Review of the Psychometric Properties of the Patient-Rated Wrist Evaluation

Saurabh P. Mehta PT, MSc[1]
Joy C. MacDermid PT, PhD[2]
Julie Richardson PT, PhD[3]
Norma J. MacIntyre PT, PhD[4]
Ruby Grewal MD, MSc, FRCSC[5]

[1] PhD Student and CIHR Doctoral Fellow, School of Rehabilitation Science, McMaster University, Hamilton, Ontario, Canada
[2]Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario and Co-director Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, 268 Grosvenor St., London, Ontario, Canada
[3]Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario
[4]Associate Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario
[5]Assistant Professor, Department of Surgery, Western University and Co-director Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, 268 Grosvenor St., London, Ontario, Canada

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Corresponding Author: Joy C. MacDermid, PhD , School of Rehabilitation Science, McMaster University, 1400 Main Street West - IAHS 402, Hamilton, Ontario L8S 1C7, Canada Email: macderj@mcmaster.ca Fax no.: 001 905 524 0069

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Abstract

Study Design: Systematic review of psychometric properties

Objectives: To synthesize the literature related to the psychometric properties of the Patient-Rated Wrist Evaluation (PRWE) and its clinical utility.

Background: PRWE is a condition specific outcome measure initially developed for individuals with distal radius fracture. However, subsequent research has expanded its use to other wrist/hand conditions. A systematic review of the psychometric properties of the PRWE can enhance the understanding of its clinical applicability across different wrist/hand pathologies.

Methods: Medline, Embase, and CINAHL databases were searched using pre-defined search terms. Additionally, a hand search of the bibliography of the primary studies was performed. Studies assessing at least one psychometric property of either the English or other languages versions of the PRWE were included in this review. Two raters performed data extraction and critical appraisal of the primary studies using standardized instruments. The primary studies were assigned a percentage score based on the quality rating.

Results: A total of 17 primary studies and 4 reviews were located that met the inclusion criteria. The quality of the 17 papers ranged from 38 % to 88 %, with seven of them scoring greater than 70 % in the rating. Agreement between the raters for determining the quality of studies was 0.75. Different psychometric properties of the PRWE were summarized in a variety of wrist/hand conditions and related data has been presented.

Conclusion: The PRWE is reliable, valid, and responsive across many wrist/hand conditions. Future studies should focus on determining values for the minimal detectable change (MDC) and minimal detectable change (MCID) for the PRWE across different patient populations.

Key Words: *Evidence-based practice, Outcome measures, systematic review, psychometrics*

Introduction

Patient-reported outcomes (PROs) are integral to treatment programs that are based on evidence-based practice that focuses on the client. PROs link the physical deficits observed during the objective assessment to patient-relevant concerns and enable hand therapists to identify aspects of disablement that are not captured by the objective examination. Psychometric properties (e.g. reliability, validity, responsiveness) of a PRO largely determine its utility and clinical application. The Patient-Rated Wrist Evaluation (PRWE) was primarily developed to assess self-reported pain and wrist/hand related function; and originally validated in individuals with distal radius fracture (DRF).[1] However, subsequent research has widened the scope of the PRWE and established its use across different hand pathologies such as osteoarthritis involving wrist/hand joints,[2, 3] carpectomy,[4, 5] and wrist pain resulting from different pathologies.[6] Further, a variant that uses the word wrist/hand has been used in an even broader range of disorders as it has been shown that the scale performs equally well in populations with hand pathology.[7] Cross-cultural adaptations and translations of the PRWE in other languages have increased its utilization in individuals whose first language is not English.[8-15]

The studies that assess the psychometric properties of a PRO such as the PRWE typically enhance the "usability" of the PRO in a given clinical subgroup. However, given the broad scope of measurement properties and purposes that require investigation, no single study is ever able to truly "validate" a tool for clinical practice. Rather, a pool of such studies builds the required evidence to allow precise clinical application of the PRO. A systematic review is the optimum research design to assess the overall performance and

utility of a PRO across a range of clinical conditions. Such a review can provide robust estimates of error associated with a single measurement, interpretation of change scores, and relative benefits of using that PRO over others competing measures in different clinical conditions; assuming that a sufficient pool of primary studies exists.

Previous reviews have summarized the comparative advantages of using the PRWE versus other PROs for assessing wrist/hand functions.[16-18] However, these reviews did not provide a systematic summary of the key measurement properties of the PRWE such as measurement error, estimates of reliability, internal consistency, and responsiveness, and estimates of clinically important differences (CID). They did not perform appraisal for assessing the methodological quality of the individual studies. This is critical given that unidentified sources of bias could skew the recommendations provided in the review. To date, no such systematic review with assessment of quality of evidence has been conducted to summarize the measurement properties of the PRWE.

Purpose of the Study

The objective of this paper was to conduct a systematic review to summarize the psychometric properties of the PRWE and discuss its applicability across different wrist/hand conditions. In particular, the paper aimed to summarize the estimates of reliability, validity, responsiveness, measurement error and CID for the PRWE.

Methods

Development of the PRWE

The PRWE was developed by MacDermid et al[1] for assessing patient-reported wrist pain and function. A survey was sent via mail to active members of the International Wrist Investigators to examine current practices in outcome measurement, opinions on appropriate content for a wrist outcome measure, structural guidelines for a tool, and barriers to using outcome measures in practice.[1] The development of the PRWE involved using the information from this survey and following other key strategies such as item generation, item reduction/selection, questionnaire construction: refining items/scoring system, and pilot testing of form.[1] The final version of the PRWE included two subscales: pain and function. The five items in the pain subscale covered questions on the severity, intensity and frequency of pain. The ten items included in the functional subscale address specific activities that require wrist-related physical function; as well as broader usual (patient-specific) function/roles. Each item is scored on a 0 to 10 scale, where 10 is worst pain or function. The total score is calculated out of 100 with equal weighting of the pain score (sum of five items) and functional score (sum of ten items divided by 2).[1]

Literature Search and Identification of Relevant Studies

Medline, Embase, and CINAHL databases were searched to identify the relevant studies. We did not place any date or language restriction on our search. The keywords that formed the search strategy for the databases were: (Patient Rated Wrist Evaluation OR PRWE OR Patient Rated Wrist/Hand Evaluation) AND (reliability OR validity OR

responsiveness OR clinically important difference OR Rasch analysis OR cross-cultural adaptation OR translation). Additionally, a hand search for the studies cited in the bibliography of the relevant studies was also performed. All titles and abstracts were reviewed by at least 2 study authors. Articles that addressed at least 1 psychometric property of the PRWE were included in the review.

The data extraction and review were performed independently by pairs of raters amongst the study authors; and disagreements arbitrated by the senior author. A standardized evaluation tool was used for critical appraisal and rating quality for the included studies.[19, 20] This tool has been used previously for conducting similar reviews and has reported to have high reliability (ICCs > 0.85).[21, 22] The data extraction form was developed for the purposes of this study and was adapted from another form which was developed by one of the co-authors (JM).[21] A consensus-based approach was used for resolving the disagreement between the reviewers in rating quality for the included studies and data extraction. This approach involved establishing the nature of the discrepancy and clarifying if it was based on the contents of the article or compliance to the appraisal or extraction tool. The raw scores for the articles were converted to percentage summary. The articles were ranked by quality, with the premise that rank order would be considered when interpreting the findings. The agreement between the reviewers was assessed for the summary scores of each article (using Intraclass correlation coefficient (ICC)) and individual items scores (using unweighted kappa (κ)). No formal procedure was created to weight articles based on ranking.

Values for the minimal detectable change (MDC) were extracted to create an evidence summary for interpreting true change on PRWE in clinical populations at different follow-up times. The values for MDC, if not provided, were calculated using SEM (standard error of measurement) values (MDC_{90} = SEM × √ 2 × 1.65; MDC_{95} = SEM × √2 × 1.96). If the SEM values were not provided, they were first calculated using ICC values (SEM = s√1-r; where r is ICC value and s is the standard deviation of occasion 1 and occasion 2).

Results

Seventeen articles met the criteria and were included in this review for critical appraisal. Brink et al[11] summarized the psychometric analysis of Dutch version; however this summary was published as a Letter to the Editor and not as a full text article. Therefore, critical appraisal of their publication was not possible. Three previous reviews that assessed the comparative benefits of the PRWE were not included for the appraisal but a summary of their recommendations is highlighted in the following paragraph.[16-18] Table 1 illustrates the characteristics of the included studies. The results of the critical appraisal are shown in Table 2 where studies are arranged in rank order. The quality of the 17 papers ranged from 38 % to 88 %, with seven of them scoring greater than 70 % in the rating. Some of the common methodological issues observed across the studies included no sample size calculation or rationalization, minimal reporting of error estimates (confidence intervals, standard error of measurement), no statements describing the psychometric hypothesis, and limited documentation of test procedures and test performance. Agreement between the raters for appraising the quality of the included

studies was deemed to be very good as indicated by the ICC of 0.85 for the summary scores for each article and unweighted κ of 0.75 for individual item scores.

Summary of the Previous Reviews

Previous reviews have investigated the comparative advantage of using PRWE in patients with wrist and hand injuries,[16, 23] distal radius fracture,[17] and upper extremity (UE) injuries.[18] Of these, three reviews[16, 18, 23] adopted systematic search strategies and pre-defined criteria for searching the databases and identifying the relevant measures; whereas the other review did not use these methods.[17] Hoang-Kim et al[23] assessed the quality of published reviews to examine the relative benefits of different PROs used for assessing wrist and hand functions. They used the GRADE approach[24] to examine the quality of published reviews and the COSMIN checklist[25] to characterise psychometric properties for inclusion in the review. The review concluded that the PRWE has slightly better construct validity and responsiveness compared to the DASH in individuals with wrist injuries. Changulani et al[16] and Goldhahn et al[17] concluded that PRWE was arguably the most suitable PRO for assessing disablement in individuals with DRF. While these reviews determined the comparative advantages of the PRWE over the other measures in patients with wrist/hand injuries, the estimates of psychometric properties which have a direct bearing on the application of the PRWE in clinical practice were not addressed.

Summary of the Primary Studies

Cross Cultural Adaptation/Language Equivalence

Cross-cultural adaptation and translation of the PRWE into other languages have increased its utility and facilitated a more detailed analysis of the PRWE as an outcome measure. Some of the included studies assessed the psychometric properties of the PRWE in Chinese (Hong Kong) (PRWE-HK),[8] Swedish (PRWE-S)[9, 13], German (PRWE-G),[10, 26] Japanese (PRWE-J),[12] Hindi (PRWE-H),[14] and Italian (PRWE-IT)[15] languages. All these studies used standardized guidelines for translating the PRWE in to other languages. Apart from these published studies, Spanish, and French translations of the PRWE have been performed but no publication was located that described the properties of these translated versions. We also came across an unpublished manuscript that performed cross-cultural adaptation of the PRWE in Czech, French, Hungarian, Italian, Portuguese (Brazil), Russian and Ukrainian languages.[27] However, this manuscript described the translation process and had no data on the assessment of interpretability and readability or the psychometric analysis of the translated versions.[27]

Wah et al[8] employed a panel of experts to examine the semantic and cultural equivalence of the Chinese (Hong Kong) PRWE. They reported 60% agreement for achieving semantic and conceptual equivalence for the translated version. Wilcke et al[9] noted no major differences in cultural and life style context between Canadian and Swedish populations; therefore translation of the PRWE in Swedish did not present challanges. However, since the door knobs are uncommon in Sweden, the item “turn a door knob” was adapted as “open a tight or new jar” in the Swedish version.[9] In contrast,

few changes were made to the German version during the cultural adaptation for optimizing the response rates and increasing clarity of the PRWE-G. Firstly, "not applicable" was added as a response option for all the questions in the function subscale.[26] Secondly, the wordings of several items were changed in the function subscale. To name a few, "Fasten buttons on my shirt" was changed to "Buttoning a shirt or blouse" and imperial unit of weight (10 pounds) was converted to nearest kilograms. It was not clear whether any changes were required during the adaptation and translation of the PRWE into Japanese language.[12] The researchers found some concerns with the introduction and instruction section while translating the PRWE into Italian.[15] In particular, they changed the word "perceive" to the word "expect" to enhance clarity of instructions. Similar to the Swedish translation, item 6 (turn a door knob) was deemed to be unsuitable for Italian population. Therefore, the word door knob was changed to door handle which is more consistent with Italian architecture.[15] The researchers ensured that the readability of the translated versions was acceptable to ensure optimal response rates.

Administrative Burden

Administrative burden for an outcome measure refers to the amount of time it takes to complete the responses on that measure. Not all the studies that assessed the psychometric properties of the PRWE measured the administrative burden. John et al[26] noted that patients took about 2-3 minutes to complete the PRWE-G. An average of 3 minutes and 39 seconds (range 1-10 minutes) was required to complete the PRWE-J. Moreover, the authors also concluded that it took less time for the patients to complete the PRWE-J compared to the Japanese version of the Disabilities of Arm, Shoulder, and hand

(DASH).[12] Wilcke et al[9] concluded that the PRWE was easy to administer and can be administered via mail or even in the waiting room. While the researchers did not report the time taken to complete the PRWE-IT, they did report that none of the patients had difficulty in completing the PRWE-IT.[15]

Scoring/Discriminative Subgroups

The developer recommended that the mean score of the respective subscale be used for substituting the score of a missing item; however the minimum number of completed items required to calculate composite score was not known.[28] John et al[26] suggested that completed responses for at least 67% of items were required in each subscale (3 questions about pain and 7 questions about function) for deriving the composite score of the PRWE. Schmitt et al[29] excluded the data for individuals who had less than 75% of completed responses on PRWE, however they did not provide any rationale.

No previous study has provided validated discriminative scores for the PRWE for categorizing patients into subgroups (minimal, moderate, and severe pain/disability). MacDermid et al[30] concluded that those with baseline scores ≥ 80 on the PRWE have poorer work outcomes and take over 17 weeks to return to work. Another paper that examined the reported pain and musculoskeletal disability (MSKD) following DRF at 1 year offered descriptors of severity for range of scores on PRWE.[31] While these descriptors indicating different pain/disability severity await validation, they can be used by clinicians to discriminate those with minimal, moderate, or severe pain/disability.

Ceiling/Floor Effect

Ceiling or floor effects depict the subset of individuals for whom the questionnaire cannot accurately determine the change in the score. This occurs when the initial assessment reveals the score to be too high (ceiling) or too low (floor). This would potentially render measurement of any deterioration or improvement in individual's clinical status difficult to estimate. This is of particular significance since the reliability of a point estimate of the score is threatened. The ceiling effect was examined for the PRWE-H[14] and PRWE-G.[10, 26] Approximately 8% individuals showed ceiling effect for the functions subscale of the PRWE-H.[14] Ceiling effect was calculated by examining the number of individuals whose score for the function subscale was 45 (out of 50) at baseline assessment.[14] Hemelaers et al[10] reported that two questions on the function subscale, 'carrying 10lb weight' and 'cut meat using a knife with my affected hand' had ceiling effects of 59% and 32% respectively. Patient were often not allowed to lift heavy weights 4-6 weeks following the wrist fracture, which triggered patients to rate that task as being unable to do. Furthermore, most patients with left sided fractures responded 'does not apply' to the task 'cut meat using a knife with my affected hand' since they always used right hand for this task.[10] John et al[26] found ceiling effect in approximately 16-24% of patients. None of these studies commented on an acceptable level for ceiling or floor effect for the PRWE scores and how the results from a single patient or a group of patients should be interpreted in view of these effects.

Reliability

The published data for the reliability of the PRWE are shown in Table 3. Test-retest reliability of an outcome refers to the ability of that outcome to provide consistent results when the patient's clinical status is stable. There is robust evidence supporting the reliability of the English as well as other language versions of the PRWE and its subscales. The ICC has been used commonly in assessing the reliability of the PRWE. Most studies have reported reliability coefficients including the values of ICC for the PRWE in excess of 0.85[1, 9, 10, 12, 13, 29] with some exceptions.[14, 26] Mehta et al[14] reported ICC value of 0.81 for the PRWE score in individuals with DRF. Similarly, John et al[26] reported the ICC value of 0.78 for the PRWE in individuals with resection interposition arthroplasty (RIAP). The reliability estimates for the subscales have varied across the studies in that the correlation coefficients have indicated lower reliability for individual subscales in certain instances.[1, 14] MacDermid et al[1] found that the ICC value for the function subscale was 0.61 for individuals with scaphoid non-union. However, the authors argue that the test-retest period was over 1 year which is fairly long to allow functional adaptation in many individuals leading to lower reliability estimates. Similarly, Mehta et al[14] reported an ICC of 0.76 for the pain subscale. While this ICC value is slightly lower than what has been observed across other studies,[1, 10, 12] it still exceeds what is required for using the subscale independently in clinical practice.

Three studies examined absolute reliability by reporting the SEM associated with a single score of the PRWE.[14, 26, 29] The SEM for the total score of PRWE reported in these studies were 5.4 points in patients with DRF,[14] 8.12 points in patients with RIAP,[26]

and 5.22 points in patients with different distal UE disorders.[29] These studies indicated that MDC at 95% was 22.5 points (MDC_{95}) and that at 90% was 12.2 points (MDC_{90}).[26, 29] The SEM and MDC values for the PRWE and its subscales are provided in Table 4. These values are only relevant to the context (clinical condition) for which they are reported and not necessarily applicable to all the wrist/hand pathologies where the PRWE is used as an outcome measure.

Validity

The published data for the validity of the PRWE are summarized in Table 5. The PRWE assesses the constructs of pain and function, hence previous studies have mainly assessed the construct validity of the PRWE by examining its relationships with other similar patient-reported measures such as the DASH,[3, 9, 10, 12, 13, 15, 26, 30] Short Form -36 (SF-36),[1, 3, 8, 10, 12, 15, 26] and the Australian/Canadian Osteoarthritis Hand Index(AUSCAN).[3] One study examined the relationship between PRWE score, the age, and the physical activity scale for elderly (PASE) in older adults with DRF.[32] The relationship of the PRWE with objective measures such as radiological outcome, wrist range of motion (ROM) and grip strength has also been explored.[3, 10, 14, 26, 33] Low to moderate correlations are consistently reported between the PRWE and performance based physical impairment measures. The PRWE demonstrated appropriate construct validity by strong correlation ($r > 0.7$) with the DASH in these studies since both measure upper extremity-related disability; and more moderate correlation (r between 0.4 to 0.7) with the SF-36 since wrist function and overall health status are less directly linked. These published studies of the PRWE have demonstrated its usefulness in measuring the

constructs of pain and function in patients with a broad spectrum of wrist/hand injuries with varying cultural and linguistic background.

The two dimensional structure (pain and function) and structural validity of the PRWE has been examined by measuring the internal consistency of the PRWE in studies that performed cross-cultural adaptation of the PRWE.[8, 12] Cronbach's alpha (CA) is a common statistic used for assessing the internal consistency. The value of the CA has consistently been > 0.80 across these studies[8-10, 12-15, 26] for the PRWE and its subscales. This indicates an excellent structural validity and minimal potential for item redundancy of the PRWE. Further to this, Wah et al[8] assessed the factor structure of the PRWE-HK using principal components analysis. Two components were revealed in the analysis with the items in the function subset of the PRWE loading on component 1 and those in the pain subscale loading on component 2. Imaeda et al[12] reported that while the pain subscale of the PRWE had a strong unidimensional structure, the function subscale revealed a two dimensional structure. This was due to the subdivision of the function subscale into "specific functions" and "usual functions" within the PRWE. These previous studies support the recommended guidelines that pain and function subscales of the PRWE can be scored separately.

Responsiveness

The published data for the responsiveness of the PRWE demonstrate high responsiveness when compared head-to-head against other scales (Table 6). The PRWE and its translated versions have shown similar good to excellent responsiveness. The reported effect sizes (ES) and standardized response means (SRM) for the PRWE and its

subscales in patients with DRF between 0-6 month period are > 1 (large) across all the studies.[1, 7, 9, 12-14, 29, 34] There are important implications to research studies where the PRWE is used as an outcome measure in that fewer participants are required for detecting a significant treatment effect or difference between groups of participants. MacDermid et al[34] suggested that the PRWE is also responsive in patients with DRF whose wrist/hand are under plaster cast where the assessment of objective outcomes such as the wrist ROM or grip strength is not possible.

Discussion

The totality of evidence synthesized from 17 articles indicates that the PRWE can provide reliable, discriminative, responsive measurement of wrist/hand related pain and MSKD across a variety of hand/wrist disorders. Further, the structure of the PRWE has been supported and the individual subscales are sufficiently stable to use them as separate measures of pain, wrist-specific disability, and usual activity/role disability. Clinicians should consider a MDC of 10 as a suitable benchmark for change over time; but also recognize that this may fluctuate with differences in clinical condition. There were some differences in estimates of psychometric properties across studies which we attribute to the diversity in patient populations, methodology, and assessment time-frames. The studies assessing the non-English versions of the PRWE deemed that the translated versions were easy to read and comprehend and had comparable psychometric properties to that of the English version. [8-15]

The test-retest reliability of the PRWE and its subscales was excellent (ICC > 0.75) across the studies. It is critical that patients' clinical status remain stable while

assessing the test-retest reliability of an outcome. It is challenging to ensure this stability in patients with acute injury. Pain and disability experience of such patients fluctuate on daily basis as the injury heals. Therefore, a shorter reassessment period is favourable for testing reliability in those with acute injury. Most studies in this review had the reassessment period of between 0-2 weeks while assessing reliability of the PRWE in patients with conditions such as DRF, arthroplasty for carpometacarpal (CMC) arthritis, or different wrist/hand injuries.[1, 9, 10, 12, 14, 15, 26, 29] This period is short enough to test reliability in such conditions. However, Mehta et al[14] noted that researchers should be cautious in determining the appropriate re-test period for an acute injury such as DRF. Individuals with an injury such as this improve rapidly resulting in imprecise estimates of test-retest reliability. True change in status across re-test intervals can result in an underestimation of actual reliability. This was observed by Mehta et al[14] where post-hoc testing revealed significant differences in the PRWE score over repeat testing performed 2-3 days after the initial assessment. The reliability of the PRWE over a long-term (reassessment period of 1 year) in patients with non-union of scaphoid is high for the total score (ICC = 0.91) but moderate for the functional subscale (ICC = 0.61).[1] One year is a long time for the assessment of test-retest reliability during which patients may adapt to their pain and disability experience leading to a response shift.[35] Patients with hand injuries such as scaphoid fracture may compensate over time by using the unaffected hand for performing functional activities. This may have affected the reliability of the function subscale in the study.[1] The potential for this may have been dampened by the fact that this was a young population with a relatively long average follow-up time (over

12 months); and so the adaptation phase may have passed. Notwithstanding these issues, the PRWE and its subscales have shown acceptable test-retest reliability in different groups of patients with wrist/hand injuries.

The SEM is an index of absolute reliability and indicates the error associated with single assessment. The MDC indicates the value that is required to determine whether the score has changed with an amount that exceeds what might be expected by chance and provides confidence to clinicians that a true clinical change has occurred. Both the SEM and MDC vary in different clinical contexts since they are dependent on reliability and the population variability. Estimates of these values from individual studies tend to be unstable since small study samples tend to result in imprecise estimates of population variability. If the values of the SEM or MDC are not known for a given patient populations, clinicians can use the referenced values for other similar patient populations published in the literature. For instance, the calculated SEM of the PRWE were 5.2 points and 5.4 points respectively in patients with different wrist/hand diagnoses and DRF.[14, 29] The only other published value of the SEM was 8.1 points in patients with CMC arthritis.[3] Since an SEM of approximately 5 points was the most common value reported and MDC is traditionally calculated to provide 90% confidence level (MDC_{90}), an MDC_{90} for the PRWE was 12 points for patients with distal UE conditions[29] and 13 points for those following DRF.[14] The MDC_{95} for the PRWE was 22.5 points for patients who underwent arthroplasty for CMC arthritis.[26] Perhaps, the MDC_{90} is more appropriate for application in clinical practice compared to points the MDC_{95} where the reassessment periods tend to be shorter. The clinically important difference (CID) in patients with

distal UE conditions has been reported to be 24 points in a sample with high variability.[29] Unfortunately, only a minority of studies reported either MDC or CID making it difficult to be confident in these values. However, since MDC is based on two factors, variance and standard deviation, the best estimate of MDC is made on the most precise estimates of these two parameters. Typically, estimation is more precise with larger sample sizes. Valid and accurate measurement of MDC or MCID is important for evaluating outcomes, prognosis, and communication between healthcare professionals. In particular, hand therapists can utilize these values while formulating patient-centered goals and communicating patients' recovery and prognosis with various stakeholders.

The PRWE showed good concurrent validity with UE region specific (DASH and Modern Activity Subjective Survey of 2007 (MASS07)) and generic health status (SF-36) PROs in assessing the constructs of wrist pain and functions across different wrist/hand conditions.[1, 3, 8-10, 12, 13, 15, 26, 30, 32] Moderate to weak associations of the PRWE with objective outcomes such as radiological findings, wrist ROM, and grip strength were found across most studies and they were consistent with what can be expected since the latter do not reflect patient-important attributes. The ability to measure dimensions related to wrist specific performance in ADLs rather than general health, is an important criteria when choosing an outcome measure for clinical use in patients with wrist/hand injuries. The key benefit of the PRWE over the other UE specific and health status measures is that it examines the aspects of disablement that are directly related to the wrist/hand injuries. None of the studies assessed the relative advantage of using the PRWE compared to other wrist/hand specific instruments such as the Michigan Hand Questionnaire

(MHQ).[36, 37] However, the PRWE with 15 items has been reported as being efficient for clinical practice compared to the 30-item DASH[7] or the MHQ which has 37 items. The PRWE is a regional (distal upper extremity) questionnaire and it is not clear whether it is as useful as disease specific measures in cases where a particular pathology has been diagnosed. It has been compared to the AUSCAN[3] in patients with CMC arthritis and has shown acceptable clinical measurement properties. However, no study has examined the PRWE with the Boston Carpal Tunnel Questionnaire[38] which is a disease specific measure for patients with carpal tunnel syndrome (CTS). The concordance between the PRWE and measures assessing behavioural factors was low to moderate which is in line with the expectation given that wrist pain/disability and behavioural factors are diverse constructs.[39]

Responsiveness of the PRWE was excellent as suggested by large effect sizes across the studies.[1, 9, 12-14, 26, 29, 34] The study that specifically assessed the responsiveness of the PRWHE also reported that the PRWHE is marginally better compared to the DASH.[7] The variations in the indices of responsiveness (SRM and effect size) were evident due to the heterogeneity in patient population, nature of hand therapy interventions, and reassessment intervals across the studies. The indices of the responsiveness of the PRWE were superior compared to the DASH across most studies indicating the relative advantage of using PRWE over global UE outcomes in patients with wrist/hand injuries. Given that the PRWHE and PRWE have exactly the same 15 questions, the evidence related to the responsiveness indices of each of these versions is applicable to each other.

The versions of PRWE in English and other languages were easy to understand and respond to for most patients. This may be related to the developmental process which involved a combination of interview and survey preparation and pilot testing of items.[1] Further, as the developer was a full-time clinician; she had a predetermined objective to keep the measure clinically feasible for a busy orthopaedic hand practice.[1]

Most of the translated versions of the PRWE have followed standardized guidelines as described in the literature during the translation of the PRWE into other languages.[40] The administrative burden of the PRWE is less than five minutes which makes it suitable for use in the waiting room of hand therapy clinics.[9] The ceiling and floor effects were negligible for most items of the PRWE except two items, 'carrying 10lb weight' and 'cut meat using a knife with my affected hand'. This "ceiling" affect has been reported since the upper limit of the function scale is "unable to do". For example, patients with an external fixator following a DRF are unable to perform specific tasks. These tasks typically show change once the fixator is removed. This is not unexpected since these items were selected to be difficult with wrist impairment. This effect is not observed with the usual activities items where patients rate their difficulty in an area of activity. Therefore, the subscales and total score are relatively unaffected by the ceiling effect on these specific items.

One challenge can be that patients may never use the injured hand for the specific activities although these activities were selected as one that most patients commonly reported where they were using both hands. Patients will have difficulty responding to these items where they do not use the affected hand for that activity. If

patients are not performing an activity because they cannot do the activity even with both hands then they report being "unable to do" the activity. However, if they never performed that activity with the affected hand, they have no frame of reference; and in this case they should leave it unanswered.[28] The PRWE does not have a "does not apply" option except the German version.[10] Functionally, the effect on the score is the same, since scoring of the unanswered item is done by averaging the scores on the remaining items of the scale (or by recording the score average as the missing item score).

The COSMIN checklist is an advanced instrument for assessing methodological quality of studies that examine clinimetric properties of outcomes measures.[25] It is being increasingly used to undertake and publish systematic reviews similar to our study. The COSMIN checklist requires each study to have an appropriate methodological quality. However, psychometric designs that incorporate analyses such as item response theory testing (IRT) and Rasch analysis are not yet common across the studies that examine clinimetric properties of rehabilitation specific PROs. The absence of these analyses which are important components of the COSMIN checklist would have suggested that the quality of the reviewed studies was extremely poor had we used the COSMIN checklist for this review. This would have prevented us from making clinically meaningful recommendations to the readers. The critical appraisal form that we used has been useful in undertaking similar systematic reviews in past, [21, 22] and in our opinion is more suitable for performing a review of rehabilitation specific PROs.

There were a few limitations of this systematic review. Firstly, we did not perform meta-analysis related to each of the psychometric properties from the data across the

studies. This was due to the fact that the reviewed studies that examined psychometric properties of the PRWE recruited individuals with a wide spectrum of clinical conditions and re-assessed them across different time periods. While this demonstrates versatility of the PRWE, it resulted in heterogeneity in patient population as well as comparative follow-up periods limiting our ability to provide a pooled analysis. There are no standardized techniques described in the literature for pooling the data for different psychometric properties across the studies. This is a difficult task given the heterogeneity in patient population, different indices used for assessing psychometric properties, and data collected from different language versions of the PRWE. The other limitation was that only studies published in English were included in the review. However, language restrictions were not applied while performing the preliminary search and therefore all the potential studies were retrieved. We did not come across any potential study that had to be excluded because they were not in English.

In conclusion, the PRWE is easy to administer, understand, and to respond to as a PRO in patients with wrist/hand injuries. The PRWE is reliable, valid, and responsive across many wrist/hand conditions. The PRWE is also available in Chinese (HK), German, Swedish, and Japanese languages. Future studies need to determine the estimates of the MDC and MCID for the PRWE across different patient populations. Future studies can be designed to incorporate IRT testing and Rasch analysis of the PRWE.

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Table 1. Summary of Studies Addressing the Psychometric Property of the PRWE

Study	Population and Intervention	N	Psychometric Properties of PRWE Examined	Study Findings
Alexander et al 2008[41]	326 patients, mean age 44.5 (18-89.7) 55% F, 33% prior history of hand problem. Assessed at an academic tertiary care orthopaedic hand clinic with the MASS07, DASH, and PRWE. Average retest interval was 68.3 days for MASS07.	326	Construct validity, relative reliability	MASS07 showed strong correlation with PRWE and DASH when adjusted for age, sex, hand problem history. There was no statistical difference found during test retest reliability. The MASS07 is a valid and reliable tool to assess patient reported hand function in a heterogeneous out patient population.
Fairplay et al 2012[15]	63 patients with chronic wrist/hand pain or post-operative completed PRWE-IT, DASH-IT, and SF-36-IT at baseline. Retest interval was 5 to 7 days for PRWE-G.	63	Translation in Italian, construct validity, test-retest reliability, internal consistency	The translation into Italian required few modifications to adapt the PRWE for Italian culture. The internal consistency of the PRWE-IT was high (Cronbach's alpha = 0.96). PRWE-IT showed high concordance with the DASH-IT.
Hemelaers et al 2008[10]	44 patients with DRF completed PRWE-G, SF-36-G, DASH-G at four to six weeks post fracture. Retest interval was 5 to 7 days for PRWE-G.	44	Translation in German, content and construct validity, internal consistency, relative and absolute reliability were examined.	The translation showed equivalence to original. The PRWE-G demonstrated high ICC and Cronbach's alpha values and a moderate correlation with DASH-G. The PRWE-G is a valid and reliable tool to assess wrist pain and disability in German speaking patients with acute DRF.
Imaeda et al 2010[12]	117 patients with a variety of wrist/hand conditions examined. 70	117	Translation in Japanese, factor structure, test-	The PRWE-J was deemed comparable to the English version of the PRWE. The

	patients had surgery of which 50 patients in total were assessed pre-operatively as well as post-operatively after 3 months. Re-test interval was between 1-2 weeks.		retest reliability, internal consistency, responsiveness	PRWE-J showed excellent reliability, high concordance with the Japanese version of the DASH as well as VAS-pain, and responsiveness as shown by the large ES.
John et al 2008[26]	103 patients who had symptomatic CMC arthritis treated with RIAP approximately 6.2 years earlier. These patients completed a booklet with the PRWE-G, SF-36-G, and DASH-G. Retest interval was 3-4 days in 51 patients.	103 (51)	Translation in German, content and construct validity, internal consistency, reliability, MDC_{95}	The translation was acceptable. The PRWE-G showed good correlation with the DASH-G and had high internal consistency and ICC values (good reliability). Thereby establishing the use of the measure in German speaking patients with RIAP.
Jupiter et al 2002[32]	20 patients with displaced DRF following initial treatment involving either cast or external fixator were operated and followed up after an average of 38 months following surgery. PRWE, PASE, and radiographic measures were obtained.	20	Correlation of the PRWE with age and PASE	Low correlations were observed between the PRWE and age as well as PRWE and PASE.
Lovgren at al 2012[39]	Sample 1 - 22 patients with DRF were tested 10 days after their fracture and again after 2-7 days. Sample 2 - 22 patients with DRF were tested 2-5 days before the removal of cast and again immediately before removing the cast. The PRWE, DASH, TSK, CAT of the CSQ, and SES were administered to both the	22 22	Test-retest reliability, internal consistency, and convergent validity	Good test-retest reliability and internal constancy was observed for the PRWE. The correlations between the PRWE and the measures of behavioural factors was low to moderate affirming that the pain/disability of wrist and behavioural aspects are two diverse constructs.

	samples.			
MacDermid et al 1998[1]	*Reliability* - 28 patients who were still being treated and 36 patients who had completed treatment, all with DRF, were examined at baseline and again after 2-7 days for reliability testing. 35 patients with non-union of scaphoid fracture examined at baseline and 1 year later.	64 in DRF group and 36 in scaph -oid group	Test-retest reliability, construct and criterion validity	The final version of PRWE was prepared and tested. This first study that examined the psychometric properties of the PRWE deemed the PRWE to be a reliable and valid measure for testing patient-rated pain and disability.
	Validity - 101 patients with wrist fracture were assessed at baseline and at two, three, and six months after the fracture. PRWE, SF-36, wrist ROM, grip strength, and dexterity testing was conducted.	101		
MacDermid et al 2000[34]	59 patients with DRF were assessed at baseline clinic visit, at 3 months, and at 6 months. DASH and PRWE were administered. ROM, grip strength, and dexterity were examined.	59	Responsiveness	PRWE was the most responsive as indicated by high SRM; responsiveness of both the PRWE and the DASH were the highest during first 3 months post injury when objective measures could not be administered.
MacDermid et al 2002[33]	120 patients with DRF were tested within 1st week after the injury and again after 6 months from the injury. PRWE was administered at baseline, PRWE and wrist ROM, grip strength, and dexterity were tested at 6 months.	120	Correlations of the PRWE with impairment measures, age, radial shortening, and education were examined.	Correlations between the PRWE and impairment measures were low to moderate. Correlations between the PRWE and impairment measures, age, radial shortening, and education were low.

MacDermid et al 2004[7]	60 patients (36 with hand conditions, 24 with wrist conditions) were assessed PRWE and DASH.	60	Responsiveness	SRMs and ESs revealed large treatment effect; PRWHE had higher responsiveness than the DASH. PRWHE was simpler for patients to complete and quicker for raters to administer and score.
MacDermid et al 2007[3]	122 patients were assessed 9-117 months following arthroplasty for osteoarthritis of the CMC joint using AUSCAN, PRWE and DASH.	122	Construct validity	Convergent validity was shown by high correlations between the AUSCAN, DASH and PRWHE. Divergent validity was shown by lack of correlation between these three and self report hand appearance.
Mehta et al 2012[14]	50 patients with DRF were assessed at baseline, after 2-3 days, and again after 4-5 weeks. PRWE-H, self-reported pain and disability using VAS, grip strength, and ROM were examined.	50	Translation in Hindi, construct validity, test-retest reliability, SEM, internal consistency, responsiveness, MDC_{90}	The PRWE-H was deemed comparable to the English version of the PRWE. The PRWE-H showed acceptable reliability, high concordance with the Hindi versions of VAS-pain and VAS-disability. Responsiveness was excellent as shown by the large ES and SRM.
Mellstrand et al 2011[13]	124 patients with different wrist injuries were assessed at two separate occasions. PRWE-Swe and DASH-Swe were administered on the two occasions.	124	Translation in Swedish, content, criterion, and discriminant validity, test-retest reliability, internal consistency, responsiveness	The PRWE-Swe was deemed comparable to the English version of the PRWE. The PRWE-Swe showed excellent reliability and validity. Responsiveness was very good as shown by the large SRM.
Schmitt et al 2004[29]	20 patients with distal upper extremity musculoskeletal problems were assessed at baseline, again in less than 2 weeks, and lastly at 3 months period from baseline. SPADI, PRWE,	20	Reliability, SEM, validity, responsiveness, MDC_{90}, and MID	PRWE had the highest ICC and it was more responsive than other outcome measures (comparable to the DASH). MDC and MCID yielded additional information for clinical application of PRWE.

	DASH, SF-12, and global disability rating were administered.			
Wah et al 2006[8]	47 patients with different wrist injuries were assessed with the PRWE-HK, SF-36-HK, VAS-HK, JHFT, wrist ROM and grip strength at baseline and six weeks later.	47	Translation in Swedish, content and construct validity, internal consistency	The Chinese version demonstrated acceptable equivalence. PRWE-HK demonstrated good concordance with VAS-HK and moderate to low concordance with SF-36-HK, wrist ROM, and JHFT. Internal consistency was excellent.
Wilcke 2009[9]	99 patients with DRF were recruited. 50 completed PRWE-Swe and DASH-Swe at 7 weeks and 6 months post-injury. 49 completed PRWE-G at 7 weeks and at 4 months.	99	Swedish translation equivalence, validity, reliability, responsiveness	PRWE-Swe showed acceptable equivalence to original. The PRWE-Swe had high correlation with fracture severity and the DASH-Swe. Test-retest and internal consistency were good. PRWE-Swe had excellent responsiveness indices (SRM, ES) compared to those of the DASH-Swe.

Abbreviations: AUSCAN, Australian/Canadian Osteoarthritis Hand Index; CAT, Catastrophizing Subscale; CMC, Carpometacarpal; CSQ, Coping Strategies Questionnaire; DASH, Disabilities of Arm Shoulder and Hand; DASH-IT, Italian translation, German translation; DASH-Swe, Swedish translation; DASH-G, German translation; DRF, distal radius fracture; ES, effect size; OA, osteoarthritis; ICC, intra-class correlation coefficient; JHFT, Jebsen hand function test; MASS07, Modern Activity Subjective Survey of 2007; MCID, minimal clinically important difference; MCD, minimum detectable change; ORIF, open reduction internal fixation; PASE, Physical activity scale for elderly; PRWE, Patient Rated Wrist Evaluation; PRWE-IT, Italian translation; PRWE-G, German translation; PRWE-H, Hindi translation; PRWE-J, Japanese translation; PRWE-Swe, Swedish translation; PRWE-G, German translation; PRWE-HK, Chinese translation; RIAP, resection interposition arthroplasty; SES, Self-Efficacy Scale; SF-36, Short Form 36 questionnaire; SF-36-G, German translation; SF-36-HK, Chinese translation; SPADI, Shoulder Pain and Disability Index; SRM, standard response measure; TSK, Tampa Scale of Kinesiophobia; VAS, visual analog scale

Table 2. Critical Appraisal of the Studies Assessing Psychometric Properties of the PRWE

Study	1	2	3	4	5	6	7	8	9	10	11	12	Total (%)
Mehta et al 2012[14]	2	2	2	2	0	1	2	2	2	2	2	2	88
MacDermid et al 1998[1]	2	1	2	2	0	2	2	1	2	2	1	2	79
MacDermid et al 2007[3]	2	1	2	1	0	2	2	1	2	2	2	2	79
Schmitt et al 2004[29]	1	1	1	2	1	1	2	2	2	2	2	2	79
Lovgren et al 2012[39]	2	1	2	1	0	1	2	2	2	2	1	2	75
MacDermid et al 2004[7]	2	2	1	0	1	2	2	1	2	2	1	2	71
Mellstrand et al 2011[13]	1	1	1	2	2	2	1	1	2	2	1	2	71
MacDermid et al 2000[34]	2	1	1	0	0	2	2	1	1	2	1	2	69
Hemelaers et al 2008[10]	1	2	1	2	0	1	1	1	2	2	2	1	67
Imaeda et al 2010[12]	2	1	1	2	1	0	1	1	2	2	1	2	67
John et al 2008[24]	2	1	1	2	0	1	1	1	2	2	2	1	67
Wah et al 2006[8]	2	1	1	1	0	2	2	1	2	2	1	1	67
Alexander et al 2008[41]	1	1	1	2	1	0	1	1	2	2	0	2	58
Fairplay et al 2012[15]	1	1	1	1	0	1	1	1	2	2	1	2	58
MacDermid et al 2002[33]	1	1	0	0	1	2	2	1	1	2	1	2	58
Wilcke et al 2009[9]	1	1	1	2	0	1	1	1	2	2	1	1	58
Jupiter et al 2002[32]	1	1	0	0	0	0	1	1	1	2	1	1	38

*Evaluation criteria (MacDermid et al 2009): 1. Comprehensive literature review to justify the research question; 2. Specific inclusion/exclusion criteria; 3. Specific hypotheses; 4. Appropriate scope of psychometric properties; 5. Sample size justification; 6. Minimal loss to follow-up; 7. Detailing the test procedures; 8. Standardization of measurement techniques; 9. Data presented for each hypothesis; 10. Appropriate statistical tests; 11. Range of analyses for each psychometric property; 12. Proper presentation of the conclusions and clinical recommendations.

Table 3. Evidence Regarding the Reliability of the PRWE

Type of Reliability	Data from the Included Studies
Test-retest Reliability	**Short-term (1-17 days)**
	ICC > 0.90 in patients with DRF; retest period 2-7 days[1]
	= 0.91 in patients with different upper extremity diagnoses; retest period 2 weeks or less[29]
	= 0.78 in patients who underwent RIAP; retest period 2 weeks or less[26]
	= 0.94 in patients with DRF; retest period 3-7 days[10]
	= 0.89 in patients with various wrist/hand conditions; retest period 2 days[11]
	= 0.92 in patients with different wrist/hand conditions; retest period 1-2 weeks[12]
	= 0.93 in patients with chronic wrist disability; retest period an average of 17 days[13]
	= 0.83 in patients with DRF assessed 10 days after the injury; retest period 2-5 days[39]
	= 0.94 in patients with DRF assessed 2-5 days before the removal of cast; retest period 2-5 days[39]
	= 0.81 in patients with DRF; retest period 2-3 days[14]
	Kendalls W coefficient = 0.79 in patients with DRF; retest interval unclear[9]
	Long-term (up to 1 year)
	ICC = 0.91 in patients with scaphoid fracture; retest period was 1 year[1]
SEM	**SEM** = 5.22 in patients with different pathologies involving distal upper extremity[29]
	= 8.12 in patients who underwent RIAP[26]
	= 5.4 in patients with DRF[14]
MDC	**MDC_{90}** = 12.2 in patients with different pathologies involving distal upper extremity[29]
	= 12.5 in patients with DRF[14]
	MDC_{95} = 22.5 for patients who underwent RIAP[26]

Abbreviations: CI, confidence interval; DRF, distal radius fracture; ICC, intra-class correlation coefficient; MDC, minimal detectable change; PRWE, Patient Rated Wrist Evaluation; PRWE-G: German translation; RIAP, resection interposition arthroplasty, Standard Error of the Measurement (SEM)

Table 4. MDC_{90} and MDC_{95} values of the PRWE for various clinical subgroups

Patient Population	Study (N)	MDC_{90}	MDC_{95}	CID
DRF	Mehta et al[14] (50)	Total score = 12 Pain = 8 Function = 10	Total score = 15 Pain = 9 Function = 12	
Chronic wrist conditions	Mellstrand et al[13] (62) (reported values for SD were used for analysis)	Total score = 12 Pain = N/A Function = N/A	Total score = 15 Pain = N/A Function = N/A	
RIAP in CMC	John et al[26] (51)	Total score = 19 Pain = 25 Function = 18	Total score = 23 Pain = 29 Function = 22	
Different distal UE diagnosis	Schmitt et al[29] (20)	Total score = 12 Pain = N/A Function = N/A	Total score = 14 Pain = N/A Function = N/A	Total score = 24 Pain = N/A Function = N/A
Different acute and chronic wrist diagnosis	Imaeda et al[12] (112) (reported values for SD were used for analysis)	Total score = 16 Pain = 10 Function = 9	Total score = 19 Pain = 12 Function = 11	

MDC, minimal detectable change; PRWE, Patient Rated Wrist Evaluation; CID, clinically important difference; DRF, distal radius fracture; SD, standard deviation; RIAP, resection interposition arthroplasty; CMC, carpometacarpal arthritis; UE, upper extremity

Table 5. Evidence Regarding the Validity of the PRWE

Type of Validity	Data from the Included Studies
Content	○ Content validity was initially ensured using survey methodology where patients with wrist injuries and hand surgeons were involved in defining the questions for the tool.[42] ○ Following up on the initial work, MacDermid et al[1] pursued a detailed questionnaire development methodology to ensure content validation and derive the final version. ○ Subsequent studies have confirmed the two factor structure of the PRWE[3, 8] which is consistent with the premise that the function and pain as separate subsets and should be scored separately. ○ Item completeness has also been evaluated and found to be acceptable with 78-84% of patients answering all questions.[9] ○ Kolmogorov-Smirnov Test examining the normality of the distribution of the data showed a perfect outcome (rating = 0) on pain and function subscales as well as total score.[26] ○ Assessment of ceiling effect has been limited for the English version, however item 10 has shown 59% ceiling effect in the German version[10] and 8% individuals showed ceiling effect for the function subscale in the Hindi version.[14] ○ Cultural equivalency for the PRWE-HK was ensured by qualitative feedback from the multidisciplinary team of members and appropriate data analysis.[8]
Construct or Criterion	<u>Wrist/Upper Extremity Specific Measures</u> ○ High correlations (r > 0.7) of the PRWE reported with MASS07,[39] AUSCAN,[3] DASH,[3, 7, 9, 11-13, 15, 26] and VAS (with pain subscale of the PRWE)[12, 14] ○ PRWE-G showed moderate concordance (r = 0.62) with the DASH in patients with DRF.[10] ○ Moderate correlations (r between 0.3-0.7) of the PRWE observed with composite wrist impairment score,[1, 32, 33] dexterity,[32] wrist ROM,[33] and grip strength[14, 26, 33] ○ Correlations between the PRWE and wrist ROM have also been low (r < 0.3) across some studies.[14, 26] <u>Generic/Global Measures</u> ○ High concordance (r = 0.73) with SF-36 bodily pain[1] ○ Moderate correlation (r between 0.3-0.7) with SF-36 summary scores[1, 3, 10, 12, 26], PASE,[32] and global disability rating[29] ○ Moderate to low correlations with the TSK and CAT of the CSQ[39]

Internal consistency	Cronbach's alpha indicated excellent internal constancy (CA > 0.75) across majority of the studies[8-15, 26, 39]

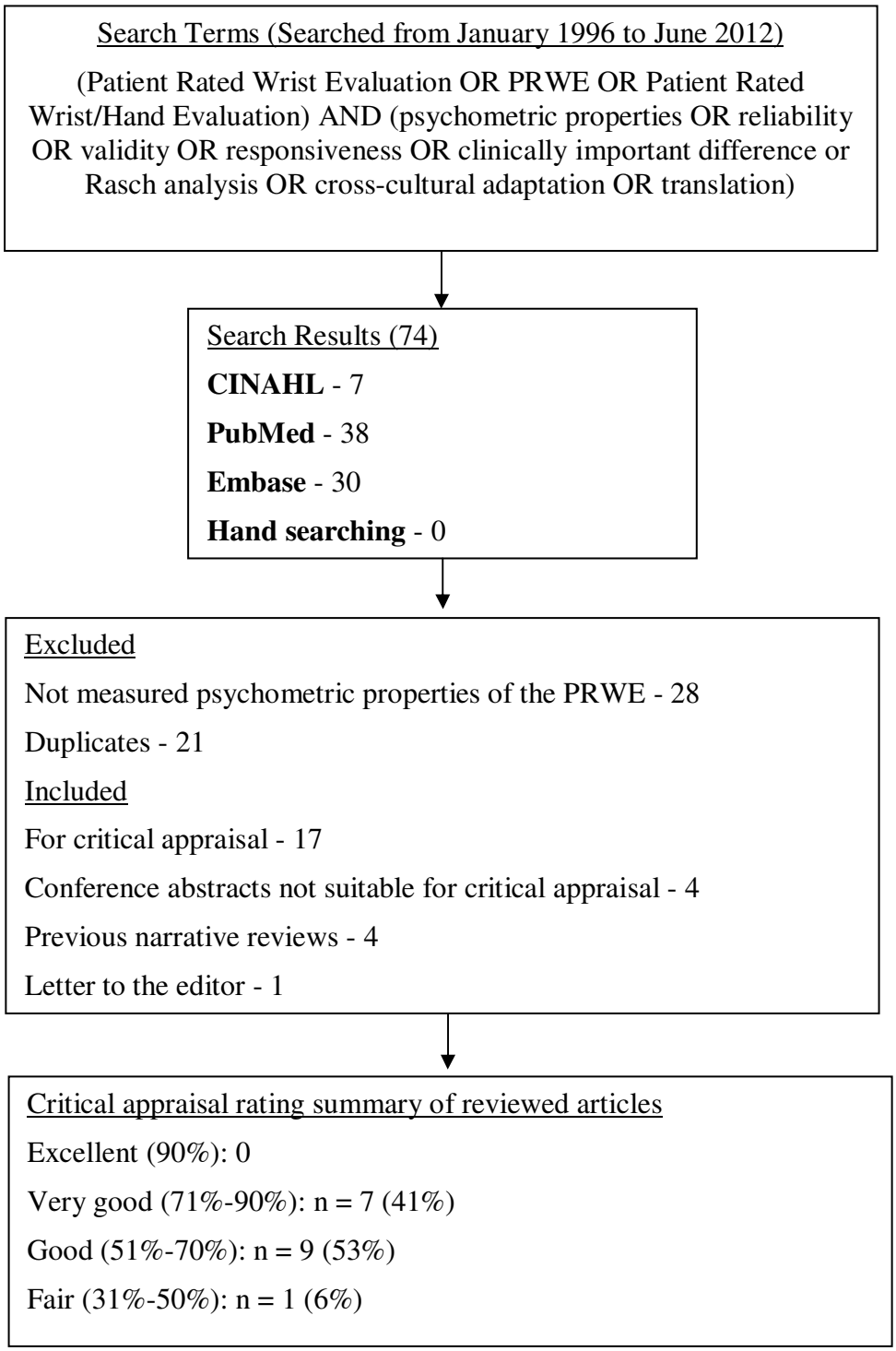
Abbreviations: ADL, activities of daily living; AUSCAN, Australian/Canadian Osteoarthritis Hand Index; CAT, Catastrophizing Subscale; CMC, Carpometacarpal; Coping Strategies Questionnaire (CSQ); DASH, Disabilities of Arm Shoulder and Hand; DRF, distal radius fracture; ICC, intra-class correlation coefficient; MASS07, Modern Activity Subjective Survey of 2007; OA, osteoarthritis; PASE, Physical Activity Scale for Elderly; PRWE, Patient Rated Wrist Evaluation; PRWHE, Patient Rated Wrist/Hand Evaluation; PRWE-HK, Chinese translation; RIAP, resection interposition arthroplasty; SF-36, Short Form - 36 questionnaire; SF-36-HK, Chinese translation; TIA, tendon interposition arthroplasty; VAS, visual analogue scale

Table 6. Evidence Regarding the Responsiveness of the PRWE

Responsiveness Index	Data from the Included Studies
ES	Large (> 0.8) ○ 3.16 for 0-3 months and 3.91 for 0-6 months comparison;[34] 2.16 for 0-5 weeks comparison;[14] 1.3 for 0-7 weeks comparison;[9] and 3.32 for 0-3 months comparison[12] in DRF population ○ 1.49 for 0-3 months comparison;[7] 1.92 for 0-3 months comparison[12] in patients with different wrist conditions ○ 1.87 for 0-3 months comparison in patients with distal UE diagnosis[29] Medium ○ 0.50 3-6 months comparison[34]
SRM	○ 2.27 for 0-3 months and 2.95 for 0-6 months comparison;[34] 2.66 for 0-5 weeks comparison;[14] 1.4-1.7 for 0-7 weeks comparison;[9] and 1.90 for 0-3 months comparison[12] in DRF population ○ 1.55 for 0-3 months comparison;[7] 1.55 for 0-3 months comparison;[12] 1.29 for 0-5 weeks comparison[13] in patients with different wrist conditions ○ 1.94 for 0-3 months comparison in patients with distal UE diagnosis[29] Medium ○ 0.74 3-6 months comparison[34]

Abbreviations: DRF, Distal Radius Fracture; Effect Size; PRWE, Patient Rated Wrist Evaluation; PRWHE, Patient Rated Wrist/Hand Evaluation; SRM, Standard response Mean

Figure. Flow Diagram for Selecting the Studies for Review



Chapter 4. Baseline Pain Intensity is a Predictor of Chronic Pain in Individuals with Distal Radius Fracture

Saurabh P. Mehta PT, MSc[1]
Joy C. MacDermid PT, PhD[2]
Julie Richardson PT, PhD[3]
Norma J. MacIntyre PT, PhD[4]
Ruby Grewal MD, MSc, FRCSC[5]

[1] PhD Student and CIHR Doctoral Fellow, School of Rehabilitation Science, McMaster University, Hamilton, Ontario, Canada
[2]Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario and Co-director Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, 268 Grosvenor St., London, Ontario, Canada
[3]Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario
[4]Associate Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario
[5]Assistant Professor, Department of Surgery, Western University and Co-director Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, 268 Grosvenor St., London, Ontario, Canada

Ethics approval was obtained from the Research Ethics Board, Western University for this study.

Corresponding Author: Joy C. MacDermid, PhD , School of Rehabilitation Science, McMaster University, 1400 Main Street West - IAHS 402, Hamilton, Ontario L8S 1C7, Canada Email: macderj@mcmaster.ca Fax no.: 001 905 524 0069

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Abstract

Background: A significant number of individuals continue to experience pain in wrist/hand area even 1 year after distal radius fracture (DRF) injury. Early prediction of those who are at risk of chronic pain can facilitate the delivery of required interventions to mitigate such risk.

Objective: The objective of this study was to examine whether baseline pain intensity is a predictor of chronic pain in individuals with DRF. The study also aimed to determine the cut-off level for baseline pain intensity that is strongly predictive of chronic pain.

Methods: Data for the Patient-rated Wrist Evaluation (PRWE) at baseline and 1 year after injury, age, sex, side of injury, and dominant side were extracted for individuals with DRF from an existing dataset. Multivariate regression analysis examined the utility of baseline pain intensity, side of injury (dominant v/s non-dominant), age, and gender in predicting chronic pain (score of ≥12.5/50 on the pain scale of the PRWE) at 1 year after DRF. Receiver operating characteristic (ROC) curves were created to examine the sensitivity/specificity of predicting chronic pain.

Results: Data was extracted for 386 individuals with DRF. Baseline pain intensity was found to be a strong predictor of chronic pain (explained 22% variance). Age, gender, side of injury (dominant v/s nondominant) did not predict pain at 1 year. The baseline score of 35 (out of 50) on pain subscale had the best sensitivity/specificity cut-off values (85/79) for predicting chronic pain at 1 year.

Limitations: No guidelines to calculate composite risk in presence or absence of other known predictors of chronic pain in DRF population such as injury compensation and educational level

Conclusion: Rehabilitation practitioners can use the score of >35 on baseline pain to screen individuals at risk of chronic pain following DRF.

Background

The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[1] Acute pain is usually a result of harmful stimuli and signals the individual to withdraw from the stimuli in order to minimize tissue damage. Acute pain can also indicate the presence of tissue damage which warrants the individual to seek medical attention. In fact, pain is the most common reason for seeking medical attention.[2] The location and severity of pain, in combination with other clinical tests, allows the healthcare professional to diagnose the condition and plan appropriate interventions to repair the tissue damage. Pain is expected to be relieved once the tissue is repaired and the source of pain is eliminated.

A significant number of individuals, however, continue to experience pain despite the expected time for tissue healing having elapsed. Pain lasting beyond the anticipated point of tissue healing, typically over 3 months duration, is characterized as chronic pain.[3] Managing chronic pain in the absence of actual tissue damage understandably poses a greater challenge to healthcare professionals than managing acute pain. Of the many types of chronic pain, chronic musculoskeletal (MSK) pain is arguably the most common and affects up to one third of the population especially older adults.[4, 5] Chronic MSK pain can have many diverse functional and socioeconomic implications ranging from emotional and psychosocial suffering, long-term analgesic use, functional limitations, and lost hours of work.[6] Management of chronic MSK pain has occupied center stage in the field of MSK research in the last decade.[7] It is increasingly being accepted that early

identification of risk factors leading to chronic MSK pain following an acute injury can minimize the transition to chronic MSK pain at least in a small subset of individuals. However, the risk factors and clinical indicators of chronic pain can be different across the many types of MSK injuries.

Distal radius fracture (DRF) is one of the most common osteoporotic fractures[8-10] with an estimated lifetime risk of 6.2% and 32.7% respectively in males and females who are 50 years of age.[11] Pain and functional limitations of the wrist/hand area are common during the acute phase of DRF. Distal radius fracture is initially managed either conservatively or through surgical fixation depending upon the type and severity of the injury.[12] Rehabilitation usually starts 6-8 weeks after the injury to restore movement, strength, and functional status of the wrist/hand to pre-injury level.

Fracture healing usually takes place in the first 6-8 weeks after DRF. The next 2-3 months can be considered as the rehabilitative phase.[13] Considering these phases, full recovery with minimal or no symptoms should be expected after 6 months.[14] Although full recovery following DRF is common, it is not always achieved. Previous research has shown that approximately 16% of patients with DRF continue to report wrist/hand pain even 1 year following the injury.[15, 16] Given the yearly incidence of DRF, this rate represents a significant number. Recently, Swart et al[17] confirmed these observations and suggested that individuals with DRF continue to experience pain even 2 years after DRF. Furthermore, pain was reported to be one of the strong predictors of functional disability at 2 years following DRF. In another study, Arora et al[18] indicated pain and disability was often present even after 4 years following DRF. Clinicians who routinely manage DRF

may be familiar about incidence of the chronic wrist/hand pain (referred to as chronic pain in remainder of the paper) in the DRF population, however they may not have understanding of the magnitude of this problem since the typical follow-up for most of these patients is up to 6 months after injury.

Individual studies have identified predictors of poor outcomes including chronic pain and functional impairment in individuals following DRF.[19, 20] These studies have mainly outlined the role of personal factors such as injury age, compensation status, education level, and presence of medical comorbidities in predicting chronic pain. These variables indeed provide some context to rehabilitation practitioners while predicting risk for poor outcomes following DRF but they are beyond the scope of rehabilitation practitioners to manage within their practice. Other studies have postulated that suboptimal radiographic outcome is a concern but does not always result in chronic pain or disability.[18, 21, 22] This indicates that some individuals can still expect favourable outcomes despite poor union of DRF.

We recently published a theoretical model describing the role of different personal and injury factors in predicting chronic pain and choosing a rehabilitation strategy to avoid it.[23] This model suggested that prior pain experience and psychosocial factors that affect the injury response would contribute to fracture outcomes. The algorithm has not been empirically validated. A starting point would be to examine whether the elements of this model are useful predictors of chronic pain and whether rehabilitation practitioners can use them for computing relative risk (RR) for transitioning to chronic pain following DRF at the level of an individual. One of the other recommendations emerging from this

model was that the cut-off score for pain intensity at baseline that is predictive of chronic pain following DRF can be identified using a validated outcome measure.

Self-reported measures have been used for predicting adverse outcomes in individuals with MSK injuries. The Disabilities of Arm, Shoulder, and Hand (DASH) questionnaire is useful in predicting time lost from work following DRF.[24] The Kujala Patellofemoral Score has been used to predict poor outcomes in individuals suffering from patellofemoral syndrome.[25] Similarly, self-reported questionnaires have been found to be useful for predicting chronic pain in individuals seeking care for the first time due to acute low back pain.[26]

The Patient-Rated Wrist Evaluation (PRWE) has previously been used for predicting return to work status in individuals with DRF.[27] The results of this study indicated that self-reported disability at baseline was strong predictive of return to work with individuals reporting higher disability taking longer to return to work. The PRWE was conceived primarily to measure disablement in DRF population.[28] Subsequent studies have demonstrated the usefulness of the PRWE in assessing disablement and measuring change in individuals with DRF.[29, 30] The PRWE has separate pain and function subscales both of which have sufficient psychometric properties such that they can be used independently.[31] The pain subscale had 5 items and function subscale has 10 items. The function subscale is further divided into two categories: 6 items specific function and 4 item usual function categories. The possible scores on both the subscales range from 0-50 resulting in a composite score between 0-100. Given the strong evidence of psychometric properties of the PRWE in DRF population[32] and its ability to independently measure

aspects of pain experience, baseline pain score on PRWE can be used for assessing whether it is predictive of chronic pain following DRF.

The purpose of this study was to explore the role of baseline pain intensity as reported on the pain subscale of the PRWE in predicting chronic pain in individuals with DRF. Secondly, the study also examined whether the baseline pain intensity predicted MSKD at 1 year in these individuals. In particular, the study aimed to examine the cut-off level for baseline pain intensity reported on the PRWE that is strongly predictive of chronic pain and MSKD in this population. The study also aimed at providing likelihood/relative risk ratios for developing chronic pain at different baseline pain intensity levels. Lastly, we also explored whether age/gender influence pain and functions at 1 year.

Materials and Methods

The study was a retrospective cohort design. Participants were recruited from the Hand and Upper Limb Center (HULC), London, Ontario, Canada between 1996 to 2009. The data collection took place once the individuals presenting to the HULC following DRF provided informed consent to participate in the ongoing cohort study. The inclusion criteria for the ongoing cohort study are: ≥ 18 years, DRF within the past 1-2 weeks, ability to understand English, and those with no cognitive impairments. In addition to the inclusion criteria for the cohort study, we only included the participants who were followed for the period of at least 1 year from the baseline and had no missing data for this period. The data for the baseline and 1 year follow-up were extracted for the selected individuals.

Variables

Among the number of variables examined at baseline, we extracted the data for age, sex, side of injury, dominant side, and scores for the PRWE. The data for the PRWE was separated for pain and function subscales. The data was extracted for baseline (within 1-2 weeks of injury) and 1 year follow-up for all the variables.

Data Analysis

Means ± standard deviations (SD) and/or percentage summaries for the demographic variables were calculated. Means ± SD were calculated for the baseline pain score as well as 1 year scores for both pain and function subscales and the total score of the PRWE. The data were reported for all the participants as well as two pre-determined subgroups based on gender (female or male) and age ($\geq$ 65 years or $<$ 65 years). The differences in baseline and 1 year scores for pain subscale, functional subscale, and total score of the PRWE were calculated for the all participants as well as for the subgroups. Independent t-tests were used for the comparison. Statistical significance was considered at $p < 0.05$.

A forward stepwise multivariate linear regression was created to examine the ability of different variables in predicting chronic pain and MSKD 1 year following DRF. Baseline pain intensity, side of injury (coded as 2 or 1 for dominant or non-dominant), gender (coded as 2 or 1 for female or male), age (coded as 2 or 1 for $\geq$ 65 years or $<$ 65 years), and age/gender interaction (male/$\geq$ 65 years or $<$ 65 years of age coded as 1 or 2;

female/≥ 65 years or < 65 years of age coded as 3 or 4) were included in the regression model.

Chronic pain and MSKD were considered the outcomes of interest. The score of ≥12.5/50 at 1 year follow-up for either the pain or function subscales of the PRWE was defined as chronic pain or MSKD being present respectively. The optimal cut-off for poor outcome on the PRWE has not been defined. Previous literature has shown that the cut-off score of 20 was not sufficiently discriminative;[22] and 12 is the median 12 months score.[16] We arbitrarily selected 25% (25 out of the possible total score of 100) cut-off for defining the presence or absence of poor outcome. This means that the score of 12.5 (out of possible total score of 50) for pain and function subscale would indicate chronic pain and MSKD respectively. Further to this, the data for the PRWE and its subscales at 1 year follow-up were coded as follows: 2 = presence of chronic pain/MSKD, 1 = absence of chronic pain and MSKD. Receiver operating characteristic (ROC) curves were created to examine the accuracy of predicting chronic pain and MSKD at 1 year using cut-off points for baseline pain intensity. Separate curves were plotted for the 'specific' and 'usual' subset of the function subscale to determine the predictive ability of the baseline pain score for MSKD across these two different types of functional activities. The score on baseline pain intensity which best predicted chronic pain and MSKD (optimal trade-off between sensitivity and 1-specificity) was selected as a cut-off. Relative risk and positive/negative likelihood ratios for transitioning to chronic pain or MSKD were examined using this cut-off score. Finally, area under the curve (AUC) was examined as a measure of overall accuracy of baseline pain intensity in predicting chronic pain and

MSKD in individuals with DRF. Area under the curve of $> 80\%$ was considered indicative of good accuracy in predicting outcomes of interest (i.e, chronic pain and MSKD). All the analyses were repeated for both the subgroups (female or male; ≥ 65 years or < 65 years).

SPSS V.17 (Chicago, IL) was used for analyzing all the data.

Results

A total of 386 participants who had complete data at baseline and at 1 year were included in the study. Demographic variables, baseline scores for the total PRWE and subscales as well as 1 year score for the total PRWE and subscales for the participants are shown in Table 1. Of the 386 participants, 278 (72%) were female and 108 (28%) were male. The male group was significantly younger than the female group ($p < 0.001$). The scores on pain and function subscales at 1 year were not different between the male and female groups at 1 year. A total of 93 participants (24%) were ≥ 65 years of age and 293 (76%) were < 65 years of age. The younger adults had significantly higher pain score at baseline compared to the older adults ($p < 0.001$). A similar trend was observed at 1 year where the younger adults continued to report significantly higher pain score compared to the older adults ($p = 0.03$). The scores for the function subscale at 1 year were not different between younger and older adults ($p = 0.84$). Using the cut-off score of 12.5/50 (25%), approximately 30% participants had transitioned to chronic pain and 18% participants had MSKD at 1 year.

Multivariate regression indicated that from our pool of potential predictors (baseline pain intensity, injury to dominant side, age, gender, and interaction of age and gender) pain had a small gender by age interaction. Table 2 shows that baseline pain and being female, ≥ 65 years of age were predictive of a higher pain score at 1 year following DRF. In particular, the baseline pain intensity alone predicted 22% of the variability in PRWE pain score at 1 year. Being female and ≥ 65 years of age was also predictive of pain at 1 year and predicted an additional 0.9% variability in PRWE pain score at 1 year. Age or gender alone as well as injury to the dominant side did not predict pain at 1 year. Table 3 shows that baseline pain was able to predict 12.4% variability in MSKD at 1 year following DRF. None of the other variables were independent predictors of sMSKD at 1 year.

Figure 1 illustrates the ROC curve showing the cut-off points for baseline pain score to predict chronic pain and MSKD for all participants. Baseline pain was a better predictor of chronic pain than MSKD at 1 year. The baseline score of 35 (out of 50) on the pain subscale had the best sensitivity/specificity cut-off values for predicting chronic pain and MSKD at 1 year. Figures 2 and 3 illustrate the ROC curves for the two subgroups (female or male and ≥ 65 years /< 65 years) and show that baseline pain intensity was a strong predictor of chronic pain at 1 year across both the subgroups. Table 4 summarizes AUC as well as the sensitivity/specificity values, positive/negative likelihood ratios, and RR ratio of developing chronic pain or MSKD (impairment in specific and usual functions) with baseline pain score of 35 for the total sample as well as the gender and age subgroups. The AUC for the ROC curves for chronic pain was 87%

for all participants and 83% - 91% for the subgroups indicating that baseline pain is a good predictor of chronic pain at 1 year in individuals with DRF. The AUC for the ROC curves of specific /usual functions (were in the range of 65 - 74 % for the total sample as well as subgroups indicating that baseline pain has less accuracy in predicting MSKD than chronic pain at 1 year in individuals with DRF.

Discussion

The present study demonstrated that baseline pain intensity is an independent predictor of chronic pain following DRF and can be used by clinicians to screen individuals who are at risk of chronic pain. The study is an extension of our previously published work that provided theory driven assessment guidelines for screening and identifying individuals at risk for poor outcomes following DRF.[23] Given that an estimated 16% of individual develop chronic pain following DRF,[15, 16] early identification of those who have potential risk creates an opportunity to modify rehabilitation interventions for minimizing the incidence of chronic pain. The clinicians should use the cut-off score of 35/50 for baseline pain intensity on the PRWE to identify persons with this score and above where the risk of chronic pain is the greatest. This cut-off had the best combination of sensitivity/specificity (85/79) with AUC of 87% indicating very good discriminative ability.[33] Furthermore, it was evident that baseline pain intensity was not useful in predicting MSKD and appeared to have little utility for this purpose. Clinicians can use PRWE pain subscale as a screening tool to assess future risk of chronic pain. This study focused on establishing the cut-off score on one scale and clinicians should be cognizant of other known predictors (i.e. injury compensation status, education level, and

presence of medical comorbidities)[19] of chronic pain in DRF population while making clinical decisions. However, it is possible that the impact of these factors is reflected in the PRWE pain scores and underlies the ability of the score to predict future outcomes.

Previous research has explored whether personal and injury factors influence chronic pain following DRF. Injury compensation and educational level are highly predictive of chronic pain and MSKD[19, 20] and can lead to difficulty in returning to work[24] following DRF. Therefore, we did not include all personal and injury factors in our regression model to determine the predictive ability of these factors. Rather, we focused on a pragmatic approach using a cut-off point on pain measurement to identify when a clinician should start to be concerned about risk of adverse outcomes and potentially instigate preventative measures. The DASH and PRWE have successfully predicted time lost from work following DRF[24] and this present work re-affirms the use of self-reported measures in predicting poor outcome following DRF. Our work provides further evidence to suggest that age, gender, and hand dominance do not influence chronic pain or MSKD in DRF population. A new finding from our study is that the females over the age of 65 years may have slightly greater risk of developing chronic pain compared to those under the age of 65 years and also compared to the males over the age of 65 years. However, the effect is very small and without replication it may not be of clinical relevance.

Baseline pain intensity provides an opportunity to design specific pain management interventions. Since this is a modifiable outcome, clinicians can conveniently track the pain level over the continuum and provide specific guidelines to modify the pain experience. A few management strategies can be drawn for individuals at

risk of chronic pain based on previous literature. One option is to manage at risk individuals using the RACE (**R**est, **A**ctivate, **C**ognitive reshaping, **E**mpower) model that we had hypothesized specifically to minimize risk.[23] However, this model still needs empirical validation and is therefore subjected to modification. Clinicians can also provide routine rehabilitation interventions to reduce pain and promote functions in the affected hand and reassess pain intensity at 6 months. While the score of ≥12.5/50 on PRWE pain scale was used for defining chronic pain at 1 year, it can be used as a 'yellow flag' at 6 months. Individuals having the score of ≥12.5/50 on PRWE pain scale at 6 months can be managed using cognitive behavioural interventions to reduce negative behaviours and attitudes related to pain and promote self-efficacy in managing pain.[34]

The optimal cut-off level for baseline pain intensity that has the best combination of sensitivity and specificity to predict chronic pain was 35 out of 50 (≥70% of total possible score). Incidentally, those with baseline PRWE score of >70% also experienced more time lost from work.[24] Chronic ongoing pain in wrist/hand area and returning to work are dissimilar constructs. Thus, the score of 70% or more at baseline appears to be a common cut-off when the pain score can be indicative of the risk of poor outcome. This is the first study to our knowledge that provided the cut-off score on baseline pain intensity using the PRWE that best predicts risk of chronic pain following DRF. The RR of chronic pain for those with baseline pain score of > 35 was 8.4 for the total sample and ranged from 6.5-21 for the age and gender subgroups. The AUC was 87 for the total sample and ranged from 83-91 for the age and gender subgroups. This suggests considerable risk calculated at high precision for prediction[33] and should provide confidence to clinicians in

using the cut-off score of 35 for screening at risk individuals. The calculated RR for those > 65 years of age was 21 which were markedly higher than the rest of the subgroups. Another relevant finding was that the females over the age of 65 years were at greater risk of developing chronic pain following DRF. Eighty four of 93 participants who were analyzed in the subgroup > 65 years of age (90%) were females. This would probably have inflated the RR ratio for the subgroup of those > 65 years of age.

The baseline pain intensity explained 22% of variance which means 78% of variance remained unexplained for the factors affecting pain intensity at 1 year. This was expected as we did not include a number of known predictors such as injury compensation, education level, as well as pre-reduction radial shortening into regression model. Our study was designed to focus on where the risk should be acted upon in clinical practice in a quantitative manner. Our result confirmed that the baseline pain intensity alone explained 22% of variance in 1 year pain score compared to a total of 15% variance which was explained by injury compensation and education level together.[19]

Our results were based on the premise that the PRWE is a useful measure to assess baseline pain intensity in DRF population. There are a number of other generic pain scales and self-reported measures that could be used to examine the disablement in the DRF population.[35] However, using the PRWE for assessing baseline pain following DRF offers distinct advantages. Firstly, the PRWE was developed specifically for the individuals with DRF[28] therefore it has items that are extremely relevant to this population. Moreover, the PRWE has a distinct pain subscale which is adequately stable to be used as a separate measure for assessing pain.[28]

Another consideration is that the "baseline pain intensity" was defined as the pain intensity reported during the appointment at the fracture clinic (within 7-10 days from the injury) at which time the individual is still under cast for DRF. Pain intensity assessment can easily be incorporated at this time but rehabilitation practitioners may not assess patients 4-6 weeks following DRF when the cast has been removed. Therefore, the cut-off of >35/50 score for pain intensity may not be applicable at 4-6 weeks following DRF for screening the individuals at risk during initial assessment in a rehabilitation clinic. Since the DRF injury would likely have healed by 4-6 weeks, the pain intensity may be lower at this time. Therefore, the cut-off score for predicting at risk individuals could be lower at this time and using the cut-off score of 35 might miss at risk individuals. Conversely, some individuals experience excellent pain control during immobilization with or without pain medicines; and may experience substantial pain in the early phase of rehabilitation. If the reported pain intensity is still > 35 at 7-10 days after DRF, it should indeed serve as a red flag. Nonetheless, rehabilitation practitioners can use this cut-off level while further studies define more suitable cut-off for rehabilitation practitioners.

Complex regional pain syndrome (CRPS) is one of the complications following DRF. A recent publication summarized that the incidence of CRPS observed in previous research was estimated to be 1-37% following DRF.[36] They reported that the incidence of CRPS was 14% following DRF.[36] In our study, a total of 30% individuals were deemed to have chronic pain (score of ≥ 13 on pain subscale) at 1 year. Our purpose was to use baseline pain intensity to predict chronic pain following DRF irrespective of whether the

pain is related to CRPS or not. Future work can examine the accuracy of the calculated cut-off score (>35/50) to predict CRPS related and non-CRPS related chronic pain.

While this study will be useful to rehabilitation practitioners to identify individuals with greater risk of chronic pain following DRF, there are some limitations of our study. We did not provide any guideline to calculate composite risk in presence or absence of other known predictors of chronic pain such as injury compensation and educational level (some high school or post-secondary training). Secondly, our findings need to be verified in prospective inquiry to build a stronger evidence to support the use of baseline pain intensity to predict chronic pain following DRF.

In conclusion, our study confirmed that the baseline pain intensity is an independent predictor of chronic pain following DRF and is an extremely clinically tool for this purpose. Rehabilitation practitioners can use the score of >35 points on pain subscale of the PRWE at baseline to screen at risk individuals while further prospective studies validate this cut-off level.

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Table 1. Demographics and PRWE Score at Baseline and at 1 Year in Subgroups

	Mean ± SD (N = 386)	**N (%)**	**p value**
Age	52.4 ± 15.9		
F	55.3 ± 15.5	278 (72)	
M	44.8 ± 14.4	108 (28)	**< 0.001**
> 65 years of age	72.5 ± 4.7	93 (24)	
< 65 years of age	46 ± 12.5	293 (76)	
Dominant side			
R		356 (92)	
L		30 (8)	
Injured side			
R		206 (53)	
L		180 (47)	
Baseline Pain Score	31.1 ± 11.6		
F	30.8 ± 12		
M	31.8 ± 10.3		= 0.44
> 65 years of age	27.7 ± 12.6		**< 0.001**
< 65 years of age	32.2 ± 11		
Baseline Function Score	42 ±13.3		
Baseline Total Score	73.1 ± 20.1		

One year Pain Score	9.9 ± 10	≥12.5 = 115 (29.8)	
F	10 ± 10	≥12.5 = 85 (30.6)	= 0.74
M	9.6 ± 10.4	≥12.5 = 30 (27.8)	
> 65 years of age	7.9 ± 9.8	≥12.5 = 20 (21.5)	
< 65 years of age	10.5 ± 10.2	≥12.5 = 95 (32.4)	**= 0.03**
One year Function Score	6.8 ± 9.6	≥12.5 = 71 (18.4)	
F	7.2 ± 10	≥12.5 = 53 (19.1)	
M	5.8 ± 8.3	≥12.5 = 18 (16.7)	= 0.18
> 65 years of age	7 ± 9.1	≥12.5 = 18 (19.4)	
< 65 years of age	6.8 ± 9.7	≥12.5 = 53 (18.1)	= 0.84
One year Total Score	16.7 ± 18.7	≥25 = 84 (21.8)	
F	17.2 ± 19	≥25 = 63 (22.7)	
M	15.3 ± 17.8	≥25 = 21 (19.4)	= 0.37
> 65 years of age	14.9 ± 18.2	≥25 = 17 (18.3)	
< 65 years of age	17.2 ± 18.9	≥25 = 67 (22.9)	= 0.31

SD, standard deviation; F, female; M, male; R, right, L, left

Significant p values are shown in bold cases. p values lower than 0.001 are reported as p < 0.001

Table 2. Model Summary - Predictive variables for chronic pain at 1 year

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	0.471[a]	0.222	0.220	8.96542	0.222	109.415	1	383	< 0.001
2	0.107[b]	0.012	0.009	10.10706	0.012	4.457	1	383	0.035

a. Predictors: (Constant), Baseline PRWE Pain

b. Predictors: (Constant), Female over 65 years of age

Table 3. Model Summary - Predictive variable for MSKD at 1 year

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	0.356[a]	0.126	0.124	8.94722	0.126	55.457	1	383	< 0.001

a. Predictors: (Constant), Baseline PRWE Pain

Table 4. Statistics showing the predictive ability of the baseline pain score of >35

	Sensitivity/Specificity (%)	Positive/Negative LR	RR	AUC (%)
Total sample				
Pain score	85/79	3.91/0.19	8.4	87
Specific functions	71/68	2.18/0.43	3.6	71
Usual functions	66/65	1.88/0.52	2.9	72
Total score	76/71	2.6/0.3	4.9	76
Females				
Pain score	85/79	4.1/0.2	8.2	88
Specific functions	72/68	2.3/0.4	4	72
Usual functions	68/65	2/0.5	3.3	74
Total score	75/71	2.6/0.4	4.6	78
Males				
Pain score	84/77	3.6/0.2	7.6	83
Specific functions	65/65	1.8/0.5	2.7	69
Usual functions	59/62	1.6/0.7	2.1	65
Total score	81/70	2.7/0.3	6.4	78
> 65 years of age				
Pain score	90/86	6.5/0.1	21	91
Specific functions	75/77	3.2/0.3	6.3	72
Usual functions	70/72	2.6/0.4	5.1	71
Total score	75/76	3.2/0.4	5.3	80
< 65 years of age				
Pain score	83/76	3.3/0.2	6.5	85
Specific functions	69/64	1.9/0.5	3	71
Usual functions	65/62	1.7/0.6	2.5	71
Total score	78/69	2.5/0.3	4.8	77

LR, likelihood ratio; RR, relative risk; AUC, area under the curve

Figure 1. ROC Curve for All Patients

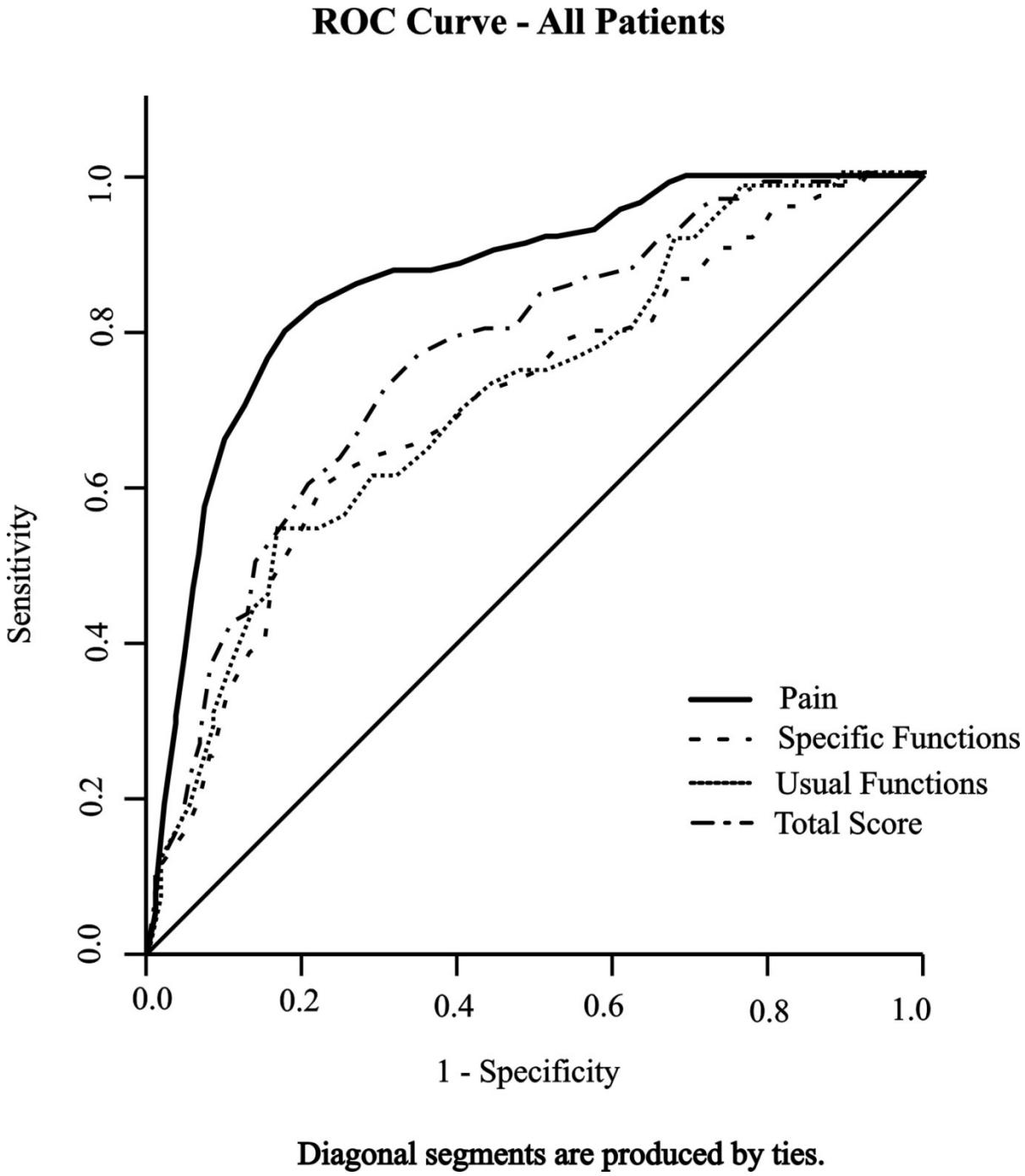


Figure 2. ROC Curve - Males and Females

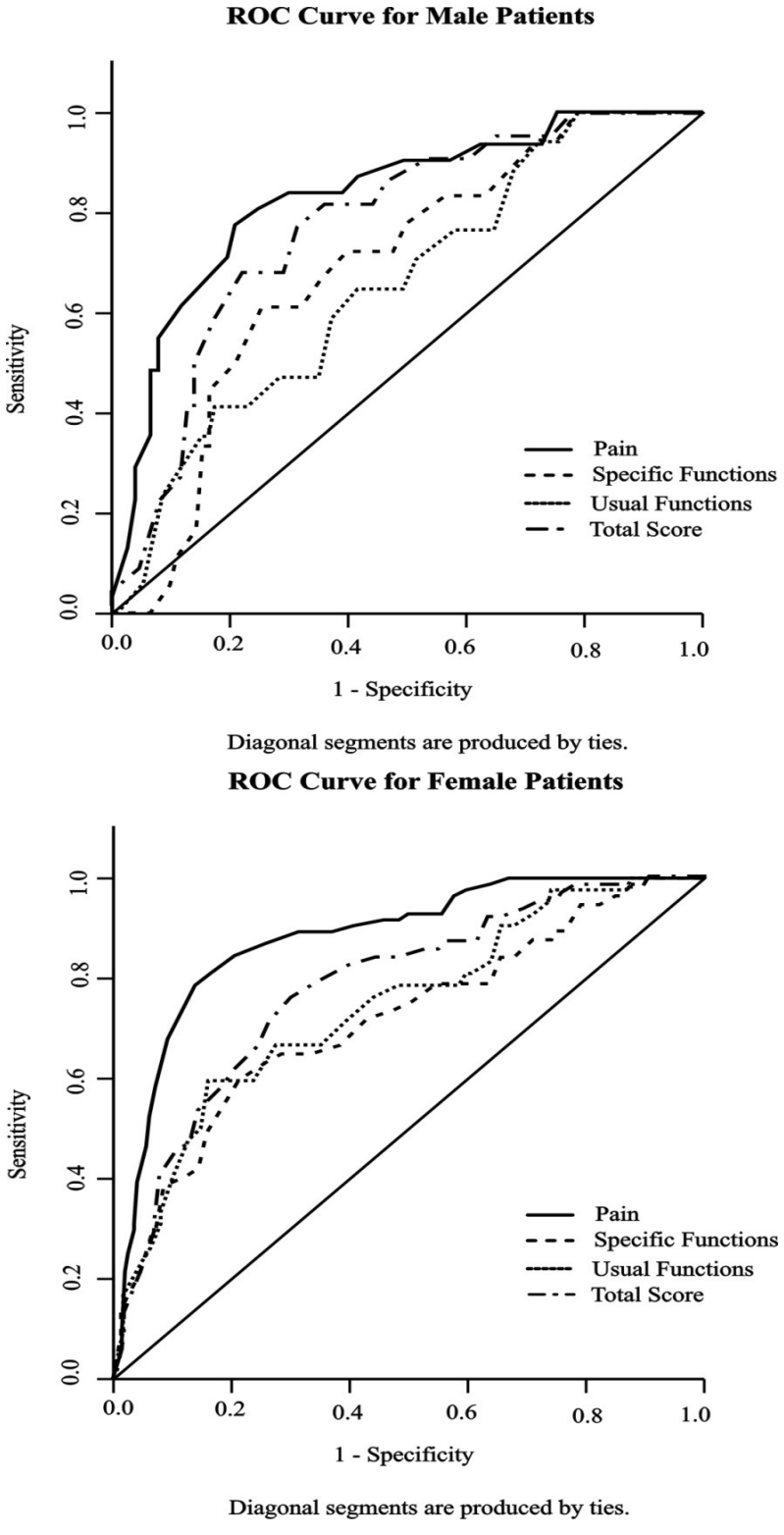
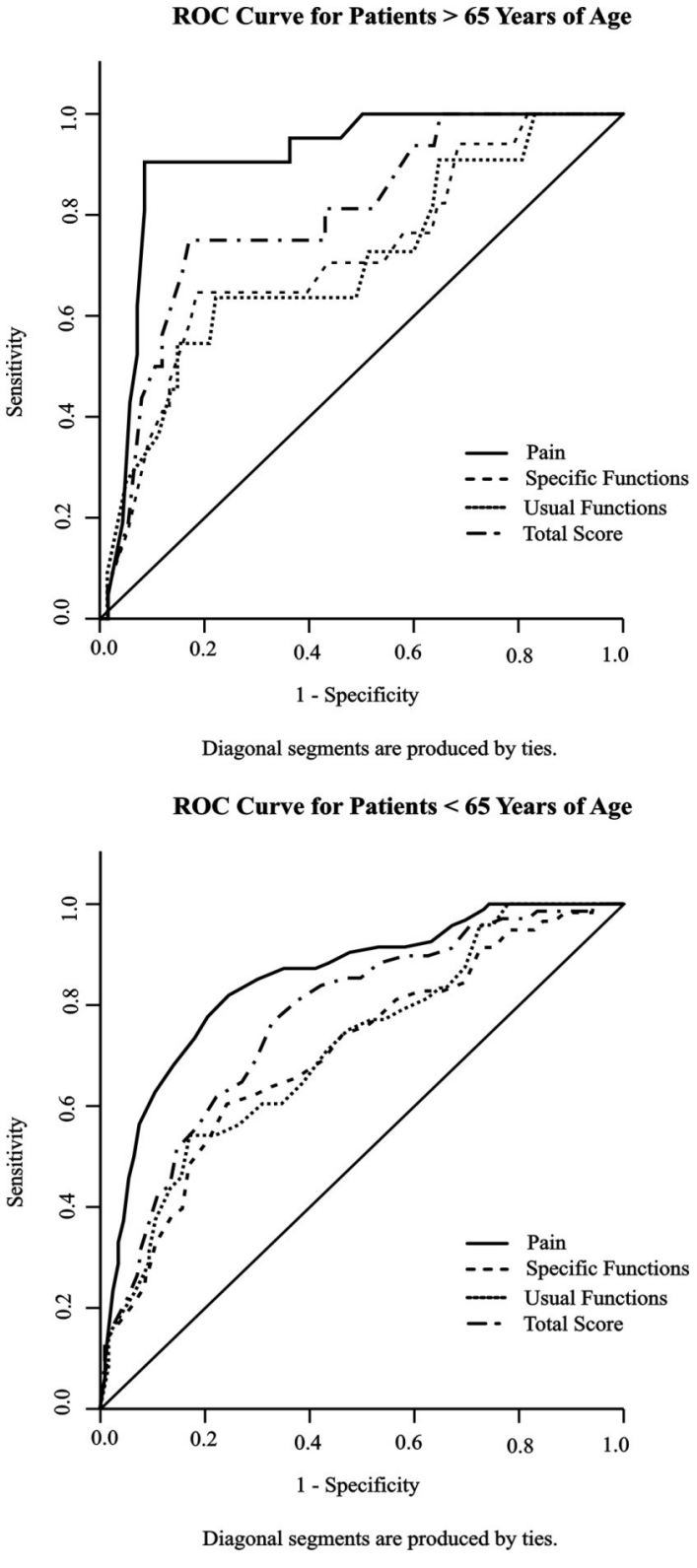


Figure 3. ROC Curve - Age groups (> or < than 65 years)



Chapter 5. Profiling Risk for Functional Decline Following Distal Radius Fracture: A Systematic Literature Review of Valid Outcome Measures

Saurabh P. Mehta PT, MSc[1]
Joy C. MacDermid PT, PhD[2]
Julie Richardson PT, PhD[3]
Norma J. MacIntyre PT, PhD[4]
Ruby Grewal MD, MSc, FRCSC[5]

[1] PhD Candidate and CIHR Doctoral Fellow, School of Rehabilitation Science, McMaster University, Hamilton, Ontario, Canada
[2]Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario and Co-director Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, 268 Grosvenor St., London, Ontario, Canada
[3]Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario
[4]Associate Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario
[5]Assistant Professor, Department of Surgery, Western University and Co-director Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, 268 Grosvenor St., London, Ontario, Canada

Ethics approval was not required for this study.

Corresponding Author: Joy C. MacDermid, PhD , School of Rehabilitation Science, McMaster University, 1400 Main Street West - IAHS 402, Hamilton, Ontario L8S 1C7, Canada Email: macderj@mcmaster.ca Fax no.: 001 905 524 0069

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Abstract

Distal radius fracture (DRF) raises a concern about bone health and elevated risk for subsequent fall-related fragility fracture. Previous research has indicated the need to screen for balance impairment, risk for future falls and fall-related fragility fractures but has not specifically targeted individuals with a DRF. Current hand therapy management of DRF focuses solely on mitigating wrist/hand related impairments. The objective of this review was to perform a systematic literature synthesis to derive a battery of measures to screen the risk for falls, fall-related fractures, impaired physical activity level, and impairment in lower extremity muscle strength in individuals with DRF. Using systematic literature search and pre-defined inclusion criteria, this review identified selected measures which reflect the 'best evidence' for the context of DRF patients for assessing these risks. The results of this review indicate that the Activity-specific Balance Confidence Scale (ABC) and the Timed Up and Go Test (TUGT) have established psychometric properties and greater potential for screening individuals with DRF who have fear of falling and balance impairment. Similarly, the Chair Stand Test is suitable for examining impairment in lower extremity muscle strength since it provides a global assessment of lower extremity muscle strength with established cut-off scores for different age and gender subgroups to rule in/out the impairment. Lastly, the FRAX® tool is suggested for computing the 10 year risk of hip fracture as well as a major osteoporotic fracture. In summary, this review provides a practical approach to integrating these measures into hand therapy practice while screening the risk for future falls, fall-related

fractures, impaired physical activity level, and impairment in lower extremity muscle strength in individuals with DRF.

Introduction

Distal radius fracture (DRF) is a common fall-related injury that is usually managed conservatively in an emergency department of a hospital or in an outpatient trauma clinic.[1] The estimated life time risk of DRF in females over 50 years of age is 32.7%.[2] Recently, Nellans et al[3] indicated that the incidence rates of DRF are increasing with the growing number of people suffering from obesity, osteoporosis, and lifestyle changes. In fact, it has been estimated that the rates of DRF have increased by up to 17% in the past 40 years.[4]

While addressing fall risk and improving bone health have shown to be important in reducing the incidence of future DRF in individuals aged 45 years and older,[5] the optimal management strategies for individuals who have already sustained DRF are not clear. However, reducing the frequency of falls, maintaining optimal bone health, and remaining physically active can all have positive effects in minimizing the risk of future DRF or other fall-related fractures.[3]

Hand therapy interventions following DRF are largely aimed at treating the direct and immediate consequences of the injury such as impaired wrist movements and strength.[6, 7] "Poor outcomes" following DRF have mostly been characterized as ongoing pain and impaired function[8, 9] rather than in terms of risk for future falls, poor bone health, and changes in physical activity (PA). It is known that fragility wrist fractures including DRF are known risk factors for future fall-related injuries such as hip fractures.[10, 11] Therefore, it would seem essential to screen individuals with DRF for fall-risk, balance impairment, PA level, and risk for osteoporotic fractures. The need for such

screening procedures have already been identified in this population.[12] Despite direct and indirect causal connections between the DRF and vertebral and hip fractures in later stages of life,[10] hand therapy assessment protocols in DRF population have not incorporated screening for fall-risk, balance impairment, PA level, and risk for osteoporotic fractures. Lack of clinical studies within hand therapy practice settings and inadequate knowledge translation of research evidence from areas other than hand therapy with respect to screening procedures may have contributed to the wrist/hand impairment-based focus that is characteristic of how hand therapists manage DRF.[13] In a typical fall prevention program, it is common for clients at high risk to undergo comprehensive multidisciplinary assessment. This approach is clearly not suitable for hand therapy practice or for the DRF population which mainly comprises of individuals at low risk for falling, impaired balance, physical inactivity, and osteoporotic fracture. Moreover, high risk individuals can often be easily identified (e.g. those who are already using mobility aids, or those who have been told that they are at high risk for falling).

The typical patients referred to multidisciplinary fall prevention programs are elderly and/or have complex health conditions that contribute to high risk for falling. When such patients present to hand therapy practice, they may also need to be referred to other health care professionals for management of risk factors that fall outside of scope of practice of hand therapists such as assessment of vision and review of medications.[14, 15] However, a substantial number of patients with DRF are likely to benefit from simple interventions to address balance deficits, physical inactivity, and fall risk that can be

implemented in hand therapy practice and are more appropriate for low to moderate risk individuals with DRF.

Hand therapists possess the training to undertake screening of fall risk, balance impairment, PA level and risk for osteoporotic fractures but may not regularly exercise that knowledge. There are no clear guidelines about which measures should be used for such screening in the DRF population. Translation of research into practice often requires that the research evidence be customized to the target audience.[16] Therefore, the fall prevention literature needs to be reviewed to identify the quality and relevance of the existing measures for use in the DRF population. A recently published review identified potential measures for determining risk for falls and fall-related fragility fractures that might be useful to hand therapists.[17] Furthermore, this review provided practical strategies to hand therapists for preventing falls and managing osteoporosis. Such a review, if systematic in design, is less likely to introduce bias into the process of recommending assessments to identify risk and prevent falls. However, to date recommendations for using different measures in hand therapy practice for fall risk screening were not derived through a process involving a detailed systematic literature review. Therefore, rationale for suggesting specific measures as most appropriate for hand therapy practice is lacking. This review by Thompson et al[17] was one of the first publications to recognize the need for screening for risk for falls and fall-related fragility fractures. Once the potential measures are identified using systematic review process, the second stage of the knowledge synthesis needs to incorporate evidence about the psychometric properties of these measures. In particular, information about the

comparative values of the measures across different age groups and discriminative scores that can identify subgroups of patients with different risk level will enable hand therapists in making informed clinical decisions.

The purpose of this paper is to conduct a systematic literature synthesis to identify the measures appropriate for screening the risk for falls, balance impairment, alterations in PA level, and risk for osteoporotic fractures (alternatively termed as adverse health outcomes) in the DRF population. In particular, this review will: 1) synthesize existing literature to identify up to 3 potential measures for each of the risk categories described above, 2) summarize the comparative and discriminative (cut-off) scores for each of the measures to define the level of risk, and 3) provide comparative advantages/disadvantages and indications of using each of these measures in the DRF population.

Methods

Searching the Evidence

Separate search terms were used to identify the relevant measures that could be used to identify risk for adverse health outcomes. The risk for falls was characterised by searching the appropriate measures for fear of falling (FOF) as well as balance impairment. Literature describing the applicability of quick portable measurement tools to assess lower extremity muscle strength was also located. This was to ensure that weakness of lower extremity muscles can be screened to compliment the assessment of balance impairment. The list of the search terms is illustrated in Table 1. PubMed, Medline, CINAHL, Embase, and Cochrane databases were searched till second week of February 2012. No restrictions for language or the year of publication were placed in the

search. We hypothesized that we may not locate screening measures specifically designed for and tested in the DRF population and our search may become too specific. In order to increase the sensitivity, we located the measures designed and tested in osteoporosis population with any fragility fracture (i.e. distal radius, hip, vertebral, proximal humerus etc).

Selection of Studies for the Literature Synthesis

The search was expected to yield a wide spectrum of studies and measures. Therefore, some decision rules were created to refine the evidence and identify measures appropriate for the purpose of the study. These rules are listed below as individual but iterative steps.

First step - the fit between the risk factor or the health outcomes for which patients are being screened (e.g. FOF, balance impairment, PA etc.) and the suitability of the measure for such screening was considered. In particular, it was considered whether the measure has been used in past for screening that particular risk.

Second step - studies that are considered to be of high quality such as systematic reviews or randomized controlled trials (RCT) for interventional studies[18] were located. A list of relevant screening measures that were used across these high quality studies for examining each risk factor was prepared. The measures were arranged relevant based on the frequency of their use across these high quality studies. Those that were used most frequently across these high quality studies were given priority in selection.

Third step - We wanted to ensure that the measures are easy to administer and do not require specific equipments since most individuals with DRF are treated in small hand

therapy clinics where therapists may not have access to specialized equipments. This final step also explored whether there is adequate evidence regarding the psychometric properties of the measures.

Once all the relevant screening measures were considered, the psychometric studies that established the criteria for ruling in/out a particular outcome were located for each measure. Additionally, the studies that assessed the reliability and validity for these measures either in patients with DRF or other at risk groups were located. Psychometric evidence was used for 2 purposes: 1) to disqualify any instrument that was not appropriate for screening DRF patients and 2) to identify cut-off values that could be applied to decision-making. The top 3 measures were selected for each adverse health outcomes based on their relevance and clinical measurement properties. Finally, the data regarding the reliability and validity of these outcomes were also extracted.

Data synthesis

A narrative synthesis of results was performed. The discriminative scores establishing the degree of disablement (mild, moderate, or severe disablement) for these top 3 measures were extracted from the psychometric studies to formulate the screening rules to determine the risk profile for individuals following DRF. Screening guidelines using the discriminative scores for the selected measures were summarized in a risk screening table. This table highlighted the purpose of the measures (the adverse outcome being assessed), scoring instructions, and discriminative scores for each measure to identify those at mild, moderate or high risk for an adverse outcome.

Results

Literature Search

The literature search was performed separately for FOF, PA, balance impairment, risk for future fractures, and lower extremity muscle strength. The search yielded multiple citations for each of these risk factors. A total of 36 articles were reviewed where FOF was assessed using various measures. Of these, no RCTs were located but 2 prospective cohort studies were found where measures were used for assessing FOF. Similarly, 33 studies were reviewed to identify the measures for screening balance impairment. Of these, there were 3 reviews assessing outcomes of fall-related fragility fractures where measures were used for assessing balance. It was uncommon to have PA assessed using self-report measures in studies of individuals with or at risk for fall-related fragility fractures, therefore we included studies where the participant group was middle-aged or older adults living with chronic conditions. A total of 12 studies were reviewed of which 4 were RCTs where PA was examined using self-report measures. Table 2 summarizes the detailed search results for each risk factor, reasons for excluding the articles from the review, the study designs of the included studies, and the 3 most commonly used measures for each adverse outcome. The most commonly used measures for screening each adverse health outcome in populations with fragility fractures are described below. How to categorize the risk into low versus high categories and relative advantage of using one measure versus another to screen for a particular risk in individuals in DRF population is also described.

The results and recommendations arising from the literature synthesis are presented below separately for each risk factor.

Risk Factors

Fear of Falling

Falls Efficacy Scale - International (FES-I) was the most common measure that was utilized for examining FOF in individuals with falls and fall-related injuries.[19-21] One article also suggested that the shortened version of the FES-I was feasible and provides comparable results to that of full version of the FES.[22] The second most common measure was a single question about FOF (e.g. How much are you afraid of falling? Or Are you afraid of falling?). The responses were either quantified using visual analogue or numeric rating scales[23, 24] or by categorical responses (yes/no or never, occasionally, often, very often).[25, 26] The Activity-specific Balance Confidence Scale (ABC) was the third most commonly used measure across the retrieved studies for assessing FOF.[27] An alternative simplified version of the ABC was validated in high functioning elderly.[28] This version is modified to make the ABC more user-friendly for community dwelling older adults. Of these three measures for assessing FOF, the ABC and the FES-I both have 16 questions examining perceived confidence in maintaining balance and preventing falls. Moreover, the FES-I and the ABC have acceptable predictive ability for community-based fall risk screening.[29] However, the ABC has shown superior predictive ability for community-based fall risk screening in comparison to the FES-I.[29] Table 2 shows the frequency of use of these measures across the studies included in this review.

Recommendations - An optimal approach for hand therapists would be to first ask a single question to the individual with DRF (Are you afraid of falling?) and if the answer is affirmative, a detailed assessment of FOF can be conducted using the ABC. Table 3 summarizes the cut-off scores that can be used for identifying low/moderate or high risk for falling while using these measures.

Balance Impairment

The OLS and the TUGT were the most frequently used measures for assessing balance across the retrieved studies as shown in Table 2.[30, 31] Forward reach was the third most commonly used measure for this purpose.[32] Often these measures were used together in a same study[33] or in combination with more intensive balance testing tools.[34] Most of these studies involved balance assessment in individuals with hip fracture [33, 34] or 'fallers' (recent history of one or more falls).[35] All these three measures for screening balance problems in individuals following DRF or other fragility fractures are relatively quick to administer and provide an instantaneous score. The administrative time for these tests on average is under 90 seconds.[36] Moreover, each of these tests has good predictive ability and established scores to characterize low versus severe balance problems.[30-32] Certain factors, however, may influence the decision while choosing a particular test. For example, forward reach test involves considerable degree of trunk flexion and therefore it may not be suitable for individuals with known history of osteoporosis. The OLS may not be suitable in individuals with active pain in lower extremity joints which could be aggravated upon standing on the painful leg. Moreover, the OLS and functional reach tests examine static balance where compensatory mechanisms of body are tested upon the

movement of the legs and trunk respectively. The TUGT is a test of mobility and functional balance. Given that the TUGT examines balance impairment with mobility tasks such as sit-to-stand transfers, ambulation, and turning, it has greater relevance and potential for use in community-based fall risk screening.[37]

Recommendations - Hand therapists can use any of these three tests to screen individuals for balance problems. Irrespective of which balance test is used, determining the risk for future falls for an individual should occur in conjunction with the results FOF assessment to determine an individual's perceived as well as actual risk for falling.

Physical Activity

The three most common measures used to assess physical activity levels were the Rapid Assessment of Physical Activity (RAPA),[38] Physical Activity Scale for Elderly (PASE),[39] and the International Physical Activity Questionnaire (IPAQ)[40]. Table 2 shows the frequency of their use across the studies included in this review. The PASE was primarily developed as a measure for assessing PA in older adults.[41] The IPAQ is used for tracking PA in community dwelling adult population and has shown good reliability and validity in comparison to performance-based PA instruments such as accelerometers.[42] The IPAQ has long and short versions and both these versions have been validated for use in adult population.[43] The RAPA is relatively a newer measure for assessing self-reported PA and the objective behind the development of the RAPA was to provide a short and concise tool for clinicians to assess PA levels in older adults quickly.[44] All the three questionnaires have been primarily used for surveillance of the PA rather than prediction of fall risk or balance problems. The long version of the IPAQ, by virtue of its length and

complexity in scoring, may not be appropriate for a quick scan of the PA which is what hand therapists would prefer to do in their clinical practice.[43] The shorter version of the IPAQ (IPAQ-SF) has shown poor concurrent validity with performance-based PA measures. Moreover, the IPAQ-SF tends to overestimate PA level and may not provide accurate assessment of the PA.[45] The PASE on the other hand has greater administrative burden which is estimated to be 10 minutes.[41] Moreover, there is a user fee for the PASE whereas the RAPA and IPAQ are available at no cost for personal or clinical use. The RAPA has 9 questions asking about the level of PA (light, moderate, vigorous) with the scoring option of 'yes' or 'no' for all the questions. The questionnaire also provides some of the common examples to contextualize what can be considered as light, moderate, vigorous PA. The RAPA has established guidelines to identify those with low physical activity and sedentary individuals as shown in Table 3.

Recommendations - Hand therapists may find the RAPA more useful over the other measures while performing a quick scan of PA in individuals with DRF.

Fracture Risk Assessment

The three most common methods for assessing fracture risk were: 1) clinical risk factors scored using the Fracture Risk Assessment Tool (FRAX®),[46] 2) hip and spine t-scores based on dual energy X-ray absorptimetry (DXA) assessment,[47] 3) the combination of clinical risk factors and proximal femur and/or lumbar spine t-scores.[48]

Recommendations - Individuals with DRF presenting to hand therapy clinic who already have a confirmed diagnosis of osteoporosis should raise concerns about compromised bone health. The FRAX® tool can provide an overall probability of sustaining hip

fracture or other fragility fractures for the next 10 years with or without the BMD scores. The tool is available at no cost to the users (http://www.shef.ac.uk/FRAX/tool.jsp). It has established norms for many developed or developing countries for calculating the risk for such fractures. Hand therapists can also determine the management needs of patients based on their 10 year risk of osteoporotic fractures.[49] For instance, an individual who is between 40-65 years of age and has 10 year risk of osteoporosis fracture of greater than 10% should be referred to physician for the assessment of BMD. The overall risk for fall-related fragility fractures should be viewed in conjunction with individual's balance problems and history of falls over the past 1 year.

Lower Extremity Muscle Strength

Measurement of lower extremity muscle strength using isokinetic devices[50] was certainly the most common across the studies. Sit-to-stand test (STS) (also known as the chair stand test)[51] and isometric muscle strength testing using hand held dynamometer (HHD)[52] were other common methods of assessing lower extremity muscle strength in middle-aged or older adults.

The STS and isometric strength testing using HHD are more feasible methods of assessing lower extremity muscle strength since it is not common for hand therapy clinics to have isokinetic strength testing instruments. The isometric strength testing with HHD is feasible for use in clinic. The STS, however, is more relevant in this context since it provides an overall assessment of lower extremity muscle strength and endurance. Moreover, the STS test provides readily 'usable' clinical information compared to

isolated muscle strength values which may not provide a composite summary to suggest impairment in lower extremity muscle strength.

Recommendations - Hand therapists can use STS to screen the impairment of lower extremity muscle strength and endurance in individuals with DRF. The STS has established normative values for age/gender subgroups (shown in the Table 3) which can help hand therapists in discriminating those with minimal, moderate, or severe lower extremity muscle weakness and endurance.

Discussion

The structured review and narrative synthesis identified a set of measures that hand therapists can use to implement a more comprehensive approach to managing individuals with DRF by incorporating fall risk and incident fracture risk screening. Considering the context of the practising hand therapists, we have identified measures that have good predictive ability, minimal administrative burden, and excellent potential for integration in clinical practice for assessing the magnitude of risk for future falls, fragility fractures, physical inactivity, and impairment in lower extremity muscle strength. Based on this review, the following measures are recommended for this purpose: the TUGT for assessing impairment of balance in functional activities, the ABC for assessing FOF, the RAPA for assessing PA level, the STS for assessing impairment in lower extremity muscle strength, and the FRAX® tool for computing 10 years risk for major osteoporotic fracture in individuals with DRF. Our review provides additional support to the previous review which underscored the importance of fall risk screening by hand therapists[17] by virtue of systematic literature synthesis that reflect best evidence with

focus on generalizability to hand therapy practice. The need to incorporate fall and fracture risk screening in the management of individuals with DRF has been voiced by several researchers in past.[10-12] Our review provides a practical approach for this risk screening in hand therapy clinic.

Clinicians can better target rehabilitation interventions and minimize adverse outcomes if they have guidelines to profile risk for a given patient. Current clinical practice guidelines for the management of DRF do not emphasize the need for screening of risk for future falls and fragility fracture.[53] Risk prediction following hip fractures has facilitated identification of a subset of individuals at greater risk for poor functional and health outcomes.[54, 55] Screening of individuals presenting to hand therapy clinics following DRF using simple valid measures can identify patients who are at risk. Preliminary management of patients deemed to be at risk can include education regarding fall prevention, encouragement to indulge in meaningful PA, and instructions in a home exercises program aimed at improving balance and lower extremity muscle strength. The patients can also be referred to their family doctors for further management of bone health depending on their 10 year risk for osteoporotic fracture.[49] Those patients at high risk for falling can be referred to community fall prevention program.

Although this study identified a subset of screening measures that are evidence-based, the effect of using these measures on practice will not be understood until a large cohort of DRF patients are screened and followed longitudinally to determine whether adverse outcomes such as falls and fragility fractures do occur in those who were identified as being at high risk versus those with moderate and low risk profiles. These

future cohort studies should include testing of clinical measurement properties since our review indicates that many of the measures were not validated in DRF population. The second objective should be to examine whether targeted interventions for fall prevention and improving bone health have long term impact or not.

A previous review by Thompson et al[17] identified the importance of fall risk screening by hand therapists and described a range of measures for examining the risk for falls and fall-related fragility fractures. Our paper used aspects of systematic review methodology (i.e. systematic search strategy, pre-defined inclusion criteria to select measures etc.) to locate the best evidence. In contrast, the previous review adopted a narrative style commentary approach to outline screening guidelines. To facilitate implementation of the recommendations in the current review, we created an evidence table (Table 3) with guidelines to rule in/out the risk and cut-off scores to determine the magnitude of risk (Table 3). Lastly, our paper also considered it important to profile the level of PA in individuals with DRF because it is a known risk factor for falls in community-dwelling adult population.[56] Our paper did not provide any treatment guidelines for cases where an adverse outcome is ruled in whereas Thompson et al[17] outlined strategies for preventing osteoporosis and fall prevention strategies using case examples. Hand therapists may find it helpful in relating the case example to their practice while incorporating the prevention strategies into their treatment plans.

Fall risk is a complex multidimensional phenomenon - the product of several intrinsic and extrinsic factors. Assessing FOF and performance-based balance impairment in individuals with DRF provides a cursory overview of overall fall-risk. The presence of

one or more intrinsic/extrinsic factors contributes to the magnitude of fall risk for an individual. Some of these factors are modifiable while others are not.[57] Appropriate management for individuals identified as having a high risk for falling requires resources beyond those found in most hand therapy practices. However, the initial assessment interview conducted by hand therapists incorporates some questions that impact fall-risk not assessed via FOF or balance screening. This includes but not limited to associated comorbidities, medications history, visual problems, and home environmental hazards.[57] Focused questions around mechanism of fall, history of falls, and fall-related injuries can allow hand therapists to identify the risk factors contributing to the falls. Thus hand therapists are well-positioned to advocate for patients at high risk for falls to see the appropriate health care providers (e.g. family doctor, optometrist, community occupational therapist) for further assessment.

Hand therapists can adopt a systematic approach to assessing fall risk category (low/moderate versus high) while managing individuals with DRF. At first, they can determine the fall risk category by assessing the FOF and balance impairment using the outcome measures suggested in Table 3. Assessment of PA and lower extremity muscle strength can add further input to the fall risk category assigned for an individual. In particular, those classified as having 'high risk' for falls should undergo more intense scrutiny for determining potential risk factors and further management for the risk for falls and osteoporotic fractures. The FRAX® tool can be implemented to assess 10 year risk for osteoporotic fracture and determine whether patient needs further assessment of BMD or simple education to improve bone health is adequate.[49] As outlined earlier, this

approach should be integrated with initial interview to obtain a broader overview of the presence of all possible risk factors and risk category. The self-reported outcome measures assessing FOF or PA can be completed by the patients while in the waiting room, so the responses to these questionnaires already available to the hand therapists during the initial interview with the patient. Though our paper does not discuss appropriate management strategies once risk level is determined, another literature synthesis such as this can be conducted to assemble current evidence of types of interventions that are feasible for hand therapy practice.

We concede that there are many relevant measures other than the ones we have described in Table 3 for assessing the potential risk factors. Our objective was to summarize the current best evidence to derive the list of measures that have established utility in assessing the risk profile of individuals with DRF or other fall-related fragility fractures. Moreover, we wanted to include the measures that are easy, quick to administer and score, and have known discriminant validity in identifying low versus high risk subgroups. In this process, we may have missed out on some of the established outcome measures. One such example is the Berg Balance Scale (BBS), which was also suggested in the previous review for assessing balance impairment.[17] The administrative burden for the BBS is estimated to be between 15-20 minutes.[58] We do feel that brevity is important for hand therapists especially while assessing for dysfunctions not related to the impairment of hand functions. Another option is that hand therapists conduct a detailed balance assessment using BBS in instances where the 'preliminary screening' using single task oriented tests (e.g. TUGT) indicates presence of risk.

The results and recommendations have been framed such that they are applicable to the DRF population. Most of the measures identified in the review have not been tested in DRF population but are included based on their application in other fall-related fragility fractures. This 'portability' of evidence is understandably not exclusive to the DRF population, rather relevant to other fall-related upper extremity fractures such as proximal humerus and elbow fractures. However, DRF being the most common fragility fracture and more importantly one of the early signs of osteoporosis and impaired bone health warranted us to emphasize that the screening practices be started for this patient population. Moreover, this review is one of the first works in the series of planned scientific inquiry to comprehensively establish evidence-based guidelines for fall prevention after DRF.

This review has some limitations which are critical to highlight. Most importantly, majority of the screening measures recommended for assessing risk profile have been used in fall-related injuries other than DRF and have never been validated for use in DRF population. Measures need adequate psychometric evidence before they can be used in specific clinical population. To overcome this limitation, we are currently conducting psychometric analysis of the measures described in Table 3 in DRF population. The results of this ongoing study will yield specific information regarding which measure can better identify clinical subgroups for fall risk in DRF population. Secondly, we have given no guidelines to hand therapists about the management of fall risk if present. Though some hand therapists may already be practising appropriate interventions for this purpose, lack of such guidelines on our part may discourage certain therapists from using

our screening guidelines. To this end, we intend to conduct a similar literature synthesis to locate, appraise, and tailor fall prevention interventions for the context of hand therapy. Lastly, the fall risk assessment guidelines outlined in this paper are not comprehensive. This may limit the ability of hand therapists to unequivocally assign patients with DRF to a fall risk subgroup (low risk, moderate risk, high risk). However, a focused initial interview questions as outlined earlier can lead to better fall screening.

In conclusion, our review provided evidence-driven assessment guidelines for assessing risk for falls, monitoring PA, and assessing risk for fragility fractures for individuals following DRF. Psychometric analysis of the suggested measures, identifying fall risk management strategies that can be implemented by hand therapists, and outcomes of such screening/management approaches in DRF population should guide further research work. Future research can also examine whether the non-modifiable factors (age, gender) affect the interpretation of screening procedure and also whether fall prevention outcomes are different across the age and gender subgroups.

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Table 1

Risk factor	Search Terms
Fear of falling	1. ((Patient-reported outcome measures OR self-reported outcome measures) AND (fall OR fear of falling OR fear of falls OR falls efficacy)) AND (wrist fractures OR distal radius fracture OR wrist injury OR hip fracture OR fall injury)
Balance impairment	2. (balance test OR fall risk assessment) AND (wrist fractures OR distal radius fracture OR wrist injury OR hip fracture OR fall injury)
Physical activity	3. ((Patient-reported outcome measures OR self-reported outcome measures) AND (physical activity level OR physical activity)) AND (wrist fractures OR distal radius fracture OR wrist injury OR hip fracture OR fall injury)
Risk for future fractures	4. (fracture risk assessment OR future fracture risk assessment) AND (wrist fractures OR distal radius fracture OR wrist injury OR hip fracture OR fall injury)
Lower extremity muscle strength	5. (lower extremity muscle strength OR lower extremity muscle strength assessment) AND (wrist fractures OR distal radius fracture OR wrist injury OR hip fracture OR fall injury)

Table 2

Risk factor (number of articles reviewed)	Number of articles in Preliminary search	Excluded articles after title and abstract review - reasons	Study designs of the remaining articles	Outcome measures across these studies (Frequency of their use)
Fear of Falling (36)	158	4 - duplicates 105 - unrelated to fall risk assessment or fall risk intervention 13 - did not measure self-reported fear of falling and fall risk was assessed using balance tests	Prospective cohort - 2 Psyhometric studies of outcome measures -21 Cross-sectional OR longitudinal study - 8 Survey/interview studies - 5	Falls Efficacy Scale (14) Single Question asking about Fear of Falls (9) Activities-Specific Balance Confidence Scale (ABC) (7)
Balance (33)	642	8 - duplicates 601 - unrelated to balance assessment of fall-related injuries such as wrist, hip, or vertebral fractures OR balance was not assessed even when the outcomes of fall injuries or fall prevention intervention were assessed, balance was assessed as a self-report	Systematic/narrative Review of - 3 Systematic/narrative Review of Psychometrics of Outcomes - 1 RCTs of Interventional Studies - 9 Psychometric Study Design - 4 Prospective Cohort - 8 Cross-sectional or Longitudinal - 9	One leg standing test (8) Timed "Up and Go" test (8) Functional reach/postural sway (6)
Physical activity (12)	170	3 - duplicates 148 - unrelated to physical activity assessment or intervention 6 - did not measure self-reported physical activity 1 - Only RCT protocol	RCT - 4 Prospective cohort - 2 Psychometric studies of the outcome measures - 6	Physical activity scale for elderly (4) Rapid Assessment of Physical Activity (2) International Physical Activity Questionnaire (IPAQ) last-7-day questionnaire (2)

		was described and no were results described		
Fracture risk assessment (51)	298	16 - duplicates 231 - unrelated to fracture risk assessment OR fracture risk prediction OR did not use any measure to determine fracture risk	Narrative/systematic review - 3 Psychometric Study Design - 8 Predictive Study Design - 23 Prospective Cohort - 11 Cross-sectional OR Longitudinal - 6	WHO FRAX® Tool - 31 BMD alone - 14 BMD with other Clinical Risk Factors - 10
Lower extremity muscle strength (19)	71	7 - duplicates 45 - lower extremity muscle strength not examined using a particular measure OR upper extremity strength and not lower extremity muscle strength was examined OR patients with neurological diagnosis were examined	Systematic/narrative Review - 2 RCTs of Interventional Studies - 2 Psychometric Study Design - 2 Prospective Cohort - 5 Cross-sectional OR Longitudinal - 8	Isometric muscle strength testing using isokinetic system - 6 Chair stand test - 4 Hand-held dynamometer - 4

Table 3

Risk factor and Suggested Outcome Measure	Scoring range	Low/Moderate Risk (yellow flag)	High Risk (red flag)
Fear of falling			
FES - International	○ Score range 16-64 with 64 indicating worst outcome	○ Scores > 23 indicate concern of falling.[20]	○ Scores > 35 indicate those who have fallen in last 1 year and may fall again.[21]
Single question about fear of falling	○ Different response options to rate fear of falling: 1) Yes or No; 2) NRS 0-10 with higher number indicating greater fear	○ No specific guidelines; however scores between 1-4 (on 0-10 scale) can be considered as moderate risk.[23]	○ Scores over 5 (on 0-10 scale) indicate those who have had multiple falls.[23]
ABC Scale	○ Score range 0-100% where higher percentage indicated greater balance confidence	○ Scores between 50-80% indicate moderate level of functioning and balance confidence.[59]	○ Scores below 50% indicate poor functioning and balance confidence.[59]
Balance			
OLS	○ Scored as number of seconds the participant is able to maintain balance in one leg.	○ Scores under 20 seconds can be considered as moderate risk.[30]	○ Scores under 5 seconds can generally be considered as significant risk for falling.[36]
TUGT	○ Scored as number of seconds it takes to complete the test.	○ Scores between 10-14 seconds indicate some balance impairment.[31]	○ Scores ≥ 15 seconds indicate high risk for falling.[31]
Functional reach	○ Scored as the distance of forward reach in inches.	○ Scores between 6-10 inches indicate moderate risk for falling.[32]	○ Scores below 6 inches indicate high risk for falling.[32]

Physical activity			
PASE	○ Time spent on each activity is multiplied by item weights, the scores are added to get composite score with higher score indicating higher PA level.	○ Indicators for moderate PA has been defined as the PASE score between 101-186.[60]	○ Indicators for low PA has been defined as the PASE score between 0-100.[60]
RAPA	○ The total score of the first seven items (RAPA 1) is between 0-7, the total score of the remaining two items (RAPA 2) is between 0-3.	○ Individuals with scores of 6 or less are considered having suboptimal PA level.[44]	○ Individuals with scores of 2 or less are considered having under active or sedentary.[44]
International Physical Activity Questionnaire	○ Continuous - MET-minute is computed by multiplying the MET score of an activity by the minutes for which that activity was performed. ○ Categorical - low, moderate, and high	○ Categories for low/moderate/high PA clearly described.[43]	○ Categories for low/moderate/high PA clearly described.[43]
Fracture risk assessment			
WHO FRAX Tool	○ Provides 10-year risk of hip fracture and a major osteoporotic fracture	○ No cut-off given for moderate risk, overall risk can be viewed by presence of other risks such as fall risk, impaired balance etc.	○ No cut-off given for high risk, overall risk can be viewed by presence of other risks such as fall risk, impaired balance etc.

<u>Lower extremity muscle strength</u>			
Chair stand test	○ Scored as number of times participant is able to perform sit-to-stand task in 30 seconds.	Following are below average score for different age/sex groups indicating muscle weakness.[61] ✓ 60-64: < 14 (F), 16 (M) ✓ 65-69: <13 (F), 15 (M) ✓ 70-74: <13 (F), 14 (M) ✓ 75-79: <12 (F), 14 (M) ✓ 80-84: <11 (F), 12 (M) ✓ 85-89: <10 (F), 11 (M)	○ < 8 for any age group indicates severe weakness and deconditioning.
HHD	○ Scored as either pound (lbs) or Newton (N)	○ The normalized values for different age/sex groups are difficult to be summarized in this section, however they can easily be accessed.[62] Deviations from these values indicate muscle weakness.	○ As indicated, the normalized values for different age/sex groups can easily be accessed.[62]

FES, Falls Efficacy Scale; NRS, Numeric Rating Scale; ABC, Activities and Balance Confidence Scale; OLS, One leg standing; TUGT, Timed up and go test; PASE, Physical activity scale for elderly; PA, Physical activity; RAPA, Rapid Assessment of Physical Activity; IPAQ, International Physical Activity Questionnaire; MET, Metabolic Equivalent of Task; HHD, Hand-held dynamometer

Chapter 6: Reliability and Validity of Fall Risk and Balance Measures in Individuals with Distal Radius Fracture - A Pilot Study

Saurabh P. Mehta PT, MSc[1]
Joy C. MacDermid PT, PhD[2]
Julie Richardson PT, PhD[3]
Norma J. MacIntyre PT, PhD[4]
Ruby Grewal MD, MSc, FRCSC[5]

[1] PhD Candidate and CIHR Doctoral Fellow, School of Rehabilitation Science, McMaster University, Hamilton, Ontario, Canada
[2]Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario and Co-director Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, 268 Grosvenor St., London, Ontario, Canada
[3]Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario
[4]Associate Professor, School of Rehabilitation Science, McMaster University, Hamilton, Ontario
[5]Assistant Professor, Department of Surgery, Western University and Co-director Hand and Upper Limb Centre Clinical Research Laboratory, St. Joseph's Health Centre, 268 Grosvenor St., London, Ontario, Canada

Ethics approval for this study was obtained from the research ethics boards at Western University, William Osler Health Center, and McMaster University.

Corresponding Author: Joy C. MacDermid, PhD , School of Rehabilitation Science, McMaster University, 1400 Main Street West - IAHS 402, Hamilton, Ontario L8S 1C7, Canada Email: macderj@mcmaster.ca Fax no.: 001 905 524 0069

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Abstract

Study Design: Pilot feasibility study

Introduction: Individuals who sustain distal radius fracture (DRF) remain at risk for falls and osteoporotic fractures. A set of measures to screen fall-risk have been identified.

Purpose: 1) To examine selected psychometric properties of measures used for screening impairment in balance, lower extremity muscle strength, and physical activity level as well as screening the risk of future osteoporotic fractures in the DRF population; and 2) Examine feasibility aspects of conducting a prospective study to reduce fall-risk in the DRF population.

Methods: Twenty one female participants with DRF recruited from two centers were assessed on two occasions. Timed up and go, Functional Reach, and One Leg Standing tests were administered to assess balance impairment. Chair stand test and isometric muscle strength testing for hip and knee was performed for assessing lower extremity (LE) muscle strength. Fear of Falling was assessed using the shortened version of the Falls Efficacy Scale, Activity-specific Balance Confidence scale, and Fall Risk Perception Questionnaire. Physical activity (PA) was examined using the Rapid Assessment of Physical Activity (RAPA) questionnaire. Ten year risk for osteoporotic fracture was calculated using FRAX® tool. Intraclass correlation coefficients (ICC) were calculated to examine the test-retest of the measures. Pearson correlation coefficients (r) were calculated to examine concurrent relationships between the measures. Recruitment

rate and sample size estimates were calculated for a future prospective study that will look examine effectiveness of a fall prevention program in the DRF population.

Results: The results demonstrated fair to excellent test-retest reliability (ICC values between 0.50 - 0.96) for the measures. Pearson correlation demonstrated low to moderate concordance between the measures (low if $r \leq 0.4$; moderate if r between 0.4 to 0.7). Sample size calculations provided varied estimates depending on the outcome of interest.

Conclusion: This pilot study provided preliminary estimates of psychometric properties of selected measures assessing balance, LE muscle strength, fear of falling, and PA in the DRF population. The study also provided valuable information for conceiving and implementing a larger study to reduce fall-risk after DRF.

Background

The risk for subsequent fragility fractures in individuals who have sustained distal radius fracture (DRF) is significant and has been repeatedly described by different studies over the past 3 decades.[1-4] Beyond the risk for future fragility fractures, some individuals with DRF also report reduced quality of life (QOL) mainly due to fear of falling (FOF) and risk of sustaining another fracture.[5] It is also interesting to note that most individuals perceive themselves as healthy and report excellent health-related QOL (HRQOL) prior to their DRF.[6] This implies that wrist fracture can change the perception of some individuals about their HRQOL. Moreover, research has shown that the economic burden of FOF and that of falls that do not necessarily result in fracture is significant and often underestimated compared to the falls that do result in a fracture.[5] While all individuals with DRF are not at risk of future falls and osteoporotic fractures, identifying those who may have this risk can be the starting point to establish practice guidelines to better manage the 'at risk' individuals.

Current hand therapy assessment and treatment practices for individuals with DRF are largely focused on wrist related pain and musculoskeletal disability (MSKD).[7] This is expected since most individuals my require hand therapy to restore hand functions. However, it is timely that the practice guidelines are revisited to include components of fall risk assessment and appropriate management guidelines. Preliminary research has shown that educational intervention alone provided in an emergency department may not be adequate to minimize the risk for falls and FOF in individuals with DRF.[8] This is possibly due to the fact that the measures used for assessment and components of

educational interventions were not derived as a result of a systematic scientific inquiry that examined the relevance of the measures in the DRF population. Moreover, it is also critical to examine the other attributes such as physical activity[9] and lower extremity muscle strength[10, 11] that could potentially modify the fall risk in individuals with DRF. This underscores the need to conduct a systematic stepwise knowledge building inquiry to assess and manage risk for falls and osteoporotic fractures in individuals with DRF. There are essentially two steps in this inquiry. The first step is to identify the appropriate screening tests to assess FOF, balance impairment, PA, and lower extremity muscle strength in individuals with DRF and examine their reliability and validity in these individuals. The second step is to design and test a treatment intervention aimed at preventing falls, increasing falls efficacy and balance confidence, and optimizing bone health.

We recently examined fall risk literature to address the first step outlined above.[12] A systematic review of fall risk literature in individuals with fragility fractures was conducted to identify appropriate tests that hand therapists can use to assess risk such as FOF, balance impairment, PA, and lower extremity muscle strength in the DRF population. A maximum of 3 tests were selected for each of the risks based on their potential for application in the DRF population.[12] The selection of tests was primarily made based on three criteria. Firstly, the fit between the risk factor for which patients are being screened (e.g. FOF, balance impairment, PA etc.) and the suitability of the test was considered. Secondly, tests that were used most commonly used across high quality studies such as systematic reviews or randomized controlled trials (RCTs) for assessing

the risks were identified. Lastly, the tests that had low administrative burden and did not require specialized equipments but still had good psychometric properties were given priority in selection since such tests will have greater potential for applicability in small rehabilitation clinics. However, these tests require empirical validation of their measurement properties in the DRF population. In particular, the test-retest (relative and absolute) reliability, variability, and concurrent convergent/divergent validity of these tests need to be examined in the DRF population. Practice recommendations to suggest which tests are better suited for risk assessment in the individuals with DRF can only be made following a comprehensive assessment of their measurement properties in the DRF population.

Establishing the effectiveness of specific fall prevention interventions tailored for the DRF population is the second step in the inquiry. At present, addressing fall prevention is not standard of practice for the rehabilitation of a DRF. Current evidence suggests that fall prevention programs are usually designed and implemented for older adults.[13] Moreover, individuals attending these programs are at very high risk for falling.[13] It is not clear what percentages of individuals with DRF have very high risk for falling who would benefit from such program. In fact, DRF is common in younger and middle aged population[14] who may not have same level of high fall-risk similar to older adults. Therefore, addressing fall-risk in the DRF population may not require an intensive approach usually taken in structured fall prevention programs.[13] There is a dearth of scientific literature discussing what approach is optimal for fall prevention in the DRF population. Thompson et al[15] offered preliminary guidelines for fall prevention practices

for hand therapists based on a case scenario. Their approach was to identify specific needs for the patient in their case scenario rather than describing specific treatment strategies for the population in general. Moreover, the recommendations were based on routine fall prevention practices in other high risk fall injuries such as lower extremity fall-related fractures. Individuals with DRF may not have any direct impairment of lower extremity strength and balance as a result of injury in contrast to individuals with fall-related lower extremity fractures who have greater impairment in lower extremity muscle strength and balance as direct consequences of the injury. No study has discussed or examined fall prevention in the context of the DRF population. Even if the fall prevention approaches described across other conditions[13] are to be applied to the DRF population, they need to be tested to ensure their precise clinical application. A carefully designed RCT can test the effectiveness of a fall prevention intervention in individuals deemed to be at risk for falls after DRF. However, the feasibility of the proposed intervention can be examined by conducting a pilot study to ascertain recruitment, required clinical resources and research staff for data collection, and necessary funding.[16] Such a feasibility study can provide preliminary indications of which tests are better able to identify individuals 'at risk' and facilitate sample size estimates for an RCT aimed at testing fall prevention interventions in the DRF population.

The purposes of this pilot work were:

1. to evaluate recruitment rates as well as retention rates for this present study and draw implications for recruitment for a RCT study,

2. to examine test-retest reliability of selected tests identified in literature synthesis[12] in the DRF population,
3. to obtain preliminary estimates of the normative scores for these tests in the DRF population and determine which tests are appropriate for this population,
4. to examine the concurrent relationships between these tests,
5. to determine sample size estimates for future RCTs that use these tests to evaluate effectiveness of interventions to modify potential risk factors (FOF, balance impairment, changes in PA, and altered lower extremity muscle strength) following DRF.

Methods

Individuals who sustained a DRF were recruited in the study. The participants were recruited from the Hand and Upper Limb Center (HULC), London, Ontario, Canada as well as William Osler Health Center (WOHC), Brampton, Ontario, Canada within 4 weeks of initiating hand therapy for the DRF. The inclusion criteria were: females ≥ 45 years whose primary language is English, participants were being treated for a DRF related to a fall injury, no pre-existing balance impairment as a result of neurological or musculoskeletal (MSK) impairment, and no known cognitive impairment. We excluded individuals who were already using walking aids due to pre-existing balance impairments and those who had other simultaneous fracture or MSK injury of same or other extremities from the fall that resulted in a DRF. One of the investigators (SM) screened and identified potential participants in the outpatient fracture clinic at the HULC. Surgeons at the HULC initially informed these individuals about the study and they were

referred to the Clinical Research Lab at the HULC if they sought more information or expressed interest in participating. The study investigator (SM) discussed the details of the study and data collection protocol with these individuals and a written informed consent was obtained. The professional practice leader (PPL) of physiotherapy identified potential participants attending the outpatient physiotherapy clinic at the WOHC. The PPL explained the study details to these individuals and scheduled the 1st assessment session with the study investigator (SM) if they agreed to participate. The research ethics boards at the Western University, McMaster University, and the WOHC, Brampton, Ontario provided the ethics approval to conduct this study.

The data collection session took place once the participants provided their consent. Demographic and injury information including age, occupation, date of injury resulting in DRF, mode of injury, type of medical treatment received, history of falls, and side dominance were collected. Data collection was divided into performance-based tests (PBT) and patient-reported tests (PRT). Participants first completed the PBT followed by the PRT. Approximately 20 minutes after completing the PBT the first time, the PBT were administered again. Participants completed the PRT in 20 minute interval. Participants were provided a set of PRT with self-addressed envelope. They were asked to complete this set of PRT one week after the data collection session and return to the Clinical Research Lab, HULC.

Performance-based Tests

Performance-based tests were administered after collecting the demographic and injury information. Five PBT were administered in this order: Timed Up and Go test

(TUGT),[17] Functional Reach (FR),[18] Chair Stand Test (CST),[19] One Leg Standing (OLS),[20] and Isometric Lower Extremity Muscle Testing using hand held dynamometer (HHD).[21] For the TUGT, the participant sat in a standard arm chair. On the word of "go" she was asked to rise from the chair, walk up to a line on the floor (3 meters away from the chair), turn back, and return to the chair to sit down. The time taken from the word of "go" to the point when the participant had returned to sitting in the chair was recorded.[17] For the FR test, the participant was positioned close to a wall to allow her to reach forward along the length of the yard stick placed on the wall. She stood with her feet shoulder width apart, made a fist with the left arm, and raised the arm up so that it's parallel to the floor. The initial reading of the knuckle of the middle finger on the yard stick was taken at this time. The participant was instructed to reach forward maximally along the yardstick without taking a step. The distance between the initial reading and the tip of the middle finger at the end point was measured.[18] For the OLS test, the participant was asked to remove her shoes/foot wear for testing and stand on one leg placing her arms across her chest with hands on the opposite shoulders. She was asked to look straight with eyes open. The testing was stopped if her legs touched each other, her foot touched down, or the arms move from the starting position. The amount of time she could stand without these postural deviations was recorded.[20] The test was repeated for the other leg as well.

For the CST, the participant was seated in a standard chair placed against a wall. The participant placed her arms across her chest with hands on the opposite shoulders, her feet rested on the floor, and her back against the back rest of the chair. On the word of

"go", the participant stood up and then sat down. She continued the sit-stand-sit cycle for 30 seconds. The number of repetitions completed for this cycle in 30 seconds was recorded. The student investigator stood beside the participant to support her in case of loss of balance.[19] A HHD (Lafayette Manual Muscle Test System model # 01163, Lafayette Instrument Company, Lafayette, Indiana) was used to assess isometric muscle strength of hip flexors (HF), hip extensors (HE), hip abductors (HA), hamstrings (KF), and quadriceps (KE). The "make" test was used to assess the strength of these muscle groups.[22] Each participant was asked to exert pressure against the HHD as strongly as possible as the examiner gradually increased force isometrically with the HHD over 3 seconds. For the HF, KF, and KE, participant sat in a raised chair such that her feet were not touching the ground. The HHD was placed on the front of the thigh above the knee for testing HF. For testing KF and KE, the HHD was placed on the posterior and anterior aspect of lower leg respectively. For testing HA, the participant stood with support in front of her at waist level and the HHD was placed on the lateral aspect of thigh above the knee. For testing the HE, the participant stood with support in front of her at waist level and the HHD was placed posterior aspect of the thigh proximal to the knee joint. These testing procedures have been described and are reliable.[21] It has been suggested that HA should be measured in side lying position.[23] However, we measured HA in standing because standing is a more functional position and the reliability estimates for HA strength are comparable for side lying and standing positions.[23] Each participant had a practice trial for each muscle group prior to the measurement session. An average of three trials was recorded in kilogram for each muscle group.

Patient-Reported Tests

Each participant completed seven PRT. The shortened version of the Falls Efficacy Scale (FES-S),[24] Activities-Specific Balance Confidence (ABC) Scale,[25] and Risk Perception Questionnaire[26] were used for assessing fear of falls (FOF). The shorter version of the International Physical Activity Questionnaire[27] and Rapid Assessment of Physical Activity[28] were used for assessing the physical activity. Lastly, the Canadian FRAX® tool was used for assessing 10 years probability of major osteoporotic fracture or hip fracture.[29] The Patient-Rated Wrist Evaluation (PRWE) was used for assessing wrist pain and functions.[30]

The percentage (%) risk of sustaining an osteoporotic fracture as well as a hip fracture over the next 10 years was calculated using FRAX® tool.[29] This tool provides an estimate of absolute risk of such fractures for an individual based on certain anthropometric characteristics, past medical history, family history of osteoporotic fracture, and certain life style factors. The tool can be accessed at no cost to the users (http://www.shef.ac.uk/FRAX/index.jsp).

Data Analysis

Participant demographics and summary of their personal as well as injury variables were presented using either mean ± standard deviation (SD) or frequency of occurrences. Histograms were plotted to examine the 10 year risk of osteoporotic fracture and hip fracture calculated using the FRAX® tool. The recruitment rates were presented by providing the summary of a) the number of patients that met the inclusion criteria who

were approached for participation in the study, b) the number of individuals who agreed to participate in the study, and c) the number of individuals who returned the second set of PRT in time for test-retest reliability analysis. This would give indication of the recruitment rates for the HULC and the WOHC. The test-retest reliability for the tests for both the sessions was assessed using the intraclass correlation coefficient (ICC). The ICC values of > 0.75 were considered to be indicative of excellent test-retest reliability.[31] Moreover, the absolute reliability was examined by calculating the standard error of measurement (SEM) for each test. The age and gender specific normative values for each test were derived from the literature. The number of participants with abnormal values for each test were presented. P-values were calculated to examine whether the difference between the mean values obtained from the sample is different from the normative values derived from the literature. P values of ≤ 0.05 were considered significant. Pearson correlation coefficients (r) were calculated to examine the strength of relationship between all tests irrespective of which risk factor they assess.

Sample size was estimated using a variety of scenarios. Firstly, mean scores that are not in the normal anticipated range for a given test were located. Minimum required change in the mean score for the tests that have abnormal values was used to determine the sample size estimates. The SD values for the mean that are required for the sample size calculation were imputed based the results of this present study. The MDC_{90} were derived from the literature and were used as the minimum required change in the mean to suggest change in the outcome (improvement in balance and lower extremity strength). Secondly, minimum acceptable change in the proportions of falls and fall injuries by 50%

as a result of fall prevention intervention was used as an outcome for powering sample size calculation for a future RCT study. Lastly, FRAX® scores were calculated to suggest 10 year risk for an osteoporotic fracture for a 50 year old female who presents to rehabilitation setting after DRF. This calculated score was used as a reference point suggesting population risk and sample size for a study aimed at reducing this risk by 50% was calculated. Similarly, another estimate for sample size was provided based on the average FRAX® score for the participants recruited in this study.

Results

A total of 50 females who met the eligibility criteria were approached from January 2012 to June 2012 at the HULC as well as the WOHC. Of these, 29 females refused to participate in the study. A total of 21 female participants (mean age 62.6 ± 7.6) were recruited in the study. The recruitment rate was, therefore, 3.5 participants recruited per month. The recruitment was the lowest in the months of May and June with only 1 participant recruited each month and a total of 8 females refusing to participate in the study. The recruitment was highest in the month of April when 6 participants were recruited and only 3 females refused to participate in the study.

Table 1 summarizes the demographics for the participants. The first assessment took place approximately 7 weeks (50 days) after the injury. The second follow-up (date of completing the PRT) was 9 days after the initial assessment. Twenty participants completed and returned the second set of PRT. A fall on ice was the most common mechanism of injury, whereas falling from a bicycle, stool, and chair were the other common mechanisms. More participants were either retired or were home makers (62%)

compared to those who were working (38%). Of the 21 participants, 1 had a history of previous fracture, 2 had a history of another fall (different from the fall that caused DRF injury), and 3 were diagnosed with osteoporosis.

Figure 1 shows 10 year risk for any osteoporotic fracture and for hip fracture specifically using the FRAX® tool. A total of 10 patients had >20% risk of osteoporotic fracture in the next 10 years. Whereas, only 1 patient had >20% risk of hip fracture in the next 10 years.

Table 2 shows the results for test-retest reliability. Test-retest reliability was poor to excellent for the tests with the ICC ranging from 0.50-0.96 for the tests. Of the PRT, the PRWE, the RPQ, and the RAPA had lower reliability estimates (ICC values of 0.63, 0.66, 0.68 respectively) when compared to the ICC values of > 0.75 which is indicative of acceptable test-retest reliability.[31] The ICC values for the isometric muscle strength tests of right HF (0.70), right HE (0.66), left HE (0.50), and left HA (0.72) were also below this benchmark.

Table 3 summarizes the average scores (mean ± SD) for the tests for the first session for all participants. The age and gender matched comparative scores are also shown in the table. While no statistical analyses were undertaken to examine whether the differences in the scores for the tests in the study were significant between the participant group and their age/gender matched cohort, a qualitative approach was used for determining the difference. The mean TUGT score for the participants, which is a measure of functional balance, was higher compared to the age and gender matched reference score indicating that the participants in the study may have some impairment in

functional balance compared to their age and gender matched cohort. Similarly, the scores for the CST, which was used for assessing lower extremity muscle strength and endurance, also indicated that the participants in the study completed 2 repetitions less compared to the age and gender matched reference.[32] Participants demonstrated superior static balance compared to age and gender matched reference value as shown by markedly higher scores for the OLS test.[33] Participants showed comparable values for isometric muscle strength to that of age matched reference values for females. Participants also demonstrated superior balance confidence and fall efficacy compared to their age matched cohort as shown by the scores for the ABC scale[34] and FES-S.[24] Lastly, participants in the study reported to be less active physically compared to the referenced values.

Correlations between the tests are shown in Table 4. Correlations between most PBT were low to moderate as seen in the Table 4a. Correlations between the PRT as seen in Table 4b indicated high correlation ($r = 0.79$) between the FES-S and the ABC both of which examine fall-related efficacy. Moreover, the correlations between the RAPA and these fall efficacy measures showed moderate but significant concordance. However, both these tests had low correlations ($r < 0.4$) with the RPQ. Similarly, the correlations between the PRT of falls efficacy and PBT assessing balance were low as seen in the Table 4c.

Table 5 shows the sample size requirements for conducting a future RCT aimed at improving balance, lower extremity muscle strength as well as reducing the risk for falls, fall-related injuries, and osteoporotic fractures. Since the mean value for the TUG in this

study was 1.4 seconds above the age and gender-matched normative values, the minimum change in the mean required as a result of intervention was considered to be 1.4 seconds. Similarly, the mean change in the values of CST by 2 repetitions was considered to be the minimum requirement to determine change in lower extremity muscle strength. The MDC_{90} values for the TUG[35] and CST[19] calculated from the literature are shown with the estimates for the sample size for the desired change in mean equivalent to these MDC_{90} values. The population risks of those over 50 years of age for sustaining falls and fall-related injuries were derived from a recent publication.[36] Considering that minimum 50% reduction in the proportion of risk to be adequate to examine the effect of fall prevention intervention on rates of falls and fall-related injuries, a total of 96 and 136 participants were required respectively. Moreover, the sample size estimates based on the FRAX® score showed that as many as 2000 participants would be needed to reduce the risk of osteoporotic fracture in a 50 year old female with DRF who has no other clinical risk factors present. Being able to recruit an average of 3.5 patients per month, it would take between 8-568 months (based on the outcome of interest) to conduct an RCT to test the benefits of fall prevention intervention after DRF.

Discussion

This pilot study examined psychometric properties of selected fall risk, balance, and PA tests where the TUGT and the CST showed some impairment in functional balance and lower extremity muscle strength in females over 45 years with DRF. Furthermore, the study estimated that an average of 21 (3.5 per months) patients can be

recruited in a 6 months period from two centers. The participants in this study demonstrated comparable isometric muscle strength of lower extremity muscles, static balance, and fall efficacy to that of their age matched cohort. However, impairments were found in lower extremity muscle endurance and functional balance which are more relevant in context of fall-risk in community. The results of this study are based on a small pilot study aimed at determining the suitability of measures in the DRF population and obtaining sample size estimates. However, to our knowledge this is one of the first studies to examine the reliability and validity of selected balance and fall efficacy tests in the DRF population.

We included only female participants in this pilot study. Balance and muscle strength tend to be higher in males compared to females even after adjusting for body size.[37, 38] It is likely that recruiting males along with females would have created higher "reference values" for balance (TUGT, OLS, and FR) as well as muscle strength (CST) tests based on computed average scores for these tests. This would make it difficult to apply these scores to females while screening for balance and strength impairment as potential risk factors for falls. Conversely, separate reference values for these balance and muscle strength tests could have been calculated for males and females. However, this would have required a larger sample. There is a potential for subsequent study that has either exclusive male patient group or no gender based criteria for recruitment with larger sample. Such study can assess selected psychometric properties for the tests as well as provide "reference values" for the tests indicating balance and muscle strength performance for male patients with DRF.

The recruitment rates described in the results are based on recruitment from two centers (HULC and WOHC). Recruitment was slowed due to a number of factors. Mainly, the restricted age and gender inclusion criteria (females over the age of 45 years) limited our ability to recruit many individuals with DRF. Secondly, we excluded those who had established balance and strength issues such as those that used gait aids or those with concurrent conditions that could affect their balance/strength performance (e.g. severe arthritis in lower extremity joints, recent history of lower extremity injury etc.). Hand therapists do not need to do screening for individuals who already have known balance issues. Rather, it is important to screen those individuals who do not have obvious balance or lower extremity strength impairment in the event that they have minimal or moderate impairment which can easily be overlooked and predispose them for future falls. Since fall risk assessment and prevention practice is highly desirable for the DRF population,[3, 4] such practice has greater potential to make an impact if targeted to those who have not been deemed to be at risk for future falls and fragility fractures as well as are not being managed for such risk.

Preliminary estimates of test-retest reliability for most tests were acceptable (ICC > 0.75) with few exceptions for tests assessing isometric muscle strength and some PRT. The test-retest reliability of HHD is known to be poor or moderate in assessing isometric muscle strength compared to fixed dynamometry or isokinetic dynamometry.[39] This could have affected the reliability of selected isometric muscle strength tests. While not having very high reliability, HHD is still more relevant in hand therapy practice due to its portability, ease of using and maintaining, and being a small device it does require large

space. Therefore, hand therapists can use the HHD in their practice to determine muscle strength of an isolated muscle group, in particular if they want to focus their intervention to a particular muscle group. Conversely, the CST provides a more global assessment of lower extremity muscle strength as well fatigability. Lower extremity muscle fatigue is known to impair balance and task performance and can be a risk for falling.[40] The strength and performance of muscles during functional activities has greater practical implications compared to single maximal isometric contraction. Therefore, the CST is a better indicator to screen for lower extremity muscle strength impairment. This was observed in the present study where isometric muscle strength for most muscle groups either met or exceeded the age/gender related benchmarks but CST showed impairment in lower extremity muscle strength. The CST is therefore more appropriate for examining the impairment in lower extremity strength for future studies that assess the outcomes of fall prevention intervention in the DRF population.

The average re-assessment period of 9 days is fairly long for accurate assessment of test retest reliability of the PRWE. There usually is a substantial improvement in wrist/hand functions in the first few days following the removal of plaster cast in individuals with DRF. In one of our previous publications, we have noted that even the re-assessment period of 3-4 days can be long where pain and function improve rapidly in this patient group.[41] This instability in clinical status makes it difficult to accurately assess the test retest reliability of the PRWE, which could have impacted the lower ICC value (0.63) for the PRWE in this study. Similarly, it is likely that the individuals' PA status changed once the plaster cast was removed. The mean scores for the RAPA were not very

different on occasion 1 and occasion 2 (3.9 ± 1.6 and 3.8 ± 1.6 respectively). However, the ICC calculation takes into account the variability in self-report between two occasions which could have resulted in lower ICC values.

The single task oriented balance tests such as OLS and FR did not reveal impairment or alteration from the benchmark values, whereas the TUGT scores were below the benchmark. The TUGT examines functional balance during a task consisting of sit to stand, walking, and turning which are common mobility activities performed by an individual. The TUGT has been shown to have superior psychometric properties and better ability to screen for balance impairment compared to the OLS and the FR in community dwelling elderly population.[42] Most falls that result in DRF occur from a standing height as an individual loses balance while walking or turning and reaching out with an outstretched arm to break the fall.[43] Therefore, it would seem logical to use a test that examines balance during a task that involves walking and turning rather than a single task such as one leg stand or functional reach. Moreover, some individuals may find it difficult to perform OLS in presence of pain in lower extremity which may aggravate upon standing on the painful leg. The FR test has been used for assessing balance in women with osteoporosis.[44] However, this test might be unsuitable for individuals who for screening balance in individuals who have osteoporosis. Therefore, the TUGT may have greater relevance and applicability for screening balance impairment in the DRF population compared to single task oriented tests.

The ABC Scale and the FES-S showed comparable test-retest reliability in the DRF population. Both the ABC scale and the FES-S showed high correlation (r = 0.79).

Participants appeared to be less concerned about falling as observed by the mean scores of the ABC scale and the FES-S values. This is likely due to the fact that most participants had only 1 fall in the past year (which resulted in DRF). Many participants had fallen on ice which is at times "unavoidable" irrespective of how good one's balance is. The ABC scale has shown to be superior in detecting loss of balance confidence and fear of falling compared to the FES in high functioning elderly population.[45, 46] The participant group in this study was younger (mean age 63 years) and also high functioning considering that none of them had any mobility issues. Therefore, the ABC might be more appropriate compared to the FES-S if the FOF is to be assessed in the DRF population in future studies.

Most of the participants in this study had not undergone bone mineral density (BMD) assessment in the past 2 years. So, the results of the FRAX® were solely based on personal and family history. The results of FRAX® tool demonstrated that as many as 15 participants (70% of total sample) had a 10 year risk of osteoporotic fracture greater than 10%. Previous research has shown that individuals with such risk should be at least referred for BMD assessment.[47] The results of this study agree with previous reports that emphasize the need for assessment of bone health using BMD testing following DRF.[3, 4]

The sample size estimates derived from two perspectives (improving balance and lower extremity muscle strength, reducing the risk falling and sustaining major injuries) provides a wide range of sample size estimates (a total of 34-1988 patients with DRF required). This variability is understandable since it might require fewer participants if the objective of an intervention is simply to improve balance and lower extremity muscle

strength compared to studies that aim to reduce the proportion of individuals at risk for falling and sustaining fall-related injuries in which a much larger sample would be required. Researchers can design and conduct a study to target surrogate outcomes such as balance impairment and reduced lower extremity muscle strength since it would seem impractical to design a study aimed at reducing risk for an osteoporotic fracture in a relatively low risk population. Both the centers where the participants were recruited from, especially the HULC, have established hand surgery and hand therapy practices with an ongoing flow of patients with DRF. Moreover, the HULC has state of the art clinical research lab where several research studies have been successfully completed by the co-authors of this paper many of which recruited the patients with DRF. The HULC also maintains large data set for patients with DRF and is equipped with high quality data management system. Considering these logistical aspects, it is feasible that future RCT aimed at reducing fall risk and optimizing bone health can be conceived, designed, and implemented at the HULC.

In conclusion, this pilot study examined the recruitment rates, sample size estimation, and suitability of measures for future RCT aimed at assessing the benefits of a fall prevention intervention following DRF. While the results of this pilot study are based on a small number of exclusively female patients, they provide valuable information for designing and implementing a larger study aimed at assessing fall-prevention intervention in individuals with DRF.

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Table 1. Demographics, Personal, and Injury Factors (N = 21 Females)

Variable	Mean ± SD	Frequency (%)
Age	62.6 ± 7.6	
Height (inches)	64.6 ± 2.7	
Weight (pounds)	153.4 ± 37.7	
Number of days since injury	50.3 ± 12.7	
Number of days between 1st and 2nd assessment	9.3 ± 2.6	
Side of injury R		13 (62%)
L		8 (38%)
Dominant Side R		20 (95%)
L		1 (5%)
Mode of injury		
Slipped on ice		15 (71.5%)
Fall on stairs		2 (9.5%)
Fall from standing on stool		2 (9.5%)
Fall from bicycle		2 (9.5%)
Occupational status		
Retired/housewife		13 (62%)
Working		8 (38%)
Previous history of fracture		1 (5%)
		20 (95%)
Falls in 1 year		2 (9.5%)
		19 (90.5%)
Parent history of hip fracture		7 (33.3 %)
		14 (66.7%)
Diagnosed with osteoporosis		3 (14.3%)
		18 (85.7%)

SD, standard deviation; R, right; L, left

Table 2. Test-Retest Reliability

Test	Mean ± SD		ICC (95% CI)	SEM
	Occ1	Occ2		
Balance tests				
Timed up and Go (s)	8.6 ± 1.2	8.4 ± 1.3	0.83 (0.61 - 0.93)	0.5
Forward reach (cm)	37.2 ± 5.2	37.8 ± 5.3	0.83 (0.63 - 0.93)	2.1
One leg standing - D (s)	57.1 ± 29.9	58.9 ± 30.4	0.81 (0.58 - 0.92)	13
One leg standing - ND (s)	62.4 ± 31.7	66.1 ± 29.8	0.96 (0.91 - 0.99)	6.3
Lower extremity strength				
Chair stand test (repetitions)	12.4 ± 2.9	13 ± 2.6	0.89 (0.74 - 0.95)	1
Hip flexors - D (lbs)	27.6 ± 3.1	27.3 ± 6.2	0.70 (0.38 - 0.87)	1.7
Hip flexors - ND (lbs)	25.6 ± 3	25.8 ± 5.7	0.78 (0.53 - 0.91)	1.4
Hip extensors - D (lbs)	22.5 ± 5.5	24.1 ± 6.1	0.66 (0.32 - 0.85)	3.2
Hip extensors - ND (lbs)	22 ± 5.8	24.1 ± 5.7	0.50 (0.09 - 0.77)	4.1
Hip abductors - D (lbs)	32.6 ± 4.4	25 ± 6.9	0.78 (0.52 - 0.91)	2.1
Hip abductors - ND (lbs)	32 ± 4	23.9 ± 7.2	0.76 (0.49 - 0.90)	2
Quadriceps - D (lbs)	53.1 ± 3.4	45.7 ± 8.6	0.89 (0.75 - 0.96)	1.1
Quadriceps - ND (lbs)	51.6 ± 6	43.7 ± 8.3	0.84 (0.64 - 0.93)	2.4
Hamstrings - D (lbs)	34.5 ± 4.3	33.1 ± 7.9	0.81 (0.58 - 0.92)	1.9
Hamstrings - ND (lbs)	31.1 ± 3.8	31.9 ± 7.5	0.72 (0.42 - 0.88)	2
Wrist/Hand funtion				
PRWE - total score	52.7 ± 24.5	43.4 ± 20.3	0.63 (0.26 - 0.84)	14.9
Perceived fall risk				
Shortened FES	8.4 ± 2.1	8.4 ± 2.1	0.86 (0.67 - 0.94)	0.8
ABC scale	92 ± 10.2	92.1 ± 11.6	0.89 (0.75 - 0.96)	3.4
RPQ	45.1 ± 9.6	43.8 ± 8.2	0.66 (0.30 - 0.85)	5.6
Physical activity measure				
RAPA	3.9 ± 1.6	3.8 ± 1.6	0.68 (0.34 - 0.86)	0.9

SD, standard deviation; Occ, occasion; ICC, intraclass, correlation coefficient; CI, confidence interval; SEM, standard error of measurement; D, dominant side; ND, non-dominant side; PRWE, Patient-Rated Wrist Evaluation; ABC, Activities-specific *balance* confidence; RPQ, Risk perception questionnaire; RAPA, Rapid assessment of physical activity

Table 3. Scores for Tests in the DRF Population and Age/Gender Matched Comparative Scores

Test	Mean ± SD - DRF	Age/gender matched Mean ± SD	Number (%) of people with impairment	p-values
Timed up and go (s)	**8.6 ± 1.2**	7.2 ± 1.6[48]	16 (76%)	**< 0.01**
Forward reach (cm)	37.2 ± 5.2	36.9 ± 5.1[48]	6 (29%)	= 0.8
Chair stand	**12.4 ± 2.9**	14.4 ± 4.3[32]	5 (24%)	**= 0.05**
One leg standing - D (s)	57.1 ± 29.9	25.1 ± 116.7[33]	2 (9%)	= 0.8
One leg standing - ND (s)	62.5 ± 32.5	25.1 ± 116.7[33]	4 (18%)	= 0.15
Hip flexors - D (lbs)	27.6 ± 3.1	27.6 ± 5.2[49]	7 (34%)	= 0.9
Hip flexors - ND (lbs)	25.6 ± 2.9	27.3 ± 4.7[49]	15 (71%)	= 0.1
Hip extensors - D (lbs)	22.5 ± 5.5	15.2 ± 5.9[50]	2 (9%)	**< 0.01**
Hip extensors - ND (lbs)	22 ± 5.8	15.2 ± 5.9[50]ǂ	1 (5%)	**< 0.01**
Hip abductors - D (lbs)	32.6 ± 4.4	42.4 ± 9.9[49]ǂ	21 (100%)	**< 0.01**
Hip abductors - ND (lbs)	32 ± 4	42.1 ± 10[49]	21 (100%)	**< 0.01**
Quadriceps - D (lbs)	53.1 ± 3.4	57.8 ± 13[49]	18 (86%)	= 0.11
Quadriceps - ND (lbs)	51.6 ± 6	55.7 ± 14.9[49]	18 (86%)	= 0.2
Hamstrings - D (lbs)	33.5 ± 4.4	35.3 ± 6.1[49]	17 (81%)	= 0.26
Hamstrings - ND (lbs)	31.1 ± 3.7	34.5 ± 6.6[49]	19 (91%)	**= 0.03**
PRWE - total score	52.7 ± 24.5	50 ± 21 (at 7 weeks)[51]	7 (34%)	= 0.6
Shortened FES	8.4 ± 2.1	11.8 ± 4.9[24]	2 (9%)	**< 0.01**
ABC scale	92 ± 10.2	79.9 ± 20.6[34] (<80 indicates impairment)	1 (5%)	**< 0.01**
RPQ	45.1 ± 9.6	Not available	N/A	N/A

RAPA	**3.9 ± 1.6**	< 6 means suboptimal PA level[28]	20 (95%)	N/T

SD, standard deviation; SE, standard error or mean; s, seconds; cm, centimeter; PRWE, patient-rated wrist evaluation; ABC, activities-specific *balance* confidence; RPQ, risk perception questionnaire; RAPA, rapid assessment of physical activity; N/T, unable to calculate

*Deviations in the scores for the measures as well as significant p values are shown in bold fonts

ǂ Average value for dominant and non-dominant side

P values less than 0.01 are reported as < 0.01

Table 4. Correlation Between the Tests

4a. Relationship Between Performance-based Tests

	FR	OLS - D	OLS - ND	CST	Hip flex - D	Hip flex - ND	Hip ext - D	Hip ext - ND	Hip abd - D	Hip abd - ND	Quad - D	Quad - ND	Hams - D	Hams - ND
Balance														
TUG	0.37	**0.45**	0.1	**0.53**	0.2	0.03	0.13	0.13	0.6	0.34	0.11	0.32	0.01	0.16
FR		0.28	0.11	0.08	0.35	0.09	0.01	0.05	.040	0.22	0.04	0.41	0.06	0.06
OLS - D			**0.61***	0.35	0.17	0.39	0.19	0.12	0.06	0.27	0.01	0.07	0.17	0.11
OLS - ND				0.03	0.01	0.4	0.27	0.19	0.03	0.21	0.08	0.05	0.05	0.19
Strength														
CST					0.30	0.03	0.34	0.26	0.22	0.02	0.42	0.17	0.15	0.05
Hip flex - D						0.09	0.02	0.23	0.08	0.05	0.09	0.04	0.05	0.01
Hip flex - ND							0.25	0.12	0.35	0.13	0.01	0.11	**0.56**	0.44
Hip ext - D								**0.87***	**0.62***	0.02	0.06	0.11	**0.47**	**0.51**
Hip ext - ND									0.43	0.29	0.16	0.09	0.32	0.31
Hip abd - D										0.43	0.06	0.18	**0.54**	**0.72***
Hip abd - ND											0.15	0.30	0.22	**0.56**
Quad - D												**0.52**	0.17	0.15
Quad - ND													0.20	0.12
Hams - D														**0.84***

FR, functional reach; OLS, one leg standing; D, dominant side; ND, non-dominant side; CST, chair stand test; flex, flexion; ext, extension; abd, abduction; Quad, quadriceps; Hans, hamstrings

4b. Relationship Between Patient-Reported Tests

	FES	ABC	RPQ	RAPA
PRWE	0.15	0.13	.17	0.02
FES		**0.79***	0.27	**0.49**
ABC			0.20	**0.52**
RPQ				0.04

PRWE, patient-rated wrist evaluation; FES, shortened version of the fall efficacy scale; ABC, activity specific balance confidence scale; RPQ, risk perception questionnaire; RAPA, rapid assessment of physical activity

4c. Relationship Between Balance Tests and Falls Efficacy tests

	FES	ABC	RPQ
TUG	0.23	0.28	0.13
FR	0.14	0.01	0.12
OLS-D	0.24	0.35	0.13
OLS-ND	0.20	0.30	0.20

FES, shortened version of the fall efficacy scale; ABC, activity specific balance confidence scale; RPQ, risk perception questionnaire; RAPA, rapid assessment of physical activity; OLS, one leg standing; D, dominant side; ND, non-dominant side

Correlation bold fonts are significant at the 0.05 level (2-tailed).
*Correlation are significant at the 0.01 level (2-tailed).

Table 5. Sample Size Required for Prospective Studies of Fall Prevention in the DRF Population

Outcome/Screening test	Change of mean required	SD of the population	Sample Size Estimate	Incorporating 20% Loss to Follow-up	Number of Months to Recruit
TUG (balance)					
Difference of mean	1.4	1.15	11 + 11 = 22	13 + 13 = 26	8
Reported MDC_{90}[35]ǂ	0.75	1.27	44 + 44 = 88	53 + 53 = 106	30
CST (strength)					
Difference of mean	2	2.91	36 + 36 = 72	43 + 43 = 86	25
Reported MDC_{90}[19]ǂ	1.6	2.4	34 + 34 = 68	41 + 41 = 82	24
Outcome	**Population risk (%)**	**Minimal acceptable Change in proportion of risk**	**Sample Size Estimate**	**Incorporating 20% Loss to Follow-up**	**Number of Months to Recruit**
Rate of falling in individuals >50years of age	62%[36]	31%	40 + 40 = 80	48 + 48 = 96	28
Rate of sustaining major injuries* in people >50years of age	52%[36]	26%	55 + 55 = 110	66 + 66 = 132	37
10 year risk (%) for osteoporotic fracture (FRAX® score)					
For a 50 year old female with no clinical risk factors**	6.5	3.5	828 + 828 = 1656	994 + 994 = 1988	568
Average FRAX® score in the present study	18.7	10	254 + 254 = 508	304 + 304 = 608	173

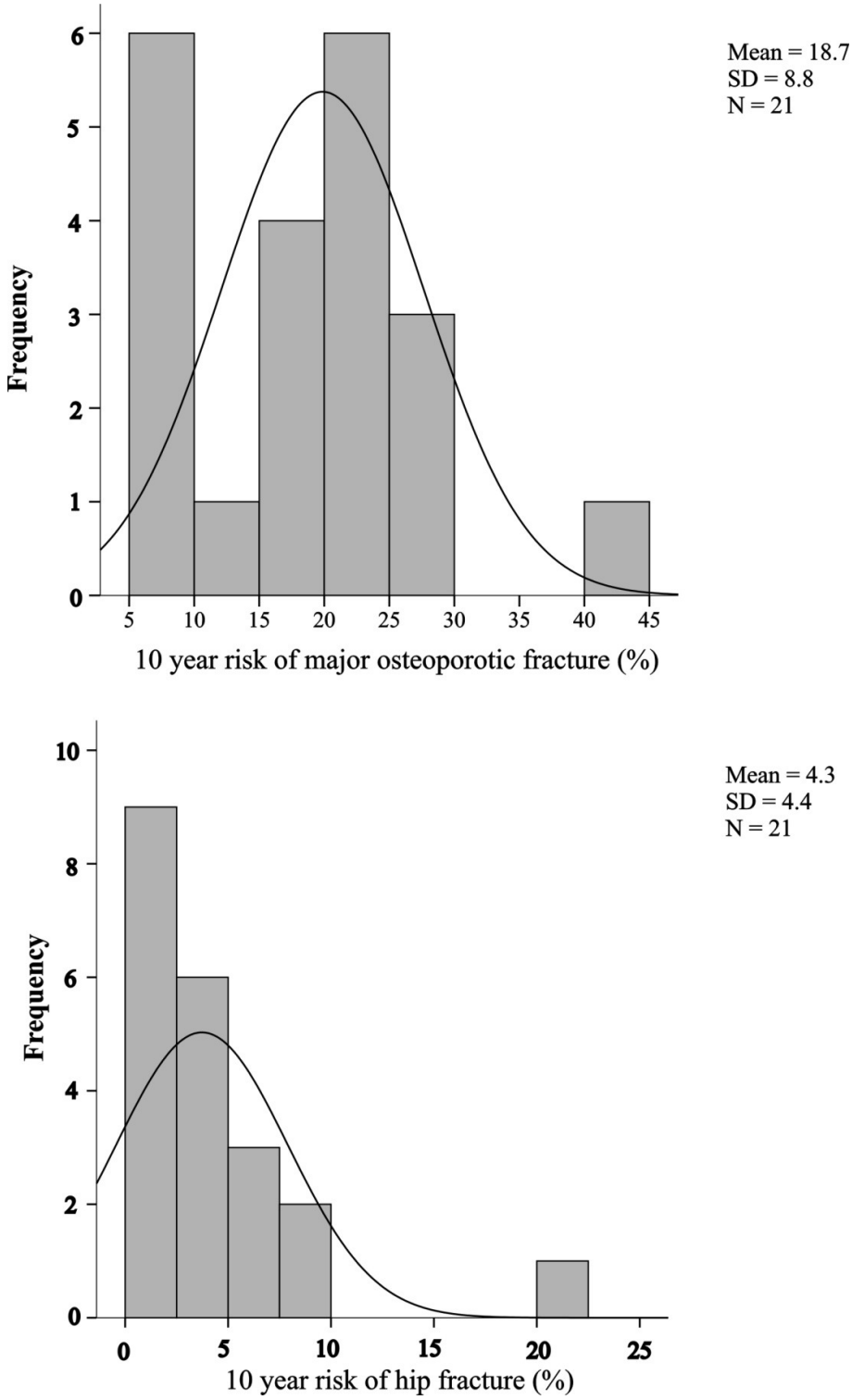
SD, standard deviation; TUG, timed up and go test; MDC, minimal detectable change; CST, chair stand test

ǂ MDC90 values were calculated from the literature where the tests were used in homogenous population

*major injuries are defined as those involving fractures, head injuries, muscular injuries, and joint strain.

**Estimated height 162 cm, weight 60 kg

Figure 1. Results of FRAX® tool (N = 21)



Chapter 7. Discussion

As many as 16% of individuals report ongoing pain and disability following distal radius fracture (DRF) (Moore & Leonardi-Bee, 2008; MacDermid, Roth, & Richards, 2003). Risk for falls and osteoporotic fractures following DRF has also been documented in literature (Schousboe et al., 2005; Nordell, Kristinsdottir, Jarnlo, Magnusson, & Thorngren, 2005). In view of this evidence, management of DRF needs to encompass a comprehensive screening to identify individuals at risk of these adverse outcomes. Rehabilitation practitioners are well-positioned to conduct such screening given their expertise in fall-risk assessment. However, a screening tool is needed that is validated and highly sensitive in identifying the individuals at risk of these adverse outcomes following DRF. This thesis identified measures that can be used for predicting risk for adverse outcomes following DRF.

The thesis provided clinical prediction guidelines using these measures to profile the risk for chronic pain, falls, and osteoporotic fractures in individuals with DRF. To achieve these objectives, a theoretical model is proposed explaining how to manage individuals based on their risk profile. Moreover, a retrospective study identified whether baseline pain intensity can be used to predict the risk of chronic pain following DRF. This study also provided a cut-off score using the pain subscale of the Patient-Rated Wrist Evaluation (PRWE) at baseline to screen individuals at risk for chronic pain following DRF. Subsequently, a two part study was conducted. A structured literature synthesis was conducted initially to identify common measures that can be used for screening individuals with impaired balance, fear of falling, impaired lower extremity muscle strength, and risk of osteoporotic fractures. Preliminary assessment of psychometric

properties of these measures in the DRF population was conducted in the second part. This second part was a pilot study which also examined the recruitment rates and sample size estimates for conducting a future study aimed at reducing the risk for falls and osteoporotic fractures after DRF. In summary, this thesis is a targeted knowledge synthesis inquiry for establishing clinical prediction guidelines to identify individuals at risk of adverse outcomes following DRF. While the implications and clinical relevance of each of the studies included in this thesis portfolio are described within the manuscripts, some specific contributions and implications of each study in relation to the overall thesis work are explained below. Also, the strength, weakness, and potential research studies that can be conducted in future for managing the risk of adverse outcomes in the DRF population are outlined.

Implications and Contributions of Individual Manuscripts

Implication of Theoretical Models of Chronic Pain in Rehabilitation of DRF (theory paper)

The most important contribution of this manuscript is that it is one of the first publications that has emphasized the importance of risk-based management of individuals following DRF. Further validation of the RACE (**R**educing pain, **A**ctivating, **C**ognitive reshaping, **E**mpowering) model may be undertaken as it offers a novel framework for management of individuals at risk of chronic pain.

The RACE model described in the manuscript provided a targeted approach to rehabilitation management of individuals depending on their risk profile for developing

chronic pain (high risk versus low risk). The implications of the RACE model should be limited to the management of the risk of chronic pain and not necessarily the risk of other adverse outcomes such as falls and injuries. This is because the constructs of learned helplessness (Abramson, Seligman, & Teasdale, 1978) and cognitive-behavioural models (Sharp, 2001) were incorporated into the model to characterize and manage individuals at risk of transitioning to chronic pain following DRF. Therefore, the RACE model does not constitute a comprehensive approach to managing risk for all adverse outcomes following DRF.

The constructs of the learned helplessness and cognitive-behavioural models described in the RACE model are usually employed by psychologists while managing a range of conditions, chronic pain being one of them. The DRF is usually managed in small private rehabilitation clinics where clinicians may not have sufficient training to deliver psychosocially based interventions. Therefore, it is imperative that the management approach described in the RACE model does not require the rehabilitation practitioners to have specialized training and is clear and practical to support its translation.

One of the key recommendations emerging from this manuscript was that future research should identify which measures can be used in predicting risk of chronic pain in the DRF population. The cut-off scores on these measures that characterize the presence or absence of risk of chronic pain following DRF need to be determined through future research. The manuscript also highlighted a pressing need to conduct prognostic studies using the cut-off scores on these measures to examine the proportion of individuals

transitioning to chronic pain. This would build additional evidence to accurately predict the risk of chronic pain following DRF. In general, the future directions outlined in this manuscript are aimed at building stronger evidence to support the notion of risk screening following DRF.

A Systematic Review of the Psychometric Properties of the Patient-Rated Wrist Evaluation (systematic review of psychometric properties)

Evidence supporting the psychometric properties of an outcome measure is essential to justify its use across a range of conditions. This manuscript summarized the results of a systematic review aimed at synthesizing the evidence of psychometric properties of the Patient-Rated Wrist Evaluation (PRWE). The key contribution of this manuscript is that it has provided a much needed reference for clinicians to ensure evidence-informed use of PRWE across a range on wrist/hand conditions. The manuscript also established that the pain and functions subscales of the PRWE have sufficient psychometric evidence and can be used in isolation, which has important implications for clinical practice. Clinicians can only use the pain subscale of the PRWE if their objective is to ascertain wrist/hand pain intensity and not wrist/hand function. The results of the manuscript also identified populations where the PRWE has superior psychometric properties compared to other measures. This should assist clinicians in selecting an appropriate measure when assessing a particular wrist/hand population.

This manuscript also has important implications for the overall thesis work, mainly the third manuscript. It provided evidence to support the use of the PRWE as the most appropriate measure for assessing self-reported pain and function in the DRF

population since it was developed as a condition-specific measure. Moreover, the finding that the pain subscale of the PRWE is sufficiently stable justified its use for assessing baseline pain intensity in the study described in the third manuscript.

Lastly, the manuscript also made contributions in identifying research priorities relating to the application of the PRWE. Most importantly, the PRWE needs further validation using advanced psychometric methods such as Rasch analysis. The manuscript also recommends further research to obtain values for the minimal detectable change (MDC) for the PRWE across a range for wrist/hand conditions to help clinicians evaluate change resulting from their intervention.

Baseline Pain Intensity is a Predictor of Chronic Pain Following Distal Radius Fracture (retrospective cohort study)

This manuscript provided further evidence to the body of research that examined the role of personal and injury factors as predictors of chronic pain following DRF (Grewal, MacDermid, Pope, & Chesworth, 2007). However, this manuscript explored the role of baseline pain intensity as a predictor of chronic pain following DRF. The key finding of this study was that individuals who score $\geq$ 35/50 on the pain subscale of the PRWE at baseline are at 8 times greater risk of developing chronic pain compared to those who score < 35/50 following DRF. This finding will help clinicians to screen individuals who at risk for developing chronic pain following DRF.

This study was also a follow-up to the theory paper which suggested the need to identify cut-off scores for measures to predict the presence or absence of risk of adverse

outcomes following DRF. Using baseline pain as a predictor of chronic pain offers two distinct advantages for clinical practice. Firstly, it is easy to measure, track, and modify pain intensity. Secondly, estimating the risk of chronic pain using baseline pain intensity allows rehabilitation practitioners and patients to formulate specific treatment goals to manage the risk. It is acknowledged that the baseline pain intensity is "reflective" of the impact that other known predictors such as age, education, and injury compensation have on chronic pain and is not necessarily a predictor in its own right (Grewal et al., 2007).

The cut-off score of 35/50 on the pain subscale of the PRWE at baseline needs further empirical validation through prospective studies in the DRF population. An ideal approach would be to categorize risk level at baseline for the individuals with DRF based on their score on the pain subscale of the PRWE. These individuals can then be followed for a year to examine the subset of individuals transitioning to chronic pain to test the accuracy of the cut-off score. Future work should also examine the stability of this cut-off score in the presence of other known predictors such as financial compensation status and education level (Grewal et al., 2007).

In general, this manuscript is the first of its kind that provides an objective method to compute relative risk of chronic pain following DRF. While the results of this study need to undergo further testing, clinicians can use the cut-off score of 35/50 on the pain subscale of the PRWE in combination of the screening approach described in the theory paper (specific interview questions, observing traits of learned helplessness, and cognitive-behavioural impairments etc.) to screen the individuals at risk of chronic pain following DRF.

A Systematic Literature Synthesis to Identify Measures for Screening the Risk of Adverse Outcomes in Patients Following Distal Radius Fracture (Literature Review)

The primary contribution of this manuscript is that it identified measures that are suitable for use in small private practice clinics for screening the risk for falls and osteoporotic fractures in the DRF population. The research methodology was designed to answer specific questions related to identification of suitable measures for screening a particular risk in individuals with DRF. This manuscript also provided additional support to some of the fall-risk screening strategies described in a previously published paper that outlined a fall-prevention approach for hand therapists (Thompson, Evitt, & Whaley, 2010). However, this previous publication outlined the measures for fall-risk screening without a systematic literature search or discussion around the feasibility aspects of using these measures in hand therapy clinics. The manuscript in this thesis describes a stepwise approach for "how to do fall-risk screening" in rehabilitation practice while managing individuals with DRF.

While the detailed summary of which measures are suggested for screening a particular risk are outlined in the manuscript, an important contribution of this manuscript is that it provides scores for the measures to determine the risk categories (low risk, moderate risk, high risk) if the risk is ruled in. The management approach for those who fall into the high risk category is unique and inter-professional in nature (de Vries et al., 2010). The individuals who fall in the low risk category can be managed with specific education and appropriate exercise prescription (Shubert, 2011). Rehabilitation practitioners can administer the same measures again to assess whether the risk has been

modified by the education and exercises for those who fall in the low risk category. The manuscript also described how to use the FRAX® tool for screening the risk for osteoporotic fractures. Rehabilitation practitioners do not have the necessary expertise to diagnose osteoporosis, however the FRAX® tool can provide the stimulus as to whether they need to refer the patient to family physician or not (Kanis et al., 2008).

The measures described in this manuscript require empirical validation in the DRF population. Research directions that emerged from the manuscript are to conduct studies to examine psychometric properties of these measures in the DRF population, examine the predictive ability of the cut-off scores of these measures described in the manuscript through a prospective inquiry, and conduct further knowledge synthesis to determine the optimal interventions to manage the fall-risk in the DRF population.

Reliability and Validity of Fall Risk and Balance Measures in Individuals with Distal Radius Fracture - A Pilot Study (Psychometric analysis and feasibility testing)

This manuscript provides preliminary evidence regarding the psychometric properties of selected fall-risk measures in the DRF population. This study was an extension of manuscript 4 in an effort to synthesize knowledge regarding the suitability of measures in the DRF population. Furthermore, the manuscript also provides sample size estimates for different desired outcomes if an intervention was conducted to reduce the risk for falls and osteoporotic fractures in individuals determined to be at risk.

One of the important findings is that 16 (76%) of the 21 females recruited in this study had the Timed Up and Go Test (TUGT) scores higher than the published reference

values for the TUGT (Isles, Choy, Steer, & Nitz, 2004). Despite this, only 1 participant reported to have impaired balance confidence as measured by the Activity-Specific Balance Confidence (ABC) Scale. This highlights the discordance between balance impairment and perceived fall-risk. This was further evidenced by the reported values for Pearson Correlation Coefficient (r values between 0.13-0.28).

The manuscript also provided values for the standard error of measurement (SEM) for selected measures in the DRF population. The psychometric properties are dynamic in nature and therefore measures should have evidence regarding the psychometric properties the clinical population in which they are used. The reported SEM values should provide an estimation of error in single measurement when these measures used in the DRF population. One of the other advantages of the SEM is that it provides this error in the same units in which the score for the measure is reported. Therefore, it is easier to interpret clinically compared to the ICC.

Lastly, the wide range of sample size estimates has important implications for future research. The researchers will have some idea whether it is feasible to recruit the desired number of patients with DRF to achieve a particular outcome from their fall-prevention intervention and the resources required in order to successfully undertake the trial. It may not be pragmatic to examine whether a 10 year risk of osteoporotic fracture has been modified or not since it is not feasible for the researchers to conduct an effectiveness study that spans over 10 years. It is more feasible to measure surrogate outcomes such as balance impairment and lower extremity muscle strength to examine whether a fall-prevention intervention is effective in modifying this risk.

Implications and Contributions of the Overall Thesis Work

The thesis has made specific contributions in different areas of DRF management. These contributions are outlined below. The specific contributions of this thesis listed below are critiqued in view of literature and they reflect an iterative stepwise knowledge synthesis.

Conceptualization of Providing Risk-based Interventions

One of the most important contributions of this thesis in view of the overall management of the DRF population is that it underscored the importance of screening the risk of adverse outcomes along with the standard wrist/hand assessment. The fact that current rehabilitation management of DRF does not incorporate risk assessment was supported through a variety of arguments and references in the manuscripts.

Primary prevention of some of the possible adverse outcomes following an injury can have significant benefits to the quality of life of individuals. Moreover, primary prevention always has important cost-benefit implications in health care expenditure. In particular, falls and fall-related injuries are preventable in a community dwelling population and do have significant cost-benefits. Prior to conceiving this thesis plan, it was evident that adverse outcomes as they relate to DRF were mainly perceived as ongoing pain, disability, complex regional pain syndrome, osteoarthritis (OA), fracture malunion, and carpal tunnel syndrome (CTS) (Grewal & MacDermid, 2007; American Academy of Orthopaedic Surgeons, 2009). Risk for falls and fall-related osteoporotic fractures was characterized in epidemiological studies in the DRF population (Owen,

Melton, III, Ilstrup, Johnson, & Riggs, 1982; Mallmin & Ljunghall, 1994; Vogt et al., 2002; Cuddihy, Gabriel, Crowson, O'Fallon, & Melton, III, 1999), but no study suggested how to profile these risks and how should individuals with a degree of risk should be managed. This drove the need to initiate this knowledge synthesis inquiry with an objective of establishing evidence-based screening guidelines to predict the risk of adverse outcomes following DRF. Chronic pain, risk for falls, and osteoporotic fractures are the only adverse outcomes studied in this thesis, which do not encompass all the adverse outcomes listed above. However, these outcomes can be modified through primary prevention compared to some of the other adverse outcomes such as wrist OA or fracture malunion. Therefore, there is a potential for making an impact if clear guidelines are available regarding screening and managing the risk for these adverse outcomes. The studies described in this thesis are not the end point of the knowledge synthesis inquiry nor should they be considered as the best possible evidence for screening the risk for chronic pain, falls, and osteoporotic fractures. There needs to be continuous inquiry to build high quality knowledge in screening and managing these risks. At best, this thesis work has provided early insight as to what are the suggested methods for assessing these risks and how these methods can undergo further scientific scrutiny to build stronger evidence.

Theoretical Framework

The RACE model described in theory paper is likely the first theoretical framework suggesting risk-based management of the DRF population. One of the drawbacks of the RACE model is that it was primarily conceived to assess and manage

the risk of chronic pain following DRF and not the risk for other adverse outcomes. This creates an opportunity for expanding the RACE model to provide a framework for more comprehensive screening and management of adverse outcomes such as falls and osteoporotic fractures following DRF.

Existing theoretical frameworks can inform the modification of the RACE model. Squitieri et al (2010) provided a framework using the components of the International Classification of Functioning, Disability, and Health (ICF) for assessing patient satisfaction in the DRF population (Squitieri et al., 2010). They concluded that patient satisfaction can be modeled and assessed using components of the ICF. The ICF is widely used to characterize a patient's activity/participation level and how they are impacted by personal and environmental factors. The modified RACE model can include components of physical activity (PA)/participation which can be assessed using specific measures suitable for the DRF population and how DRF has adversely impacted the PA/participation in life roles. Similarly, Arnold et al (2012) summarized literature on fall-risk screening and offered an algorithm regarding how to screen and manage fall-risk in individuals with hip or knee OA. This algorithm provides stepwise guidelines for fall-risk screening. However, some of the risk factors described in the algorithm (hip and knee range of motion, hip/knee pain intensity, perceived barriers to fall prevention) are more appropriate for elderly population having OA of the hip or knee joints who can have severe fall-risk and not for the DRF population many of whom are middle-aged and may have only low to moderate risk. These risk factors may be omitted when re-designing the RACE model. There are a number of fall-prevention models described in the literature,

however the benefit of the algorithm proposed by Arnold et al (2012) is that it can easily be used for screening and intervention by rehabilitation practitioners. One of the common suggestions between the fall-prevention algorithm described by Arnold et al (2012) and the RACE model is that those who are deemed to be at no risk also need to be assessed periodically to ensure that the risk has not worsened from the previous assessment. Moreover, some of the screening measures described in the algorithm (TUGT, chair stand test (CST), ABC Scale) for risk screening were also identified through our literature synthesis process and are described and tested in chapter 5 and chapter 6 of this thesis.

Identifying and Testing the Measures for Risk Screening

This thesis work has provided a list of measures for screening the risk for chronic pain, falls, and osteoporotic fractures in the DRF population. The importance of this contribution is that the approach to derive these measures was systematic in nature, the scores that reflect the degree of risk (low, moderate, high) are included, and preliminary psychometric analysis to further support their use in the DRF population was performed.

The PRWE is commonly used to assess pain and function in the DRF population (MacDermid, Turgeon, Richards, Beadle, & Roth, 1998). The systematic review on the psychometric properties of the PRWE summarized the evidence of the psychometric properties to date. The review also identified the values for minimal detectable change (MDC_{90}) and SEM specifically for the DRF population. The subsequent manuscript established the cut-off score on the PRWE pain subscale that is predictive of the risk for chronic pain following DRF. This emphasizes that PRWE has several potential applications in the DRF population. Firstly, the PRWE assists with short-term goal setting

to reduce pain and improve functions in DRF and also evaluate the change in status using MDC_{90}. The cut-off score identified on the pain subscale of the PRWE provides insight into long-term risk of chronic pain and assists in determining the treatment needs of those who may have higher risk.

Fall-risk as it relates to individuals with DRF was proposed to be measured by assessing balance impairment, fear of falling (FOF), impaired lower extremity muscle strength, and PA level. Such an approach would yield a better understanding about whether a specific impairment exists (i.e. impaired balance, FOF, impaired muscle strength etc.); therefore the treatment approach can be customized to address the specific need. The structured literature synthesis was designed such that the fall-risk measures identified in the study are quick, easy to administer, and provide accurate assessment of potential risk. The measures identified in the review reflect these attributes. For example, it would only take 10-12 minutes if rehabilitation practitioners were to administer the TUGT, CST, ABC, and Rapid Assessment of Physical Activity (RAPA) respectively for assessing balance, lower extremity muscle strength, FOF, and PA level.

It is debatable whether fall-risk screening should be conducted in all patients with DRF or what should trigger rehabilitation practitioners to conduct such screening. The measures were primarily derived for screening the individuals who may have low or moderate fall-risk which may be easily overlooked. The fall-risk measures were tested in females over the age of 45 years which implies that the measures should only be administered in this age/gender group until further studies provide additional evidence regarding their use in other age/gender groups. Rehabilitation practitioners can consider

the age group (>45 years of age), presence of other risk factors (history of falls, multiple comorbidies, visual deficits), and any verbal reports of FOF during initial assessment to be indicative of the requirement for screening. The mechanism of injury is also one of the factors that need to be considered while determining the need for screening. In particular, a fall from standing height that occurs during mobility tasks such as walking, turning, or reaching within or outside of one's base of support should cue the need to quickly screen for impairments in balance and lower extremity muscle strength. Falls that occur from height or during recreational sports (skate boarding, biking, ice skating, skiing) may not be indicative of balance impairment and should not trigger fall-risk screening.

Overall, this thesis work has presented the first practical approach for screening the risk for chronic pain, falls, and osteoporotic fractures in individuals following DRF. The appropriate measures that are suitable for this purpose have been identified and their usability in determining the degree of risk has been evaluated. Further research in this area, which is outlined below, is highly recommended to extend the evidence emerging from this thesis, examine whether this risk screening approach improves patient outcomes, undertake primary management of fall-risk, and advance the science in the area of managing DRF.

Limitations

Apart from limitations of each study described in individual manuscripts, there are certain limitations of the overall approach that resulted in this thesis work. One of the main limitations is that we have not asked or surveyed rehabilitation practitioners who treat the DRF population whether they perceive fall-risk screening essential and what

approach they would find useful to do such screening. Moreover, we have not surveyed them to seek their opinion about the approach for fall-risk screening that we proposed in this thesis. This may prove to be a barrier to knowledge translation (KT) of the fall-prevention strategies in rehabilitation practice. Specific KT interventions might be needed to involve rehabilitation practitioners in recognizing the extent of the problem and how can they make an impact in the area of fall-prevention following DRF. There is also a possibility that some of the clinicians might already be conducting fall-risk screening to an extent and may not be open to implementing the results of this thesis. Moreover, if some of the clinicians are indeed conducting fall-risk screening, it would have had valuable implications in informing this thesis work. To this end, we have initiated a survey to assess fall-risk screening practices of physiotherapists (PT) and occupational therapists (OT) while managing individuals with DRF. The survey is ongoing and we have no results yet to support our hypothesis that fall-risk screening is uncommon while managing individuals with DRF.

Based on the literature, it appears to be extremely beneficial to conduct a fall-risk assessment and to adopt an evidence-based primary fall-prevention in the DRF population. However, the success of such a fall-prevention approach depends on several factors which may not be controlled by rehabilitation practitioners. Firstly, the fall-prevention approach is to target middle-aged and older adults who are high functioning and have no established balance issues. Moreover, the approach is intended for those who may have low to moderate risk for falls after DRF. The individuals who have low risk may not perceive fall-prevention as a priority health issue compared to other ongoing

health issues such as diabetes, hypertension, or increased cholesterol level which are common in middle-aged or older adults. This was evidenced in the results of the pilot study where as many as 16 of the 21 individuals had the TUGT scores that were abnormal when compared to the age and gender matched control, whereas only 1 of these 16 individuals reported FOF. Therefore, they may not be motivated to learn and implement necessary fall-prevention intervention. This may render the fall-prevention approach in this age group to be an unproductive exercise. The other concern is that the fall-risk intervention for this age group has not been designed and tested yet; therefore it is difficult to establish whether the fall-prevention intervention has distinct benefits over no intervention.

The other important limitation that needs to be mentioned is that the predictive ability of the screening aimed at determining the risk for chronic pain, falls, or osteoporotic fractures is yet to be examined. Ideally, a prospective study to follow individuals who were deemed to be at risk for these adverse outcomes following DRF needed to be undertaken. However, we are better equipped now with the necessary screening measures, sample size estimates, and recruitment rates which would allow us to undertake such a prospective study.

While not a limitation as such, we still do not know what the risk reduction interventions are for individuals who have low to moderate risk for falls and osteoporotic fractures following DRF.

Lastly, the RACE model not being a comprehensive framework for managing the risk for falls and osteoporotic fractures has been discussed earlier and potential solutions for modifying the model have been proposed.

Not withstanding these limitations, this thesis underscores the importance of screening for the risk of some of the adverse outcomes following DRF and provides preliminary evidence of how such screening can be conducted in small outpatient clinics.

Future Directions

A number of future research initiatives have been outlined under each of the manuscripts. The following section provides an overview of some of the important research undertakings required to advance the science.

Most importantly, a predictive study needs to be undertaken to examine the accuracy of screening measures in estimating the risk for adverse outcomes. Individuals with DRF can initially be assessed to profile their risk for chronic pain, falls, and osteoporotic fractures. These individuals can then be periodically assessed over 1-2 years to examine the subset of individuals who had adverse outcomes (chronic pain, incidence of falls, osteoporotic fracture). Such a predictive study will further refine the cut-off values indicating risk for chronic pain or fall-risk which were presented in the manuscript 3 and 4. The research design for this study can be similar to that described in the manuscript 3, where sensitivity and specificity of the cut-off score can be analysed to determine its predictive ability.

Simultaneously, the results of the survey examining the fall-risk assessment practices of PT and OT in the DRF population need to be explored. These results will provide an understanding as to whether rehabilitation practitioners consider the fall-risk assessment an essential component in managing the DRF population. Another follow-up survey can be designed asking PT and OT about their preferred methods of learning if researchers were to undertake KT initiative to disseminate the knowledge regarding the screening procedures. Customizing the knowledge and delivery of knowledge to the needs of the target group can increase its uptake (Tetroe, Graham, & Scott, 2011). Therefore, the survey can help in defining KT strategies to ensure that the screening procedures become a part of clinical practice while managing the DRF population.

Another research area that needs to be explored is to design appropriate interventions for managing the risk of adverse outcomes in those deemed to be at risk. Some possible options for managing the risk of chronic pain were provided in the theory paper and the RACE model, however these solutions can be further refined through a structured literature synthesis similar to the one presented in manuscript 4. This literature synthesis can also examine the components of a fall-prevention intervention for the DRF population. While doing so, it needs to be ensured that the interventions are feasible to be implemented in small outpatient clinics and provide clear guidelines to rehabilitation practitioners to manage the risk based on the risk profile on an individual.

Once the appropriate fall-prevention treatment approach is designed, an interventional study might be conducted to test the effectiveness of risk screening and intervention approach versus usual care that is aimed at optimizing wrist/hand functions

in the DRF population. The suitable research design for such a study would be a parallel design randomized controlled trial. The sample size estimates provided in the manuscript 5 should enable researchers to determine the feasibility of conducting such a study and organizing their resources. It may not be feasible to consider falls and osteoporotic fractures as the endpoints of the trial since this may require a substantial number of patients that are followed for many years. There is a possibility of a multicenter trial to facilitate recruitment of a large sample of patients if falls and osteoporotic fractures were the only outcomes in which researchers are interested in. However, the surrogate measures such as balance impairment, lower extremity muscle strength, and FOF can all be assessed to determine the benefits of the treatment interventions and such trial can be completed with recruiting fewer patients.

These future research directions are presented such that these studies can be done in a sequential and stepwise manner. This will allow the researchers to be confident in their existing knowledge so they can proceed with the further inquiry.

Conclusion

This thesis work summarizes early research and directions into risk-based interventions to individuals with DRF. This area is highly under-researched in the context of rehabilitation management of DRF. Though the studies in this thesis should not be considered as definitive to knowledge creation in this area, they represent high quality knowledge upon which further work in this area can be designed and undertaken. Different research studies conducted in this thesis work offer guidelines regarding how to measure the risk for chronic pain, falls, and osteoporotic fractures in individuals with

DRF. Research priorities to advance the findings of this thesis to the next stage of knowledge creation have been outlined. The thesis work also examined the feasibility of conducting future studies to determine the benefits of fall-prevention intervention in individuals at risk for falls after DRF. These future research studies will broaden the knowledge base and ensure a more comprehensive care delivery to individuals with DRF.

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Appendix 1. Acronyms (in their order of appearance in this thesis)

DRF - distal radius fracture

RCT - randomized controlled trial

ED - emergency departments

HRQOL - health-related quality of life

PRO - patient-reported outcome measures

PBT - performance-based tests

PRWE - Patient-Rated Wrist Evaluation

DASH - Disabilities of Arm, Shoulder, and Hand

MSKD - musculoskeletal disability

KTA - knowledge-to-action

RACE - **R**educing pain, **A**ctivating, **C**ognitive reshaping, **E**mpowering

MDC - minimal detectable change

MDIC - minimal clinically important difference

PA - physical activity

FOF - fear of falling

HS - helplessness subscale

RAI - Rheumatology Attitudes Index

PRWHE - Patient Rated Wrist/Hand Evaluation

IPQ - Illness Perception Questionnaire

CI - Comorbidity Index

PSFS - Patient-Specific Functional Scale

CID - clinically important differences

ICC - Intraclass correlation coefficient

κ - unweighted kappa

SEM - standard error of measurement

UE - upper extremity

RIAP - resection interposition arthroplasty

AUSCAN - Australian/Canadian Osteoarthritis Hand Index

PASE - physical activity scale for elderly

ROM - range of motion

CA - Cronbach's alpha

ES - effect size

SRM - standardized response means

CMC - carpometacarpal

MASS07 - Modern Activity Subjective Survey of 2007

SF-36 - Short-Form 36

MHQ - Michigan Hand Questionnaire

CTS - carpal tunnel syndrome

IRT - item response theory testing

CAT - catastrophizing subscale

CSQ - coping strategies questionnaire

OA - osteoarthritis

JHFT - Jebsen hand function test

SES - self-efficacy scale

SPADI - shoulder pain and disability index

TSK - Tampa scale of kinesiophobia

VAS - visual analogue scale

CI - confidence interval

SD - standard deviation

ADL - activities of daily living

TIA - tendon interposition arthroplasty

RR - relative risk

HULC - Hand and Upper Limb Center

AUC - area under the curve

CRPS - complex regional pain syndrome

LR - likelihood ratio

ABC - activity specific balance confidence scale

TUGT - Timed Up and Go Test

OLS - one leg standing

FES-I - Falls Efficacy Scale - International

IPAQ - international physical activity questionnaire

RAPA - rapid assessment of physical activity

FRAX - Fracture Risk Assessment Tool

DXA - dual energy X-ray absorptiometry

BMD - bone mineral density

STS - sit-to-stand test

HHD - hand held dynamometer

BBS - Berg Balance Scale

NRS - numeric rating scale

MET - metabolic equivalent of task

WOHC - William Osler Health Center

PPL - professional practice leader

FR - forward reach

CST - chair stand test

RPQ - risk perception questionnaire

ICF - International Classification of Functioning, Disability, and Health

KT - knowledge translation

PT - physiotherapists

OT - occupational therapists

Appendix 2. Research Ethics Board final approval letter - Western University

Research Western

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
Review Number:18441
Review Level: Delegated
Approved Local Adult Participants:60
Approved Local Minor Participants:0
Protocol Title: Developing a Screening Tool for Assessing Risk Profile of Patients following Distal Radius Fracture
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,University of Western Ontario
Sponsor:
Ethics Approval Date: April 05, 2012 **Expiry Date:**August 31, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Revised Western University Protocol	Revised inclusion criteria	

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Signature

Ethics Officer to Contact for Further Information

Janice Sutherland (jsutherl@uwo.ca)	Grace Kelly (grace.kelly@uwo.ca)	Shantel Walcott (swalcot@uwo.ca)

This is an official document. Please retain the original in your files.

The University *of* Western Ontario
Office of Research Ethics
Support Services Building Room 5150 • London, Ontario • CANADA - N6G 1G9
PH: 519-661-3036 • F: 519-850-2466 • ethics@uwo.ca • www.uwo.ca/research/ethics

Appendix 3. Research Ethics Board final approval letter - William Osler Health Center

WILLIAM OSLER HEALTH SYSTEM

Research Ethics Board
William Osler Health System
2100 Bovaird Drive East, Room S.3.907
Brampton ON L6R 3J7, Canada
Tele: (905) 494-2120, Ext. 50402 Fax: (905) 494-6562

Study Approval

Date: November 29, 2011

To: Saurabh Mehta
William Osler Health System
2100 Bovaird Dr
Brampton ON L6R 3J7

From: Ronald Heslegrave

RE: **Developing a Screening Tool for Assessing Risk Profile of Patients following Distal Radius Fracture**

Approval Date: *November 29 2011*
Expiry Date: *November 29 2012*

The Research Ethics Board of the William Osler Heath System has conducted a Delegated Review of the research protocol referenced above and approved the involvement of human subjects on the above captioned date. The quorum for approval did not involve any member associated with this project.

The approval of this study includes the following documents:

- ☐ WOHS Application for Human Subjects Research Review by Research Ethics Board
- ☐ Letter of Information and Consent Form dated November 24, 2011
- ☐ Research Protocol

Study continuation beyond one year requires submission of a renewal form prior to the expiry date or a study completion report must be received to close the file with the REB.

All REB approved studies may be subject to review by the William Osler REB and, as Principal Investigator, you are responsible for the ethical conduct of this study. If, during the course of the research, there are any serious adverse events, changes in the approved protocol or consent form, significant deviations or any new information that must be considered with respect to the study, these should be brought to the immediate attention of the Board.

On behalf of the William Osler Health System Research Ethics Board,

Ronald Heslegrave
Chair, Research Ethics Board
Room S.3.907
William Osler Health System
Brampton Civic Hospital
2100 Bovaird Drive East
Brampton ON L6R 3J7

Appendix 4
Research Ethics Board final approval letter - McMaster University

Hamilton Health Sciences

RESEARCH ETHICS BOARD

McMaster University

REB Office, 293 Wellington St. N., Suite 102, Hamilton, ON L8L 8E7
Telephone: 905-521-2100, Ext. 42013
Fax: 905-577-8378

March 29, 2012

PROJECT NUMBER: **12-161**

PROJECT TITLE: Developing a Screening Tool for Assessing Risk Profile of Patients following Distal Radius Fracture

PRINCIPAL INVESTIGATOR: **Saurabh Mehta**
LOCAL PI: **Dr. Joy MacDermid**

As you are aware your study was presented at the March 20, 2012 Research Ethics Board meeting where it received ***provisional*** approval from the full Research Ethics Board. The REB has identified the following issues/revisions:

- Please note in the original submission it was only signed by the LPI on page 17/18 – we also require the signature of the Principal Investigator on this same page;
- Also note we require an alternate/delegate signature on page 17/18 of the REB application as J. MacDermid cannot sign off on her own behalf.

Please note your revised submission should include a cover letter, which addresses each of the bullets identified in this letter, and the revisions should be ***clearly*** highlighted in each revised document. Upon receipt of the revised submission, final approval will be forthcoming.

PLEASE QUOTE THE ABOVE-REFERENCE PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE

Sincerely,

S. Salama

Suzette Salama PhD.,
Chair, Research Ethics Board

Appendix 5
Information letter and consent for participants - Hand and Upper Limb Center

Dr. Joy C. MacDermid, Local Principal Investigator
Saurabh Mehta, PhD Student
School of Rehabilitation Science, McMaster University, Canada

Address:
Lawson Health Research Institute, Room DB-222
268 Grosvenor Street
London, Ontario N6A 4L6
Phone: 519-646-6100 Ext: 64636 **(Office HULC)**
Fax: 519-646-6049
E-mail: jmacderm@uwo.ca

LETTER OF INFORMATION AND CONSENT FORM

Title of Project: Developing a Screening Tool for Assessing Risk Profile of Patients following Distal Radius Fracture

Study Local Principal Investigator: Dr. Joy MacDermid, PhD, Associate Professor, Departments of Surgery and Epidemiology, University of Western Ontario, London, Canada, Tel no: 519-646-6100 Ext: 64636 **(Office HULC)**

Project Leader: Saurabh Mehta, PhD Student, School of Rehabilitation Science, McMaster University, Canada, Tel no: 647-242-9899

Co-Investigator: Ruby Grewal, MD, MSc, FRCSC, Assistant Professor, Division of Orthopedics, University of Western Ontario, London, Canada, Tel no: 519-646-6286

Participant/Patient Name, Age, and ID#:

Sponsors: None

Introduction and Purpose of the Study: You are being invited to participate in this research study conducted by Joy MacDermid and Saurabh Mehta. The purpose of this is study is to assess your balance and risk for future falls following the wrist fracture injury that you have sustained. The study will recruit approximately 80 patients in total who have sustained wrist fracture within the last 4-8 weeks. Of these, 60 patients will be recruited locally from the Hand and Upper Limb Center (HULC) within 4-8 weeks following their injury. In order to decide whether or not you want to be a part of this research study, you should know what is involved and the potential risks and benefits.

This Letter of Information gives you detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign the consent form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.

Description of Research and Testing Procedures: If you participate in this study, you will undergo five tests to assess your balance and muscle strength of selected leg muscles. Moreover, you will be asked to complete a total of eight standardized questionnaires aimed to assess your fear of falling, your physical activity level, possibility of sustaining future fractures, and your wrist pain and functions. Many of these tests and questionnaires are not routinely used by therapists while assessing patients with wrist fractures such as you. However, they are commonly used in patients with other fall related injuries such as hip fractures or vertebral fractures.

Initially, demographic data such as your age, occupation, hand dominance, date of injury, treatments received, weight, and height will be recorded. Following that, you will undergo the testing procedures described below.

Three tests will be conducted to assess your balance. In the first test, you will sit in a chair and on the count of "go" you will get up, walk for 10 feet, turn back to return in the chair. The time taken to complete this procedure will be recorded. For the second test, you will stand near a wall with your dominant arm elevated at the shoulder level parallel to the wall. You will then reach forward as far as you can without having to take a step. The distance of this forward reaching will be measured. For the third test, you will be asked to stand on one leg with your arms folded. The length of time that you can stand for without losing your balance will be recorded. This test will be done for both the legs. In the fourth test, you will seat in a chair. Following that you will be asked to stand up and sit down for as many times as you can in the span of 30 seconds and the number of times you get up from the chair will be recorded. For the final test, the strength of hip and knee muscles will be assessed for both sides with you either in sitting, standing or lying on your back. You will have 1 minute rest between each of the tests. If you are very tired, you will be free to rest longer. These tests will take approximately 30 minutes.

The questionnaires that you will be asked to complete involve answering questions that ask your current activity level and your perceptions about fear of falling. It will take approximately 30 minutes to complete these questionnaires. To avoid any fatigue, you will undergo the first three tests above, then answer the questionnaires, and finally undergo the remaining two tests.

In total, the assessment session will last for 60-70 minutes. You will be asked to return again in 2-7 days to undergo the same testing. At this time, the assessment sessions

will last for approximately 60 minutes. All the testing will be conducted at the Clinical Research Laboratory located within the Hand and Upper Limb Centre, St. Joseph's Healthcare, London, Ontario.

Risks and discomforts to you if you participate in this study: Research related injuries are not anticipated since this is an assessment study and primarily involves common tests and answering standardized questionnaires**.** Some aspect of the study involves assessing your balance. These tests may cause loss of balance and may also cause injury to your arms and/or legs. However, a study investigator will always be in a position to provide support and prevent falls. Since these tests are extremely common, the study investigators are well trained to administer them and prevent any potential injuries. Also, in our experience these tests have rarely caused any falls or related injuries when administered by trained professionals.

Benefits of Participating in the Study: There is no direct benefit to you from participation in this study. However, your participation will help us get new knowledge to determine which tests are suitable to screen patients with wrist fractures for balance impairment, risk for falls, and risk for future fractures.

Voluntary Participation: You may refuse to participate, refuse to undergo any tests or answer any questions. Your participation in the study is completely voluntary and you may choose to stop participating or withdraw your consent at any time during the period of the study. Your decision of not participating in the study will not influence the treatment you may be receiving either now, or in the future at the Hand and Upper Limb Center, London, Ontario.

If you are participating in another study at this time, please inform the study researcher to determine if it is appropriate for you to participate in this study. However, our study does not involve any intervention which may affect the outcome of any other interventions you may be receiving currently.

Privacy and Confidentiality: The investigators of the study will assign a 'code' that will act as a unique identifier to you. The physical data sheets and electronic data will <u>not</u> be labeled with your name. The unique code number is the only identifier people outside the study will see. Your research records will be stored in a locked cabinet in a secure office.

The data will be retained for a minimum of 3 years following the completion of the study and the publication of the results. All records will be destroyed using confidential recycling program adopted by the hospital. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your explicit consent to the disclosure.

Representatives of research team and authorized study personnel may require access to your records for the purpose of monitoring the research. Also, representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Questions about the Research? If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute at (519) 667-6649.

No waiver of rights: You do not waive any legal rights by signing this consent form.

Compensation: There will not be any compensation provided to you for your participation in the study. We will reimburse you for any parking expenses (at maximum of $15) that you may incur when you visit the Research Laboratory at the Hand and Upper Limb Center, London, Ontario for data collection.

Costs of participating in the study: No, there will not be any direct costs to you for participating in the study.

Publication Results: If the results of the study are published, your name will not be used. If you would like to receive a copy of the overall results of this study please put your name and address on a blank piece of paper (separate from the questionnaire) and give it to the study researcher.

You will be given a copy of this letter of information and consent form once it has been signed.

CONSENT FORM

SIGNATURE OF RESEARCH PARTICIPANT:

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

I_____, consent to participate in the above research study titled "Developing a Screening Tool for Assessing Risk Profile of Patients following Distal Radius Fracture" conducted by Joy MacDermid and Saurabh Mehta.

_____	_____	_____
Name of Participant	Signature of the Participant	Date

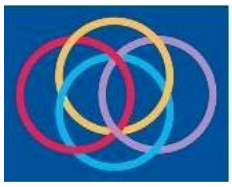
_____	_____	_____
Name of Person Obtaining Consent	Signature of the Person Obtaining Consent	Date

SIGNATURE OF INVESTIGATOR:

In my judgment, the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____	_____
Signature of Investigator	Date

Appendix 6
Information letter and consent for participants - William Osler Health Center



WILLIAM OSLER HEALTH SYSTEM

Saurabh Mehta, PhD Student and Principal Investigator
School of Rehabilitation Science, McMaster University, Canada
Dr. Joy C. MacDermid, Co-Investigator

Address:
Rm 402 - 1400 Main Street West
Hamilton, Ontario L8S 1C7
Phone: 905-525-9140 Ext: 26410 **(graduate Student Office)**
E-mail: mehtas8@mcmaster.ca

LETTER OF INFORMATION AND CONSENT FORM

Title of Project: Developing a Screening Tool for Assessing Risk Profile of Patients following Distal Radius Fracture

Principal Investigator: Saurabh Mehta, PhD Student, School of Rehabilitation Science, McMaster University, Canada,
Participant/Patient Name, Age, and ID#:

Sponsors: None

Introduction and Purpose of the Study: You are being invited to participate in this research study conducted by Saurabh Mehta and his colleagues. The purpose of this is study is to assess your balance and risk for future falls following the wrist fracture injury that you have sustained. The study will recruit approximately 66 patients who have sustained wrist fracture within the last 4-8 weeks. In order to decide whether or not you want to be a part of this research study, you should know what is involved and the potential risks and benefits. This Letter of Information gives you detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign the consent form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.

Description of Research and Testing Procedures: If you participate in this study, you will undergo five tests to assess your balance and muscle strength of selected leg muscles. Moreover, you will be asked to complete a total of eight standardized questionnaires aimed to assess your fear of falling, your physical activity level, possibility of sustaining future fractures, and your wrist pain and functions. Many of these tests and questionnaires are not routinely used by therapists while assessing patients with wrist fractures such as you. However, they are commonly used in patients with other fall related injuries such as hip fractures or vertebral fractures.

Initially, demographic data such as your age, occupation, hand dominance, date of injury, treatments received, weight, and height will be recorded. Following that, you will undergo the testing procedures described below.

Three tests will be conducted to assess your balance. In the first test, you will sit in a chair and on the count of "go" you will get up, walk for 10 feet, turn back to return in the chair. The time taken to complete this procedure will be recorded. For the second test, you will stand near a wall with your dominant arm elevated at the shoulder level parallel to the wall. You will then reach forward as far as you can without having to take a step. The distance of this forward reaching will be measured. For the third test, you will be asked to stand on one leg with your arms folded. The length of time that you can stand for without losing your balance will be recorded. This test will be done for both the legs. In the fourth test, you will seat in a chair. Following that you will be asked to stand up and sit down for as many times as you can in the span of 30 seconds and the number of times you get up from the chair will be recorded. For the final test, the strength of hip and knee muscles will be assessed for both sides with you either in sitting, standing or lying on your back. You will have 1 minute rest between each of the tests. If you are very tired, you will be free to rest longer. These tests will take approximately 30 minutes.

The questionnaires that you will be asked to complete involve answering questions that ask your current activity level and your perceptions about fear of falling. It will take approximately 30 minutes to complete these questionnaires. To avoid any fatigue, you will undergo the first three tests above, then answer the questionnaires, and finally undergo the remaining two tests.

In total, the assessment session will last for 60-70 minutes. You will be asked to return again in 2-7 days to undergo the same testing. At this time, the assessment sessions will last for approximately 60 minutes. All the testing will be conducted at the outpatient rehabilitation department located within the Brampton Civic Hospital, Brampton, Ontario.

Risks and discomforts to you if you participate in this study: Research related injuries are not anticipated since this is an assessment study and primarily involves common tests

and answering standardized questionnaires**.** Some aspect of the study involves assessing your balance. These tests may cause loss of balance and may also cause injury to your arms and/or legs. However, a study investigator will always be in a position to provide support and prevent falls. Since these tests are extremely common, the study investigators are well trained to administer them and prevent any potential injuries. Also, in our experience these tests have rarely caused any falls or related injuries when administered by trained professionals.

Benefits of Participating in the Study: There is no direct benefit to you from participation in this study. However, your participation will help us get new knowledge to determine which tests are suitable to screen patients with wrist fractures for balance impairment, risk for falls, and risk for future fractures.

Voluntary Participation: You may refuse to participate, refuse to undergo any tests or answer any questions. Your participation in the study is completely voluntary and you may choose to stop participating or withdraw your consent at any time during the period of the study. Your decision of not participating in the study will not influence the treatment you may be receiving either now, or in the future at the Brampton Civic Hospital, Brampton, Ontario.

If you are participating in another study at this time, please inform the study researcher to determine if it is appropriate for you to participate in this study. However, our study does not involve any intervention which may affect the outcome of any other interventions you may be receiving currently.

Privacy and Confidentiality: The investigators of the study will assign a 'code' that will act as a unique identifier to you. The physical data sheets and electronic data will not be labeled with your name. The unique code number is the only identifier people outside the study will see. Your research records will be stored in a locked cabinet in a secure office.

The data will be retained for a minimum of 3 years following the completion of the study and the publication of the results. All records will be shredded in a confidential manner. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your explicit consent to the disclosure.

Representatives of research team and authorized study personnel may require access to your records for the purpose of monitoring the research. Also, representatives of The William Osler Health Center Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

If you have any questions about your rights as a participant in a research study, you may contact the William Osler Health System – Research Ethics Board at 905-494-2120 x50448

No waiver of rights: You do not waive any legal rights by signing this consent form.

Compensation: There will not be any compensation provided to you for your participation in the study. We will reimburse you for any parking expenses (at maximum of $15) that you may incur when you visit the outpatient rehabilitation department at the Brampton Civic Hospital, Brampton, Ontario for data collection.

Costs of participating in the study: No, there will not be any direct costs to you for participating in the study.

Publication Results: If the results of the study are published, your name will not be used. If you would like to receive a copy of the overall results of this study please put your name and address on a blank piece of paper (separate from the questionnaire) and give it to the study researcher.

You will be given a copy of this letter of information and consent form once it has been signed.

CONSENT FORM

SIGNATURE OF RESEARCH PARTICIPANT:

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

I_____, consent to participate in the above research study titled "Developing a Screening Tool for Assessing Risk Profile of Patients following Distal Radius Fracture" conducted by Saurabh Mehta and Joy MacDermid.

_____	_____	_____
Name of Participant	Signature of the Participant	Date

_____	_____	_____
Name of Person Obtaining Consent	Signature of the Person Obtaining Consent	Date

SIGNATURE OF INVESTIGATOR:

In my judgment, the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____

Signature of Investigator Date