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The Effect of High Baseline Pain on Impairment Outcomes One Year After Distal Radius Fracture

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Abstract

Objective

The purpose of this study is to evaluate whether high baseline pain predicts impairment outcomes in grip strength or wrist range of motion (ROM) at one year after a distal radius fracture (DRF). Impairments occur for less than 15% of patients.

Methods:

In this cohort study patients with a DRF were recruited from a hand clinic in London, Ontario. This data was collected at two evaluation time points: at baseline (within the first 10 days after fracture) and at one year after fracture. Baseline pain was assessed using the pain subscale of the Patient-Rated Wrist Evaluation (PRWE) and classified as high if it exceeded 35/50. Grip strength and ROM scores were evaluated at one year and compared to patient satisfaction benchmarks. Relative risks (RR) were calculated to assess the magnitude of impairment risk with high pain.

Results:

A sample of 277 patients with a DRF, with a mean age of 60 ± 11.5 years, was included. The majority of relative risks were not significant and did not support that high baseline pain is a clinically important risk factor for poor impairment scores: grip strength RR 1.5 CI (0.69 – 3.09) and ROM's flexion-extension RR 1.2 CI (1.05 – 1.36), radial-ulnar deviation RR 1.1 CI (0.94 – 1.29) and pronation-supination RR 1.0 CI (0.86 – 1.38).

Conclusion:

Therapists can reassure patients that even when high pain is present after a fracture, the potential for recovery of grip strength and ROM is not much different from patients with lower pain.

Keywords: Pain, grip strength, range of motion, physical impairment, patient satisfaction

Co-Authorship Statement

The thesis format and research question were developed with the assistance and supervision of Dr. Joy Christine MacDermid. My advisory committee members, Dr. Ruby Grewal and Dr. Michael L. Szekeres, assisted me by providing me valuable guidance. Data collection was done by two research assistants at the Roth | McFarlane Hand and Upper Limb Centre located in the St. Joseph's Hospital, London, Ontario, Canada. Statistical analysis, interpretation of results and preparation of the manuscripts were done by Farrukh Riaz.

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Chapter 1 Introduction

Distal radius fractures (DRFs) are common upper extremity fractures caused by a fall on a overextended wrist (Rubin, Orbach, Chezar, & Rozen, 2017; MacIntyre & Dewan, 2016). A DRF usually occurs due to the displacement of the lower end of the radius within 1.5 inches from the wrist joint (Young & Rayan, 2000). Depending on the amount of movement of the fractured segment, DRFs are broadly categorized into extra-articular and intra-articular fractures. In extra-articular DRFs, the fractured segment does not translate into the articulating surfaces forming the wrist joint. In intra-articular DRFs, the fractured segment translates into the wrist joint causing internal derangements within the carpals. DRFs are also characterized as either open or closed. In open DRFs, the fractured segments are exposed through the skin and may need surgical intervention. In contrast, the fractured segments are not exposed in the closed type of DRFs. Among various identified factors that determine poor functional recovery after surgical reduction of DRF, higher age, lower grip strength, and the low underlying status of bone mineralization are known to be few of the key predictors (Roh, Noh, Gong, & Baek, 2017).

Given that a wide variation exists in the treatment and rehabilitation of patients with DRF, (Michlovitz, Harris, & Watkins, 2004), long-term physical impairments continue in patients even up to four years after a DRF (Ploegmakers, The, Wang, Brutty, & Ackland, 2015). A thorough examination of baseline pain and its role in predicting physical impairment measures in grip strength and ROM at one year may enable clinicians to communicate with their patients about the probable level of functional recovery.

1.1 Epidemiology

The incidence of DRF is reported to be increasing globally (MacIntyre & Dewan, 2016). DRF cases in the USA range from 76,080 to 87,315 per year (Chung, Shauver, & Birkmeyer, 2009). It has been anticipated that the total costs for surgical management of DRFs could reach up to USD 240 million annually (Shauver, Yin, Banerjee, & Chung, 2011). Moreover, in Britain 71,000 adult women and men reported a DRF in 1991 (O'Neill et al., 2001). A population-based study from Finland showed the incidence of DRF to be 258 per 100,000 per year (Flinkkilä et al., 2011) and the incidence rate in Italy was found to be 298 DRF individuals per 100,000 (Piscitelli et al., 2011). A study from Norway reported that the incidence of DRF in women who are 85 years of age is 120 per 10,000 population annually and in men 33 per 10,000 in those older than 85 years (Diamantopoulos et al., 2012).

A 3:1 DRF incidence ratio between females to males is found in Canada (Jaglal et al., 2004). It has been revealed that in the USA, a female to male rate ratio in white peoples was 4.88 (95% C.I 4.66 to 5.11) (Baron et al., 1996). Moreover, in a British study a female to male ratio of 3.9:1 has been reported (Thompson, Taylor, & Dawson, 2004). Similarly, a Norwegian population-based study showed 4:1 incidence between females and males (Diamantopoulos et al., 2012).

A DRF is a common injury among the elderly (Liporace, Adams, Capo, & Koval, 2009). Females over 65 years of age were reported to be at a higher risk for DRF (Baron et al., 1996). Older adults sustain these fractures by falling from a standing height or due to a low-energy trauma (Diaz-Garcia et al., 2011). It may be reasonable to assume that obesity among elderly individuals may predispose them to complex DRFs when they fall from a standing height (Ebinger, Koehler, Dolan, McDonald, & Shah, 2016). The severity of these fractures has been associated with the amount of bone mineralization (Liporace et al., 2009) and may not only be a postmenopausal factor (Singer, McLauchlan, Robinson, & Christie, 1998). Among young adults, DRFs occur mainly due to outdoor sporting activities or motor vehicle accidents (Diaz-Garcia et al., 2011; Flinkkilä et al., 2011).

Seasonal variation due to snowy weather conditions in winter months when sidewalks are slippery has been identified to play a role in increased incidence of DRF (Burget et al., 2016; Flinkkilä et al., 2011; Róbertsson, Jónsson, & Sigurjónsson, 1990). Individuals living in urban areas have been reported to present with more DRFs than their rural counterparts (Diamantopoulos et al., 2012). However, this trend shifts in summer season due to the nature of work in the countryside which frequently involves manual labor with high-risk activities (Diamantopoulos et al., 2012).

1.2 Etiology

Each type of DRF seems to differ depending on where the actual break occurs and also in relation to the movement of the fractured segment. In most cases, DRFs occur due to falling on an outstretched hand (Meena, Sharma, Sambharia, & Dawar, 2014). A Colles fracture is an extra-articular fracture that involves the distal metaphyseal end of the radius, which is displaced dorsally and angulated with radial shortening (Colles, 1814). In comparison, a Smith fracture is a fracture of the distal radius with volar displacement (Smith, 1847).

1.3 Classification systems

No consensus for treatment recommendations exists (Bruce et al., 2016; Burnier, Herzberg, & Izem, 2016; Cherubino, Bini, & Marcolli, 2010; Shehovych et al., 2016). In fact, there are currently 15 acknowledged classifications of DRFs (Shehovych et al., 2016). The classification of a DRF may be important for accurate assessment, to plan suitable treatment and to predict the outcome (Ilyas & Jupiter, 2010; Cooney, 1993). Regardless, a lack of standard classification of DRFs has been reported for satisfactory clinical use (Slutsky & Osterman, 2009). A recent study that examined the most suitable classification of DRFs concluded that although classification plays a vital role in education, research, understanding the severity of fractures, and determining options for treatment (Bruce et al., 2016; Flinkkilä et al., 2011), determining clinical reliability and its validity was difficult given the existing classification systems (Bruce et al., 2016; Obert et al., 2016). Injuries to soft tissue structures like the Triangular Fibrocartilage Complex (TFCC) have not been included in the classification systems and are infrequently assessed (Scheer, Hammerby, & Adolfsson, 2010). Additionally, it has been found that a consistent classification of DRF should consider the pattern of fracture, the involvement of articular surfaces, and the extent of communition and soft tissue involvement (Flinkkilä, 2014).

1.4 Definitions of terms impairments, activity limitations and participation restrictions after a DRF

The World Health Organization introduced a framework in 1980 to classify consequences of disease (World Health Organization [WHO], (1980). This framework was mainly focused on three domains of health outcomes: impairment, disability, and handicap. In 2001 the WHO updated its framework to International Classification of Functioning, Disability and Health (ICF) to better understand the health condition of a patient (Kostanjsek, 2011). This updated version of the (ICF, 2001) classifies the impact of health conditions based on three domains: body structure/function, activity and participation. Impairments are issues in bodily functions or with body structures. Activity limitations relate to problems in accomplishing activities. Participation restriction refers to difficulties in participation in normal life settings (ICF, 2001).

Various authors have studied the relationship between measures of physical impairments and activity limitations after a wrist fracture or a DRF (MacDermid, Donner, Richards, & Roth, 2002; Tremayne, Taylor, Mcburney, & Baskus, 2002). MacDermid et al., (2002) found moderate relationship between physical impairments and the patient-reported function (r = 0.50) at six months following a DRF. Optimal recovery in function after a DRF has been reported to occur by six months after fracture management (Chung et al., 2006; MacDermid, Roth, & Richards, 2003; MacDermid, Donner, Richards, & Roth, 2002; MacDermid, Richards, & Roth, 2001). The clinical outcomes after a DRF have been assessed by measuring impairments in the body structure by radiographs (X-rays), or by measuring physical impairments such as grip strength, range of motion, pinch strength or dexterity. During hand rehabilitation, a patients progression in the therapy program is commonly evaluated on the physical impairment measures such as grip strengh and ROM by using quantitative measurement instruments like dynamometer and a goniometer and/or by self-reported function scales such as the Patient-Rated Wrist Evaluation (PRWE) (MacDermid, 1996), or the Disabilities of the Arm, Shoulder, and Hand (DASH) (Hudak, Amadio, & Bombardier, 1996), or the Michigan Hand Outcomes Questionnaire (MHQ) (Chung, Pillsbury, Waiters, Hayward, & Arbor., 1998).

1.5 Risk factors for poor impairment outcomes after a DRF

Previous studies have identified several factors known to influence outcomes after a DRF, some of which relate to the nature of the injury itself. For example, fracture communition (Cowie, Anakwe, & McQueen, 2015) and the length of the radius (MacDermid et al., 2002; Trumble, Wagner, Hanel, Vedder, & Gilbert, 1998) both influence outcome in different ways. It has also been reported that despite deficient radiographic results after a DRF satisfactory functional outcomes may be achieved (Plant, Parsons, & Costa, 2017; Uzoigwe & Johnson, 2016; Young & Rayan, 2000).

Many other factors related to the patients themselves such as their general health levels, lifestyles, and psychological well-being, can have even greater influence on possible outcomes. For example, factors intrinsic to patients' health can determine outcomes, and such factors include complex regional pain syndrome (CRPS) (Erhard, 2016), hand stiffness (Egol, Karia, Zingman, Lee, & Paksima, 2014), multiple disease diagnoses (Grewal, MacDermid, Pope, & Chesworth, 2007), decreased bone density (Roh et al., 2017; Hollevoet & Verdonk, 2003) and malunion (Brogren, Wagner, Petranek, & Atroshi, 2013).

Nonetheless, patient-reported outcomes after the fracture itself is determined by lifestyle and other factors like female gender with 65 years of age or over (Mehta et al., 2015b), age (Roh et al., 2017; Chung, Kotsis, & Kim, 2007; Chung & Haas, 2009; Cowie, Anakwe, & McQueen, 2015), education level (Grewal et al., 2007), socioeconomic status (Chung et al., 2007), injury compensation (Grewal et al., 2007; MacDermid et al., 2002), and work demands (MacDermid, Roth, & McMurtry, 2007). This indicates a potential indirect effect of these factors on DRF outcomes.

Other studies have examined another determinant of health psychological well-being informs outcomes after a DRF. A cohort study by Yeoh and colleagues (2016) looked at the association of baseline symptoms of depression on one-year outcomes (SF-36, the DASH, complication and CRPS). The study was conducted on 228 patients after a DRF with a mean age of 67 (SD = 0.59). Depression in that study was measured at the baseline (measured within seven or ten days of a DRF, or emergency department visit) using the

Centre of Epidemiologic Studies Depression (CES-D) scale. The results indicated that patients with a high baseline depression scale scores (CES-D \geq 16) reported higher one year DASH scores (poor outcome) (M = 20, SD = 2.3) compared to patients who did not report high baseline depression score (CES-D < 16) (M = 11, SD = 1.3) (P = 0.003) and a gradual progression in the DASH score within one-year (P = 0.02). The multivariate linear regression analysis indicated that baseline depression is a significant predictor of higher scores (poor outcome) on the DASH scale at one year (3.7, P = 0.007). These findings indicate that for each unit increase in the baseline (CES-D score), patients showed a 3.7 units difference in their one-year DASH scores and to a lower degree predicted change in DASH scores in the first one year (2.9, P = 0.026) (Yeoh et al., 2016). Additionally, Bot and colleagues (2012) indicated that in patients after a DRF, the pain anxiety as measured by the pain anxiety symptoms scale (PASS) was correlated with grip strength scores of the injured hand. Pain anxiety explained 9% of the variability in grip strength score (adjusted $\mathbb{R}^2 = 0.086$, P = 0.022) which was measured at six weeks after a non-surgical treatment of a DRF (Bot, Mulders, Fostvedt, & Ring, 2012).

Pain is an anticipated complication following a DRF (Mehta et al., 2015b), but is most severe in the first week (Josefsson, Rosengren, & Karlsson, 2014). However, each patient experiences pain differently, and this partially relates to their previous medical history (Grewal et al., 2007). In patients who report atypically high pain, intensities require additional evaluation.

1.6 Management of DRF

1.6.1 Surgical management

The treatment of DRFs mainly involves conservative management by immobilization in a cast or orthosis. If surgical management is required, it usually includes internal or external fixation or percutaneous pinning. In the absence of multiple injuries, the majority of patients achieve optimal functional levels within six months after a DRF (MacDermid et al., 2003). The management of DRFs is complex, as there are no clinical practice guidelines in place for surgical or conservative management (Bruce et al., 2016; Burnier et al., 2010; Hammert et al., 2013). Therefore, it has been

suggested that treatment decisions should be based on the overall health and functional needs of the patient (Burnier et al., 2016).

Cherubino et al. (2010) suggested that a simple approach to management should be reasonable, less invasive and efficient in controlling the fracture variables. Hence, the more difficult interventions should be set aside for conditions presenting with difficulty in reduction and stabilization (Cherubino et al., 2010). Several essential factors should be taken into consideration for the effective management of a DRF: bone mineralization (Cherubino et al., 2010), number of bony fragments (Cherubino et al., 2010), risk of reduction loss (Cherubino et al., 2010), health condition of the patient (Cherubino et al., 2010), experience of the surgeon (Childs et al., 2016), cost to benefit ratio for the patient and society (Cherubino et al., 2010), functional demands (Young & Rayan, 2000) and patient preferences (Hammert, Kramer, Graham, & Keith, 2013). However, surgeons' preferences are known to have a strong influence on the selection of suitable treatment option (Walenkamp, Mulders, Goslings, Westert, & Schep, 2017).

1.6.2 Rehabilitation management

The goal of DRF rehabilitation is pain management and early mobilization (Hammert et al., 2013; Diaz-Garcia, 2012; Hagenaars et al., 2016; Michlovitz, LaStayo, Alzner, & Watson, 2001; Plate et al., 2015) which may reduce the limitations in ROM and function. Moreover, exercise and education remained the most commonly prescribed interventions by physical therapists for patients after a DRF (Bruder, Taylor, Dodd, & Shields, 2013). Early initiation of ROM exercises is essential, as disuse is reported to be a causative factor for decreasing wrist function (Hagenaars et al., 2016). Supervised hand therapy or a home exercise program (HEP) are commonly prescribed after removing the cast (Valdes et al., 2015). Valdes et al. (2015) reported that both supervised therapy and HEP would improve function in patients with DRF in the absence of complications.

The rehabilitation of a DRF is reported to be chiefly divided into 3 phases, with the first phase considered to be Phase I: Post-operative day (POD) 1 to 45 days (Thomas & Zanin, 2016). The main aim is to provide an optimum environment for the healing of the fracture segments, control pain, manage edema, prevent tendon adhesions maintaining the cortical

image of movement and prevent tendon adhesions (Thomas & Zanin, 2016; Harhaus et al., 2016). Phase II, POD 45 to 3 months, attempts to avoid scar tissue contracture, pain modulation modalities such as Transcutaneous Electrical Nerve Stimulation (TENS), heat modalities, functional orthoses, active ROM exercises, passive ROM with caution and joint mobilization (Thomas & Zanin, 2016; Weinstock, 1999). Furthermore, a systematic review concluded that there is moderate evidence supporting the use of passive ROM exercises to increase ROM after fracture and immobilization (Michlovitz et al., 2001). Lastly, Phase III, three months POD and onwards, centers on muscle strengthening and proprioception (Thomas & Zanin, 2016) and re-education of functional pattern of movement (Michlovitz et al., 2001).

A systematic review of the effectiveness of interventions used for rehabilitation in patients after DRF treated either surgically or non-surgically concluded that there is inadequate evidence for the relative effectiveness of different rehabilitation interventions used for the treatment of adult patients with DRF (Handoll & Elliott, 2015).

1.7 Common physical impairment measures after a DRF

1.7.1 Grip strength

The purpose of measuring grip strength is to evaluate hand muscle strength to determine the efficacy of various surgical interventions or treatment programs (Waljee, Ladd, Macdermid, Rozental, & Wolfe, 2016; Shim et al., 2013; MacDermid, Richards, Donner, Bellamy, & Roth, 2000; Mathiowetz, et al., 1985; Rantanen et al., 1999). Evaluations of the grip strength can be done by using a dynamometer (Roberts et al., 2011). Comparing the affected grip strength scores over the unaffected side scores is known to reduce the high variation commonly seen across genders and age across participants (Bot, Mulders, Fostvedt, & Ring, 2012; MacDermid et al., 2000; Thorngren & Werner, 1979).

1.7.2 Range of motion (ROM)

The standard types of ROM assessment include active, active-assisted or passive movements. Force applied by the examiner against one of the limbs involved in motion for the quantitative measurements of passive ROM may be a source of inaccurate ROM measures (Domholdt, E. 2000). Most often goniometers are used as a clinical tool to quantify available degrees of motion at a particular joint. The ROMs are commonly measured using a standard goniometer (Norkin & White, 2009) or by computerized goniometers (Tajali, MacDermid, Grewal, & Young, 2016).

1.8 Common patient-reported measures (PROs) after a DRF

1.8.1 Patient-rated wrist evaluation (PRWE)

The PRWE (MacDermid, 1996) is used to measure pain and disability outcomes in wrists and hands after a DRF (Mehta, MacDermid, Richardson, MacIntyre, & Grewal, 2015a). The PRWE is a 15-item questionnaire, which includes separate sub-scales for measuring pain (5 items) and function (10 items) (MacDermid, 1996). The scores on the function subscale are averaged, and the total score of pain and function is calculated by dividing the pain scores over the function scores (MacDermid, 1996). For clinical interpretation, lower scores mean better outcomes, whereas scores on the higher end mean poor results (MacDermid, 1996). This scale has demonstrated measurement accuracy when using either its sub-scales or the questionnaire in its entirety (MacDermid, Turgeon, Richards, Beadle, & Roth, 1998; Mehta et al., 2015a).

1.8.2 Disabilities of the arm, shoulder and hand (DASH)

The DASH is a patient-reported outcomes questionnaire used to measure the musculoskeletal disability in the upper extremity as a whole or for an individual joint (Hudak, Amadio, & Bombardier, 1996). This scale enquires about the extent of physical inabilities in function and presenting symptoms experienced within the last week (Hudak et al., 1996). This scale is comprised of 30 questions: 1 to 21 enquire about the extent of disability while performing functional activities of arm; 22 to 23 determine the influence of functional inability on social activities and work or ADL; 24 to 28 examine pain at rest, pain while doing particular activity, tingling sensation, weakness, and stiffness; and finally 29 to 30 ask about the interference of pain with sleep and coping strategies. The above questions are rated by patients from 1 (absence of disability) to 5 (maximum disability) and may not be calculated if there are more than three missing responses

(Hudak et al., 1996). The DASH scale is reported to be valid (Beaton et al., 2001) and to reflect the extent of treatment efficiency achieved (Husted et al., 2000). A relatively concise version, the Quick DASH, is also used clinically (Gummesson, Ward, & Atroshi, 2006). It constitutes 11 items and is also reported to be reliable (Gummesson et al., 2006). The Quick DASH scale measures final disability scores on a scale of 0 to 100, with lower scores indicating less disability (Gummesson et al., 2006).

1.8.3 Michigan hand outcomes questionnaire (MHQ)

The MHQ is used to evaluate hand function after various hand related disorders (Chung et al., 1998). The MHQ evaluates responses based on 37 questions on six domains, including hand function, activities of daily living (ADLs), pain, work performance, aesthetics and patient satisfaction (Chung et al., 1998). In this questionnaire, patient responses are based on a score of 100 (0 = poor hand function and 100 = good hand function) (Chung et al., 1998). In contrast, the response to pain domains are rated on a scale of (0 = absence of pain and 100 = severe pain), and these pain responses are reverse coded for the final calculation (Chung et al., 1998). Response criteria of 50% should be met in each domain to obtain a final score, and an overall MHQ score can be achieved by summing the scores of all 6 scales and then dividing by 6; however, if there are any missing responses an average score is still used for calculation (Chung et al., 1998). The MHQ has demonstrated reliability and validity (Kotsis et al., 2007). Also, the MHQ has been reported to be responsive to detecting variations in clinical presentation over time (Chung, Hamill, Walters, & Hayward, 1999), especially in patients after they have received a diagnosis of DRF (Kotsis, Lau, & Chung, 2007).

The psychometric properties of both the PRWE and DASH specifically in relation to the DRF population has been previously studied (Goldhahn, Beaton, Ladd, Macdermid, & Hoang-Kim, 2014; Hoang-Kim, Pegreffi, Moroni, & Ladd, 2011; Goldhahn, Angst, & Simmen, 2008). The PRWE was primarily developed as a clinical tool for measuring self-reported pain and functional disability in wrist and hand after a DRF (MacDermid, 1996). DASH is a regional tool that is used to assess patient-reported musculoskeletal disability in the upper extremity or at a specific joint (Hudak, Amadio, & Bombardier, 1996). Both the PRWE and DASH have a different weighting for pain items. The PRWE

equally evaluates its pain and function subscales (50% each). Of the five pain subscale questions, item one enquire about resting pain, items two to four address aggravating factors while performing various activities and the fifth item enquire about the frequency of pain. Moreover, the responsiveness of the PRWE have been demonstrated in patients immobilized in a cast in which the evaluation of physical impairment measures are contraindicated immediately after a DRF (MacDermid et al., 2000). On the contrary, the DASH addresses symptoms pertaining to pain only in two of its questions (less than 7%) out of a maximum 30 questions. In the DASH the first item enquires about region specific pain and the second question pertains to pain pattern while performing any particular activity.

1.9 Objective of this thesis

A previous study determined that high baseline pain predicts one-year chronic pain and physical disability (Mehta et al., 2015b) but did not examine physical impairment outcome measures (grip strength and ROM). Therefore, the aim of this thesis is to examine the whether high pain intensity as measured by the PRWE at baseline (within 10 days after DRF) is related to poor impairment outcome measures (grip strength and ROM) one year after a DRF. A secondary aim is to describe the one-year impairment scores.

1.10 Research questions

1. Are there differences in physical impairment measures (grip strength and range of motion) among people with or without high baseline pain?

2. Is there a relationship between baseline pain scores and physical impairments (grip strength or range of motion) scores at one-year?

3. Does high baseline pain present a risk for poor physical impairments (grip strength or range of motion)?

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2 Does high baseline pain on the PRWE predict impairment measures of grip strength and wrist range of motion in adults one-year post distal radius fracture?

2.1 Introduction

Distal radius fractures (DRFs) remain one of the most common types of fractures (MacIntyre & Dewan, 2016; Slutsky & Osterman, 2009). The incidence of DRFs is reported to be increasing worldwide, with the highest incidence seen among younger men and older women (MacIntyre & Dewan, 2016). Females over 50 years of age are more susceptible to osteoporosis-related DRFs as compared to males (Dalzell et al., 2009). In Ontario, Canada, the DRF ratio between females to males is reported to be 3:1 (Jaglal et al., 2004). These fractures usually occur after a fall from standing height, onto an outstretched hand (Rubin, Orbach, Chezar, & Rozen, 2017; Meena, Sharma, Sambharia, & Dawar, 2014). Majority of patients after a DRF are reported to achieve optimum self-reported function within six months (MacDermid, Roth, & Richards, 2003). However, in a minority the DRF affects activities of daily living (ADLs), leads to prolonged impairments and causes dependence (Vergara et al., 2016) and motion deficits that can persist for up to four years (Brogren, Hofer, Petranek, Dahlin, & Atroshi, 2011; Ploegmakers, The, Wang, Brutty, & Ackland, 2015) and beyond (Kopylov, Johnell, Redlundjohnell, & Bengner, 1993).

Pain is defined by The International Association for the Study of Pain [IASP] as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Merskey & Bogduk, 1994, 2012). Acute pain sets in rapidly and sometimes it can be severe. During the acute phase, pain is expected (Galos et al., 2016; MacDermid, Roth, & Richards, 2003). It has been reported that pain (measured within two weeks of a DRF) is a significant predictor of persistent pain (Mehta, MacDermid, Richardson, MacIntyre, & Grewal, 2015b) and self-reported function at two years in patients with DRF (Swart, Nellans, & Rosenwasser, 2012). Persistent postoperative pain beyond this time may result in greater physical and emotional consequences (Apfelbaum, Chen, Mehta, & Gan, 2003). Moreover, states of elevated acute pain may be responsible for a prolonged recovery time (Waljee et al.,

2016), increased risk of emerging chronic pain (Mehta et al., 2015b; Sinatra, 2010), higher financial costs due to hospital readmissions (Curtin & Hernandez-Boussard, 2014), altered quality of life (Diaz-Garcia, Oda, Shauver, & Chung, 2011; Strassels et al., 2004), deficits in wrist movements (Valdes, Naughton, & Burke, 2015) and higher patient-reported disability (Souer, Lozano-Calderon, & Ring, 2008), which may eventually be perceived as poor outcomes.

The overarching aims of DRF management, as per the recommendations of the American Academy of Orthopedic Surgeons for 2013 (Hammert, Kramer, Graham, & Keith, 2013), are to decrease pain and restore function. Early identification of patients at risk of physical impairment is needed. Understanding the impact of baseline pain intensities in predicting physical impairments in grip strength and ROM at one year may improve clinicians' communication with their patients by including a discussion about the probable level of recovery in patients' grip strength and ROM at one year after a DRF. The purpose of this study was to determine whether high pain intensity as measured by PRWE at baseline (within 10 days after DRF is related to poor impairment outcome measures (grip strength and ROM) one year after a DRF. A secondary aim is to describe the one-year impairment scores.

2.2 Research questions

The specific research questions were:

1. Are there differences in physical impairment measures (grip strength and range of motion) between people with or without high baseline pain?

2. Is there an association between baseline pain scores and physical impairments (grip strength or range of motion) at one-year?

3. Does high baseline pain present a risk for poor physical impairment measures (grip strength or range of motion)?

2.3 Methods

2.3.1 Study design

This cohort study was reported using the STROBE checklist. Participants were recruited between the years 1995 to 2014 by obtaining informed consent and were assessed at the Roth | McFarlane Hand and Upper Limb Centre in London, Ontario, Canada.

2.3.2 Ethics

Ethics approval was obtained, and all procedures were approved by the Health Sciences Research Ethics Board at the University of Western Ontario. The data was collected by research assistants who were not informed about the treatment and who were trained in taking measurements according to established protocols.

2.3.3 Inclusion criteria and participants

Within the first 10 days of injury, patients with a DRF were included in the study if they were 18 years of age or older, with a demonstrated ability to understand and rate their responses in English and no existing cognitive impairments. Demographic data, age, gender, dominant hand and an injured hand, were also collected. The evaluations were performed at baseline (10 days of injury) and one year after DRF and included 277 subjects.

2.3.4 Predictor variable

2.3.4.1 PRWE assessed baseline pain

The Patient-Rated Wrist Evaluation (PRWE) is a patient-reported outcome questionnaire that measures pain and disability at the level of the wrist and hand following an injury (MacDermid, 1996). Every subscale of the PRWE has been reported as having excellent reliability (Mehta, MacDermid, Richardson, MacIntyre, & Grewal, 2015a). The pain subscale was reported to have an ICC of 0.90 demonstrating high inter-rater reliability (MacDermid, Turgeon, Richards, Beadle, & Roth, 1998). A recent systematic review of 22 studies to determine the psychometric properties of the PRWE among patients with wrist/hand conditions concluded that the PRWE is reliable, valid and responsive (Mehta

et al., 2015a). Mehta et al.'s (2015a) study has indicated excellent content validity and responsiveness for the PRWE's use in patients with a DRF.

The pain subscale consists of five questions which are scored on a scale from 0 to 10 (0 = no pain and 10 = maximum tolerable pain). The five items are combined to give a total score out of 50 (0 = no pain and 50 represents worst pain experience).

2.3.5 Outcome variables (physical impairments)

2.3.5.1 Grip strength

Grip strength was measured using either a Jamar hydraulic hand dynamometer (Saehan Corporation, Masan, Korea) or a J-Tech computerized grip dynamometer (J-Tech Medical, Salt Lake City, USA) (Figure 1 & 2) at one year after a DRF. The reliability of the Jamar (MacDermid, Alyafi, Richards, & Roth, 2001) and the J-Tech instrument (Clerke, A. M., Clerke, J. P., & Adams, 2005) has been studied. Clerke et al. (2005) in their study on 149 healthy subjects reported excellent test-retest reliability with (ICC =0.954 to 0.973) for the J-Tech device. The second handle position on the dynamometer devices was used for measurements as per the American Society of Hand Therapists (ASHT, 1992) clinical assessment recommendations, and an average of three measurements was recorded. The patients were seated with shoulders held in adduction and at the neutral rotation, elbow flexion at 90 degrees (Coldham, Lewis, & Lee, 2006; Mathiowetz, Rennells, & Donahoe, 1985), forearm in neutral rotation (Coldham et al., 2006), wrist in extension between 0 to 30 degrees (Coldham et al., 2006) with 0 to 15 degrees of ulnar deviation (Coldham et al., 2006). The measurements for both the affected and the unaffected hand were taken in kilograms. We normalized the raw grip strength scores by computing a ratio of the affected side score with the unaffected side scores (MacDermid et al., 2002; MacDermid, Richards, Donner, Bellamy, & Roth, 2000).

2.3.5.2 Range of motion

Wrist and forearm active ROM were measured at one year following a DRF using the NK computerized goniometer (NK Biotechnical Engineering Company, Minneapolis, USA) (Figure 3), which is reported to be reliable (Tajali, MacDermid, Grewal, & Young, 2016).

We created three arcs for six components of active ROMs which included the wrist flexion-extension arc, (LaStayo & Wheeler, 1994) the radial-ulnar deviation arc, and the forearm pronation-supination arc (Armstrong, MacDermid, Chinchalkar, Stevens, & King, 1998). A ROM score was computed as the ratio of the contralateral side. The study participants were positioned as per the measurement requirements for goniometric use (Norkin & White 2009; Reese, Bandy, & Yates, 2010). Tajali et al. (2016) examined 44 patients and found moderate to high-reliability coefficients in the range of 0.64 to 0.97 for the NK and the J-Tech computerized goniometers in patients with limitations in the wrist and hand joint structure or functions.

2.3.6 Criteria used for classification of baseline pain and one-year physical impairments

Based on the study by Mehta et al. (2015b) baseline pain scores have been classified as high pain and without high pain. High pain in this study has been defined as a PRWE, pain subscale score of greater than or equal to 35 out of 50) at baseline. Mehta et al. (2015b) reported that irrespective of the management approach adopted, patients who report high baseline pain had eight times the risk of one-year chronic pain (RR = 8.4) in the wrist and hand regions.

The definitions used in this study for dichotomizing the physical impairment measures indicated that 65% of grip strength and 95% of ROM is necessary for patient satisfaction with their recovery at three months after a DRF in comparison to the contralateral side (Chung & Haas, 2009). The satisfaction domain of the Michigan Hand Outcomes Questionnaire (MHQ) and its questions related to wrist mobility and grip strength were used to evaluate patient satisfaction in that study (Chung & Haas, 2009). The MHQ's satisfaction domain is reported to be reliable and to possess a high ICC of 0.96 (Chung, Pillsbury, Waiters, Hayward, & Arbor, 1998). Hence, the quantitatively measured physical impairments (grip strength and ROM) scores below the normative benchmarks score for patient satisfaction from the study by Chung and Haas (2009) were used to distinguish impairment from non-impairment. At one year, the physical impairments (grip strength and ROM) were measured in both the affected and the unaffected hands. Both the grip strength scores (measured in kilograms) and ROM (measured in degrees)

were calculated as a ratio, obtained by dividing the affected side scores with that of unaffected side scores. The one-year recovery was reported as a percentage of the unaffected side (Cowie, Anakwe, & McQueen, 2015; Bot, Mulders, Fostvedt, & Ring, 2012). At one year if the grip strength scores were less than 65%, the scores were reported as impaired, whereas, if the grip strength scores were more than or equal to 65%, the scores were categorized as non-impaired. Likewise, ROM arcs were defined as impaired if the one-year ROM scores were recorded as less than 95% and non-impaired if the ROM scores were greater than or equal to 95%. Classification of baseline pain and one-year physical impairments is shown in Figure 4.

2.3.7 Data analysis

IBM SPSS version 23.0 was used for the data analysis. Means and standard deviations were reported for the interval level variables i.e., age. Categorical variables like dominant hand and injured hand were summarized using percentage. Levene's test was used to confirm the assumption of homogeneity of variances.

The grouping variable (PRWE baseline pain) was measured on an ordinal scale, and the outcome variables were measured on a continuous scale; both were evaluated to compare the mean difference between high baseline pain and low baseline pain on one-year grip strength and ROM arc variables using the independent samples *t*-test. The Pearson's correlation coefficient (r) was used to analyze the associations between the raw scores of baseline pain and the impairment measures (grip strength and ROM) at one year after a DRF. The significance cut-off was set at p less than or equal to 0.05.

In order to investigate how the exposure to high baseline pain affects the magnitude of risk of impairments in grip strength and ROM at one year in relation to those patients not exposed, we have calculated relative risks (RR). Both the predictor and outcome variables were dichotomized to calculate relative risk. The relative risk was defined as the incidence rate of impairments in grip strength and ROM when exposed to high baseline pain scores divided by the incidence rate of impairments in grip strength and ROM when exposed to low baseline pain scores. To facilitate the clinical interpretability of our results, a value of more than or equal to two for relative risk was deemed to be clinically

relevant (Andrade, 2015). Statistical significance was determined by calculating 95% confidence intervals [CI].

2.4 Results

Overall, 277 participants with DRF having completed the PRWE (Pain subscale) at baseline and grip strength and ROM scores at one year were included. The average age of our sample was 60.25 years (SD = 11.4, age range: 19 - 83 years). Females constituted approximately 80.5% (223), and the remaining 19.5% (54) were males. (Table 1).

Characteristics	High pain	Low pain		
Total participants (N=277)	107 (39%)	170 (61%)		
Age $M \pm SD$	59 ± 11.4 (range 19-83 yr)	61 ± 11.5 (range 20-82		
		yr)		
Gender:				
Females	91 (85%)	132 (78%)		
Males	16 (15%)	38 (22%)		
Dominant hand:				
Right	97 (91%)	155 (91%)		
Left	10 (9%)	15 (9%)		
Injured hand:				
Right	44 (41%)	71 (42%)		
Left	63 (59%)	99 (58%)		

Table 1 Demographic characteristics of the participants by subgroups of pain

Note. SD: standard deviation; n: number of participants; yr: year

The higher threshold for ROM is reflected in our results since the mean grip strength scores were 87.8% as compared to the unaffected side, which indicates that the average grip strength scores of our study participants scores met the pre-defined benchmark for satisfaction and the average ROM arcs met this pre-defined benchmark for patient satisfaction. (Table 2).

Outcome variables	Affected side	Unaffected side	Ratio to unaffected side	
	$M \pm SD$ (Kg)	$M \pm SD$ (Kg)		
Grip strength:	24 ± 9.7	28 ± 14.4	0.88 ± 0.20	
Females	21 ± 6.1	25 ± 13.6	0.87 ± 0.19	
Males	36 ± 11.8	40.2 ± 10.3	0.90 ± 0.20	
	Affected side	Unaffected side	Ratio to unaffected side	
	$M \pm SD$ (degrees)	$M \pm SD$ (degrees)		
ROM Flexion- extension	107 ± 20	126 ± 17.2	0.85 ± 0.15	
ROM Radial- ulnar deviation	43 ± 12.2	49.4 ± 10.8	0.88 ± 0.21	
ROM Pronation- supination	150 ± 16	159 ± 12.5	0.94 ± 0.08	

Table 2 Outcomes (grip strength and ROM) and the satisfaction scores at 1-year after DRF

Note. Kg: kilogram; M: Mean; SD: standard deviation

The Levene's test showed that the variances in groups of high pain and without high pain are equal. The independent samples *t*-test indicated a non-significant difference in the mean scores of grip strength and ROM arc variables between the high pain and without high pain groups. The scores are reported as a ratio, which was obtained by comparing the affected side scores to the contralateral side. (Table 3).

Physical impairments	Levene's test		Independent <i>t</i> -test				
			High pain		Low pain		
	F statistic	<i>p</i> -value	М	SD	М	SD	<i>p</i> -value
Grip strength	.22	.63	0.87	0.21	0.88	0.20	.59
ROM Flexion-extension	.70	.40	0.84	0.14	0.86	0.15	.30
ROM Radial-ulnar deviation	.31	.57	0.87	0.24	0.88	0.19	.67
ROM Pronation-supination	1.5	.22	0.94	0.07	0.94	0.08	.78

Table 3 Levene's test and independent t-test comparing for physical impairments by pain categories

Note:M: Mean; SD: standard deviation

There was no significant correlation between baseline PRWE pain and the one-year physical impairments. (Table 4).

Physical impairments	Correlation to baseline pain	P-value		
Grip strength	10	.09		
ROM Flexion-extension	05	.36		
ROM Radial-ulnar	05	.39		
deviation				
ROM Pronation-supination	.006	.92		

Table 4 Pearson's correlation of the 1-yr physical impairments with baseline pain

Note. Yr: year; P-value < .05 statistically significant

The relative risk (RR) analysis showed statistical significance only in the ROM flexionextension. Although at baseline, those patients who reported high pain had 1.2 times the risk of poor ROM flexion-extension outcome relative to patients without high baseline pain, clinical relevance was not achieved (RR of \geq 2). Furthermore, no significant findings were observed in the remaining outcome variables (grip strength, ROM radialulnar deviation, and ROM pronation-supination) (Table 5). The distribution of study participants classified based on their respective baseline pain categories (high baseline pain and low baseline pain), and one-year physical impairments (impaired or nonimpaired) are shown in Table 6.

Table 5 Risk of 1-yr impairment outcomes in grip strength and range of motion in patients with high baseline pain after a DRF

PRWE	/E 1-yr Physical impairments						
Risk factor	Grip strength	ROM Flexion- extension	ROM Radial- ulnar deviation	ROM Pronation- supination			
	RR [CI]	RR [CI]	RR [CI]	RR [CI]			
High pain	1.5 [0.7, 3.10]	1.2 [1.05, 1.36]	1.1 [0.95, 1.30]	1.0 [0.86, 1.4]			

Note. RR: relative risk; CI: 95% confidence interval; yr: year

Table 6 Number of participants showing 1-yr impairment outcomes when exposedto baseline pain intensities

Exposu	ire			1-yr physical impairment outcomes					
PRWE	Grip strength		ROM Flo	ROM Flexion-extension		ROM Radial-ulnar deviation		ROM Pronation-supination	
	Impaired	Non-impaired	l Impaired	Non-impaired	Impaired	Non-impaired	Impaired	Non-impaired	
High pain (n = 107)	1	2 95	89	18	78	29	57	50	
Low pain (n = 170)	1	3 157	118	52	112	58	83	87	
Total	2	5 252	207	70	190	87	140	137	

Note: PRWE: Patient Rated Wrist Evaluation; ROM: range of motion; n: number of participants; yr: year

2.5 Discussion

This study found that high baseline pain categorized by using a previously established risk cut-off for the PRWE (pain subscale) did not have a clinically important impact on either grip strength or ROM at one year following a DRF. Both the tests of mean differences in pain scores and tests of associations, the Pearson's correlation and the relative risks concur that high baseline pain did not predict physical impairments in grip strength and ROM at one year. Our findings support observations made by MacDermid et al., (2003) who followed 129 patients with a DRF for one year and reported that the majority of patients (79%) had a resolution of the pain and disability that occurs during the acute phase of a DRF. Mehta et al. (2015b) added to this by showing high baseline PRWE-predicted chronic pain at one year (RR = 8.4), and to a lesser extent predicted poorer patient-reported function (RR = 3.6). This suggests that high pain predicts the most proximal outcome, future pain. The patient-reported outcome might be considered more closely linked to pain than would the strength and joint motion. This suggests specificity of prediction.

In a cohort study of 190 patients who underwent surgical reduction of a DRF, the pain was measured by Visual Analog Scale (VAS) within the first two weeks and at multiple evaluation time points extending up to 2-years (Swart et al., 2012). Higher pain levels were found to be a significant predictor of functional disability as measured by the Disabilities of the Arm, Shoulder And Hand (DASH) score at two years (Regression coefficient = 3.91, 95% CI 3.1, 4.7, p < .001) (Swart et al., 2012). However, these studies did not explicitly measure physical impairments, and we know that physical impairments and self-reported function are only moderately related (r = 0.50) (MacDermid et al., 2002). When it comes to clinical decision-making, knowledge of both performance-based physical impairments and patient ratings of their outcome status can facilitate a better understanding of the capabilities and functional issues that will affect recovery and rehabilitation planning (MacDermid et al., 2002; Swart et al., 2012). In the current study, physical impairments (grip strength and ROM) were measured on a continuous scale, and we have applied previously identified patient satisfaction benchmark scores which were derived by comparing impairments to the MHQ-assessed satisfaction with impairment domain (Chung & Haas, 2009). If this cut-off is not generalizable, then this would have adversely affected our prediction analyses.

The average grip strength and ROM scores in the study participants reached the benchmark for patient satisfaction. To treat DRF, rehabilitation therapists share a common goal of restoration of hand grip strength and wrist ROM. It is already known that, during routine clinical practice, therapists (hand therapists, occupational therapists, and physical therapists) use objective measurements of physical impairments more frequently than patient-reported outcomes to evaluate a patient's progression in a rehabilitation program (Michlovitz, LaStayo, Alzner, & Watson, 2001). Additionally, the therapists use functional ranges as a potential measure to assess the extent of mobility limitations in ADL's. Moreover, authors have considered different degrees of functional motion requirements for wrist and forearm movements. Ryu et al. (1991) found that 40 degrees of wrist flexion, 40 degrees of extension and 40 degrees of radial-ulnar deviation were required to perform ADL's. In comparison, another study showed that for ADLs a functional range of motion for the wrist was 5 degrees of flexion, 30 degrees extension, 10 degrees radius deviation and 15 degrees of ulnar deviation (Palmer, Werner, Murphy, & Glisson, 1985). Similarly, 60 degrees of supination and 40 degrees of pronation were reported as the requirement for functional motion (Safaee-Rad, Shwedyk, Quanbury, & Cooper, 1990). Recovery in functional ROM may not necessarily translate to patient satisfaction (Chung & Haas, 2009).

There are likely many reasons for our findings. The lack of relationship between high baseline pain and physical impairment measures might be related to the therapeutic effects of hand therapy treatment. We assume that patients that reported relatively higher pain intensities attended hand therapy, and after attending these hand therapy sessions, a convergence of the results might have occurred and no difference of high baseline pain on impairments at the one-year time point. Additionally, previous studies have shown the confounding effect of psychological factors, such as depression on both the baseline pain intensity and patient-reported disability (Yeoh et al., 2016). Bot et al., (2012) reported that pain anxiety estimated 9% of the grip strength score variability (adjusted $R^2 = 0.086$, P = 0.022). Teunis et al., (2015) studied 206 patients with a mean age of 53 years (*SD* =

15) after a DRF whose fracture was reduced using a Volar Locking Plate System (VLPS). Catastrophic thinking was identified as an independent contributory factor for both the patients reporting higher pain intensities at baseline (measured within 14 days of injury) (regression coefficient = 0.12, 95% C.I 0.06 to 0.17, P<0.001) and physical disability as measured by the DASH scores (regression coefficient = 1.1, 95% C.I 0.78 to 0.15, P<0.001) (Teunis et al., 2016). The potential effects of therapeutic interventions and psychological factors on the physical impairment measures were not explored in this study. Future studies may control for therapeutic attendance and psychological variables to investigate the efficacy of high baseline pain in predicting impairment outcomes after a DRF.

In the high baseline pain group, we found that 51 (47.6)% of our study participants reported atypically very severe pain levels (PRWE pain subscale scores in the range of 41 to 50 out of 50) (MacDermid et al., 2003). It may be possible that these patients are showing initial signs of a complex regional pain syndrome. A complex regional pain syndrome (CRPS) may begin to appear during the immobilization phase (within six weeks) (Field & Atkins, 1997) or the mobilization phase (after six weeks) (Brunner, Bachmann, Perez, Marinus, & Wertli, 2017). The incidence of CRPS in patients with a DRF is reported to be in the range of 1% (Hove, 1995) to 37% (Atkins, Duckworth, & Kanis, 1990). It is one of our limitations that we have not analyzed patients based on other medical diagnoses. Future studies should plot Receiver Operating Characteristic (ROC) curves to investigate the precision of this PRWE high pain benchmark score (35 or more out of a maximum score of 50) to predict impairments by including DRF patients with a diagnosis of the CRPS.

Another limitation of this study is the fact that the method used to select the patient satisfaction cut-off scores were based on the surgically managed DRF population, (Chung & Haas, 2009) while our sample included both surgical and non-surgical patients with a DRF. Additionally, the outcome levels for satisfaction established by Chung and Haas (2009) may not generalize beyond that sample or outcome measure (MHQ), and other studies have not reported similar satisfaction requirements on an independent dataset. For this reason, an ROC curve to establish what patients consider optimal or satisfactory

outcomes in other samples and with other outcome instruments is warranted. We also used a previously defined cutoff for high pain; (Mehta et al., 2015b) it is possible that even moderate pain intensities experienced continuously may result in larger impairments than high pain experienced intermittently (Scudds & Robertson, 2000). When data is dichotomized, information is lost, (Altman & Royston, 2006) and it is always possible that the cut-offs are not stable across contexts. If a RR cut-off does not show prediction beyond its original development, this suggests it should not be used in clinical decisionmaking. Changes in the DRF surgical management strategies over the recruitment period (1995 to 2014) may have influenced outcomes. A demonstrated shift has been reported in surgical approaches after a DRF from external fixation to open reduction and internal fixation (ORIF) mainly using a VLPS (Yoon & Grewal, 2012). It is our limitation that we have not analyzed the physical impairments based on the differences in management approach between that group of patients in the first and the last ten years of enrollment. Finally, the study data was derived from a specialized hand center and had female overrepresentation, which may limit the generalizability to community hospitals and men.

2.6 Conclusion

This study found that a high baseline pain score, i.e., a score of greater than or equal to 35 out of 50 as measured by the PRWE (pain subscale), did not predict clinically meaningful impairments in grip strength and ROM scores at one year after a DRF. We believe these findings can guide rehabilitation professionals to communicate with their patients about the likelihood of achieving satisfactory functional recovery and the minimal impact of high baseline pain on impairments in grip strength and ROM by one year.

2.6.1 Findings

High pain intensity at baseline was not clinically indicative of impairments in grip strength and ROM at one year in patients with a DRF.

2.6.2 Implications

Therapists can reassure patients that even when high pain is present after a fracture, the potential for recovery of grip strength and ROM is not much different from patients with lower levels of pain.

2.6.3 Caution

A high pain benchmark score of 35 or more out of a maximum score of 50 as measured by the PRWE scale may not be one of the best indicators of one-year physical impairment measures after a DRF. The optimal recovery of grip strength and ROM for patient satisfaction or function has not been adequately defined.

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Figure 1 Jamar hydraulic grip dynamometer



Figure 2 J-Tech computerized grip dynamometer



Figure 3 N-K computerized goniometer device



Figure 4 Flow chart explaining classification of DRF patients into pain and impairment groups

3 Summary

The primary aim of this study was to understand whether high baseline pain (based on the PRWE pain subscale scores) predicts poor physical impairments in grip strength and active wrist ROM arcs (flexion-extension, radial-ulnar deviation, and pronation-supination) at one year after a DRF. Three research questions were developed to study this association:

1. Are there differences in physical impairment measures (grip strength and ROM) outcomes among people with or without high baseline pain? An independent samples *t*-test was used to compare the mean differences in physical impairments between baseline pain groups. The results indicated no significant differences in one-year grip strength and ROM in patients with or without high baseline pain.

2. Is there a relationship between baseline pain scores and physical impairments (grip strength or ROM) scores at one-year? A Pearson correlation analysis (r) was used to measure the associations, and the results were suggestive of nonsignificant correlations between baseline pain and grip strength or ROM.

3. Does high baseline pain present a risk for poor physical impairments (grip strength or ROM) outcome? The relative risks were calculated and the findings indicated that high baseline pain intensity does not predict a clinically meaningful increased risk of poor grip strength and ROM outcomes at one year after a DRF.

A secondary aim of this study was to describe the one-year impairment scores. The results of the descriptive analysis indicated that the average one-year physical impairment outcome score of our participants met the predefined benchmark for patient satisfaction.

Our findings highlight the minimal clinical impact of high baseline pain classified by using a previously established risk benchmark for the PRWE (pain subscale) score on one-year physical impairments. These findings are in support of observations made by MacDermid and colleagues (2003). In their study of 129 patients, the authors demonstrated the typical recovery trends in pain and disability experience within one year after a DRF (MacDermid, Roth, & Richards, 2003). MacDermid et al. (2003) found that

81% of patients in their study reported severe PRWE assessed baseline pain (31-40/50) or very severe pain (41-50/50), and by one year 79% of their patients showed minimal pain and disability in comparison to the acute pain and disability scores. A previous study has indicated that a baseline PRWE pain subscale score of more than or equal to 35 out of a maximum score of 50 measured within one to two weeks of sustaining a DRF is eight times more likely to predict the risk of one year chronic pain (RR = 8.4) and predicted patient reported functional disability to a lesser extent (RR = 3.6) (Mehta, MacDermid, Richardson, MacIntyre, & Grewal, 2015b).

The Patient-Rated Wrist Evaluation (PRWE) (MacDermid, 1996) was used in this study to measure pain in wrist and hand after a DRF, and this scale is shown to be reliable (Mehta, MacDermid, Richardson, MacIntyre, & Grewal, 2015a). The pain was assessed at the baseline (within the initial 10 days of a DRF). The PRWE, besides being reliable, is also shown to be responsive to a patient whose fracture is immobilized in a cast application immediately after a DRF (MacDermid, Richards, Donner, Bellamy, & Roth, 2000). During this acute phase, the wrist is immobilized, and no physical impairment evaluations are possible. Evaluations may be performed during the sub-acute phase which is usually at four to six weeks after a radiographic confirmation of healing and removal of the cast. Our findings of no significant differences in one-year grip strength and ROM in patients with or without high baseline pain may also be due to the therapeutic effects of hand therapy. The number of patients who attended hand therapy and the likely influence of hand therapy treatment over the course of recovery was not studied.

Pain is an expected complication after a DRF (Mehta et al., 2015b). Some of the other factors that have shown to influence outcomes include: female gender (Mehta et al., 2015b), age (Roh et al., 2017; Chung, Kotsis, & Kim, 2007; Chung & Haas, 2009; Cowie, Anakwe, & McQueen, 2015), education level (Grewal et al., 2007), socioeconomic status (Chung et al., 2007), injury compensation (Grewal et al., 2007; MacDermid et al., 2002), and work demands (MacDermid, Roth, & McMurtry, 2007). Additionally, soon after the traumatic incident other psychological factors such as depression (Yeoh et al., 2016), pain anxiety (Bot, Mulders, Fostvedt, & Ring, 2012; Keogh, Book, Thomas, Giddins, & Eccleston, 2010) and catastrophic feelings (Teunis,

Stoop, Park, & Ring, 2015; Keogh, Book, Thomas, Giddins, & Eccleston, 2010) were shown to have an effect on patient outcomes after a DRF

Our findings also indicate that the average physical impairment scores of our sample achieved patient satisfaction. In this study, the quantitative physical impairment measures (grip strength and ROM) were compared to patient satisfaction benchmark scores (Chung & Haas, 2009). Chung & Haas (2009) indicated that patients need a minimum of 65% or higher grip strength and 95% or higher ROM scores to be satisfied with their outcome after a DRF. Previous studies have shown that functional hand outcome evaluation after a DRF, which is reported on both the objective physical impairment measures and subjective evaluation of patient-reported outcomes, provide vital information to the clinician regarding physical impairments and a patient's perception of their injury (Waljee, Ladd, Macdermid, Rozental, & Wolfe, 2016; MacDermid, Roth, & Richards, 2003). The physical impairments and the patient-reported function are moderately associated (r = 0.50) at six months following a DRF (MacDermid et al., 2002).

Our findings may improve clinicians' communication with their patients by including a discussion about the probable level of recovery in patients' grip strength and ROM at one year after a DRF. Moreover, health care providers may use the acute phase of DRF as an opportunity to engage in understanding the recovery expectations from their patients' perspective, which may help in effective treatment planning.

3.1 Limitations

One limitation of this study was that the majority of the subjects were female. This female over representation limits the generalizability of our findings to males. A second limitation was that the analysis of other potential risk factors for impairments was not included in the study, such as other comorbidities including obesity, smoking status, work status and education status. Finally, the NK goniometer used to measure ROM in this study may not be widely available.

3.2 Future directions

Future studies create receiver operating characteristic curves (ROC) to investigate the precision of the patient satisfaction cut-off from the study by Chung and Haas (2009) for predicting impairments based on satisfaction or optimal outcomes would be beneficial.

3.3 Conclusion

Our findings were suggestive of the minimal role of high pain at baseline on one-year impairment measures after a DRF. We recommend that therapists reassure patients that even when high pain is present after a fracture, the potential for recovery of grip strength and ROM is not much different from patients without higher pain intensities.

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Appendix A: Patient Rated Wrist Evaluation

Name:

Date: _____

PATIENT RATED WRIST EVALUATION

The questions below will help us understand how much difficulty you have had with your wrist in the past week. You will be describing your **average** wrist symptoms **over the past week** on a scale of 0-10. Please provide an answer for **ALL** questions. If you did not perform an activity, please **ESTIMATE** the pain or difficulty you would expect. If you have **never** performed the activity, you may leave it blank.

1. PAIN

Rate the **average** amount of pain in your wrist over the past week by circling the number that best describes your pain on a scale from 0-10. A zero (0) means that you **did not** have any pain and a **ten** (10) means that you had the **worst pain you have ever experienced** or that **you could not do the activity because of pain**.

RATE YOUR PAIN: Sample Scale L		0	1	2	3	4	5	6	7	8	9	10
	No Pain										W	/orst Ever
At rest		0	1	2	3	4	5	6	7	8	9	10
When doing a task with a repeated wrist movement		0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object		0	1	2	3	4	5	6	7	8	9	10
When it is at its worst		0	1	2	3	4	5	6	7	8	9	10
How often do you have pain?	Nev	0 /er	1	2	3	4	5	6	7	8	9	10 Always

Continued on next page

2. FUNCTION

A. SPECIFIC ACTIVITIES

Rate the **amount of difficulty** you experienced performing each of the items listed below - over the past week, by circling the number that describes your difficulty on a scale of 0-10. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do it at all. Sample scale \hat{u} 0 1 2 3 4 5 6 7 8 9 10

No Difficulty

Unable

											To Do
Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Cut meat using a knife in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

B. USUAL ACTIVITIES

Rate the **amount of difficulty** you experienced performing your **usual** activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities you performed **before** you started having a problem with your wrist. A **zero** (0) means that you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do any of your usual activities.

Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

Appendix B: Ethics Approval

Western

Research Ethics

University Health Science Research Ethics Board HSREB Annual Continuing Ethics Approval Notice

Date: October 08, 2015 Principal Investigator: Dr. Joy MacDermid Department & Institution: Schulich School of Medicine and Dentistry/Surgery,Western University

Review Type: Expedited HSREB File Number: 5697 Study Title: Wrist and Elbow Outcomes Measures Database -15602E Sponsor:

HSREB Renewal Due Date & HSREB Expiry Date: Renewal Due -2016/11/30 Expiry Date -2016/12/10

The Western University Health Science Research Ethics Board (HSREB) has reviewed the Continuing Ethics Review (CER) Form and is re-issuing approval for the above noted study.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH E6 R1), the Ontario Freedom of Information and Protection of Privacy Act (FIPPA, 1990), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

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



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

Appendix C: Patient information and consent form

Project Title: Wrist and Elbow Outcome Measures Database

Investigators:	Dr. Joy MacDermid, PhD
	Dr. Ruby Grewal, MD
	Dr. Douglas Ross, MD
	Dr. George Athwal, MD
	Dr. Graham King, MD
	Dr. Ken Faber, MD
	Dr. Darren Drosdowech, MD
	Dr. Bing Gan, MD

What is the purpose?

At The Hand and Upper Limb Centre (HULC) we routinely measure the impact of care to ensure we evaluate the quality of our care. You are asked to participate because you have a wrist/elbow injury affecting your activities of daily living. The purpose of this measuring your status and keeping this information in a database is so that we can evaluate how much improvement you experience with treatment.

What is involved?

At the Hand and Upper Limb Centre we routinely test your motion and strength and use questionnaires that ask about your pain and disability. We do this to monitor your usual recovery. If you agree to participate in this study, you will be asked to fill out additional questionnaires that measure the impact of the wrist/elbow fracture on your participation in activities that are important to you. Follow-up visits for the study will be similar to our usual follow-up which takes place on multiple occasions over the early recovery and at visits scheduled at 3, 6, 9, and 12 months after your injury/surgery. For the study you

will fill out forms at one early visit and the 4 later visits- 6 weeks, 3, 6, and 12 months after your injury/surgery. The usual forms take about 15 minutes and the study forms take another 10-15 minutes. You will be asked to complete the same forms at each visit. Once your wrist/elbow injury has healed completely, your strength and hand movement will also be measured according to our routine follow-up. We will test you strength (flexion/extension, and pronation/supination) by using the Biodex system and your grip strength with NK system. Research Assistant will explain all the tests to you before asking to perform them.

We will use information collected during your follow-up such as these measures to describe your injury and physical recovery. Other than the routine follow-up required for this type of injury, we will not ask you to return to clinic more often or perform additional x-rays for this study. With certain wrist/elbow injuries, participants over 50, we be offered an assessment for osteoporosis and evaluation of their postural stability.

Tests (optional for patients 50 and over)

Bone density scan will be performed on the lower spine and hips.

- Bone density testing is the most accurate method available for the diagnosis of osteoporosis and is also considered an accurate estimator of fracture risk. Bone densitometry is a simple, quick (30 min) and noninvasive procedure will be performed at 1 year visit.
- We will use the Biodex balance system SD to assess your ability to maintain dynamic bilateral postural stability on a static or unstable surface. You will be asked to perform the following two tests:
- 1. Postural Stability Test (PST) emphasizes a patients ability to maintain centre of balance.
- 2. Fall Risk Test (FRT) allows identification risk of a potential future fall

You will be instructed to maintain the balance as instructed by the Research Assistant. Platform stability will be varied during the test. The researcher will instruct and help you during the test.

What are the benefits of having my data in the database?

You may not personally benefit from your allowing us to keep your data in the database his study. Your participation will allow HULC and those who develop implants to have a better understanding of the outcomes or complications with different treatment options. This information can be used for quality assurance or in the future for research – if we ask the ethics board for permission to do so. HULC is committed to improving the quality of care and participates in these processes ion a regular basis.

Is there any compensation?

There is no payment for participating in this data collection. We will provide parking passes on the days that you complete the questionnaires, so that your parking will be free on the days you fill out study forms. We are trying to interact with the patients during their visits to the HULC, however, if it is not convenient for the patient, we will schedule another appointment that only includes a visit to the HULC research lab, and in this case coverage for parking will be provided.

Are there any risks of discomfort associated with this study?

The amount of radiation used is extremely small—less than one-tenth the dose of a standard chest x-ray, and less than a day's exposure to natural radiation. There is a small risk of losing the balance during the Postural Stability and Fall Risk Tests, however, a Research Assistant will always be behind you to help control instability during testing and to prevent you from falling. The system is equipped with safety features such as support handles and an "abort" button to stop the testing at any time.

Other than questionnaires

No additional testing for research purposes other than that stated above will be performed. The clinic routinely uses strength testing, motion testing, and x-rays to ensure your fracture is healing properly. This is normal care.

Will your results be kept confidential?

The overall results of the study will be available to you upon request. Your individual results will be held in strict confidence. No person, other than your doctor or therapist and the study co-investigators will have access to your records without your permission. Your data that is sent into the study database will have your personal identifying information removed or coded so that the study database will be anonymous.

Information collected during the study may be presented to other doctors in a presentation or paper. Your results would be part of a group of anonymous data, and would not identify you in any way. 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.

Alternatives to Study Participation:

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. You will receive a copy of the letter of information and consent form for your records. You do not waive any of your legal rights by signing the consent form.

If you decide not to participate in the study, your surgeon will determine which technique will be used based on his/her discretion and your discussions together. Currently, there is no preference among the surgeons.

Consent to Participate In: Wrist and Elbow Outcome Measures Database

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

Signature of Participant

Print Name

Date

Signature of personPrint Name of personDateobtaining consentobtaining consent

Appendix D: Curriculum Vitae

Name:	Farrukh Riaz
Education:	
2015-Present	The University of Western Ontario London, Ontario, Canada M.Sc. Candidate, Health and Rehabilitation Sciences (Physical Therapy)
2006-2008	College of Applied Sciences London, United Kingdom Diploma in health care management. 2006-2008
1999-2004	Dr. NTR University of Health Sciences, Vijayawada, Andhra Pradesh, India Bachelor of Physiotherapy
Honors and Awards:	Western University Graduate Research Scholarship 2015-2017
Related Work Experience:	Graduate Teaching Assistant The University of Western Ontario 2015-2017
Conference Presentation:	Health and rehabilitation sciences graduate research conference Topic: Baseline predictors for impairments following a distal radius fracture, February 2017
Certifications:	Teaching Assistant Training Program Teaching support center, Western University, September 2015
	Certificate of completion TCPS 2: CORE, Ethical conduct of research involving humans, Tri-council Policy Statement, October, 2015