8-22-2012 12:00 AM

Optimizing Physical Function Following Distal Radius Fracture

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Graduate Program in Health and Rehabilitation Sciences
A thesis submitted in partial fulfillment of the requirements for the degree in Doctor of Philosophy
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OPTIMIZING PHYSICAL FUNCTION FOLLOWING

DISTAL RADIUS FRACTURE

(Spine title: Function Following Distal Radius Fracture)

(Thesis format: Integrated-Article)

By

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Graduate Program in Health and Rehabilitation Science (Physical Therapy)

A thesis submitted in partial fulfillment

of the requirements for the degree of

Doctor of Philosophy

The School of Graduate and Postdoctoral Studies

The University of Western Ontario

London, Ontario, Canada

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THE UNIVERSITY OF WESTERN ONTARIO
SCHOOL OF GRADUATE AND POSTDOCTORAL STUDIES

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Optimizing Physical Function Following Distal Radius Fracture

is accepted in partial fulfillment of the

requirements for the degree of

Doctor of Philosophy

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Chair of the Thesis Examination Board

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ABSTRACT AND KEYWORDS

Distal Radius Fracture (DRF) is one of the most frequent of all human bone fractures. Wrist and/or finger range of motion (ROM) and grip strength are standard outcome measures used by clinicians to evaluate recovery after a hand injury. ROM is considered to be an important component of joint mobility and relates to measures of functional impairment and disability. Impaired wrist and hand ROM are related to a decrease in grip strength, grasp ability, fine manipulation, and hand function. The relationship between ROM and other physical impairments as they relate to patient-rated outcomes after DRF have not been well identified.

The thesis includes three studies. The first study (Chapter 2) is a systematic review and meta analysis of existing literature on the effects of laser irradiation on bone regeneration, suggesting that low power laser can enhance biomechanical indicators of bone during fracture healing in animal models. The second study (Chapter 3) explores the intra-rater, inter-rater, and inter-instrument reliability and construct validity of two digital electro goniometers to measure active wrist and active/passive index finger ROM in patients with limited wrist and/or hand. The results of this study demonstrate that digital goniometry is highly reliable for all measures across occasions, raters and instruments. The moderate correlation between individual joint motions and patient-rated self-reported function suggests that joint motion impairments contribute to functional disability. The third study (Chapter 4) has a specific focus on the relationship between physical impairment outcome measures and patient-rated wrist pain and function in early and late stages after distal radius fracture. Wrist flexion, extension, supination, pronation, grip strength, age and gender, were found to contribute significantly with wrist pain and function. Good wrist arc of motions (close to normal) and moderate grip strength must be recovered to have optimal wrist functional outcomes after distal radius fracture. The thesis concludes with a discussion of the next steps required toward understanding effective mechanisms to promote bone healing and earlier function after DRF, which may lead to more effective patient-centered treatment protocols. Keywords: Bone Healing, Distal Radius Fracture, Physical Impairment, Patient-Rated Wrist Evaluation.

CO-AUTHORSHIP STATEMENT

This thesis contains material from one published manuscript (Chapter 2), and two submitted manuscript (Chapters 3 and 4). All studies in this thesis were conceived, performed, analyzed, interpreted and written by me with invaluable input, guidance and advice from my supervisor   Dr. Joy C. MacDermid. There are other important collaborators which must be recognized because of their roles in various aspects of this thesis.

Advisory Committee

Dr. Ruby Grewal provided guidance on the design of the research program overall, as well as specific guidance and support for methods, interpretation of results and revisions of the manuscripts for Chapters 2, 3 and 4.

Dr. Pamela Houghton provided guidance on the design of the research program overall, as well as specific guidance and support for methods of systematic review and meta analysis, interpretation of results and revision of the manuscript for Chapter 2.

Other Collaborators

Chris Young was employed as a research assistant under Dr. MacDermid at the time of completing the reliability study in Chapter 3. He helped to recruit appropriate patients, performed physical impairment measures as an independent rater during the reliability study and reviewed the final manuscript of Chapter 3.

Kate Kelly was employed as a research assistant under Dr. MacDermid at the time of completing all Chapters. She helped to recruit appropriate patients and provided useful suggestions to complete the ethics application for Chapter 3.

DEDICATION

I would like to dedicate my thesis

To my lovely mother, who has been a source of never ending encouragement, love, and kindness to me throughout my life.

To my beloved father, who taught me the values of humanity, gave me the courage to dream and the will to achieve. He is not with me in this important moment, but he is/will be alive always in my heart and my soul.

To my brother and sisters, who gave me their kindness and extensive support in this important time of my life.

ACKNOWLEDGEMENTS

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List of Abbreviations

AUC   Area Under Curve

CI   Confidence Interval

CMA   Comprehensive Meta Analysis

DASH   Disabilities of the Arm, Shoulder and Hand

DRF   Distal Radius Fracture

HULC   Hand and Upper Limb Centre

ICC   Intraclass Correlation Coefficient

J-Tech   J-Tech Electrogoniometer

LoA   Limit of Agreement

MDC   Minimal Detectable Change

NK   NK Hand Assessment Joint Motion (NK Electrogoniometer)

PIP   Proximal Inter Phalangeal

PRWE Patient-Rated Wrist Evaluation

QATRS Quality of Animal/Tissue Research Scale

ROC   Receiver Operating Characteristic

ROM   Range of Motion

RR   Relative Risk

SD   Standard Deviation

SEM   Standard Error of Measurement

CHAPTER 1

Introduction and Background

1.1 Bone Injury and Fracture in Upper Extremity – Distal Radius fracture

A bone fracture is a complete or incomplete break in the continuity of a bone.[1] A fracture can be the result of high force impact or stress, or as a result of certain medical conditions that weaken the bones, such as osteoporosis or cancer.[1] Approximately 5.6 million bone fractures occur yearly in the United States.[2] Pain, tenderness, bleeding, bruising, tingling, numbness, loss of pulse, loss of sensation, weakness, instability, deformity, paralysis and loss of function are common signs and symptoms of bone fractures.[3] Anatomical classifications may discriminate fractures subtypes based on the involved parts of the body, such as head or arm fractures, which can be followed with more specific localization. There are a number of fracture classifications based on various criteria.[1]

In 1814, Abraham Colles described a wrist fracture with a remarkable deformity.[4] He reported that the fracture caused "considerable lameness", but eventual "perfect freedom" in all its motion.[4] The injury was defined as a displaced fracture of the lower end of radius within 1.5 inches of wrist joint.[5] About 200 years after the initial description by Colles, this common fracture is still controversial for its classification, treatment, assessment and clinical outcomes. Nonunion in distal radius fracture (DRF) is uncommon, but many immediate or late complications may occur following this fracture.[6] The rate of reported complications after distal radius fracture varies from 6% to 80%.[7-9] These complications may result from the fracture or its treatment. Mckay et al.[9] reviewed the incidence of complications and constructed a checklist for the complications following distal radius fracture. The authors identified that patients and physicians differently reported the complications rate after distal radius fracture (27% versus 21%)[9], since patients focused on symptoms, whereas physicians classified the complications based on diagnosis. Immediate complications include nerve and/or skin injury, compartment syndrome, associated injury, cast complications, loss of reduction, infection, neurologic issues and tendon ruptures. These happen in the early stages of distal radius fracture (earlier than 6 weeks)[6], whereas the disorders such as bone, joint, nerve, or soft tissue complications may happen in late stages (after 6 weeks). Nerve complications, complex regional pain syndrome, arthrosis, delayed or malunion, Dupuytren's disease, and tendon issues are common late complications following distal

radius fracture.[6,11,12] Although nonunion in distal radius fracture is rare (0.2%)[10], these fractures can sometime result in permanent pain and impairment, and should not be considered as a minor injury.[11-14]

1.2 Epidemiology and Prevalence

Although the descriptive epidemiology is well understood and researchers have actively investigated the risk factors, there are relatively little epidemiologic data available for upper extremity fractures.[15] The data for extremities fracture in industrialized countries indicate they occur at the most proximal and the most distal ends of the extremities, with the highest incidence being among the elderly.[15] Fractures of proximal humerus and distal forearm in adults are common in upper extremities, while hip and ankle fractures are dominant in lower extremities.[15,16] Fractures occur at higher rates in women, including upper extremity fractures.[15] Blacks of either gender have lower risk for these fractures as compared with other ethnicities.[17] The risk of fracture correlates well with age.[18] Different studies reported similar prevalence and incidence rates for upper extremity fractures based on age, gender, ethnicity, geographical location, and other factors.[19,20] For instance, the incidence of childhood fractures in Malmo - Sweden among 8682 cases between 1950 and 1979 showed that boys in all age groups had higher upper extremity fracture rates than girls (62% vs. 38%).[21] However, the incidence and gender ratio changes with increasing age.[18,19,21]

There are many studies published regarding fracture in the forearm.[15,22,23] These have the highest rate among other types of upper limb fractures.[22] The incidence of forearm fractures has increased, beginning at ages 40 to 50, but the rate becomes steady around age 60.[22] The risk of forearm fracture is generally lower in men, than in women; however, the rate increases slightly after midlife.[15] Fracture of the proximal shafts of both radius and ulna is less common than the distal ones.[24] The incidence of small bone fracture in the wrist and hand is lower, with approximately equal rates in men and women, but significantly lower in Blacks.[17] Fracture of distal radius represents approximately 16% of all fractures treated by orthopaedic surgeons.[25] Distal radius fracture is estimated to be more than one-sixth of all fractures treated in the emergency.[26]

The National Hospital Ambulatory Medical Care Survey[25] indicated that there were approximately 644,985 fractures of the distal radius in 1998 in the United States. The epidemiologic studies [27,28] have reported that the incidence of distal radius fracture increases in both genders with advancing age which occurs frequently because of falls. The distribution of distal radius fracture peaks in three populations: children ages 5-14, men under age 50, and women over the age of 40.[29] Among patients older than 60, the rate of distal radius fracture is seven times higher in women than that in men.[30]

Approximately 75% of distal radius fractures occur due to falls from standing height and approximately 13% occur during sports activities[25], but the pattern of distal radius fracture varies with respect to age. Among younger people, this fracture is most likely due to fall from a height or sports activity. Older people suffer this fracture because of falls from standing height.[26] Epidemiologic studies indicate that distal radius fracture in younger adults is not strongly related to gender, and occurs approximately equally in both genders.[28,31] It should be considered that distal radius fracture in this population is often related more to high energy accidents than to simple falls.[32,33] The risk of distal radius fracture rises in both sexes with age, especially in postmenopausal women when osteoporosis has developed as a critical risk factor.[34-36] Some researchers believe that distal radius fracture is the most common fracture when osteoporosis is present.[29,37] This condition has been linked to estrogen deficiency and reduced mineral density in bones.[36,38] However, there is controversy over the role of osteoporosis as a risk factor for distal radius fracture, since it has been reported that woman with distal radius fracture have nearly similar mineral content in bones compared with the age matched controls without fracture.[39,40] On the contrary, several studies have implicated postural instability as an important risk factor for a fracture of distal radius.[41-43] Postural instability (fall) has been reported to be the most common etiology for distal radius fracture in women older than 50.[41] In the aging populations, the pattern of distal radius fracture is consistent with the falls.[42,43] Falls are more commonly seen among late middle-age women; however, both genders are equally affected in extreme old age.[41] Risk factors for distal radius fracture in the elderly have been studied extensively.[44,45] Decreased bone mineral density, postural instability, gender, ethnicity, heredity, and early menopause have all been demonstrated to be risk factors for this injury.[44-47] The prevalence of distal radius fracture

has recently increased in younger people, since they engage more often in high energy sport activities.[46,48,49]

1.3 Bone Healing in Upper Extremity after Distal Radius Fracture

Bone healing after fracture is an important homeostatic process, and depends on specialized cell activation and bone immobility during the repair process.[50,51] Bone repair is an essential process for reconstitution of skeletal integrity after trauma or skeletal surgery.[50] Fracture reduction and fixation are prerequisites for optimal bone healing; however, a variety of other factors, such as age, nutrition, and medical co-morbidities, influence the healing process.[52,53] In general, fracture healing is initiated by a sequence of inflammation followed by repair, and ends up with remodeling, thereby restoring the bone to its original state.[54,55] Once the damaged cells and matrix have been replaced during the repair phase, a prolonged remodeling phase follows.[56] Although the components of healing are similar in almost all fractures, the amount and quality of bone repair may vary based on type of cancellous or cortical bone, the extent of injured soft tissue around the fracture, and other factors which will be discussed below.

There are two types of bone healing processes: e*ndochondral ossification* and i*ntramembraneous bone formation. Endochondral* bone formation takes place closest to the fracture site where the oxygen tension is low and vascularity is disrupted. On the other hand, *intramembraneous* bone formation occurs distal to the fracture where intact vasculature is present.[53] Another key factor which affects the progenitor cells at the site of fracture is the level of mechanical stability. Intramembraneous ossification is activated in stabilized fractures, whereas endochondral ossification is activated in non-stabilized fractures and results in production of abundant cartilage at the fracture site.[53] The level of mechanical instability at the fracture site is the key to the release of cytokines, which attract various local progenitor cells into the fracture area.[52] A closed clavicle fracture without internal fixation is an example of an unstable fracture repair (i.e., endochondral ossification), whereas a stabilized fracture of the radius diaphysis (by internal fixation) is an example for stable fractures repair (i.e., intramembraneous ossification).

1.3.1 Endochondral Bone Ossification

Bone fracture damages cells, blood vessels, matrix, and the surrounding soft tissues, such as the periosteum and muscles, leading to hemorrhage and hematoma within the medullary canal, between the fracture ends and the elevated periosteum. The hematoma is considered as the first step in the repair process, and loss of hematoma leads to impaired fracture healing process.[57-59] Damage of the bone blood vessels leads to malnutrition and death of osteocytes. Severe damage in the periosteum, bone marrow, and the surrounding soft tissue may contribute to tissue necrosis at the fracture site. Inflammatory mediators released from platelets and injured cells cause blood vessel dilation, which leak plasma into the fracture area, and produce acute edema in the fracture site.[58,59]

Hematoma, surrounding periosteal and soft tissues that contain blood vessels may facilitate the initial stages of repair.[58,59] Open fractures and the treatment of fractures by open reduction disrupt hematoma formation and may slow down the repair process. The reason why hematoma formation affects fracture healing is still unclear; however, it is believed that hematoma provides a fibrinous scaffold that facilitates migration of certain cells to initiate the repair process. More importantly, growth factors, such as platelet-derived growth factors (PDGF) and transforming growth factors beta (TGF-β) and other proteins, are released by platelets and injured cells in the hematoma. These factors have an important role early in the healing process, including cell migration and proliferation, and the synthesis of new tissue matrix.[58,60]

Vascular proliferation, i.e., *angiogenesis*, occurs at the fracture site. The invading vessels are surrounded by pericytes that are a source for mesenchymal stem cells (MSC).[61] The most important mediators of this angiogenesis process are fibroblast growth factor (FGF); however, the exact nature of stimulation of vascular invasion is still unclear. The fracture ends become necrotic and are resorbed together with the injured cells at the fracture site. The cells responsible for the resorption are osteoclasts, which originate from a different cell line.[62,63] They are derived from circulating monocytes in the blood and monocytic precursor cells in the bone marrow, whereas osteoblasts originate from the periosteum or undifferentiated mesenchymal stem cells. Some of these cells originate from the injured

tissues, while others migrate to the fracture site with blood vessels. Angiogenesis provides a large source of undifferentiated mesenchymal stem cells which differentiate into different cell types. In addition, these undifferentiated mesenchymal stem cells produce bone morphogenic protein (BMP), which is an important growth factor for the differentiation process.[64] Periosteal cells of the cambium layer (i.e., inner layer of periosteum) have an especially prominent role in the healing process and form the earliest bone material. This role is more visible in children and young people because the periosteum is thicker and more cellular. The periosteum becomes thinner with increasing age and its contribution to fracture healing becomes less apparent.[64] Osteoblasts from the endosteal surface also participate in bone formation. Most cells responsible for osteogenesis appear in the fracture site within the granulation tissue that replaces the fracture hematoma.[63,64]

Mesenchymal stem cells proliferate, differentiate, and produce the callus that consists of fibrous tissue, cartilage, collagen and woven bone. Biological growth factors, such as BMPs, stimulate the early differention process.[65] The callus covers the fracture parts, and provides either the hard (bony) callus or the soft (fibrous) cartilaginous callus. The new bone at the fracture site, which is formed by intramembraneous ossification, is the hard callus. Soft callus is formed in the central regions, where there is relatively low oxygen tension, and consists primarily of cartilage and fibrous tissue. Bone gradually replaces this cartilage through the process of endochondral ossification. The process continues until the new bone bridges the fracture site and the continuity of bone is established.[66] The composition of the fracture callus matrix changes through the repair process. The cells gradually replace the clot with a loose fibrous matrix, containing glycosaminoglycans, proteoglycans, and types I and III collagen. The tissue is then converted to dense fibrocartilage or hyaline-like cartilage. In the next stages, the new woven bone remodels to lamellar bone and the content of collagen and other proteins approaches normal levels. Increasing bone mineral content is associated with a rise in the stiffness of the callus.[66] Clinical bone union occurs when the stability increases, because of the internal and external callus formation, and the fracture site becomes stable and pain-free. Radiographic healing occurs usually after clinical healing, when plain

radiographs show trabecular and cortical bone crossing the fracture site. However, even at this stage, healing is not complete yet. The new bone is weaker than normal bone; however, it gradually gains strength during the remodeling phase.

Remodeling begins with replacement of the woven bone by lamellar bone, and resorption of excessive callus. The new bone tissue at the fracture site moves toward rigid stability by progressing through calcified cartilage, woven bone, and finally lamellar bone. The important and functional consequence of remodeling is an increase in mechanical stability. The remodeling phase may continue for years after clinical and radiographic bone union.[67] It is notable that the bone density at the fracture site may be decreased years after the fracture, even after a successful fracture healing.[68,69] The reason for this density deficiency unclear but it should be considered that a fracture may cause persistent changes in the tissues and function.[70]

1.3.2 Intramembraneous Bone Ossification

When the fracture site is rigid and stable (by internal or external fixation), fracture healing occurs with less callus formation. This type of fracture healing is refered to *intramembraneous bone ossification* or *primary bone healing,* indicating that the healing process occurs without the formation and replacement of callus.[71] In the presence of full contact between the fracture ends, lamellar bone can form directly across the fracture line by generation of new osteons.[72]

There is a special cone-shaped group of osteoclasts that cuts across the fracture line; osteoblasts follow these osteoclasts and deposit new bone, and blood vessels follow the osteoblasts at the base of the cone.[71] Following the specific cone (called cutting cone), the new bone matrix, osteocytes, and blood vessels form new Haversian system through the fracture site.[71] In the presence of gap between fracture ends, osteoblasts fill the defect with woven bone in first step. Then, Haversian remodeling begins and re-establishes cortical bone.[71-72] Cutting cones move through the woven bone in the fracture gap, depositing lamellar bone and providing cortical bone and blood supply across the fracture

site without the formation of callus. In many impacted epiphyseal, metaphyseal, and vertebral fractures, both cancellous and cortical bone surfaces provide ample stability to establish primary bone healing where the bone surfaces are in direct contact.[73] Figure 1.1 represents the stages of bone healing after a fracture.
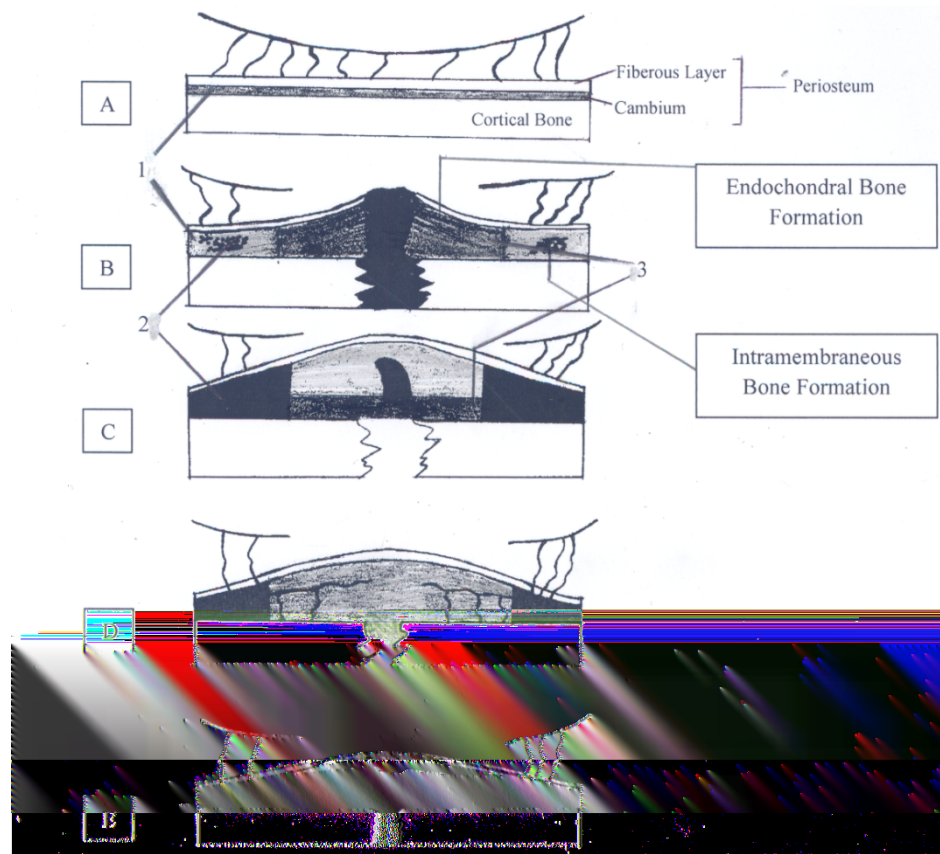
Figure 1.1: Bone healing after a fracture. (A) The cambium layer of periosteum contains progenitor cells that can differentiate into bone and cartilage. (B) Blood supply is disrupted and a hematoma is formed. Progenitor cells differentiate into osteoblasts and facilitate intramembraneous bone formation where the blood supply is preserved, and differentiate into chondrocytes to facilitate endochondral bone formation where the blood supply is injured. The numbers show the osteogenic layers with newly mineralized tissue (1), in tissues supporting osteogenesis (2), and tissues supporting chondrogenesis (3). (C) Intramembraneous and Endochondral bone formation proceed to the fracture site. (D) Cartilage tissue continues to mature and forms bone callus in the fracture site. Revascularization happens in the callus. Chondrocytes perform terminal differentiation and the matrix is mineralized leading to woven bone formation. (E) The remodeling process proceeds with osteoclasts and osteoblasts facilitating the conversion of woven bone into lamellar bone. The appropriate anatomic shape is reconstructed in this stage. © Adapted from American Society for Bone and Mineral Research.[73]

1.4 Physical Modalities and Bone Healing

Over the past 50 years, researchers have looked into various physical and biologic methods to develop new ways of enhancing fracture healing.[74] Early work on physical agents as mediators of bone healing was performed by Yasuda, Noguchi and Sata who studied the electrical stimulation effects on bone healing in the mid 1950s.[50,75] In subsequent years, other researchers have studied effects of variety of physical modalities as potential mediators of bone healing. The physical agents include mechanical stimulation[76], electromagnetic fields[2], capacitive-coupled electrical stimulation[77,78], direct current[50,79], microcurrent[80], low intensity pulsed ultrasound[81-84], and laser radiation[85,86]. With increasing influence of lasers in different medical specialities in 1970s, the researchers focused on potential effectiveness of this new physical agent on bone healing.[87-89] Although, in recent years, clinicians have recognized the importance of these non invasive physical modalities on healing of different connective tissues, there is still controversy on the characteristics and effectiveness of these physical agents.[84,85,89]

1.5 Function, Structure, Activity and Participation after Distal Radius Fracture

The goal of any type of treatment of the upper extremity is to restore function not only in the affected site, but also in the entire upper extremity and the body.[90] Performing accurate and complete physical examination is the first step of a successful treatment plan, regardless of the type of injury. Function is the most important key in the treatment plan. An injury in a small finger could severely affect life of a piano player. The upper extremity is considered an integrated system that enables the person to do most complicated tasks; from throwing a ball to producing a fine work of art.[90]

In 1980, the World Health Organization (WHO) published a universal framework for classifying the consequences of disease.[91] This classification system included the domains of body function and structure, activities, participation, personal and environmental factors.[92,93] The method provided an international, comprehensive and psychosocial model for the concept of health and delineated the multifaceted nature of health. This descriptive method was known as the International Classification of Functioning,

Disability and Health (ICF), which led to changes in the measurement of health outcomes, specifically the evaluation of disability and handicap.[92,94] Complications within these domains are called impairment, activity limitation, and participation restriction.[95] Using this model, researchers have been able to evaluate how well the existing outcome measures assess the overall health concept associated with specific conditions.[94,96-100]

Function is a broad concept, beyond physical function and mobility.[93] Based on the ICF framework, function is an umbrella that covers body functions, structures, activities and participations.[92] Function is not a fixed state for all individuals. Rather, it must be considered as the result of dynamic interaction between health, environment and personal characteristics.[93] Full function is achieved if there are no health-related complications, including any problem with function, structure, activities and participations.[92] For instance, effective treatment of a patient with distal radius fracture successfully prevents structural impairment, decreases pain and stiffness, and enables the person to perform full range of activities and participation in social events. Conversely, disability, which is a negative concept for function, is achieved if there is structural impairment, pain, stiffness, limitations of activities or participation, despite the treatment.[92] The relationship between impairment, activity limitation and participation restriction is bidirectional and can be affected by environmental factors, such as social or healthcare support and other personal factors, such as age, gender, weight, height or ethnicity.[93,94]

Most previous studies have reported that patients with distal radius fracture achieve a substantial restoration of function by 6 months after fracture treatment.[96,101-104] Reported clinical outcomes of distal radius fracture often focus on impairment in anatomical structures (i.e., radiographic) or physical impairments (i.e., range of motion, key pinch, grip strength, pain, weakness, or level of dexterity). Functional assessment of activity limitation and participation restriction can be based on self-administered functional assessment methods such as patient-rated wrist evaluation-PRWE, and/or Michigan Hand outcome Questionnaire-MHQ). Some researchers have examined broader concepts of outcome following distal radius fracture that represent performance in work, household

tasks, self-care, recreational, and social activities.[103,105,106] Results of these studies suggest that despite surgical and rehabilitation treatment care after distal radius fracture, patients continue to have difficulty with work, self-care, sports, and leisure activities.[103,105,106] Figure 1.2 represents framework of the ICF which is composed on patient's function and disability and the contextual factors that impact overall health after distal radius fracture.
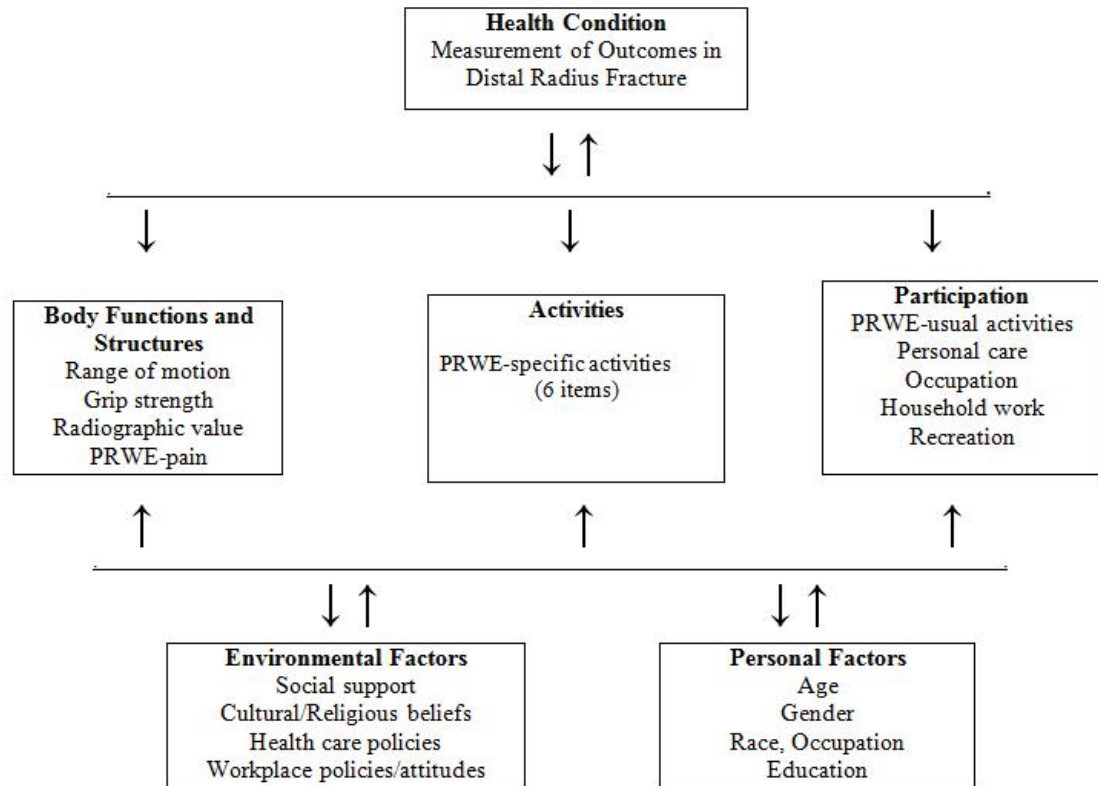
Figure 1.2: Framework of the ICF which is composed of patient's function and disability (based on patient-rated wrist pain and function evaluation) and the contextual factors that impact overall health after distal radius fracture.

1.5.1 Measurement of Physical Impairments after Distal Radius Fracture

Traditionally, the measures used to evaluate distal radius fracture have mainly focused on wrist and hand impairment, including range of motion, strength, pain or structure like radiographic data. However, impairment does not always necessarily reflect activity limitation or participation restriction.[105,107,108]

1.5.1.1 Range of Motion: Testing ROM, as a clinical measure for impairment, is an accepted method of musculoskeletal assessment, recommended by the American Medical Association.[109] This method faces some challenges and controversies against the relevance of mobility deficits with functional loss. ROM can be measured by traditional manual or advanced electro digital goniometers.[110,111] (Figure 1.3)
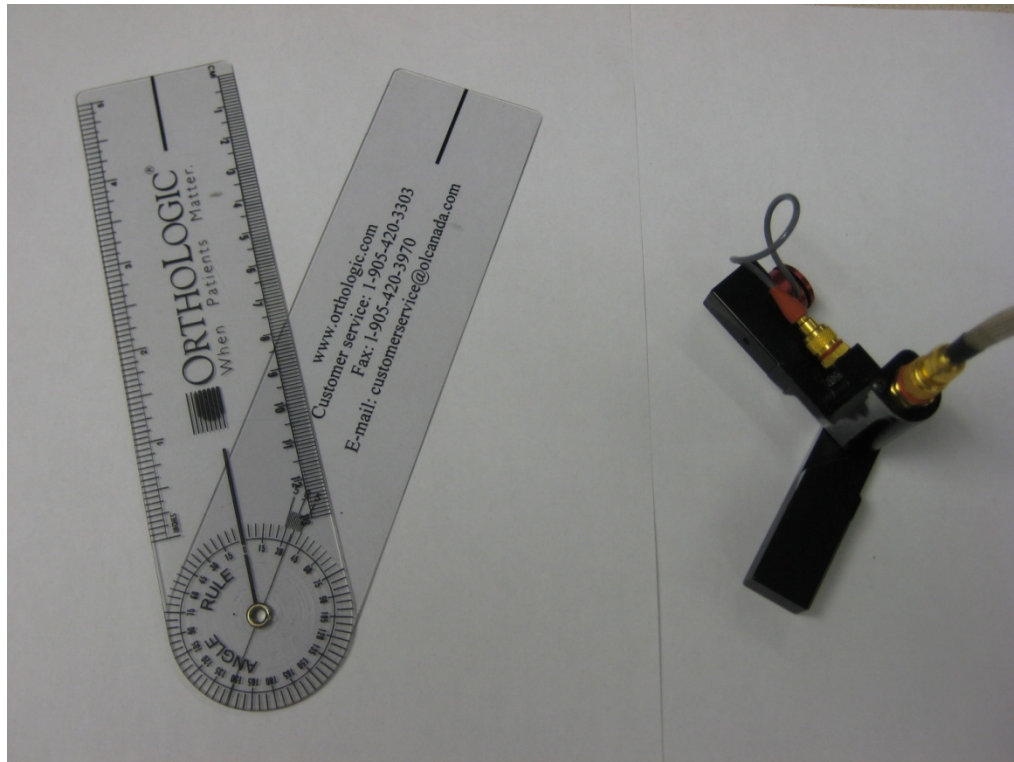
Figure 1.3: Traditional (left) and digital (right) goniometer can be used for range of motion measurement.

1.5.1.2 Grip and Pinch Strength: Grip strength is the force applied by the hand to keep, suspend or pull on an object.[112] The average values for grip strength can be different based on the age, gender, power of muscles, measurement position and types of grip. In medicine, grip strength is often used as a specific type of hand strength.[112,113] The purposes of grip strength in medicine can be to identify loss of muscle functionality, evaluate treatment efficacy, document improvement in muscle strength, and provide feedback on patient progress.[113] The pinch is generally weaker than grip, in which the fingers are on one side of an object and the thumb is placed on the other side.[112] The

pinch strength is used to measure delicate hand function and grabbing something like a paper or plate.[110,112] Grip or other relevant measure of hand strength can be assessed by a dynamometer.[112,113] (Figure 1.4).

Figure 1.4: Grip Dynamometer

1.5.1.3 Pain: Pain can be caused by intense or damaging stimuli.[114] The International Association for the Study of Pain (IASP) defines pain as: "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[115] The IASP classified pain according to specific characteristics: (1) region of the body (e.g., stomach, hand), (2) body system which its dysfunction may cause the pain (e.g., nervous, skeletal), (3) duration and pattern of pain (e.g., acute, chronic) (4) intensity and time since onset (e.g., severe, periodic) and (5) etiology (e.g., neuropathic, ischemic, idiopathic).[116] A simple effective way to document pain severity is the Visual Analogue Scale (VAS), by which patient rates his/her pain from 0 (no pain) to 10 or 100 (most severe pain) as an illustrated numerical rating scale[117] (Figure 1.5). Another method of pain measurement is the McGill-Melzack Pain Questionnaire, which clarifies symptoms.[118] This questionnaire includes 20 groups of words. Patient circles one

word in each group that best describes his/her pain and leaves out descriptions that are not applicable. Next, patient is asked to go back and circle the three words in groups 1 to 10 that most likely explain his/her pain response. Then, patient is asked to choose two words in groups 11 to 15, and one word in groups 16 to 20. The first 10 groups of words are somatic (describing what the pain feels like), groups 11-15 are affective, group 16 is evaluative, and groups space 17-20 are miscellaneous.[119] Using this method, patient provides seven words to describe both the quality and intensity of pain.
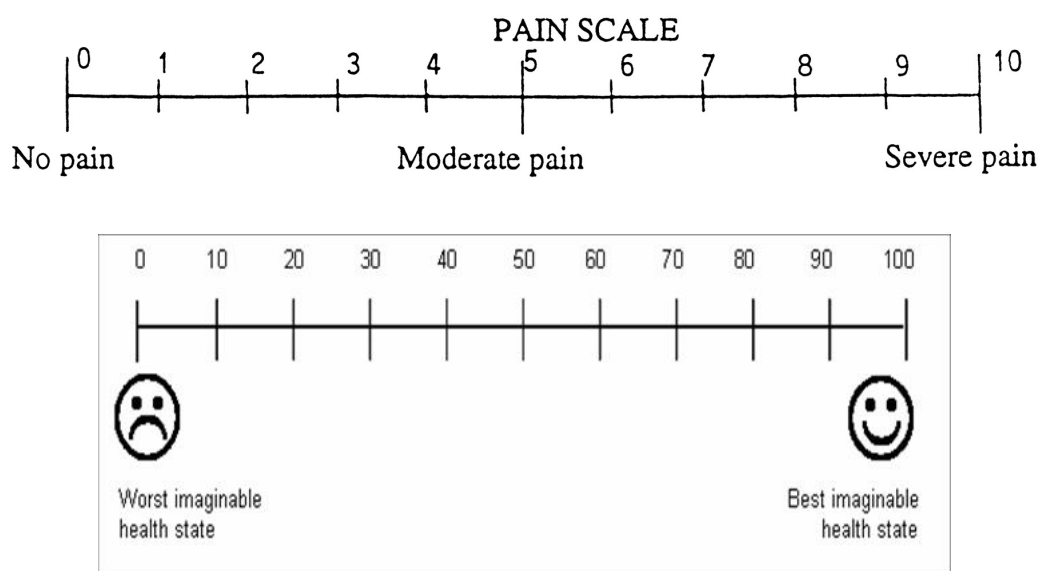
Figure 1.5: Samples of Visual Analogue Scale (VAS)

1.5.1.4 Radiographic Values: The radiographic images demonstrate the cortical and cancellous bone at high resolution, as well as the abnormalities affecting the bone. The visualization of bony tissues is due to strong attenuation of the x-ray beam by calcified structures. Clinicians can evaluate the bony abnormalities of wrist and hand through radiographic imaging.[120,121] Radial shortening and dorsal angulation are common radiographic measures after distal radius fracture.[25] Radial shortening greater than 10 mm is often associated with symptoms, while shortening of up to 3-5 mm can be associated with satisfactory result if there is an accurate articular restoration.[25] Dorsal angulation is measured on lateral view, from the angle created between the articular surface of the distal radius and a line perpendicular to the long axis of the radius. The normal volar tilt

measures between 0 to 22 degrees (mean 11-14.5 degrees). The dorsal tilt greater than 20 degrees leads to significant transfer load onto the ulna, which will be following with pain and limited grip strength.[121]

1.5.2 Measurement of Function after Distal Radius Fracture

Traditionally, distal radius fracture outcomes have concentrated on impairment measures that were often called "objective functional measures" to evaluate outcomes following injury. However, in recent years, clinicians have recognized the importance of patient-reported outcome measures to assess functional status and health-related quality of life.[122-124] As a result, the number of studies that have evaluated treatment effectiveness from the patient's perspective are progressively increasing.

1.5.2.1 Patient-Rated Wrist Evaluation (PRWE): This method uses a 15-item questionnaire to measure wrist-related pain and disability during functional activities.[103,125-129] PRWE allows the patient to rate his/her level of wrist pain and disability on an 11-point scale (0–10). On this scale, zero means no pain or complication and 10 represents severe pain or disability during a specific task. Pain is scored based on five specific questions that about the level of pain when performing an activity, at rest, repeated motion, and lifting. This method consists of two categories of specific and usual activities. The specific activities rate the amount of difficulty that the patient experiences with performing six specific tasks, including turning a doorknob, cutting meat, fastening a button, pushing up from a chair, carrying a 10 pound object, and using bathroom tissue over the past week. The usual activities subscale is scored based on the amount of difficulty that a patient has with performing four usual tasks including personal care (dressing or washing), household chores (such as cleaning), job-related duties, and recreational activities over the past week. The total of combined scales in the PRWE is 100 (50 from pain, 60/2 from specific, and 40/2 from usual categories). The psychometric properties of this scale has been shown to be excellent [103,125-128] and the patterns of recovery following a fracture have been described using this scale.[103,106] (See Appendix A)

1.5.2.2 Disabilities of the Arm, Shoulder and Hand (DASH): This questionnaire is a self-administered region-specific outcome instrument developed as a measure of self-rated upper extremity disability and symptoms. The DASH consists mainly of a 30-item disability/symptom scale, scored 0 (no disability) to 100 (most severe disability). The DASH addresses difficulty in performing various physical activities that require upper extremity function (21 items); symptoms of pain, activity-related pain, tingling, weakness and stiffness (5 items), or impact of disability and symptoms on social activities, work, sleep and psychological issues (4 items). A shorter version called the *Quick* DASH is also available. Both tools are valid, reliable and responsive and can be used for clinical and/or research purposes. However, because the full DASH Outcome Measure provides greater precision, it may be the best choice for clinicians who wish to monitor arm pain and function in individual patients.[128,129] (See Appendices B and C)

1.5.2.3 SF-36 Health Survey: The Short Form 36 Health Survey (SF-36) is a self-assessed functional outcome measure to assess quality of life. The SF-36 is a broad health-related outcome measure, which includes eight scales and two summary scores.[42-45] The original SF-36 came out from the Medical Outcome Study (MOS, http://www.rand.org/health/surveys_tools/mos/mos_core_36item.html), but scoring of the general health and pain are different.[130,131] Each scale of SF-36 is directly transformed into a 0-100, assuming equal weight for each question. The eight sections represent various domains of health including: vitality, physical function, physical role, bodily pain, general health perceptions, emotional role, social role, and mental health. The physical and mental health summary scores represent two main dimensions of health. These scores are calculated in a 3-step process, which involves weighting, transforming and aggregating the subscale scores to compute summary scores for a typical US population. The SF-36 method of health measures separates physical and mental health, providing a more complete concept for overall health. [130-133]

1.5.2.4 Michigan Hand outcome Questionnaire (MHQ): This method is a comprehensive and sensitive tool and measures various health status and important domains in patients with hand disorders.[134] The Michigan hand outcome questionnaire is a 57-item, hand-specific outcome questionnaire that contains 6 domains including:

function, activities of daily living (ADLs), pain, work performance, aesthetics, and patient satisfaction.[135] Each domain is scored from 0 to 100, with 0 being the worst score and 100 being the best. Conversely, 0 in pain domain indicates no pain and higher scores indicate more pain. All domains are assessed for each hand separately (exception of work). There is no adjustment scoring for hand dominance. This validated survey may be used for overall hand function, activity daily living, pain, work performance, aesthetics, and patient satisfaction.[134-137]

Difficulties in the ICF domains of activity and participation are able to explain a significant portion of physical health.[94,96] Post-fracture treatment and outcome measurements should extend beyond physical impairment to provide a comprehensive effective treatment to patients with distal radius fracture.

1.6 Reliability

A major concern for all clinical measurements is to what extent the data are accurate and meaningful. Reliability is the first prerequisite to insure measures are useful for clinical decision making. Reliability is the extent to which a measurement is consistent and free from errors.[138] A reliable measure has two important characteristics: *a)* it must provide consistent values with small errors of measurement, and *b)* it must be capable of differentiating among the subjects to whom the measurements are applied.[139] Both consistency and ability to differentiate among the objects of measurement are prerequisites to a reliable measure.

1.6.1 Measurement Errors

In reality, the measurements can rarely be perfectly reliable. Some degree of inconsistency always exists when measures are achieved using instruments that contain inherent measurement error whether due to, measurement methods, or inter-observer variation. The difference between a true value and the observed value is measurement error.[140,141] It is necessary to estimate how much of the measurement is attributable to error and how much reflects the true score. There are two types of measurement errors:

systematic and *random. Systematic errors* occur consistently in one direction and overestimate or underestimate the true scores. Systematic errors are predictable errors of measurement.[141] These errors can be considered a consistent "bias" in the measurement. Incorrect marking of a tape measure is a simple example for systematic errors. *Random errors* occur inconsistently due to chance and affect the true scores in an unpredictable way. There is no specific direction for random errors and they can lead to an increase or decrease the true scores. Lack of attention, non standardized methods, mechanical inaccuracy or simple mistakes are examples of simple reasons for random errors. As random errors decrease, the observed scores approach the true scores and the measurement is more reliable. Fatigue, learning, instrument limitations can result in random errors.

1.6.2 Measurement of Reliability

The measure of the reliability is often summarized in two methods. Relative and absolute reliabilities.

1.6.2.1 Relative Reliability

The relative reliability represents a measure's ability to distinguish among clients.[142] The relative reliability is defined as the ratio of true variance to observed or total variance which includes true variance plus error variance.[140] The relative reliability coefficient is intraclass correlation coefficient which may vary from 0 to 1, with higher values represent higher reliability.

$$\text{Relative Reliability Coefficient} = \frac{\text{True variance Variance}}{\text{Observed (Total) Variance}} = \frac{\text{Between Client}}{\text{Between + Within Client Variance}}$$

1.6.2.2 Absolute Reliability

The absolute reliability is the second method to represent reliability. The absolute reliability expresses the measurement error in the same units. The standard error of measurement (SEM) is used to quantify the absolute reliability of a measure.[140] In general, statisticians have reported a single score of SEM for a measure. But, some researchers believe that the amount of absolute reliability (SEM) varies based on the client's condition and must be reported as the conditional standard error of measurement (CSEM).[141]

$$SEM = \sqrt{Within\ Client\ Variance}$$

1.6.3 Types of Reliability

There are three general approaches to reliability measurement: Test-retest reliability, rater reliability, and internal consistency.[138]

1.6.3.1 Test-Retest Reliability

Test-retest reliability is based on parallel assessments of clients on different occasions.[140] This type of reliability is used to establish that an instrument is capable to measure a variable with consistency.[138] In test-retest reliability one variable is subjected to the identical test on two different occasions, while all test conditions are kept in a consistent situation. The rater must consider that many variables change naturally over time. So, if the responses are labile over time, test-retest reliability may not be possible.[138] The intraclass correlation coefficient (ICC) is the preferred statistical method to measure test-retest reliability, as it reflects both correlation and agreement.[140]

1.6.3.2 Rater Reliability

Human observers are necessary for many clinical measurements. The rater involvement in clinical measurements can be different; from a subjective observation through the measurement process, such as functional assessment or gait analysis, to part of an

instrument to measure a variable, such as blood pressure or muscle testing. As a result, the individual who performs the rating must be consistent in the application of criteria for scoring responses. Data cannot be interpreted with confidence unless the raters who collect the data are reliable. The rater reliability should be documented as a part of the research protocol; and it is also critical for confidence in clinical decision making in practice.[138,141]

1.6.3.2.1 Intrarater Reliability

Intrarater reliability refers to consistency of data recorded by one rater across two or more occasions.[138] Some researchers assume that the experienced raters can simply perform all measurements with high level of reliability. But, it should be considered that expertise may not always match with the level of precision which is necessary for the measurement. The statistical measurement of reliability strengthens the research conclusion, and also prevents critiques about the measurement accuracy.

The rater bias is considered in intrarater reliability assessment. When assessing this, it should be considered that raters can be influenced by their memory from the first measurement results. The most effective way to control this type of error is to blind raters from the first measurement scores. However, this technique may not work in many cases where the clinical measurements are observational. For instance, it is not possible to blind a clinician to measure function or gait procedures.[138] Measuring range of motion on two different occasions by one rater is an example for intrarater reliability.

1.6.3.2.2 Interrater Reliability

Interrater reliability refers to consistency of data recorded by two or more raters who measure the same group of subjects. The best way to measure interrater reliability is the way that all raters are able to measure a response simultaneously and independently. This method helps to eliminate the other sources of errors when comparing raters' scores. However, simultaneous measurement is not possible for many variables. For examples, either range of motion or muscle testing cannot be measured simultaneously. In these cases, the raters have to perform the measurements individually. With these types of measures, rater reliability may be affected when the results of first rater affect the second

rater's measurements. For instance, range of motion may stretch the joint structure and change the results of the second rater's measurements. Interrater reliability allows the researcher to know that the measurements obtained by one rater represent the true scores, and therefore, the results can be interpreted with greater confidence.[138,143,144] Simultaneous (approximate) ROM measuring by two raters is an example for interrater reliability. The statistical method to evaluate intra and interrater reliability is the ICC model 2 or 3, depending on whether the raters are representative of other similar raters (model 2) or no generalization is considered (model 3).[144]

1.6.3.3 Internal Consistency

Internal consistency reliability is based on parallel assessments of clients at an instant time.[139] In other words, internal consistency reflects the extent to which items measure various aspects of the same characteristic. This form of reliability mostly associates with questionnaires, but it is also applied to multi-item performance tests. The most important approach to measure internal consistency is correlation among all items in a scale.[138] For instance, the Short Form 36-item (SF-36) health status measure has eight subscales (See 1.4.2 Measurement of Function after Distal Radius Fracture). Each of these subscales has been evaluated for internal consistency.[145] The statistic method mostly used for internal consistency is Cronbach's coefficient alpha.[146] The Cronbach's coefficient alpha evaluates homogeneity, suggesting the extent that the items in a scale are measuring the same construct.[146]

1.7 Summary of the Limitations in Knowledge

Since fracture outcomes remain suboptimal, a number of modalities have been investigated as adjunct to accelerate or improve the quality of bone healing. The knowledge base for these physical agents is insufficient. The outcomes of fractures include physical impairments and, amongst these, range of motion is one of the most commonly measured. Range of motion measures have been studied for reliability; but there are gaps in knowledge. These gaps include knowledge about the reliability of different goniometers; including the more recently introduced computerized devices.

Further, since the devices are used by an evaluator, it is not clear if torque is consistently applied by different raters. Finally, since joint motion and grip strength are key indicators of joint status and muscle function following fracture, it is important to know to what extent these must be restored to maximize functional outcomes.

1.8 Thesis Purpose

The overall purpose of this thesis was to inform our understanding of optimizing recovery following fracture; with a focus on distal radius fracture.

The main purpose of this study was followed by the secondary goals:

1) To perform a systematic review and meta analysis of a physical modality (low level laser), which may potentially affect fracture healing.

2) To estimate reliability and validity of physical impairment (range of motion) measures by computerized digital electro goniometers.

3) To examine the consistency of torque which apply by different raters for physical impairment (range of motion) measures.

4) To clarify relationship between physical impairment outcome measures (range of motion, grip strength) and pain and function at different time points in recovery after distal radius fracture.

5) To determine the contribution of physical impairment outcome measures (range of motion, grip strength) and demographic variables to pain and function at early and late stages after distal radius fracture.

6) To identify levels of physical impairments (range of motion and grip strength), which are necessary to achieve optimal functional outcomes after distal radius fracture.

7) To identify risk of suboptimal function in patients with good physical impairments outcome measures (range of motion and grip strength) after distal radius fracture.

8) To examine whether the impairment recovery needed for optimal functional outcomes may vary in patient population based on age (younger vs. older than 65) and gender.

1.9 Overview of Chapters

There were a few studies that focused on bone healing and stimulatory effect of physical modalities on the distal radius fracture.[82,147-150] Therefore, we decided to broaden our search strategy to examine the effects of physical modalities on bone healing in general and not specific to the location/type of fracture. We were aware of the fact that bone healing process follows a similar pattern in the skeletal system.[151] The details of the effective methods used to facilitate bone healing are also applicable to distal radius fracture.

In chapter 2, we initiated a systematic review and meta-analysis of the newest physical modalities, Low Level Laser, which may impact bone healing in fractures of animal models, since there were no published data available on human bone healing treated with laser irradiation and considering that bone healing process is similar in vertebrates.[151] Although there is still insufficient evidence to establish optimal dosage, the results appear to be sufficient evidence of improved bone healing in animal models to warrant clinical trials evaluating the role of low-level laser irradiation on human bone healing. Please see chapter 2 for details.

Chapter 3 addresses reliability and validity aspects of physical impairment measurements, in term of range of motion, in patients with wrist and hand limitations. The intrarater, interrater and inter instruments reliability of two digital goniometric instruments (NK and J-Tech) were evaluated in this chapter. Moreover, the relationship between joint motion impairments obtained by digital goniometry and functional disability were studied in this chapter. The quick disability of arm, shoulder and hand (quick DASH) and patient-rated wrist evaluation (PRWE) self-reported pain and function questionnaires were used to identify functional disability of the patients with wrist and hand limitations. Please see chapter 3 for details.

Chapter 4 describes the definition of risk recovery cut-offs in wrist motion for poor functional outcomes, and identifies effect of age and gender in function after distal radius

fracture. We identified the levels of physical impairments that discriminated the functional outcomes at early and late stages of recovery after distal radius fracture. We also studied the relationship of physical impairment outcome measures and patient-rated wrist pain and function after distal radius fracture. Finally, we identified the levels of range of motion and grip strength which were necessary to achieve optimal function after distal radius fracture. Please see chapter 4 for details.

The final chapter (Chapter 5) presents a general conclusion and discussion of the above studies, including the most important findings, and provides recommendations to be considered in future studies. In summary, this thesis attempts to lead the reader through evidence-based and clinical approaches to items stimulate healing, examine the reliability of range of motion measures by electro goniometers, define the physical impairments and their contribution, identify the clinical discriminators of functional outcomes, and identify the levels of physical impairment measures required for optimal function after distal radius fracture. The findings that form the head of the results in this study are just a branch of the research road that must follow to establish the methods to stimulate healing process and function after distal radius fracture.

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CHAPTER 2

Effects of low power laser irradiation on bone healing in animal models: A systematic review and meta-analysis

Bashardoust Tajali S, MacDermid JC, Houghton P, Grewal R

2.1 Summary

Purpose: The meta-analysis was performed to identify animal research defining the effects of low power laser irradiation on biomechanical indicators of bone regeneration and the impact of dosage.

Methods: We searched five electronic databases (MEDLINE, EMBASE, PubMed, CINAHL, and Cochrane Database of Randomised Clinical Trials) for studies in the area of laser and bone healing published from 1966 to October 2008. Included studies had to investigate fracture healing in any animal model, using any type of low power laser irradiation, and use at least one quantitative biomechanical measure of bone strength. There were 880 abstracts related to the laser irradiation and bone issues (healing, surgery and assessment). Five studies met our inclusion criteria and were critically appraised by two raters independently using a structured tool designed for rating the quality of animal research studies. After full text review, two articles were deemed ineligible for meta-analysis because of the type of injury method and biomechanical variables used, leaving three studies for meta-analysis. Maximum bone tolerance force before the point of fracture during the biomechanical test, 4 weeks after bone deficiency was our main biomechanical bone property for the Meta analysis.

Results: Studies indicate that low power laser irradiation can enhance biomechanical properties of bone during fracture healing in animal models. Maximum bone tolerance was statistically improved following low level laser irradiation (average random effect size 0.726, 95% CI 0.08 - 1.37, p 0.028).

Conclusion: While conclusions are limited by the low number of studies, there is concordance across limited evidence that laser improves the strength of bone tissue during the healing process in animal models.

2.2 Introduction

Bone and fracture healing is an important homeostatic process that depends on specialized cell activation and bone immobility during injury repair.[1,2] Fracture reduction and fixation are a prerequisite to healing but a variety of additional factors such as age,

nutrition, and medical co-morbidities can influence the healing process.[3,4] Different methods have been investigated in attempts to accelerate the bone-healing process. Most studies have concentrated on drugs, fixation methods or surgical techniques; however, there is a potential role for adjunctive modalities that affect the bone-healing process.

Laser is an acronym for "Light Amplification by Stimulated Emission of Radiation".[5] The first laser was demonstrated in 1960 and since then it has been used for surgery, diagnostics, and therapeutic medical applications.[6] The physiological effects of low level lasers occur at the cellular level[7,8], and can stimulate or inhibit biochemical and physiological proliferation activities by altering intercellular communication.[9] Early work on physical agents as stimulators of bone healing was performed by Yasuda, Noguchi and Sata who studied the electrical stimulation effects on bone healing in the mid 1950s.[1,10] In subsequent years, others repeated this work in humans[1,11] and a variety of physical agents have been investigated as potential stimulators of bone healing.[12-16] With increasing availability of lasers in the early 1970s, the potential to investigate its use as a modality to affect the healing of different connective tissues became possible[17-19]. In 1971, a short report by Chekurov stated that laser is an effective modality in bone healing acceleration.[19]

Subsequently, other researchers studied bone healing after laser irradiation using histological, histochemical, and radiographic measures.[18-24] These studies have demonstrated mixed results where some observed an acceleration of fracture healing[19,21-24], while others reported delayed fracture healing after low-level laser irradiation.[20,25]

In 1996, David and his colleagues presented the first biomechanical evaluation of bone healing after laser irradiation.[25] They did not find any positive changes in biomechanical bone properties after laser irradiation, and concluded that low power laser irradiation did not help to promote bone healing. David and his colleagues stated that their results were more valid than previous studies because they used objective biomechanical outcome measures rather than subjective methods such as histology or radiology.[25] A single study has not definitive results because it cannot address different types of fractures, dosages,

or factors that might influence the potential role for low-power laser across different constructs. However, this study did define the need for additional biomechanical research to identify the role for low-power laser across different fracture constructs and the need for definitive biomechanical measures of bone strength in such studies.

The purpose of this study was to conduct a systematic review and meta-analysis of animal studies that investigated low-level laser irradiation effects on bone healing. Our inclusion criteria required that studies have quantitative biomechanical measures of bone strength since this is considered the most reliable and definitive indicator of bone healing in animal studies.[25,26]

2.3 Methods

2.3.1 Study Design

The study was designed as a systematic review and meta analysis. A systematic search of five electronic databases including MEDLINE from 1966 to October 2008; and EMBASE, PubMed, CINAHL and Cochrane from 1980 to October 2008 was conducted using an iterative strategy. The search was repeated following review of the eligible papers to specifically search for the biomechanical outcome measures identified within the initial retrieval. The researchers also reviewed the bibliographies of all retrieved articles to identify possible additional studies. One researcher (SBT) did a hand search of one journal known to publish in the area of interest of study (Osteosynthesis and Trauma Care) from September 2002 to December 2003. Two researchers independently checked the inclusion criteria in the method sections of each eligible article. The inclusion criteria of this systematic search were: 1) live animals subjects; 2) a long bone fracture or deficiency model was created; 3) random allocation of treatment; 4) any type of low level (power) laser irradiation was provided as an intervention to at least one of the treatment groups; 5) a quantitative measure of bone biomechanics was performed; 6) English language. Abstracts were reviewed by at least two raters to determine if they met eligibility criteria.

The most common reasons for excluding articles were lack of data from an animal fracture model and in particular measures of bone biomechanics. Histology, radiology, and histomorphometry measurement methods were the most commonly methods used to monitor bone healing in located articles. Through the abstract review, we excluded articles that clearly referred to a surgical laser device or used laser as an outcome measurement (Laser Doppler). All remaining abstracts were reviewed as the full paper articles. A total of 49 full papers were reviewed as full text to determine eligibility.
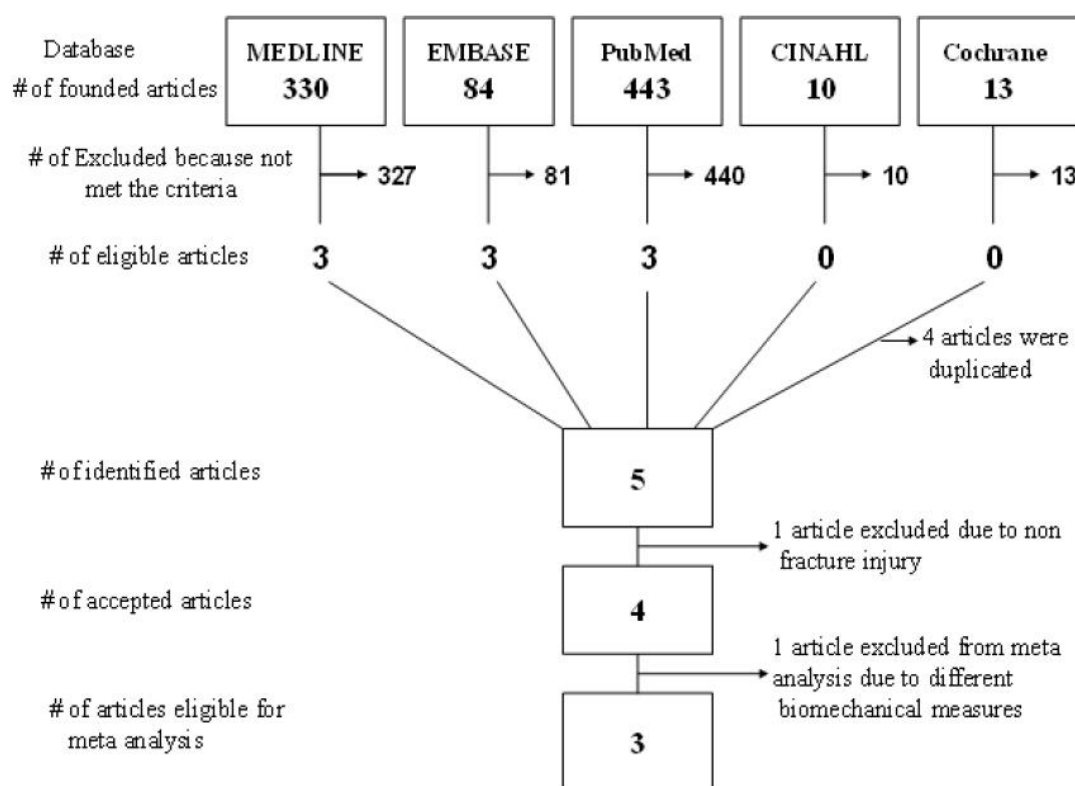
Figure 2.1: Flow diagram for identification the eligible animal studies evaluating effects of low power laser irradiation on bone healing based on bone biomechanical properties.

Of the 49 potential relevant papers only five articles met the inclusion criteria and reported on the effects of laser irradiation effect on biomechanical properties of bone during a fracture healing model (Figure 2.1). One article (Akai et al)[27] that evaluated biomechanical properties of bone was excluded at full text review because it did not include a fracture model and evaluated bone biomechanical properties after joint

immobilization. Another article [28] was also excluded from the meta analysis, since the authors (Teng et al) used two different biomechanical bone properties as the outcome measurements (the anti-torsion torque and the torsion-breakage moment). As a result, it was not possible to match and calculate Teng biomechanical results with data from the other articles data in a meta analysis. However, we assessed the quality of Teng article base on the QATRS and common quality measurements methods.

Three articles [25,26,29] were entered into meta analysis, since these three had a common metric biomechanical measures (maximum force), whereas one[28] used another biomechanical measures (the anti-torsion torque and the torsion-breakage moment). A time point where data was retrievable across all three studies was selected for meta analysis. Thus, the maximum bone tolerance force (Maximum force or F-max.) four weeks following fracture was defined as main biomechanical bone properties for the meta analysis. Figure 1 summarizes the search strategy and keywords review [See Additional File 2.1].

Potentially eligible articles were printed, reviewed and critically appraised for quality rating by two independent reviewers. Systematic reviews are commonly performed in human research but rarely in animal research. Quality rating scales commonly used in human research may not be appropriate for the animal studies, since they do not consider issues like the appropriateness of the animal model to construct being evaluated. The second author (JM) developed a quality rating scale for animal/tissue research scale (QATRS) questionnaire to assess the quality of animal studies. The QATRS is a 20-point scale evaluation chart that is designed based on randomization, blinding, similarity of animal/tissue model with human application, standardization and reliability of measurement techniques, the management of study withdrawals, and appropriateness of statistical methods [See Additional File 2.2].

Two raters independently reviewed all four papers using the structured critical appraisal tool designed for studies evaluating interventions in animal models (QATRS). We arbitrarily classified the quality of the animal studies by defining QATRS cut off scores

for quality as excellent (16-20), moderate (11-15), low (6-10) and very low (5 or lesser) quality based on their overall score on this scale. We also performed a similar critical appraisal using Jadad* and PEDro** methods [See Additional File 2.3, or Appendix D], to find how close our quality animal research scale is with the common quality studies measurement method (Table 2.1). The Jadad and PEDro quality measurement methods are used for human studies [30,31], and were not altered to apply specifically for the animal studies. We used these previously published scales to cross validate our quality measurement (QATRS) scores. There was complete agreement between the reviewers on the score of eligible articles.

Table 2.1: Mean maximum force (SD), effect size and quality score of included studies.

		Sample size		4 weeks after fracture			Quality score		
Trial	Location of fracture	Treatment group	Control group	Treatment group	Control group	Effect Size	PEDro/10	Jadad/5	QATRS/20
David et al	Tibia (Mid portion)	62	62	a) 1630 (1020)	1340 (540) (1)	0.36	5	0	12
				a) 1120 (900)	1190 (570) (2)	-0.09			
				b) 1110 (650)	1510 (820) (1)	-0.30			
				b) 670 (680)	1020 (890) (2)	-0.40			
Luger et al	Tibia (Mid portion)	25	25	74.4 (43.1)	46.5 (20.2) (1)	0.82	7	3	17
Tajali et al	Tibia (4 cm below tibial tubercle)	30	30	36.82 (7.42)	27.79 (6.14) (2)	1.34	7	1	15
Teng et al	Radius	8	16*	N/A	N/A	–	6	2	13

* 8 samples for He-Ne and 8 samples for CO_2. (1) F Plan: Vertical (Sagital), (2) T Plan: Horizontal, (a) 2 (J) and (b) 4 (J) Laser irradiation per session. Maximum force values were measured based on Newton.

2.3.2 Data Extraction

Two researchers independently extracted the data from each eligible article. All authors evaluate bone-healing process based on biomechanical bone properties as the objective index assessment, but the biomechanical variables were different between the studies. The researchers coded all related variables. The coded variables were: a) animal type, b) animal race, c) sex, d) age, e) weight, f) evaluation surface, g) evaluation time (week), h) type of surgery, i) type of fixation, j) bone type, k) mechanical test, l) speed of test, m)

graph type, n) type of laser (independent variable), o) laser output, p) irradiation distance, q) irradiation time per day, r) number of treatment sessions, s) irradiated energy per day, t) total irradiated energy, u) dependent variables (including: maximum force, callus area, stress high yield, extension maximum load, callus stiffness, energy absorbed capacity, deformation, ultimate bending strength, force at elastic stage, anti-torsion torque, torsion-breakage moment) (Table 2.2).

Table 2.2: The biomechanical bone properties (dependent variables) of included studies.

Authors	Biomechanical Bone Properties (Dependent Variables)
David et al., 1996	Force - Deflections Values
Luger et al., 1998	Maximum load, Callus area, Stress high yield, Extension Maximum, Callus stiffness
Tajali et al., 2003	F - Max, Energy absorbed capacity, Deformation, Ultimate bending strength, Force at elastic stage
Teng et al., 2006	Anti - torsion torque, Torsion - breakage moment

2.3.3 Statistical Analysis

The Q statistic was calculated to test the homogeneity of studies. A significant Q statistic indicates the presence of between study variance that is not consistent with study sampling error.[32] A significant p value in homogeneity test would indicate that the studies are heterogeneous and are not measuring an effect of the same size.[33] On the contrary, if the studies are not heterogeneous, the studies' results are considered similar and therefore they can be combined[34] (Table 2.3).

Table 2.3: Computed random effect size, CI 95% and Q value (Heterogeneity test).

Model	Effect size and 95% confidence interval				Test of null (2-Tail)			Heterogeneity	
Model	Number Studies	Point estimate	Lower Limit	Upper Limit	Z-value	P-value	Q-value	df (Q)	P-value
Random	3	0.726	0.079	1.373	2.199	0.028	2.652	2	0.196

There are two types of statistical models, which can be used for effect size calculation in meta analysis; fixed effects model and random effects model.[32] The homogeneity of effect sizes has been associated with the selection of fixed versus a random effects method of analysis.[32] Both random and fixed effects models are used to determine the statistical differences of the combined results; however, the random effects model is advised when there is an evidence of heterogeneity in variance (Hedges & Vevea, 1998).[32] We chose the random effects model because the random model is more conservative [33] and it is also advised when the authors want to generalize their findings.[32] Effect sizes for the studies were calculated by using the equation.[35]

$$d = \frac{m_t - m_c}{s}$$

Where d is the effect size; m_t is the mean change of maximum force in the treatment group; m_c is the mean change of maximum force in the control group; and s is the pooled SD between m_t and mc. We used this equation to calculate the pooled SD.[36]

$$S^2 = \frac{(n_t - 1)(S^t)^2 + (n_c - 1)(S^c)^2}{n_t + n_c - 2}$$

Where n_t and n_c are the sample size of the treatment and control groups; and S^t and S^c are the standard deviations of the treatment and control groups. The effect sizes were reported as standardized mean differences and 95% CI and the random effects model were run to determine the statistical differences of the results. The effect size (d) values of 0.20, 0.50, and 0.80 were considered as the small, medium, and large effect sizes, suggested by Cohen authors.[32] All data were entered into Comprehensive Meta Analysis (CMA) program [37] to provide a Z value and to construct the forest plots to show the overall effect size and the related 95% CI.

We also evaluated the bias of publication via analysis option by Fail Safe N computation in CMA. The Fail Safe N can be calculated by the equation K0 = K (Mean d – d $_{trivial}$)/d $_{trivial}$, where K0 is the number of needed studies to produce a trivial effect size, K is the number of studies in meta analysis, Mean d is the mean effect size from all studies, d $_{trivial}$ is the estimate of a trivial effect size.[32]

Finally, we evaluated to what extent the number of treatment sessions can be considered a moderator variable. Therefore, we stratified the articles data based on the number of treatment sessions and then compared them by t test and ANOVA measurement methods through CMA.[37]

2.4 Results

2.4.1 Description of studies

Descriptive information of all eligible studies is shown in Tables 4, 5 and 6. Among three selected studies for the final analysis, two studies (Luger et al., and Tajali et al.) supported the positive effects of low-level laser irradiation on bone healing and one researcher (David et al.)
did not find a significant effect for laser effectiveness on bone healing. Two studies (Luger et al. and Tajali et al.) evaluated the bone healing process using only biomechanical measurements, while another (David et al.) also used histology and radiology measurement methods.

All studies measured the biomechanical bone healing changes four weeks after fracture. David measured the bone healing changes 2, 4 and 6 weeks after fracture, Luger checked these measurements just 4 weeks after the fracture, and Tajali did the biomechanical measurements 2, 3 and 4 weeks after bone deficiencies (Table 2.4). Two authors (Luger et al. and Tajali et al.) applied intervention to separate experiment and control groups, while the other author (David et al) operated both hind limbs of the animals and considered one limb as the experiment and the other limb as the control. This approach

may be questionable, as it could not control the systematic effects of low power lasers irradiation.[38-40]

Fixation also varied across the studies; internal fixation (k-wires) was used in two studies (David et al. and Luger et al.), while external fixation was used in the other article (Tajali et al.). All three eligible studies used the low power He-Ne laser as their independent variable. Laser treatment parameters varied markedly across studies. All three studies included a treatment of He-Ne laser at a wavelength of 632.8 nm, which would have resulted in similar absorption properties in the target area. However, none of the studies provided complete descriptions of laser dosage, treatment parameters and application techniques. Therefore, it was not possible to compare the amount of laser energy delivered in the included studies. David et al (1996) reported the amount total irradiated energy, but did not explain the irradiation application technique. In the study performed by Tajali et al (2003), a grid technique was used to apply laser irradiation to each square centimeter of tissue; however the number of points over which laser was applied was not defined. Luger et al (1998) used and applied the laser at a distance of 20 cm from the skin, which would have significantly reduced total energy delivered to the target tissue. All studies evaluated biomechanical properties of the bone at 4 weeks post fracture. David used the laser irradiation every other day during the period of study, and Luger and Tajali used laser irradiation on a daily basis. Luger stopped treatment after 14 days whereas the other studies continued daily treatments for at least 4 weeks (Table 2.5).

Table 2.4: Maximum force (Mean $\pm$ SD) 2, 3, 4 or 6 weeks after fracture or surgery.

Authors	2 week	3 week	4 week	6 week
			2 Joules/day	
David et al. (1996)	N/A	N/A	E 1630 $\pm$ 1020 * C 1340 $\pm$ 540 *	E 1880 $\pm$ 1080 * C 2330 $\pm$ 1210 *
	N/A	N/A	E 1120 $\pm$ 900 ** C 1190 $\pm$ 570 **	E 1750 $\pm$ 1060 ** C 2330 $\pm$ 1050 **
			4 Joules/day	
	N/A	N/A	E 1110 $\pm$ 650 * C 1510 $\pm$ 820 *	E 2480 $\pm$ 1140* C 2000 $\pm$ 680 *
	N/A	N/A	E 670 $\pm$ 680 ** C 1020 $\pm$ 890**	E 1680 $\pm$ 1280 ** C 2280 $\pm$ 140 **
Luger et al. (1998)	N/A	N/A	E 74.4 $\pm$ 43.1* C 46.5 $\pm$ 20.2*	N/A
Tajali et al. (2003)	E 28.82 $\pm$ 8.19** C 24.44 $\pm$ 3.19**	E 29.85 $\pm$ 5.50** C 27.70 $\pm$ 5.32**	E 36.82 $\pm$ 7.42** C 27.79 $\pm$ 6.14**	N/A
Teng et al. (2006)	N/A	N/A	N/A	N/A

E Experiment, C Control. * Data refers to biomechanical evaluation in vertical plan. ** Data refers to biomechanical evaluation in horizontal plan. Maximum force values were measured based Newton.

Table 2.5: Study characteristics of selected articles on effects of He-Ne low power laser irradiation on bone healing.

Authors	Animal Type	Animal Race	Gender	Age (month)	Weight (gr)	Evaluation Surface	Evaluation Time (week)
David et al. 1996	Rat	Sprague - Dawely	Female	N/A	225-300	Horizontal (T) Vertical (F)	2 − 4 − 6
Luger et al. 1998	Rat	Wistar	Male	4	400 $\pm$ 20	Vertical (Sagital)	4
Tajali et al. 2003	Rabbit	Dutch	Male	4-6	1600-2000	Horizontal	2 − 3 − 4
Teng et al. 2006	Rabbit	New Zealand	Male	N/A	2000-2500	N/A	5

Table 2.5: *(Continued)*: Study characteristics of selected articles on effects of He-Ne low power laser irradiation on bone healing.

Authors	Surgery Type	Type of Fixation	Bone Name	Mechanical Test	Test Speed (mm/min)	Graph Type	* Laser Type
David et al, 1996	CO	IF (Intramedullary 1/32" Kirschner wire)	Tibia	Four Point Bending Test	5	Stress-Strain	He - Ne
Luger et al, 1998	CO	IF (Kirschner wire)	Tibia	Tension - Stress Test	5	Load-Strain	He - Ne
Tajali et al, 2003	PO	EF	Tibia	Three Point Bending Test	N/A	Load-Deformation	He - Ne
Teng et al, 2006	PO	Without Fixation	Radius	Biomechanics Anti - Torsion Test	N/A	N/A	He - Ne & Co2

CO = Complete Osteotomy, PO = Partial Osteotomy, IF = Internal Fixation, EF = External Fixation, * Independent Variable.

Table 2.5 *(Continued)*: Study characteristics of selected articles on effects of He-Ne low power laser irradiation on bone healing

Authors	Laser Output (mw)	Distance between Producer and Skin (cm)	Irradiation Time per Day (min)	Number of treatment sessions	Irradiated energy per session	Total Irradiated Energy		
						2 week	4 week	6 week
David et al., 1996	10	N/A	N/A					
				(2 week) 6	0	0	0	0
				(4 week) 13	2	12	26	40
				(6 week) 20	4 (J) every other day	24	52 (Joules)	80
Luger et al., 1998	35	20	** 30	14	***	***		
					21 J (each area)		294 (J) (each area)	
					63 J (in total)		882 (J) (in total)	
Tajali et al., 2003	2	N/A	** 30	14	1.2 (J/cm2)		16.8 (J/cm2) ***	
				21			5.2 (J/cm2)	
				28			33.6 (J/cm2)	
Teng et al., 2006	N/A	N/A	10	35	***	***		
					He-Ne: 16.8 (J/cm2)		He - Ne: 588 (J/cm2)	
					Co2: 90 (J/cm2)		Co2: 3150 (J/cm2)	

** Including 10 minutes on fracture area, 10 minutes on the area above the point of fracture, and 10 minutes on the area below the fracture. *** Meta analysis authors calculated amount of irradiated energy based on the articles data with this equation [43]:
Set Power (w) * Time (s) = Total Amount of Energy (J)
Total Amount of Energy/Treatment Surface (cm2) = Energy Density (J/cm2)

2.4.2 Outcomes measures

The eligible studies used different indicators of the biomechanical properties indicating bone healing. There were 11 biomechanical bone properties measured. Maximum bone force tolerance (Maximum Force) was considered the major dependent variables in three studies (out of four). The other biomechanical variables were different from study to study. Although David et al (1996) studied just one main biomechanical variable (Maximum Force), they also used histological and radiological assessment methods. Luger et al (1998) studied callus area, stress high yield, extension maximum load, and callus stiffness as the biomechanical variables. Tajali et al (2003) studied energy absorbed capacity (EAC), deformation, ultimate bending strength (UBS), and force at elastic stage as the biomechanical variables (Table 2.2).

2.4.3 Calculation of effect size

The maximum bone tolerance force before the point of fracture was the most common biomechanical variable in all eligible studies and was used to calculate effect size of each article in this meta analysis. A total of 234 samples across all three identified studies were entered in the meta analysis based on the maximum force. We chose to evaluate the biomechanical data 4 weeks following surgery or fracture. We chose this as a clinically relevant endpoint, since earlier time may not have demonstrated sufficient healing [25,26,29], and also expect that healing would be completed in both the experiment and control groups at later time points.[26,29] Although the time points for biomechanical evaluation was different in each study (Table 2.5), all eligible articles performed a biomechanical evaluation at 4 weeks after surgery or fracture allowing us to perform data synthesis on a common metric. David et al. [25] measured the force maximum variable changes with two different doses of low power He-Ne laser irradiation (2 and 4 Joules per/day), while the other researchers (Luger and Tajali) used one dosage for all experiment groups (Table 2.5). To standardize the doses used in each study, we calculated an average effect size between two effect sizes of force maximum changes in David article by CMA program. All effect sizes were calculated by SPSS and CMA.[37]

2.4.4 Testing for homogeneity of variance

The Q statistic result showed that the value of Q for the samples in this study (n = 3) was not statistically significant (Q 2.652, p 0.196). Therefore, the distribution of the effect sizes was homogenous and we could combine study results. The average effect size demonstrated a statistically significant effect for laser being beneficial in terms of bone strength (n 3, d = 0.73, CI 95% 0.08 - 1.38) (Table 2.3).

2.4.5 Merits of different published studies (variables)

The effect sizes of eligible studies were computed by CMA to evaluate the merits of different published studies (Table 2.1). The CI 95% for maximum force F-max includes zero, indicating there is no significant difference in terms of force maximum in the study by David et al. (1996) (mean 0.072, CI 95% 0.976-1.120, p 0.89). The effect size in David article [25] was not statistically significant. The average effect size in David article for two different dosage (2 and 4 J/day) 4 week after surgery is equal d = - 0.072 which shows the low effect size in this article. On the contrary, the CI 95% for F-max for Luger study (mean 0.820, CI 95% 0.087-1.553, p 0.028), and also Tajali study (mean 1.400, CI 95% 0.137-2.662, p 0.030) showed high effect sizes in these two articles and statistically significant differences.

Calculation of pooled standard deviation and average effect size in each article showed the lowest effect size for David study.[25] This study also had relatively low quality scores (QATRS 12/20, Jadad 0/5, PEDro 5/10). On the contrary, Luger and Tajali studies [26,29] had larger effect sizes (more than high limit of effect size for good articles d > 0.80). The quality evaluation results of these articles also showed good quality for Luger and Tajali (QATRS 17/20, Jadad 3/5, PEDro 7/10 for Luger et al article, and QATRS 15/20, Jadad 1/5, PEDro 7/10 for Tajali et al article).

In summary, the effect size calculation of force maximum, 4 week after bone injury in eligible articles shows that one article has low value effect size (David et al. d = 0.072),

and two articles have excellent value effect size (Luger et al d. = 0.82, Tajali et al. d =1.400). The computed random effect size (mean 0.726, 95% CI 0.079 - 1.373, p 0.028) suggests main research hypothesis that low power laser irradiation can increase bone-healing process in animal samples based on an evaluation of biomechanical bone properties (Figure 2.2).

Effect of He-Ne Low Level Laser Irradiation on Bone Healing, A Meta Analysis Approach

Study name	Std diff in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
David et al.	0.072	0.535	0.286	-0.976	1.120	0.135	0.893
Luger et al.	0.820	0.374	0.140	0.087	1.553	2.191	0.028
Tajali et al.	1.400	0.644	0.415	0.137	2.662	2.173	0.030
Random Effects Model	0.726	0.330	0.109	0.079	1.373	2.199	0.028
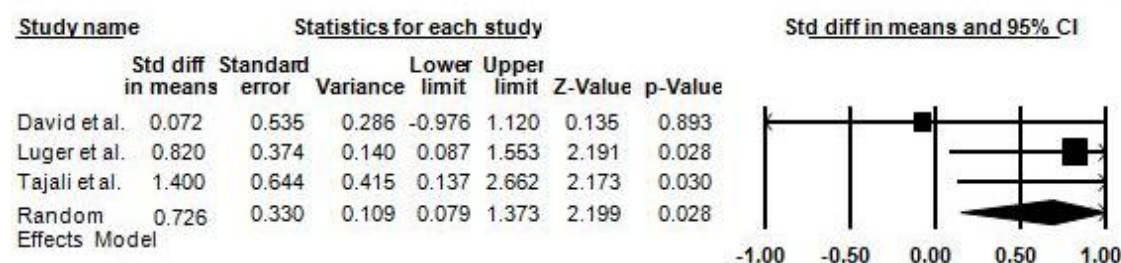
Figure 2.2: The forest plot of the random effects model based on bone biomechanical properties (force maximum) changes four weeks after bone injury.

2.4.6 Fail Safe N and the number of treatment sessions

The results of Fail Safe N calculation showed that 38.28 (= 39) more unpublished articles are needed to nullify our results. The d results also showed that it is possible to divide the number of treatment sessions to three parts: a) Less than 14 Treatment sessions, b) Between 14 to 21 Treatment sessions, and c) 28 Treatment sessions. There was no significant difference between experimental and control groups after 14 treatment sessions (mean - 0.072, 95% CI - 1.204 - 1.060, ns). On the contrary, low power laser irradiation for 14 to 21 sessions significantly improved the bone-healing process in animal (mean 0.557, 95% CI 0.079 - 1.035, p 0.022). Finally, 28-session low level laser irradiation caused the significant increase on bone healing process in animal (mean 1.400, 95% CI 0.137 - 2.662, p 0.030) (Table 2.5, Figure 2.2).

2.5 Discussion

Three of the four selected articles reported a positive effect of low-level laser therapy on bone healing [26,28,29], and one article reported negative results.[25] Meta analysis revealed that overall positive impact of laser on bone healing. Although there are different kinds of low power lasers e.g. Carbon Dioxide (CO_2), Helium- Neon (He-Ne), Gallium-Aluminum-Arsenide (Ga-Al-As), and Infra-Red (IR), all the identified studies used continuous wave He-Ne lasers. This may be because He-Ne laser has some support in earlier studies on connective tissue healing.[18,19,22-24] Teng et al (2006) was the only author who compared the He-Ne with CO_2 lasers irradiation effects based on the bone biomechanical properties and also radiology.[28] He reported the composition and biomechanical properties were improved over controls following irradiation for 35 days with either type of laser. However, these results were excluded from the final meta analysis due to non-similarity of biomechanical variables. Nevertheless, it is important to note that the conclusions were in agreement with the present study. Incomplete and inconsistent information provided about laser treatment protocols prevented an evaluation of laser dosimetry. Future studies that compare different wavelengths and amount of laser irradiation are needed to define the optimum application strategy. However, these studies must provide complete information about the power, time (per point applied and the number of points), and area of treatment (beam spot size), so that energy density and total energy delivered with each treatment can be calculated. In this way, useful comparisons can be made between studies with regards to laser dosimetry. Although randomization and the use of internal controls can increase power in studies where the effects are localized, the use of two hind limbs of each animal, one as the experiment and the other as the control, in the study by David[25] might lead to a false negative findings, since low level laser therapy has some systemic effects.[38-40] Moreover, surgery or fracture of both hind limbs in each animal, created excessive limitations in normal mobility for animals in David study [25] and may have affected the bone healing process.[3] Finally, the use of intermedullary nails in some experimental groups may affect the study results[41,42], especially when the authors had to remove the nails before the biomechanical assessment and reaming of fractures [41,42] possibly explaining David's negative results. Our meta-

analysis was only able to identify a limited number of studies that have addressed the impact of laser on the strength of healed bone in an animal fracture model. Despite these limitations, there was a statistically significant impact of laser on the biomechanical properties of healed bone-particularly in more than 14 sessions laser application. Furthermore, our failsafe n calculation indicates that a large number of contrary studies would be required to refute this finding. This would suggest that sufficient animal research is available to support experimental use of laser for bone healing in humans.

Findings of improved bone healing in animal models with adjunctive laser therapy are consistent with other research on the effects of laser. The cellular reactions such as ATP synthesis promotion, electron transport chain stimulation, and cellular pH reduction might form the basis for the clinical benefits of low-level laser therapy [43,44], and these biochemical and cell membrane changes may increase activities of macrophages, fibroblasts, lymphocytes and the other healing cells.[45,46] Increase of collagen and DNA synthesis, faster removal of necrotic tissue[20], increase of Ca deposition [19,21,22], increase of periosteum cell function[18], increase of osetoblast and osteocyte function[18,19], new vascularisation [21,22], stimulation of enchondral ossification, earlier differentiation of mesenchymal cells, increase of preosteogenic cells[23], and stimulation of callus formation[21,22] are some of the positive effects of low level laser therapy on bone healing process which have been reported by former researchers and can explain the bone healing stimulation under low level laser therapy.

2.6 Study Limitations

Our study findings must be viewed with caution at this time because of substantial limitations. 1) It is possible that we missed some published or unpublished related articles. 2) Although the results of random and fix effects models are in favor of laser effects on bone healing (fixed effects model, n3, mean 0.727, CI95% 0.184 to 1.269, p 0.01), the small sample size of selected studies may cause the insignificance result in Q statistic. 3) We tried to identify a core outcome measure that would allow comparability across studies. Although we ran analysis to check for appropriateness of combining data

from analysis, our results were based on the fractures from two different animal types (tibia in rat and rabbit models).[33] 4) Given the small number of studies, we could not formally incorporate quality measurement scores into our synthesis. The results of quality measurement methods and power of the selected studies could not be used in our Meta analysis. 5) The samples in one study (David) were used as the experimental and control at the same time. The data came from this study could not be considered as independent data, but they were still independent from the other eligible studies' data. 6) Although we know that the process of fracture healing is consistent [47], variations in tissue type and depth may have affected the impact of laser. And finally 7) the actual dosage delivered is questionable across the studies given that laser transducer calibration was not mentioned.

2.7 Conclusion

Our meta-analysis identifies that low level laser therapy improves the biomechanical properties of bone following fracture healing in animal models. There is still insufficient evidence to establish optimal dosage, but low-level laser irradiation for at least 14 to 21 sessions was required for preferential effects. The results appear to be sufficient evidence of improved bone healing in animal models. More studies to identify the effective dosage, specifically animals with higher similarities in human bone properties and sizes (i.e. sheep, dog)[48,49], lead to warrant clinical trials evaluating the role of low-level laser irradiation on human bone healing.

2.8 Additional Files

Additional File 2.1: The initial key words for systematic review were selected from relevant articles. Mesh and SCOPUS international data lines were used to find more related key words with close meanings. The following key words were used in search strategy:

"Fracture" or "Fractures" or "Fracture healing" or "Fracture healings" or "Bone healing" or "Bone regeneration" or "Fracture regeneration" or "Bone remodeling" or "Fracture

remodeling" or "Bone consolidation" or "Fracture consolidation" or "Fracture repair" or "Bone repair" or "Osteosynthesis" or "Osteogenesis" or "Osseointegration" or "Osteoconduction" AND

"Biomechanics" or "Biomechanical properties" or "Bending strength" or "Tensile strength" or "Energy absorbed capacity" or "Deformation" or "Callus stiffness" or "Maximum force" or "Compressive strength" or "Elasticity" or "Friction" or "Shear strength" or "Mechanical stress" or "Torsion" or "Elastic resistance" or "Dissipation of energy" or "Breaking strength" AND

"Laser" or "Lasers" or "Laser therapy" or "Low level laser" or "Low power laser" or "Photo therapy" or "Light therapy" or "Photon" or "Therapeutic light" or "Therapeutic photon" or "Laser biostimulation" or "Photon biostimulation"

Additional File 2.2: The Quality of Animal/Tissue Research Scale. Please see appendix D, or click here for file.

http://www.biomedcentral.com/content/supplementary/1749-799X-5-1-S2.DOC

Additional File 2.3: *The Jadad scale is a three-item questionnaire that scores studies from 0 to 5 based on the randomization, double blinding and withdrawals or dropouts.[30] **The PEDro scale is a ten point questionnaire that scores studies from 0 to 10 based on the randomization, subject and assessor blinding, validity of outcome measures, appropriateness of treatment methods, proper statistical analysis, and withdrawals or dropouts management.[31]

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CHAPTER 3

Reliability and Validity of Electro-Goniometric ROM Measurements in Patients with Hand and Wrist Limitations

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3.1 Summary

Study Design: Cross-sectional reliability and validity study.

Introduction: Measurements of wrist and/or finger range of motion (ROM) are frequently performed after wrist or hand disorders. Joint ROM measurements are used to assess patients' status and progress. Goniometric measurements must be reliable because the results are used to determine impairment ratings and functional progress. Electro-goniometer measurements may be a viable alternative for traditional goniometry.

Purpose: To determine intrarater, interrater and inter instrument reliabilities and validity of two digital electro-goniometers (NK and J-Tech) to measure active wrist/finger ROMs in patients with limited wrist and/or hand motion, and to determine intrarater and interrater reliabilities of digital goniometry (NK) to measure torques of PIP passive flexion of the index finger in patients with limited wrist/hand motion.

Methods: The study was performed in a randomized block design on 44 patients (24 women, 20 men, 21-68 years old) with limited wrist and/or hand motion. Two experienced raters (one physical therapist and one kinesiologist) measured active wrist ROMs (flexion & extension, radial & ulnar deviations, pronation & supination), and active and passive PIP index flexion using two digital electro-goniometers. The torque of passive PIP flexion of the index was measured following passive index flexion using one digital goniometer. The raters were blinded to the clinical information. The ROM measures were repeated by one rater (physical therapist) 2-5 days after the initial measurements. Testing was performed with standardized consistent landmarks taken from previous research. The construct validity was determined by correlation coefficients between sub measurements of NK, J-Tech scores and patient-rated pain and function scores; quick Disabilities of the Arm, Shoulder and Hand (quick DASH) and Patient-Rated Wrist Evaluation (PRWE).

Results: Intraclass Correlation Coefficient (ICC) was used to assess reliabilities. The intrarater, interrater and inter instrument reliabilities were high in most of the ROM measures (ICCs range 0.64-0.97) for both types of electro-goniometers. The 95% limit of agreements and Bland and Altman plots did not show progressive changes. There was a significant difference in force application between the raters when performing passive

ROM measures for PIP index, but the same rater produced consistent force. Most of the NK and the J-Tech ROM measures were moderately correlated with the patient-rated pain and function scores (*r* range 0.32-0.63).

Conclusion: Digital goniometric devices (NK and J-Tech) can be used to reliably measure active wrist ROMs and active or passive PIP flexion in patients with limited wrist and/or hand motion. The moderate relationship between wrist and hand ROM measures (obtained by NK and J-Tech digital goniometers) and quick DASH and PRWE self-reported disability suggested that joint motion impairments contributed to functional disability.

Level of Evidence: Not applicable (clinical measurement).

3.2 Introduction

Loss of range of motion (ROM) in the wrist and hand can arise secondary to pain, swelling, muscle weakness, or deformity.[1] Loss of ROM is related to a decrease in grip strength, grasp ability, fine manipulation, and hand function.[1] ROM measurement is considered an important component of hand joint assessment to measure impairment, as well as to evaluate the effects of therapeutic interventions.[2] Goniometry is an easy, noninvasive, and inexpensive method of measurement[3] and is considered a precise method to assess movement capability.[4]

A number of studies have evaluated the reliability of manual goniometry, providing support for current use of goniometry. Flowers et al.[5] studied intra and interrater reliability of passive wrist flexion and extension ROM in the patients of eight clinics around the United States. The evaluators (4 therapists in each clinic) randomly measured passive wrist flexion/extension ROM of 141 patients with a plastic manual goniometer and in a blinded design. The authors (who were not the raters) determined that six of the eight clinics had significant differences among the various goniometric techniques. Ellis and Bruton[6] reported about a 5˚ difference for intrarater reliability and 7˚ to 9˚ difference for interrater reliability with 95% confidence interval for finger manual goniometry.

Previous studies have provided limited evidence about computerized goniometers. Jonsson and Johnson[7] compared ROM measurement accuracy between two types of wrist goniometers: a biaxial single-transducer and a biaxial two-transducer. The research showed that the biaxial single-transducer goniometer had larger errors compared to that of the biaxial two-transducer system. However, neither system is commercially available. Armstrong et al.[8] reported intraclass correlation coefficients (ICCs) and standard errors of measurement (SEM) for forearm rotation while reporting intrarater, interrater and inter instruments reliability across 5 raters and 3 types of goniometers: a universal standard, an NK computerized goniometers, and a mechanical rotation measuring device. The reliability of the pronation/supination was moderate to high across different occasions or raters. Rotation measurements tended to have larger SEM that did elbow flexion/extension measures examined within the same study. However, there was no bias between rates or instruments. The researchers also identified that reliable ROM measurements of elbow flexion/extension and forearm pronation/supination were obtainable regardless of the level of experience when the raters used a standard measurement method. The NK Hand assessment system goniometers although reliable are no longer supported commercially, so clinicians who wish to adopt this approach would need to know the reliability of commercially available devices. Jonsson et al.[9] studied the accuracy and feasibility of using a biaxial electro-goniometer for measuring simple thumb movements in healthy subjects. The researchers compared the results of eight positions for thumb flexion/extension and abduction/adduction between digital and manual goniometers and indicated that the only significant difference was found between the goniometers when the thumb was in full flexion. The researchers identified that electro goniometric measurement errors were lower than 5˚ for the thumb ROM measures in comparison to manual goniometry.

A reliable ROM measurement helps clinicians make a treatment plan based on accurate measurement of motion impairments. Although manual goniometers have stable in hand therapy practice, the use of computerized tools is expected to increase over time as the costs become lower; and as computers become integrated in other aspects of practice. The digital electro goniometric devices (such as NK and J-Tech) potentially offer mechanical

precision and reduced rater reading errors; and thus may enhance the accuracy of assessment of hand joint ROM, mobility and severity of impairment. The NK device has advantages, in that we already know it is precise; while the J-tech has an advantage in that is commercially available as part of a complete hand assessment system designed for clinical practice.

NK torque-motion goniometer allows assessment of torque applied when a given joint motion is measured. Torque values cannot be measured by traditional manual goniometers; unless extra instrumentation is applied. It has been suggested that Torque ROM measurements can inform our understanding of the compliance of the soft tissues limiting ROM; and thus could contribute to decisions about the need for conservative therapy or surgery interventions.[10,11] For instance, the decision for tendon transfer surgery in patients with flexion contracture after median/ulnar nerve palsy can be made using the information derived from torques ROM measurements. In this case, the magnitude of stiffness can be evaluated by a series of torque angle curves over time, and when the curves do not change and a steep curve is persisted, the patient may need surgery.[10] A further purpose of torque goniometry is to understand the force applied while assessing ROM, since it is assumed that this might contribute to differences in motion estimates obtained by different raters. Patients are often measured repeatedly by different therapists during the course of their hand therapy program. Thus, it is important to know how comparable these measures are likely to be. The evidence to date on computerized hand/wrist goniometry is very limited.

The primary purpose of this study was to determine the intrarater, interrater and inter instrument reliability and construct related validity of wrist and PIP index finger ROM measures using two digital electro goniometric devices in patients with limited wrist and/or hand motion. The secondary purpose was to assess whether the torque applied during ROM measurements varied across different raters; using PIP passive flexion of the PIP index finger as the construct.

3.3 Methods

3.3.1 Study Design

The study was designed as a cross-sectional reliability and validity study, so that the reliability of two digital electro-goniometry instruments was assessed between two occasions, across two raters and between two instruments.

3.3.2 Participants

Patients with limited wrist and/or hand motion who met eligibility criteria and consented to participation were enrolled in the study. Participants were included if they were 19 years of age or older and had limited wrist and/or hand motion 8 to 12 weeks following a musculoskeletal disorder. They also must have been able to speak and understand English and learn simple instructions. Patients were excluded from the study if they were under 19 years old or unable to follow study instructions, had an acute infection or open wound, a history of neurological or rheumatologic conditions, bilateral hand disorders or combined arm/shoulder or multiple disabled joints.

Forty nine patients participated in the study, and a written consent form was obtained before measurement. All participants were outpatients of the Hand and Upper Limb Center at St. Joseph Hospital in London Ontario. The participants were recruited and measured within the initial eight to twenty four weeks of their injury. All participants completed a brief survey including demographic data (age, gender, affected side, medical history, etc) before data collection. The study was reviewed by the university and hospital academic and ethical boards and was approved before starting data collection.

3.3.3 Raters and Instruments

Two raters obtained the measurements in two different sessions. One rater was a PhD physical therapist and the other was a kinesiologist. Both were experienced in ROM assessment.

The raters used the NK Hand Assessment Laboratory joint motion (NK Biotechnical Engineering Company, Minneapolis), and the J-Tech digital hand assessment (J-Tech Medical, Salt Lake City, UT) goniometers; and their associated software for ROM measurements. The NK and J-Tech are two instruments which can be used to assess hand joint ROM, mobility and severity of impairment (Figures 3.1). Data collection was performed with standard computer software sensitive with a foot switch, so that the rater's hands were free to adjust the goniometric alignment. Active ROM of the wrist motion (flexion and extension, radial/ulnar deviation, pronation and supination), and active and passive ROM of proximal inter phalangeal (PIP) joint of the index finger (flexion) were measured for each participant by both NK and J-Tech Hand electro-goniometers. There was a self calibrating device in both electronic measurement instruments so that the raters could calibrate both instruments prior to the study and before each measurement. The lengths of the arms were equal in NK (2 inches), while the lengths of the short and long arms were 7.5 and 10.5 inches in J-Tech. The NK digital instrument had a specific gauge and a digital force transducer which could be used to measure the amount of passive force applied for the hand ROM measurements. Patients were asked if they were relaxed and comfortable before the measurements were taken.
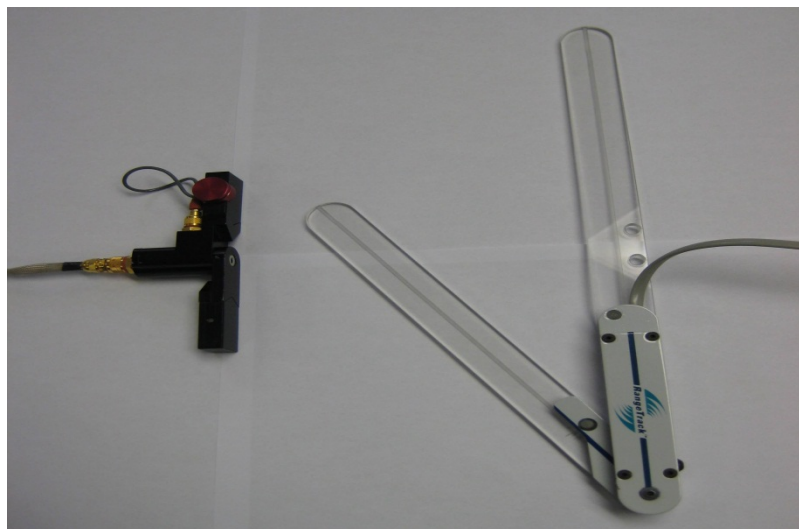
Figure 3.1: NK (left) and J-Tech (right) goniometer instruments.

Patient positioning: Three positions were used for different ROM measurements. To measure wrist flexion/extension, ulnar/radial deviation, and index finger flexion, each participant sat in front of a hand assessment table with their elbow placed on the table. The elbow was held in 110° - 120° of flexion for wrist flexion/extension and PIP flexion measurements, and was held at 90° flexion for the measurements of radial/ulnar deviation. To measure wrist pronation/supination, each participant stood in front of the assessment table and kept her/his arm close to the body and the elbow was positioned at 90° of flexion. The forearm was in neutral position for all measurements.[12,13]

Landmarks: Established reliable landmarks were used for goniometry.[12]

Wrist Flexion: The stationary arm was aligned on the dorsal midline of the forearm, the movable arm on dorsal surface of third metacarpal, and the center fulcrum over the capitates on the dorsal aspect of wrist. *Wrist extension:* The stationary arm was aligned on the palmar midline of forearm, the movable arm over palmar midline surface of third metacarpal, and the center fulcrum on the palmar surface of the wrist at the level of the capitate.[13]

Radial/Ulnar Deviation: The stationary arm was aligned on midline of the dorsal surface of the forearm, the movable arm dorsally over midline of third metacarpal, and the center fulcrum on capitate.[12]

Pronation: The stationary arm was at the dorsal aspect of the wrist paralleled to anterior longitudinal midline of humerus, the moveable arm on the widest dorsal area of the wrist proximal to the styloid processes of radius and ulna, the center fulcrum on lateral and proximal aspect of ulnar styloid process. *Supination:* The stationary arm was at ventral aspect of the wrist parallel to anterior longitudinal midline of humerus, the moveable arm on volar surface of the wrist at level of ulnar styloid processes, the center fulcrum on volar surface of the wrist in line with ulnar styloid process.[12]

Index PIP Flexion: The stationary arm was aligned dorsally over proximal and the moveable arm over middle phalanxes, the center fulcrum dorsally over PIP joint.[12] Figure 3.2 provides samples of the ROM measures by NK and J-Tech digital goniometers.
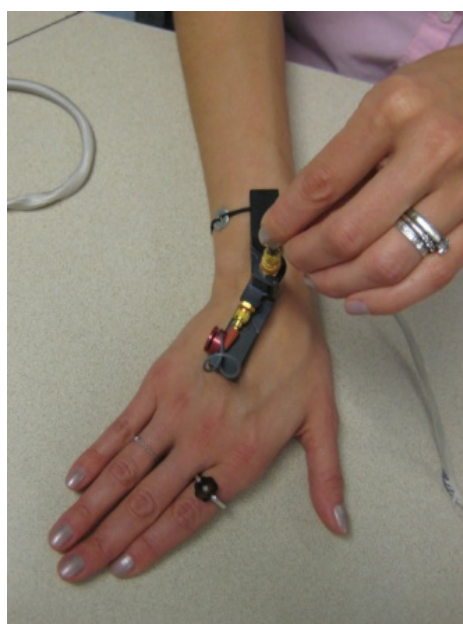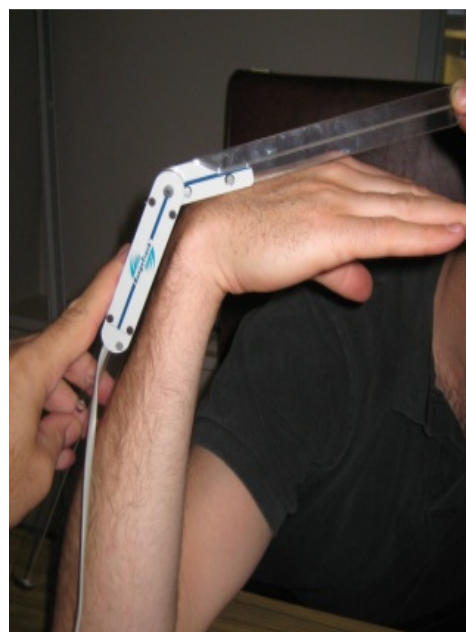
(A)   (B)

Figure 3.2: A) NK goniometer placement for active ulnar deviation measure.

B) J-Tech goniometer placement for active wrist flexion measure.

Data were collected on 2 separate days with 2-5 days between sessions. The raters used a random number generator program to randomize both raters and instruments for each participant (random.org). In first day, the ROM measurements were started randomly by either rater one or rater two and by NK or J-Tech. After a short period of rest (5 minutes), the second rater performed the similar ROM measures for wrist and index finger motions. After a longer period of rest (10 minutes), the ROM measurements were repeated in a similar way by the other digital goniometer (NK or J-Tech). In next stage, the participants were asked to come back to the clinic two to five days later for the second day of the measurement. In second day, the first author repeated digital goniometry ROM measures with both instruments and with considering randomization for the electro-goniometers. Figure 3.3 provides a diagram of the study design.

Study Design

Day 1

Day 2

Rater 1 — 2-5 days → Rater 1
NK, J-Tech   NK, J-Tech
(Intrarater R.)

44 men & women, 21-68 yrs with wrist & hand injury leads to limit wrist and/or fingers range of motions
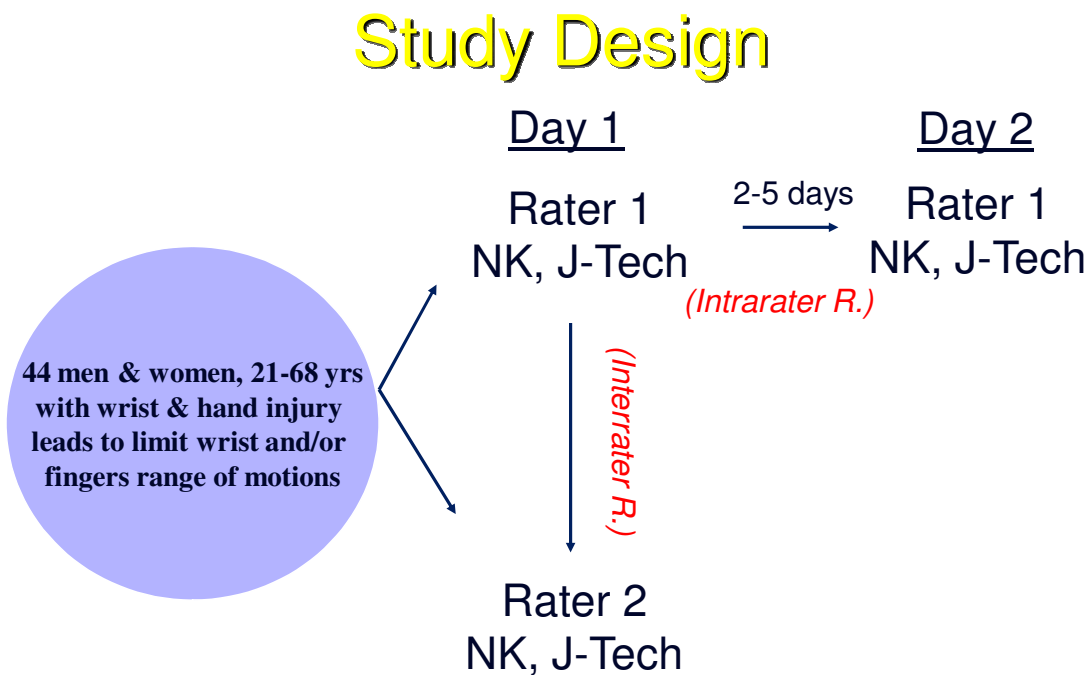
(Interrater R.)

Rater 2
NK, J-Tech

Figure 3.3: Diagram of the study design.

In each measurement session, the participant sat on a comfortable chair in front of the digital goniometer and in a relaxed position. The raters asked the participant to actively perform a movement using the greatest possible ROM they could perform comfortably. The ROM measurements were performed after a brief period of instruction and practicing the movement. The raters then asked the participant to repeat the movement as far as she/he could for two more times. The mean of three repetitions were taken as data for each ROM measure. Following the active ROM measurements, passive ROM of PIP index flexion was taken only with the NK instrument. For the torque measurements of passive flexion of the PIP index, the raters were manually hold the metacarpophalangeal (MCP) joint at neutral position throughout the testing procedure. Then, the raters applied a flexion force perpendicular to the middle phalanx at the dorsal surface over the PIP index and at the ending range of active flexion of the PIP index. The transducer recorded each force measurement and average of three torque measures was considered as torque value for passive PIP flexion of index finger in each session.

A Patient-Rated Wrist Evaluation (PRWE) questionnaire and the Disability of the Arm, Shoulder and Hand (Quick DASH) questionnaire, were completed by the participant before or after the first session of the measurements. Data was recorded by the relevant software in each instrument and transferred to a data collection form by the raters.

3.3.4 Statistical Analysis

Data was analyzed by SPSS version 19 (SPSS Inc., Chicago). Descriptive statistics were reported based on means + SD. Tests of difference and reliability coefficients were calculated to compare the data between different occasions, raters and instruments. Repeated measures analyses of variance (RM-ANOVA) were used to determine similarity of the ROM results obtained on different occasions or across raters. If the results were statistically significant, multiple comparison post hoc Tukey Honestly test were performed to determine which means were different from the others. The Tukey Honestly post hoc test is one of the most conservative multiple comparison designs.[14] A factorial ANOVA was used to identify the interaction effects among the ROM results

(dependent variable) across the raters and the electro-goniometers (fixed variables). This analysis informs whether or not these two different measurement techniques can be used interchangeably.[5]

Intraclass correlation coefficients model (2,1) ($ICC_{2,1}$) and their associated 95% confidence interval (CI) were calculated [15,16] to compare the scores of each measurement across occasions in same rater (intrarater reliability), between the raters (interrater reliability), and between the instruments for each rater (inter instrument reliability). The $ICC_{2,1}$ was used to represent the scores by two raters or instruments and a single measure was taken for each of them.[17] We used the mean results of three repetitions for each measurement per session. The ICC values of each rater in first day of measurements were used for interrater reliability analyses, and the ICC values of rater one in first and second days of measurements were used for intrarater reliability analyses. The cut-off values of ICC >0.75, 0.40-0.75, and <0,40 were chosen as an indication for high, moderate, and low reliability, respectively.[18] The Standard Error of Measurement (SEM) was calculated to identify absolute reliability of the measures and estimated the measurement error in a set of repeated scores.[15] The SEM is calculated by the equation SEM= SD × $\sqrt{1-r}$ [17,19]. The Minimum Detectable Change (MDC) was calculated to define the smallest amount of change needed to be certain that a real change was occurring beyond a measurement error.[20] The MDC was calculated with 90% and 95% confidence interval using the specific equation (MDC $_{90, 95}$ = z $_{(df, \alpha)}$ × SEM × $\sqrt{2}$).[13]

The agreement parameters show the size of the measurement errors.[21] We calculated 95% limits of agreement (LoA) and constructed Bland and Altman plots to account for potential systematic bias between the raters or instruments. Bland and Altman plots[21] are commonly seen description that graphically demonstrates the agreement between these measures. The LoA was calculated based on the equation LoA= Mean difference $\pm$ 1.96 × Standard Deviation (SD). The mean differences describe any systematic difference (bias) between measurements. The limits of agreement defines the range in which repeated measurements might be expected to vary with 95% confidence.[22]

The association between motion measures and PRWE or DASH was described by Pearson's r correlation coefficients. Pearson correlation r <0.40, between 0.40-0.75, >0.75 were considered as low, moderate and high.[23] The alpha was 0.05 and the results were considered significant if $p < 0.05$.

3.4 Results

Three participants were excluded because rheumatologic (one patient) or neurologic-stroke (two patients) conditions that might affect their wrist and hand motion. Two other participants were excluded since they did not come for the second session of the measurements. In total, 44 participants completed the study (24 women and 20 men; 55% vs. 45%), with an age range between 21 to 68 years old (52.5 $\pm$ 12.9). Twenty one participants (47.7%) had an injury on their dominant hand, while twenty three (52.3%) had an injury on their non-dominant hand. A chi-square test of independence showed that there were no significant difference between the proportions of dominant and non-dominant injured sides [$x^2_{(1)}$ 0.72, NS]. The participants' height and weight were 172 $\pm$ 12 cm and 77 $\pm$ 21 kg. The initial diagnosis of participants were: 32 patients (73%) distal radius fracture, 6 (14%) carpal tunnel syndrome, 3 (7%) scaphoid fracture, 2 (4%) finger fracture, 1 (2%) metacarpal fracture.

The summary of means $\pm$ SDs for the occasions and raters in both instruments and ANOVA statistical analysis to compare the ROM measures in different occasions were not substantially different between the raters for each goniometer. However, the raters did not demonstrate consistent use of force when performing passive ROM measures for PIP index flexion. The Tukey post hoc test showed that there were significant differences in torques across the raters during passive ROM measures for index PIP flexion ($F_{(1, 42)}$ 44.17, mean difference – 26.61, p<0.01, q 12.60) (Table 3.1).

The factorial ANOVA for main effects (rater and instrument) and interaction effects (rater × instrument) showed that there were no interaction effects through the outcome measures (Table 3.2). The raters did not affect results of ROM measures; however, type

of the instrument affected the results of ROM measures for wrist extension ($F_{(1, 42)}$ 5.09, mean difference – 3.25, $p<0.02$), ulnar deviation ($F_{(1, 42)}$ 5.96, mean difference – 2.22, $p<0.02$), and pronation ($F_{(1, 42)}$ 8.80, mean difference – 2.69, $p<0.03$) (Tables 3.1 and 3.2).

Table 3.1: Mean of the range of motion measures based on degree in different raters/occasions and analysis of variances summary for the digital goniometers.

Measure	Tool Used	Rater/Occasion	Mean $\pm$ SD	ANOVA Statistical Analysis	
Wrist Flexion	NK	1/1	54.48 $\pm$ 12.07	F 0.307	Sig 0.736
		1/2	54.69 $\pm$ 11.82		
		2/1	52.85 $\pm$ 12.29		
	J-Tech	1/1	57.58 $\pm$ 11.95	F 0.971	Sig 0.381
		1/2	58.12 $\pm$ 11.31		
		2/1	54.90 $\pm$ 11.60		
Wrist Extension	NK	1/1	52.27 $\pm$ 9.41	F 0.736	Sig 0.481
		1/2	52.60 $\pm$ 9.31		
		2/1	54.54 $\pm$ 9.65		
	J-Tech	1/1	55.52 $\pm$ 10.72	F 0.201	Sig 0.818
		1/2	56.59 $\pm$ 11.33		
		2/1	56.96 $\pm$ 11.17		
Wrist Radial Dev.	NK	1/1	17.57 $\pm$ 4.69	F 0.015	Sig 0.985
		1/2	17.73 $\pm$ 4.73		
		2/1	18.56 $\pm$ 5.34		
	J-Tech	1/1	18.76 $\pm$ 4.90	F 0.168	Sig 0.846
		1/2	18.28 $\pm$ 5.22		
		2/1	19.56 $\pm$ 5.34		
Wrist Ulnar Dev.	NK	1/1	32.69 $\pm$ 6.78	F 2.802	Sig 0.064
		1/2	33.45 $\pm$ 6.81		
		2/1	29.89 $\pm$ 8.54		
	J-Tech	1/1	34.91 $\pm$ 8.21	F 0.827	Sig 0.440
		1/2	34.95 $\pm$ 8.19		
		2/1	32.99 $\pm$ 8.11		
Wrist Pronation	NK	1/1	77.39 $\pm$ 6.20	F 0.023	Sig 0.977
		1/2	77.19 $\pm$ 6.56		
		2/1	77.08 $\pm$ 7.58		
	J-Tech	1/1	80.08 $\pm$ 6.09	F 0.099	Sig 0.906
		1/2	79.80 $\pm$ 5.53		
		2/1	80.49 $\pm$ 7.01		

Table 3.1*(Continued)*: Mean of the range of motion measures based on degree in different raters/occasions and analysis of variances summary for the digital goniometers.

Measure	Tool Used	Rater/Occasion	Mean ± SD	ANOVA Statistical Analysis	
Wrist Supination	NK	1/1	77.62 ± 9.16	F 0.708	Sig 0.494
		1/2	77.33 ± 9.52		
		2/1	75.36 ± 10.40		
	J-Tech	1/1	79.76 ± 8.63	F 1.479	Sig 0.232
		1/2	78.80 ± 9.46		
		2/1	76.41 ± 10.10		
Active PIP Index Flexion	NK	1/1	100.49 ± 7.16	F 0.073	Sig 0.930
		1/2	100.76 ± 6.37		
		2/1	101.04 ± 6.65		
	J-Tech	1/1	101.41 ± 6.43	F 0.324	Sig 0.724
		1/2	101.75 ± 6.35		
		2/1	100.70 ± 5.85		
Passive PIP Index	NK	1/1	106.28 ± 6.42	F 0.121	Sig 0.886
		1/2	106.76 ± 6.38		
		2/1	106.89 ± 5.56		
Passive PIP Index	NK	1/1	106.28 ± 6.42	F 0.121	Sig 0.886
		1/2	106.76 ± 6.38		
		2/1	106.89 ± 5.56		
Torque (Passive Index Flex)	NK	1/1	25.90 ± 10.72	F 44.171	Sig 0.000
		1/2	27.32 ± 12.01		
		2/1	52.51 ± 20.25*	TE 12.60	

Note: ANOVA= One-Way Analysis of Variance; F= F ratio; Sig= Significance Level; TE= Tukey Estimate of Significance

Table 3.2: Factorial analysis of variance for main effects (rater and instrument) and interaction effects (rater × instrument) for the range of motion measures.

Measure	F ratio (Rater)	P	F ratio (Instrument)	P	F ratio (Rater × Instrument)	P
Wrist Flexion	2.317	0.129	2.968	0.086	0.156	0.693
Wrist Extension	1.258	0.263	5.091	0.025 *	0.198	0.657
Wrist Radial Deviation	0.127	0.722	1.132	0.288	0.053	0.817
Wrist Ulnar Deviation	6.347	0.062	5.958	0.015 *	0.371	0.543
Wrist Pronation	0.150	0.699	8.799	0.033 *	0.020	0.888
Wrist Supination	4.021	0.056	1.315	0.053	0.092	0.762
Active Index Flexion	0.074	0.786	0.134	0.714	0.586	0.444

Note: P= Significance Level

The ICC values for intrarater reliability (test-retest) were excellent for most wrist ROM measures (flexion, extension, radial deviation, ulnar deviation, supination), and PIP index flexion measures by both instruments (ICC ranges 0.91-0.97). The intrarater reliability was also high for wrist pronation measures for both NK (ICC 0.89) and J-Tech (ICC 0.86). The highest intrarater reliability values were in wrist flexion ROM measures by both the NK (ICC 0.97) and J-Tech (ICC 0.95). The lowest intrarater values were measured in wrist pronation measures by the NK (ICC 0.89) and also J-Tech (ICC 0.86) (Table 3.3).

The ICC values for interrater reliability were high for active and passive ROM measures (ICC ranges 0.79-0.93). The highest interrater reliability values were in wrist flexion ROM measures by the NK (ICC 0.91) and wrist extension ROM measures by the J-Tech (ICC 0.93). The lowest interrater reliability values referred to ulnar deviation ROM measures by the NK (ICC 0.82) and pronation ROM measures by the J-Tech (ICC 0.79). The ICC values for inter instrument reliability were high in all wrist ROM measures (ICC ranges 0.77-0.96), with the exception of radial deviation (ICCs 0.64 and 0.70 for the raters one and two, respectively). The reliability coefficients for torques in passive index

flexion were moderate in different occasions by rater one (ICC 0.71) and low across the raters (ICC 0.16) (Tables 3.4 and 3.5)

Table 3.3: Intrarater (test-retest) reliability values for NK and J-Tech digital goniometers.

Measure/Reliability	Instrument	ICC	95% CI	SEM	MDC_{90}	MDC_{95}
Wrist Flex.	NK	0.97	0.95-0.98	1.98	4.62	5.49
	J-Tech	0.95	0.91-0.97	2.59	6.04	7.18
Wrist Ext.	NK	0.95	0.91-0.97	2.06	4.81	5.71
	J-Tech	0.94	0.72-0.94	2.47	5.76	6.85
Wrist Radial Dev.	NK	0.96	0.92-0.98	0.96	2.24	2.66
	J-Tech	0.93	0.88-0.96	1.26	3.04	3.49
Wrist Ulnar Dev.	NK	0.91	0.85-0.95	1.98	4.62	5.49
	J-Tech	0.93	0.89-0.96	2.06	4.81	5.71
Wrist Pron.	NK	0.89	0.80-0.94	2.10	4.90	5.82
	J-Tech	0.86	0.77-0.92	2.24	5.23	6.21
Wrist Sup.	NK	0.94	0.89-0.96	3.20	5.13	6.10
	J-Tech	0.95	0.90-0.97	1.95	4.55	5.40
Act. PIP Index Flex.	NK	0.93	0.89-0.97	1.78	4.15	4.93
	J-Tech	0.91	0.84-0.95	1.93	4.50	5.35
Pas. PIP Index Flex.	NK	0.91	0.85-0.95	1.90	4.43	5.27
Torque	NK	0.71	0.44-0.89	7.57	17.66	20.98

Note: ICC = Intraclass Correlation Coefficient; CI = Confidence Interval; SEM = Standard Error of Measurement; MDC_{90} = Minimum Detectable Change associated with 90% CI; MDC_{95} = Minimum Detectable Change associated with 95% CI.

Table 3.4: Interrater (between raters) reliability values for NK and J-Tech electrogoniometers.

Measure/Reliability	Instrument	ICC	95% CI	SEM	MDC_{90}	MDC_{95}
Wrist Flex.	NK	0.91	0.83-0.95	3.64	8.49	10.09
	J-Tech	0.87	0.73-0.94	4.28	9.99	11.86
Wrist Ext.	NK	0.87	0.88-0.97	3.48	8.12	9.65
	J-Tech	0.93	0.90-0.97	2.82	6.58	7.82
Wrist Radial Dev.	NK	0.84	0.73-0.91	2.16	5.04	5.99
	J-Tech	0.83	0.72-0.91	2.08	4.85	5.76
Wrist Ulnar Dev.	NK	0.82	0.51-0.92	2.60	6.07	7.17
	J-Tech	0.87	0.72-0.93	1.94	4.53	5.38
Wrist Pron.	NK	0.83	0.71-0.90	3.11	7.26	8.62
	J-Tech	0.79	0.69-0.89	3.02	7.05	8.37
Wrist Sup.	NK	0.87	0.73-0.93	3.78	8.82	10.48
	J-Tech	0.84	0.49-0.94	3.96	9.24	10.98
Act. PIP Index Flex.	NK	0.85	0.74-0.91	2.81	6.56	7.79
	J-Tech	0.81	0.69-0.90	2.75	6.42	7.62
Pas. PIP Index Flex.	NK	0.83	0.71-0.90	2.63	6.14	7.29
Torque	NK	0.16	0.08-0.23	9.83	22.94	27.25

Note: ICC = Intraclass Correlation Coefficient; CI = Confidence Interval; SEM = Standard Error of Measurement; MDC_{90} = Minimum Detectable Change associated with 90% CI; MDC_{95} = Minimum Detectable Change associated with 95% CI.

Table 3.5: Inter instrument reliability values for NK and J-Tech digital goniometers.

Measure/Reliability	Instrument	ICC	95% CI	SEM	MDC_{90}	MDC_{95}
Wrist Flex.	Rater 1	0.96	0.92-0.98	2.37	5.53	6.57
	Rater 2	0.94	0.89-0.97	2.93	6.84	8.12
Wrist Ext.	Rater 1	0.89	0.81-0.94	3.07	7.16	8.51
	Rater 2	0.93	0.88-0.96	2.74	6.39	7.59
Wrist Radial Dev.	Rater 1	0.64	0.42-0.79	2.79	6.51	7.73
	Rater 2	0.70	0.52-0.83	2.92	6.81	8.10
Wrist Ulnar Dev.	Rater 1	0.86	0.77-0.92	2.49	5.81	6.90
	Rater 2	0.87	0.78-0.93	3.11	7.26	8.62
Wrist Pron.	Rater 1	0.77	0.62-0.87	3.17	7.40	8.79
	Rater 2	0.78	0.64-0.88	3.86	9.01	10.70
Wrist Sup.	Rater 1	0.94	0.88-0.96	2.75	6.42	7.62
	Rater 2	0.90	0.83-0.94	3.25	7.58	9.01
Act. PIP Index Flex.	Rater 1	0.89	0.82-0.94	2.41	5.62	6.68
	Rater 2	0.79	0.64-0.88	3.05	7.12	8.45

Note: ICC = Intraclass Correlation Coefficient; CI = Confidence Interval; SEM = Standard Error of Measurement; MDC_{90} = Minimum Detectable Change associated with 90% CI; MDC_{95} = Minimum Detectable Change associated with 95% CI.

The standard error of measurement (SEM) calculations indicated higher errors when the ROM was measured by two raters (interrater SEMs range 1.94-9.83) compared to time than when the ROM was measured by one rater on two occasions (intrarater SEMs range 0.96-7.57). The SEMs 90% (95%) indicated 4.62° (5.49°) variation when the wrist flexion ROM was measured by one rater in different occasions, and less than 8.49° (10.09°) variation when the wrist flexion ROM was measured by two raters in same occasion (NK goniometer). The SEM and MDC scores between instruments were similar to that between raters' measurements (Tables 3.3, 3.4, and 3.5).

The highest level of agreement between the raters was found for ulnar and radial deviation ROM measures for both instruments (LoA -4.33 to 10.69), while the torque measures of passive PIP index ROM flexion by NK goniometer had the widest limits of agreement across the raters (LoA -66.32 to 14.54) (Table 3.6). The most precise limits of agreement between the instruments was in active PIP index flexion for both raters (LoA -6.71 to 4.81 for rater one; -7.68 to 8.36 for rater two), while the lowest level of agreement between the instruments for rater one was in wrist extension (LoA -12.64 to 5.40), and for rater two was in pronation (LoA -11.83 to 7.03) (Table 3.6). The Bland - Altman plots and scatter of mean differences between measurements (raters or instruments) did not show progressive changes across the range of ROM measures (no heteroscedasticity)[24] (Figures 3.4, 3.5, and 3.6).

The relationship between ROM measures and patient-rated self-reported pain and function indicated a low to moderate relationship ranging from 0.32 to 0.63. Both the NK and the J-Tech were moderately correlated with self-reported disability (Table 3.7). The Pearson's r correlation coefficient between the functional outcome measures (Quick DASH and PRWE) were high (r= 0.94).

Table 3.6: Limit of agreement analysis for the range of motion measures across raters or goniometers.

Measure	LoA (across raters)		LoA (across instruments)	
	NK	J-Tech	Rater 1	Rater 2
Wrist Flex.	- 8.18 to 11.66	- 6.32 to 12.22	- 9.92 to 3.40	- 10.04 to 5.96
Wrist Ext.	- 9.98 to 5.78	- 7.01 to 5.19	- 12.64 to 5.40	- 9.94 to 5.08
Wrist Radial D.	- 5.39 to 5.55	- 6.19 to 6.97	- 8.91 to 7.17	- 9.12 to 8.00
Wrist Ulnar D.	- 4.33 to 10.69	- 5.29 to 9.17	- 9.37 to 5.65	- 11.35 to 5.15
Wrist Pron.	- 7.22 to 7.64	- 6.35 to 7.25	- 10.50 to 5.22	- 11.83 to 7.03
Wrist Sup.	- 6.42 to 10.66	- 6.62 to 11.36	- 8.07 to 4.47	- 9.95 to 7.85
Act. PIP Flex. (Index)	- 7.83 to 6.99	- 6.63 to 8.39	- 6.71 to 4.81	- 7.68 to 8.36
Pas. PIP Flex. (Index)	- 7.11to 6.37	--	--	--
Torque (Pas. PIP Index Flex)	- 66.32 to 14.54	--	--	--

Note: LOA = 95% Limit of Agreement.

Table 3.7: Pearson's r correlation coefficient between the range of motion measures of the digital goniometers (NK, J-Tech), patient-rated wrist evaluation and short version of the disability of the arm, shoulder and hand scales.

Measure	*r correlations with PRWE*				*r correlations with quick DASH*			
	Rater 1		Rater 2		Rater 1		Rater 2	
	NK	J-Tech	NK	J-Tech	NK	J-Tech	NK	J-Tech
Wrist Flex.	**-0.44**	**-0.41**	**-0.48**	**-0.44**	**-0.41**	**-0.45**	**-0.45**	**-0.43**
Wrist Ext.	**-0.63**	**-0.55**	**-0.51**	**-0.55**	**-0.48**	**-0.48**	**-0.45**	**-0.44**
Wrist Radial D.	**-0.44**	**-0.41**	**-0.48**	**-0.41**	**-0.40**	**-0.47**	**-0.44**	**-0.36**
Wrist Ulnar D.	**-0.39**	**-0.44**	**-0.39**	**-0.35**	**-0.39**	**-0.45**	-0.32	-0.35
Wrist Pron.	**-0.38**	-0.25	-0.24	**-0.37**	-0.34	**-0.38**	**-0.38**	**-0.46**
Wrist Sup.	**-0.52**	**-0.48**	**-0.46**	**-0.46**	**-0.48**	**-0.46**	**-0.52**	**-0.55**
Act. PIP Flex. (Index)	**-0.46**	**-0.50**	**-0.47**	**-0.48**	**-0.55**	**-0.50**	**-0.45**	**-0.50**
Pas. PIP Flex. (Index)	**-0.46**	--	**-0.42**	--	**-0.46**	--	**-0.48**	--
Torque (Pas. PIP Index Flex)	0.18	--	0.05	--	0.29	--	0.16	--

Note: PRWE = Patient-Rated Wrist Evaluation; quick DASH = short version of the Disability of the Arm, Shoulder and Hand.
Bold = Significant at $P <0.05$
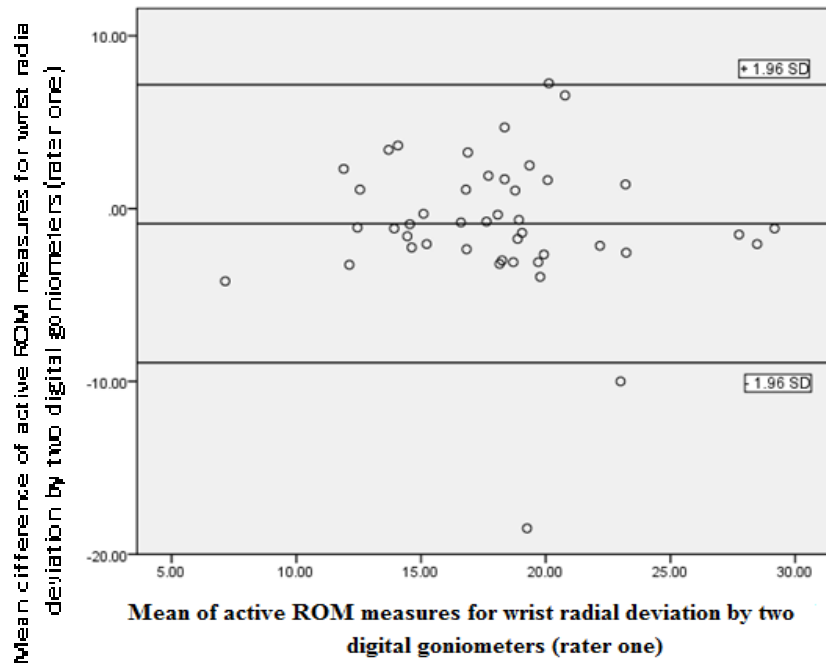
(A)
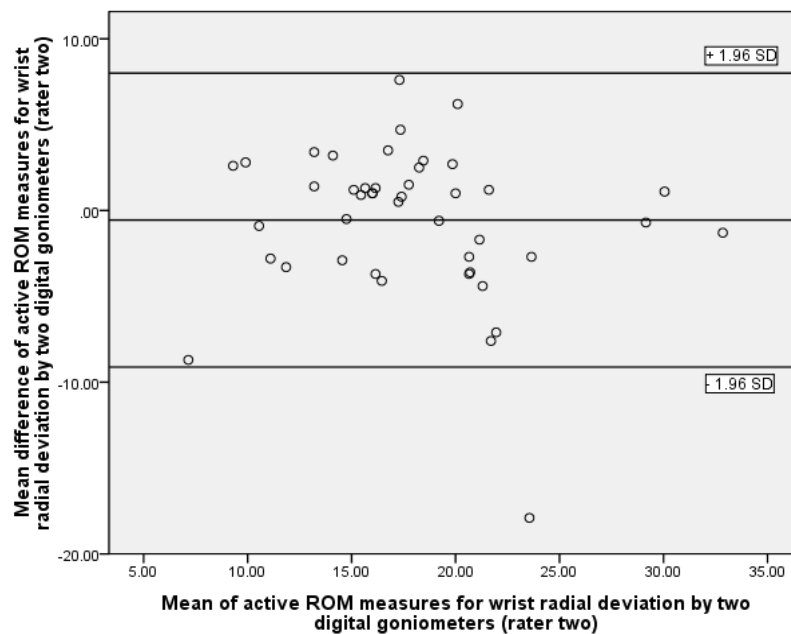
(B)

Figure 3.4: Bland and Altman plots of mean differences (vertical axis) versus means (horizontal axis) of radial deviation ROM measures by two digital goniometers: (A) rater one, (B) rater two. *The middle line shows the mean difference between measures taken with two digital goniometers (NK-JTech). The lines above and below mean difference represent range of measurement error with 95% confidence interval (data in degrees).*
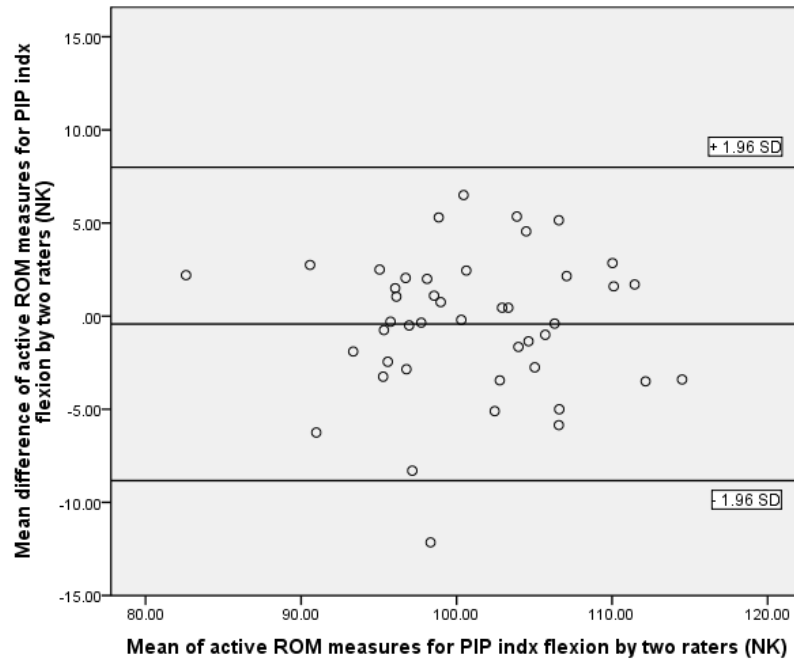
(A)
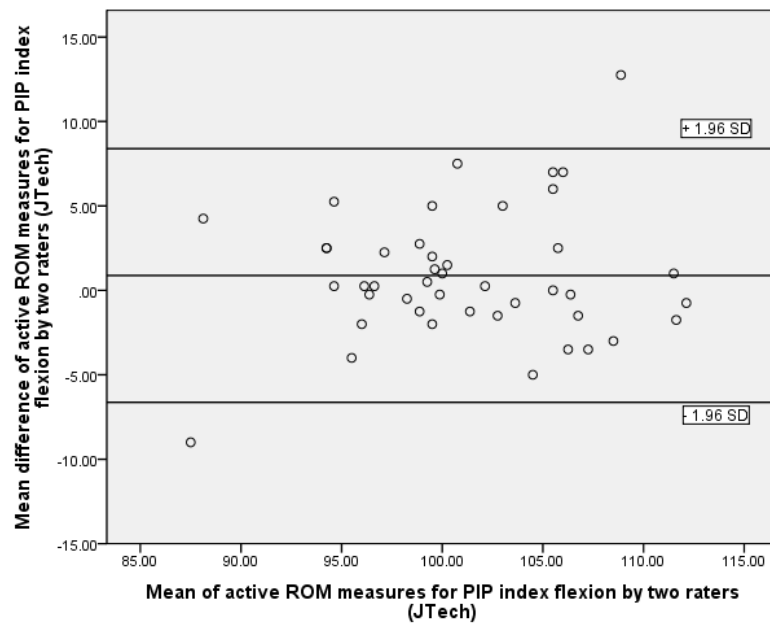
(B)

Figure 3.5: Bland and Altman plots of mean differences (vertical axis) versus means (horizontal axis) of active ROM measures for PIP index flexion by two raters; (A) NK goniometer, (B) J-Tech goniometer. *The middle line shows the mean difference between measures taken with two raters in each instrument. The lines above and below mean difference represent range of measurement error with 95% confidence interval (data in degrees).*
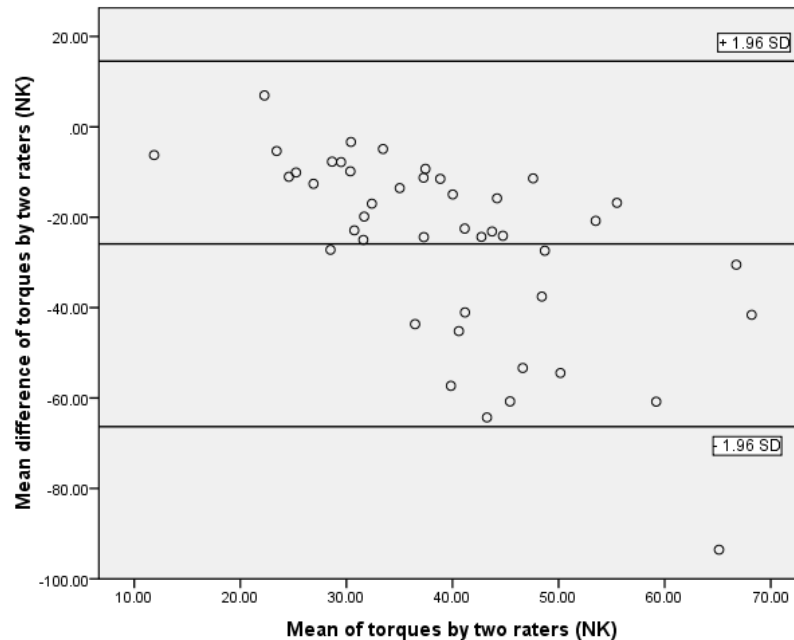
Figure 3.6: Bland and Altman plot of mean differences (vertical axis) versus means (horizontal axis) of torques of passive PIP index flexion ROMs by two raters (NK instrument). The mean difference between measures taken with two raters is noticeable. *The lines above and below mean difference represent range of measurement error with 95% confidence interval (data in degrees).*

3.5 Discussion

This study demonstrates that reliable measurements of wrist and finger motion are obtainable in different occasions and across different raters with two different computerized goniometers; despite the fact that different raters do not provide consistent pressure when taking passive flexion ROM measurements. As we expected, the ICCs were slightly higher when the ROM measures are obtained by the same rater than when the ROM measures are obtained by two raters. The fact that raters tend to use more consistent force on re-application than occurs between raters, suggests that the application force may make a small contribution to lower group-level reliability in PIP index finger ROM measures. However, since the reliability was high this did not make any important difference to the measurements obtained. This may be because both raters were able to achieve end range; and the application of extra force did not make an appreciable change. Since the PIPJ is a joint with a hard end feel, it is not clear that this

finding will be transferable to other joints with a soft tissue end feel like elbow flexion. There are a limited number of studies that measured reliability and validity of wrist and finger ROM measurements. These mostly focused on healthy people [6,7,9] or patients with normal ROM[5] who were measured by different therapists or occasions.

Our findings of high reliability are in agreement with previous studies that use electrogoniometer for elbow pronation/supination[7] and healthy thumb ROMs measures[9], and also for manual goniometry for wrist ROM measures.[5,6,7] The precision of measurement compared favorably with what has been reported for manual goniometry suggesting that some small advantages in precision may be obtained by the use of computerized goniometry. Potential reduction in error occur with the computerized goniometry relate to the use of the footswitch which may reduce error from movement of the goniometer arm from the tested position until when it is read since the footswitch collects the data at the time of placement. This data collection process also reduces errors numbers of the goniometer. Further, plastic goniometers may not be calibrated; and markers may vary; whereas computerized goniometers are calibrated for each use. Radial deviation ROM measure was the only measure that did not demonstrate high reliability. Possible reasons including difficulty in precise landmarking for this movement; and the relatively small ROM measures of the radial deviation must be considered. The SEM analysis identified that differences of 2° to 4° could be considered as measurement error when the ROM measure was repeated by same rater and same instrument, while the measurement errors might be higher when the ROMs were measured by different raters or different instruments (3° to 5°). Both of these estimates were within the 5° measurement error, which sometimes used as a rule of thumb in measuring joint motion[9,17] and so were not considered clinically meaningful.

In this study we only measured finger flexion of one joint. This was because the study had substantial response burden; and adding more measures may have contributed to fatigue that would have increased error. We cannot be confident that this one finger flexion measurement reliability is representative of the reliability of all digits. However, there is not substantive reason to expect differences across PIPJ of other fingers. Our

analyses indicate differences in application of force between raters when performing goniometry. This was demonstrated by low rater agreement; and the significant differences in force application. Since there was only one pair of raters, it is risky to generalize the reasons for differences in force application but since the physical therapist had more experience with patients; and the kinesiologist had more experience with healthy people this may have affected how comfortable felt with applying force to joints. However, the 2 – 3° in difference in force application had relatively small impact on reliability measurements, since reliability coefficients were high for both instruments.

The reliability indices and SEMs calculation showed that the errors were higher when the ROM was measured by two raters compared to when both measures were done by one rater (Tables 1, 2, and 3). The differences was small; but is common when intra and inter rater reliability are compared. Difference in positioning, alignment of landmarks and force application are thought to contribute to this. This study is was able to verify that differences in force application can be quite large between raters, and can explain this traditional wisdom that repeated measurements made by different therapists be interpreted more conservative.[6,8] The Bland and Altman plots across mean differences between measurements (raters or instruments) did not show progressive changes when the mean changes occurred for all ROM measurements. These plots show that there is no heteroscedasticity in ROM measures across the raters or instruments, which means the variance of the error terms does not differ across observations.[24]

The relationship between the DASH and PRWE scores and ROM was moderate across the 2 scales. This is consistent with previous findings that motion makes a moderate contribution to disability.[26] Since no single impairment can be expected to fully explain disability; the moderate relationship indicates that ROM makes a substantial contribution that is worth measuring in hand therapy practice. Further, since the two measures were highly correlated it is not unexpected that the strength of the association was similar. ROM was slightly more strongly related to the PRWE compared to Quick DASH; which may be related to the fact it is a wrist-specific scale.

A few authors have investigated the relationship between impairment and function. Karnezis and Fragkiadakis[28] reported that grip strength could be considered as a predictor for patient-rated pain and function (PRWE), but arcs of wrist flexion/extension and forearm rotation did not. Adams et al.[26] reported significant relationship between patient-rated function (DASH and PRWE) and ROMs limitations. MacDermid et al.[31] identified a correlation between grip strength, ROM, dexterity (objective variables) and patient-rated pain and function (PRWE) after distal radius fracture, but they also reported these outcome measures could not be considered strong predictors for pain and disability.[32]

3.6 Study Limitations

Although this study used quality procedures like randomization and verification of landmarks. However, the study also has limitations. We did not have a gold standard criterion for comparison. Both of our evaluators had experience measuring ROM; but one was not a therapist (kinesiologist who had 5 years experience measuring upper extremity ROM), and the other had was not a hand therapist. This study was limited to the measurements of PIP flexion torque of the index finger. The measurements of active and passive ROM torques of the other wrist and hand joints help to have better understanding of reliability of the torque measurements in wrist and hand motion.

3.7 Conclusion

Digital goniometric instruments (NK and J-Tech) demonstrated high reliability coefficients and tight error margins in active wrist ROM and active or passive PIP index flexion in patients with limited wrist and/or hand motion. There was a substantial statistical difference in force application between the raters when performing passive ROM measures for PIP index, but the same rater produced consistent force. However, this difference in force application had relatively small impact on reliability measurements, since reliability coefficients were high for both instruments. The relationship between individual joint motions obtained by digital goniometric instruments

(NK and J-Tech) and patient self-rated pain and function scores (quick DASH and PRWE) suggesting that joint motion impairments contributes to functional disability.

3.8 Disclosure

3.9 References

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CHAPTER 4

Definition of Risk Recovery cut offs in Wrist Motion for Poor Functional Outcomes after Distal Radius Fracture; And Effects of Age and Gender

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4.1 Summary

Study Design: Retrospective cohort.

Introduction: Measurements of wrist and/or finger range of motion (ROM) are standard measures used to evaluate outcomes after distal radius fracture (DRF). The relationship between ROM and other physical impairments as they related to patient-rated outcomes after DRF have not been well identified.

Purpose: 1. To identify relationship between physical impairment outcome measures, pain and function of the wrist after DRF. 2. To determine the contribution of physical impairments (ROM and grip) on pain and function of the wrist at early and late stages after DRF. 3. To identify thresholds of ROM and grip strength that discriminate between good and suboptimal patient-rated functional outcomes after DRF. 4. To identify the risk of having suboptimal functional outcomes when the patients have good physical impairments (arcs of motion, grip strength) one year after DRF 5. To examine whether the relationship between physical impairment and good functional outcomes is different in patients more or less than 65 years of age and in women or men.

Methods: A retrospective cohort of 1360 DRF patients was evaluated for physical impairment outcome measures including wrist ROM, arcs of motion, grip strength, pain and function at two, three, six, and 12 months after fracture. The proportion of injured/uninjured grip strength and arcs of motion were calculated to obtain the percentages of normal function. The Patient-Rated Wrist Evaluation (PRWE) scores and sub scores (pain, specific and usual activities) were calculated at each session to identify wrist pain and function. Receiver operating Characteristic (ROC) curves were constructed using wrist pain and function scores and each functional impairment measure as a discriminator of good and poor function.

Results: Most physical impairment outcome measures of the wrist were moderately correlated with patient-rated pain and function after the DRF. The ROM measures of wrist flexion, extension, supination, pronation, grip strength, age and sex, contribute significantly with the patient-rated wrist pain and function score in early and late stages after the DRF. For patients to have reported good function (based on PRWE), they must have regained 81-94% of the wrist arcs of flexion/extension, radial/ulnar deviations,

pronation/supination and 64% of contralateral grip strength.

Conclusion: The greater wrist ROMs (close to normal) and grip strength must be recovered for patients to have good patient-rated wrist functional outcome after DRF.

Level of Evidence: Diagnosis level 2.

4.2 Introduction

Distal Radius Fracture (DRF) is one of the most frequent of all human bone fractures.[1] Range of motion (ROM) and grip strength are standard outcome measures used by clinicians to evaluate recovery after a hand injury.[2] ROM is considered to be an important component of joint mobility and relates to measures of functional impairment and disability.[3] Loss of ROM in the wrist and hand can arise due to pain, swelling, muscle weakness, or deformity.[4] Impaired wrist and hand ROM leads to a decrease in grip strength, grasp ability, fine manipulation, and hand function.[4]

There are few studies that report the contribution of physical impairments on patient-rated wrist pain and function. Ryu et al.[5] reported that 40 degrees of both wrist flexion and extension and some complementary forearm rotation were necessary for performing most activities of daily living (ADL) in healthy people. Palmer et al.[6] identified that healthy people needed 30 degrees of wrist extension, 5 degrees of wrist flexion, and 25-57% of the normal ROM arc to perform 52 ADL tasks.

The relationship between physical impairments and outcomes after DRF has not been studied extensively. Physical impairments are core outcome measures that are typically evaluated in studies reporting outcomes of DRF.[7-10] Studies that report outcomes following DRF tend to focus on motion, grip strength, and self-reported function.[8,11-13]

A number of additional studies have focused on identifying factors that predict or explain the outcomes achieved by following treatment of DRF.[7,14] Several previous studies focused on outcome measures as the predictors for fracture risk.[15, 16] Early prognostic studies focused on explaining impairment and radiographic indicators[17-19], whereas more

recent studies have focused on predicting self-reported function[12]. Demographic variables and radiographic indicators of fracture alignment are the most common predictors across prognostic studies.[11,17,20]

Age is typically considered as a potential predictor in many physical health problems including fracture outcomes.[11] MacDermid et al.[11] reported that neither age and sex, nor post reduction radial shortening were predictors, but could potentially affect the strength of outcomes. Similarly, age affected the subscale scores on the physical health of the SF-36 survey.[19] Makhni et al.[21] reported that secondary displacement of DRF increased with increasing age and suggested that results warranted closer monitoring after initial reduction of older patients.

Grip strength and arcs of motion are potential determinants of outcome that have been studied. Trumbel et al.[22] reported an R^2 of 0.40 for an injury score can be predicted by variation in outcome scores of ROM, grip strength, and pain. Chung et al.[12] studied the relationship between patient satisfaction and physical impairments three months after DRF surgery. He found that patients who were satisfied with their outcomes at three months after DRF had regained 65% of their contralateral grip strength, 87% of key grip strength, and 95% of normal wrist flexion/extension arc.

Previous research has identified the extent of impairment that discriminates between patient satisfaction levels at three months.[12] The goal of this study was to further expand our understanding of what level of physical impairment discriminates functional outcomes at both early and later time points in recovery after DRF. Since previous work has established that age and gender effects may mediate this relationship, we also considered these as potential effect modifiers. Thus, the specific aims of this study were: 1. To examine the relationship between physical impairments (ROMs and grip strength) and patient-rated pain and function (based on PRWE) at different time points in recovery (two, three, six, and 12 months) after DRF. 2. To determine the contribution of physical impairments (ROMs, grip strength) and demographic variables to pain and function (based on PRWE) at early and late stages after DRF (three and 12 months after fracture).

3. To identify the extent that physical impairments (ROMs and grip strength) may discriminate between patients who have good versus suboptimal functional outcomes one year following DRF. 4. To identify the risk of having suboptimal function (based on PRWE) when the patients have lower levels of physical impairments (arcs of motion, grip strength) one year after DRF. 5. To examine whether the recovery of ROM/grip strength needed for good functional outcomes is different in patients more or less than 65 years of age and based on gender.

4.3 METHODS

4.3.1 Study Design

The study was designed as a retrospective cohort study. Patients with distal radius fractures who met eligibility criteria and consented to participation were enrolled consecutively in a prospective cohort. Standardized data collection by an independent research assistant was performed at standardized intervals (baseline, 2, 3, 6, and 12 months). The study questions were identified after data was collected.

4.3.2 Participants

Participants were included if they were 18 years of age or older and had distal radius fractures. Participants attended the Hand and Upper Limb Centre (HULC) at St. Joseph Hospital in London Ontario, for primary care from March 1998 to July 2011. Patients were excluded from the study if they were under 18 years old; had bilateral, combined radial/ulnar, arm/shoulder or multiple fractures; or did not attend the follow up assessments.

All patients were assessed initially by a hand or orthopedic surgeons. Fractures were treated using a variety of immobilization/fixation approaches at the discretion of the treating surgeon. Participants responded to a brief survey including demographic data (age, gender, affected side, medical history, et cetera) before entering the study. The

study design and protocols were approved by the Ethics Boards of the University of Western Ontario. All eligible patients signed an informed consent form for the use of their data in the study.

4.3.3 Outcome Measurements

4.3.3.1 Physical Impairments

Wrist ROM (flexion, extension, radial and ulnar deviations, pronation, supination) and the grip strength were measured by the NK Hand Assessment joint motion (NK Biotechnical Engineering Company, Minneapolis, MN). The ROM testing was performed using the NK digital goniometer, which has been shown to have high reliability at wrist ROM measurements.[23] Data collection was performed with standard computer software sensitive with a foot switch, so that the rater's hands were free to adjust the goniometer alignment. The mean of three ROM measurements were taken for each joint movement. The arcs of motion were calculated as the combined degrees of flexion and extension, radial deviation and ulnar deviation, or pronation and supination. The evaluators used the approved landmarks for the ROMs measurements: midline of dorsal and palmar forearm and third metacarpal with the fulcrum on dorsal and palmar aspects of capitate for wrist flexion and extension[24], midline of dorsal surface of forearm and third metacarpal with the fulcrum over capitate for wrist radial and ulnar deviations[25], and the lateral and medial aspects of the distal forearm with the fulcrum on styloid process for wrist pronation and supination.[26] The intrarater reliability values for active wrist ROM measurements by the NK Hand Assessment device were in excellent agreement (ICCs 0.89 to 0.97).[23]

The grip strength was tested using the NK Digit Grip device which was calibrated prior to each measurement, and has been shown to have high reliability.[27] The grip strength for each subject was the mean of three measurements according to the recommendations of the American Society of Hand Therapists (ASHT) .[28] The grip strength for each hand was adjusted using the 10% rule for the hand dominance.[21] The grip strength score for the

injured hand was divided by the score of uninjured hand to obtain a percent of normal function for grip strength (injured/uninjured percentage). The grip strength device had a self calibrating feature, so that the raters could calibrate instrument before each measurement. The reliability values of measurements for grip strength by NK Hand Assessment device were in excellent agreement (ICCs 0.96-0.98).[27,29]

4.3.3.2 Self-reported Pain and Disability

The Patient-Rated Wrist Evaluation (PRWE) form was completed by the participants after each measurement. The PRWE is a 15-item questionnaire designed to measure wrist related pain and disability in activities of daily living. The PRWE form includes two subscales for pain and function (including specific and usual activities). The total PRWE score can be calculated based on equal weight for pain and function.[30] The PRWE helps patients to identify levels of wrist pain and disability and has been shown to have high reliability.[18, 31] The PRWE total scores and sub scores (pain, specific and usual activities) were calculated as indicated by the developer where pain and function each contribute 50% to the total score out of 100.[30] [See Appendix A]

4.3.4 Statistical Analysis

Data were analyzed by SPSS version 19 (SPSS Inc., Chicago). Descriptive statistics were reported based on means $\pm$ SD and normal distribution were measured for all physical impairments outcome measures. Pearsons correlation coefficient was used to determine the association between physical impairment independent variables (ROMs, grip strength) and pain and function dependent variables (PRWE scores) at two, three, six, and 12 months after fracture. Pearson correlation of r <0.30, between 0.30-0.50, and >0.50 were considered as low, moderate and high values for the relationship between physical impairment outcome measures and pain and function.[32,33] The alpha was 0.05 and the results were considered significant if $p < 0.05$.

A series of models were created to determine which factors explained functional outcomes. The PRWE was the dependent variable (outcome measure) in each of these models. Stepwise multiple regression technique was used to retain or eliminate variables within regression models that maximize contribution/prediction accuracy with the smallest number of contributors/predictors.[34] The stepwise regression models in this study were completed sequentially to evaluate separately the constructs of demographics, motion and strength. In the first model, demographic variables (age, gender and interaction between age and gender) were entered into the regression using a forward regression model. In the second model, demographic variables and ROMs, including the six different ROM measures for the wrist were entered to the analysis. Finally in the third model, all demographic, ROMs, and grip strength variables were entered to the regression. The criterion for entering variables in this analysis was: entering each independent variable with the smallest probability of F (the probability of F is lower than 0.05). The variables were removed if their probability of F was higher than 0.10. We used the adjusted R^2 values for the analysis to identify the proportion of variance of the dependent variable explained by the independent variables.

To meet the third objective, it was necessary to differentiate good from suboptimal (moderate/poor) function based on the PRWE score. In previous research, a cutoff score of 20 has been used for this distinction on both the DASH and PRWE [35], but was less discriminative for the latter. Since the PRWE has higher responsiveness than the DASH[19], and recovery curves are steeper[13], the optimal cut point might be expected to be higher on the PRWE. Since there is no gold standard for the optimal cutoff, we performed a sensitivity analysis by evaluating whether our results would have changed at either 20 or 30 as a cutoff score. We tested cut off scores at 20, 25, and 30 for the PRWE total scores to evaluate the result frequencies and relationship to our explanatory variables and selected the score of 25 as the cut off score for the PRWE total score. We arbitrarily dichotomized the PRWE total scores of equal or lower than 25 as good and more than 25 as suboptimal function (failing to reach the expected standard) based on our observations of mean scores.[34] Then, we used a Receiver Operating Characteristic (ROC) curve to determine the optimal cutoff for arcs of motion in each of the three motion

planes that best differentiated good from suboptimal functional outcomes. The ROC curves were plotted based on the sensitivity and 1 – specificity data.[34] The Area Under Curve (AUC) was calculated for each ROC curve to describe the overall accuracy in discrimination and curves were displayed graphically. We calculated the data at three and twelve months after fracture for the ROC analysis, since this data could represent wrist function at early and late stages of the treatment after DRF and enable a comparison to previous research.[12] These analyses were repeated for two age subgroups using 65 as a cut-off since this is where we have found an inflection point in previous studies.[21]These analyses were also repeated for gender subgroups.

Finally, the Relative Risk (RR) was calculated to identify the risk of having a suboptimal functional outcome with a poor arc of motion and grip strength one year post DRF. The Relative Risk (RR) was calculated to provide a clinically interpretable indicator of how much risk was associated with cutoffs established through the ROC curve process.[34]

4.4 Results

One thousands three hundred sixty patients were eligible for the statistical analysis based on the inclusion criteria. The sample size for the analysis varied across comparisons because patients occasionally did not complete the follow-up visits resulting in some missing data. The average age of participants was 54.4 ± 39.9 years old (range 18-85), including 418 (30.7%) men and 942 (69.3%) women. The patients were treated by either closed reduction (729 patients - 72.5%) or surgery (279 patients - 27.5%). The number of participants with dominant hand injuries was 584 (47.2%).

There was a low to moderate correlation between impairments in wrist ROM and PRWE scores (Total, Pain, Specific Activities, Usual Activities) (range 0.20-0.48). The wrist flexion ROM measure was most strongly correlated to function (range 0.24-0.48), while wrist pronation was less correlated with patient-rated wrist pain and function through all time points measurements (range 0.01-0.27). The grip strength measures had low correlation to wrist pain and function through the initial months (range 0.02-0.12),

moderate at six months (range 0.28- 0.39), and low (but close to moderate) at one year after fracture (range 0.20-0.34) (Table 4.1).

Table 4.1: Pearson's r correlation coefficient between the ROM measurements and patient-rated wrist evaluation scores.

| Measure | r correlations with PRWE Scores | | | | | | | |
| | 8 weeks | | | | 3 months | | | |
	T	P	SA	UA	T	P	SA	UA
Wrist Flexion	**-0.45**	**-0.34**	**-0.48**	**-0.39**	**-0.48**	**-0.34**	**-0.41**	**-0.37**
Wrist Extension	**-0.38**	**-0.23**	**-0.38**	**-0.33**	**-0.40**	**-0.26**	**-0.40**	**-0.36**
Wrist Radial Dev.	**-0.34**	**-0.25**	**-0.35**	**-0.30**	**-0.20**	**-0.22**	**-0.20**	**-0.21**
Wrist Ulnar Dev.	**-0.26**	**-0.21**	**-0.29**	**-0.25**	**-0.27**	**-0.22**	**-0.30**	**-0.25**
Wrist Pronation	**-0.24**	**-0.20**	**-0.27**	**-0.23**	0.02	0.03	-0.01	0.02
Wrist Supination	**-0.35**	**-0.24**	**-0.38**	**-0.32**	**-0.32**	**-0.25**	**-0.35**	**-0.31**
Grip Strength	-0.10	-0.06	-0.12	-0.08	-0.05	-0.02	-0.07	-0.05

| Measure | r correlations with PRWE Scores | | | | | | | |
| | 6 months | | | | 1 year | | | |
	T	P	SA	UA	T	P	SA	UA
Wrist Flexion	**-0.39**	**-0.26**	**-0.36**	**-0.34**	**-0.42**	**-0.24**	**-0.38**	**-0.31**
Wrist Extension	**-0.32**	**-0.22**	**-0.33**	**-0.29**	**-0.28**	**-0.21**	**-0.28**	**-0.28**
Wrist Radial Dev.	**-0.24**	**-0.23**	**-0.22**	**-0.22**	-0.15	-0.14	-0.13	-0.14
Wrist Ulnar Dev.	**-0.21**	**-0.20**	**-0.23**	**-0.20**	**-0.19**	-0.15	**-0.22**	-0.16
Wrist Pronation	-0.08	-0.07	-0.07	-0.09	-0.11	-0.08	-0.11	-0.12
Wrist Supination	**-0.25**	**-0.20**	**-0.27**	**-0.24**	**-0.24**	**-0.20**	**-0.29**	**-0.24**
Grip Strength	**-0.39**	**-0.28**	**-0.42**	**-0.32**	**-0.29**	**-0.20**	**-0.34**	**-0.28**

Note: T = PRWE Total, P = PRWE Pain, SA = PRWE Specific Activities
UA = PRWE Usual Activities
Bold = Significant at $P < 0.05$

The ROMs were measured based on degree and the grip strength was measured based on kg.

Table 4.2 summarizes the regression analysis for PRWE total scores by demographic variables, ROM values and grip strength at three and 12 months after fracture (early and late stages after DRF. The first model that evaluated the importance of demographics indicated that age, gender, and age/gender interaction did not significantly contribute to pain and function (PRWE scores) at the early stage after DRF, but age significantly contributed to the functional outcomes at the late stages of DRF follow-up (Adj R^2 0.04, Pv<0.04). Age/gender interaction effect on functional outcomes at later stage cannot be considered as a significant contribution, but substantially close to significance level (Adj R^2 0.04, Pv>0.05). The second stepwise regression model that evaluated the additional contribution of ROM impairments identified that wrist flexion, extension, and supination ROM measures significantly contributed to pain and function at three and 12 months after DRF, accounting for 9% to 20% of variance. A significant regression R^2 was also found for wrist pronation ROM measure at early stage, and for age of participants at late stage after DRF (Adj R^2 0.21, Pv=0.01; Adj R^2 0.13, Pv< 0.01, respectively) (Table 4.2).

The third regression model with additional contribution of grip strength identified that grip strength did not contribute in functional status at the three month evaluation, but made a substantial contribution at one year follow-up. The grip strength of uninjured side could affect patient-rated wrist pain and function at three month after DRF (Adj R^2 0.21, Pv<0.01). The injured/uninjured percentage of grip strength was the strongest subset of contributors for pain and function at late stages of DRF (Adj R^2 0.16, Pv<0.01). Age, grip strength of injured side and sex also significantly contributed to patient-rated pain and function at late stages after DRF (Table 4.2).

Table 4.2: Adjusted R^2 and regression analysis to identify contributors of patient-rated wrist evaluation total scores at three and twelve months after fracture.

Regression		3 months after DRF					12 months after DRF					
	Measure	Adj R²	SE	St β	F	Pv	Measure	Adj R²	SE	St β	F	Pv
Multiple Linear Regression												
PRWE TS	Age	0.02	22.74	0.18	1.28	0.20	Age	0.04	19.08	0.25	1.54	0.04
+ Dem V.	Sex	0.02	22.74	0.16	1.33	0.18	Sex	0.04	19.08	0.29	2.03	0.12
	Age/Sex Interaction	0.02	22.74	-0.20	-1.01	0.32	Age/Sex Interaction	0.04	19.08	-0.46	-1.93	0.05
Stepwise Regression (Model 2)												
PRWE TS	Flex	0.15	20.34	-0.39	129.10	0.00	Flex	0.09	17.62	-0.30	56.39	0.00
+ Dem V.	Ext	0.19	19.88	-0.22	84.73	0.00	Sup	0.11	17.37	-0.18	37.49	0.00
+ ROMs	Sup	0.20	19.74	-0.13	61.37	0.00	Age	0.13	17.21	-0.16	29.29	0.00
	Pro	0.21	19.65	0.09	48.32	0.01	Ext	0.15	17.03	-0.16	25.73	0.00
Stepwise Regression (Model 3)												
PRWE TS	Flex	0.15	20.35	-0.39	127.21	0.00	GS_IC	0.16	17.10	-0.40	104.45	0.00
+ Dem V.	Ext	0.19	19.86	-0.23	85.26	0.00	Flex	0.20	16.65	-0.22	70.28	0.00
+ ROMs	Sup	0.21	19.66	-0.15	62.94	0.00	Age	0.22	16.45	-0.15	52.76	0.00
+ GS	GS_U	0.21	19.54	-0.11	50.37	0.00	GS_I	0.25	16.17	-0.21	46.04	0.00
	Pro	0.22	19.48	0.08	41.58	0.02	Ext	0.27	15.94	-0.16	41.25	0.00
							Sup	0.28	15.79	-0.13	36.84	0.00
							Sex	0.29	15.71	-0.14	32.81	0.01

Note: Adj R² = Adjusted R Square, SE= Standard Error of estimation, St β = Standardized Beta, F= Significance Level at F test, Pv= Significance Level, PRWE TS= Patient Rated Wrist Evaluation Total Score, Dem V.= Demographic Variables, GS_U= Grip Strength – Uninjured hand, GS_I= Grip Strength – Injured hand, GS_IC= Grip Strength – Internal Comparison (the proportion of the grip strength for injured/uninjured hands).

The ROMs were measured based on degree and the grip strength was measured based on kg.

Tables 4.3 and 4.4 report ROC analysis results and the area under curve one year after fracture. Based on our PRWE cut off score of equal 25, 80.78% of the participants with available data (N=458) had good function one year after DRF, whereas 19.22% (N=109) did not meet this criterion. The flexion/extension arc was highest arc of motion value at differentiating good versus suboptimal functional outcomes (AUC 0.70, 95% CI 0.65-0.76), which was determined as 105 degrees (81%) of the contra lateral normal hand. The pronation/ supination arc had the lowest AUC of 0.62 (95%CI 0.56-0.69) at differentiating good versus suboptimal functional outcomes (cut off at 150 degrees at 94% of the contra lateral normal hand). The cutoff points had the highest sensitivity and specificity of 0.67 and 0.62 for flexion/extension arc (Tables 4.3, 4.4, and Figure 4.1). The grip strength differentiated function with an AUC of 0.67 (95%CI 0.61-0.70) and a cut off at 22 kg (64% of the contra lateral normal hand). This cutoff point had the sensitivity of 0.64 and specificity of 0.55 for grip strength. The discriminators' characteristics for wrist pain and function based on proportion of injured/uninjured percentages showed better accuracy for all wrist arcs of motion and grip strength (AUCs range 0.61-0.74). The injured/uninjured percentage of grip strength calculation identified that the participants must have at least 64% of grip strength (compared to uninjured side) to provide good function after DRF (Sensitivity/Specificity 0.69/0.71) (Tables 4.3, 4.4, and Figure 4.2).

The stratified results of ROC analysis based on the participant's age (less than 65 or equal/over 65 years old) identified that the best cut off points of arcs of motion were similar for older and younger participants. The only exception was the best cut off point of absolute grip strength was lower for the older participants (16 vs. 23 kg). The wrist flexion/extension arc of motion was more discriminative in younger in comparison than older participants (AUCs 0.74 vs. 0.62) (Table 4.3). The injured/uninjured percentage of the arc of wrist flexion/extension and also grip strength was the strongest discriminator of good or suboptimal function for the participants younger than 65 years old, while the strongest discriminator for the older participants was the injured/uninjured percentage of grip strength (Table 4.4).

Table 4.3: The discriminators' characteristics for wrist pain and function based on injured hand physical impairment measures one year after distal radius fracture.

Outcome Measure	N	Optimal Cut Off	Sen/Spe	AUC (95% CI)	RR (95% CI)
All Participants					
Wrist Flex/Ext Arc	580	105	0.67/0.62	0.70 (0.65-0.76)	1.18 (1.08-1.29)
Wrist U/R Dev Arc	576	42	0.66/0.53	0.65 (0.60-0.71)	1.20 (1.10-1.30)
Wrist Pro/Sup Arc	576	150	0.66/0.55	0.62 (0.56-0.69)	1.16 (1.07-1.26)
Grip Strength	574	22	0.64/0.55	0.67 (0.61-0.70)	1.15 (1.06-1.25)
Equal/over 65 years old					
Wrist Flex/Ext Arc	176	105	0.61/0.55	0.62 (0.48-0.76)	1.07 (0.95-1.20)
Wrist U/R Dev Arc	174	40	0.61/0.52	0.64 (0.49-0.76)	1.03 (0.92-1.15)
Wrist Pro/Sup Arc	176	145	0.65/0.60	0.62 (0.49-0.75)	1.07 (0.94-1.21)
Grip Strength	173	16	0.61/0.72	0.66 (0.53-0.79)	1.21 (1.02-1.43)
Less than 65 years old					
Wrist Flex/Ext Arc	404	109	0.72/0.64	0.74 (0.68-0.80)	1.28 (1.12-1.45)
Wrist U/R Dev Arc	402	43	0.72/0.55	0.69 (0.63-0.75)	1.28 (1.15-1.42)
Wrist Pro/Sup Arc	400	150	0.63/0.61	0.63 (0.56-0.70)	1.19 (1.07-1.32)
Grip Strength	401	23	0.61/0.62	0.68 (0.61-0.74)	1.10 (1.00-1.22)
Female					
Wrist Flex/Ext Arc	427	105	0.61/0.62	0.66 (0.58-0.74)	1.22 (1.10-1.36)
Wrist U/R Dev Arc	412	42	0.60/0.57	0.62 (0.55-0.69)	1.12 (0.96-1.28)
Wrist Pro/Sup Arc	425	150	0.62/0.59	0.61 (0.54-0.69)	1.07 (0.94-1.22)
Grip Strength	416	22	0.68/0.60	0.67 (0.62-0.76)	1.64 (1.44-1.82)
Male					
Wrist Flex/Ext Arc	58	101	0.76/0.69	0.74 (0.66-0.84)	1.86 (1.46-2.42)
Wrist U/R Dev Arc	147	39	0.69/0.62	0.68 (0.61-0.79)	1.28 (1.12-1.45)
Wrist Pro/Sup Arc	149	142	0.60/0.58	0.62 (0.52-0.73)	1.07 (0.94-1.21)
Grip Strength	142	29	0.71/0.70	0.74 (0.66-0.84)	2.78 (1.72-3.82)

Note: N= Number of valid participants, Sen= Sensitivity, Spe= Specificity, AUC= Area Under Curve, CI= Confidence Interval, RR= Relative Risk.

The ROMs were measured based on degree and the grip strength values were measured based on kg.

Table 4.4: The discriminators' characteristics for wrist pain and function based on physical impairments injured/uninjured percentages one year after distal radius fracture.

Outcome Measure	N	Optimal Cut Off	Sen/Spe	AUC (95% CI)	RR (95% CI)
All participants					
Wrist Flex/Ext Arc I/U	257	81%	0.72/0.68	0.74 (0.66-0.81)	1.38 (1.18-1.62)
Wrist U/R Dev Arc	253	82%	0.72/0.58	0.70 (0.62-0.78)	1.24 (1.08-1.42)
Wrist Pro/Sup Arc I/U	256	94%	0.58/0.56	0.61 (0.51-0.71)	1.08 (0.96-1.22)
Grip Strength I/U	559	64%	0.69/0.71	0.74 (0.69-0.80)	2.88 (1.79-4.64)
Equal/over 65 years old					
Wrist Flex/Ext Arc I/U	88	79%	0.67/0.68	0.70 (0.52-0.87)	1.24 (1.00-1.53)
Wrist U/R Dev Arc	86	76%	0.67/0.73	0.72 (0.56-0.91)	1.23 (0.96-1.58)
Wrist Pro/Sup Arc I/U	87	92%	0.58/0.61	0.60 (0.39-0.80)	1.12 (0.92-1.36)
Grip Strength I/U	171	65%	0.75/0.66	0.76 (0.65-0.81)	2.12 (1.15-3.88)
Less than 65 years old					
Wrist Flex/Ext Arc I/U	169	82%	0.77/0.70	0.75 (0.67-0.84)	1.59 (1.28-1.98)
Wrist U/R Dev Arc	167	82%	0.71/0.62	0.70 (0.61-0.79)	1.27 (1.04-1.54)
Wrist Pro/Sup Arc I/U	169	94%	0.52/0.80	0.62 (0.50-0.73)	1.47 (1.12-1.93)
Grip Strength I/U	388	64%	0.69/0.73	0.74 (0.68-0.81)	3.67 (1.81-7.46)
Female					
Wrist Flex/Ext Arc I/U	199	81%	0.71/0.69	0.72 (0.64-0.82)	1.64 (1.42-1.82)
Wrist U/R Dev Arc	188	78%	0.64/0.69	0.69 (0.60-0.78)	1.22 (1.08-1.36)
Wrist Pro/Sup Arc I/U	201	94%	0.58/0.59	0.65 (0.54-0.76)	1.18 (1.12-1.56)
Grip Strength I/U	415	65%	0.67/0.74	0.73 (0.67-0.80)	1.86 (1.15-2.84)
Male					
Wrist Flex/Ext Arc I/U	58	83%	0.80/0.69	0.77 (0.63-0.86)	1.94 (1.28-1.98)
Wrist U/R Dev Arc	56	83%	0.80/0.67	0.73 (0.57-0.86)	1.37 (1.16-1.70)
Wrist Pro/Sup Arc I/U	59	96%	0.60/0.49	0.59 (0.28-0.70)	1.44 (1.12-1.86)
Grip Strength I/U	142	69%	0.74/0.76	0.77 (0.66-0.87)	3.46 (2.04-7.46)

Note: N= Number of valid participants, Sen= Sensitivity, Spe= Specificity, AUC= Area Under Curve, CI= Confidence Interval, RR= Relative Risk, I/U= Injured/Uninjured Side.

The ROMs were measured based on degree and the grip strength values were measured based on kg.
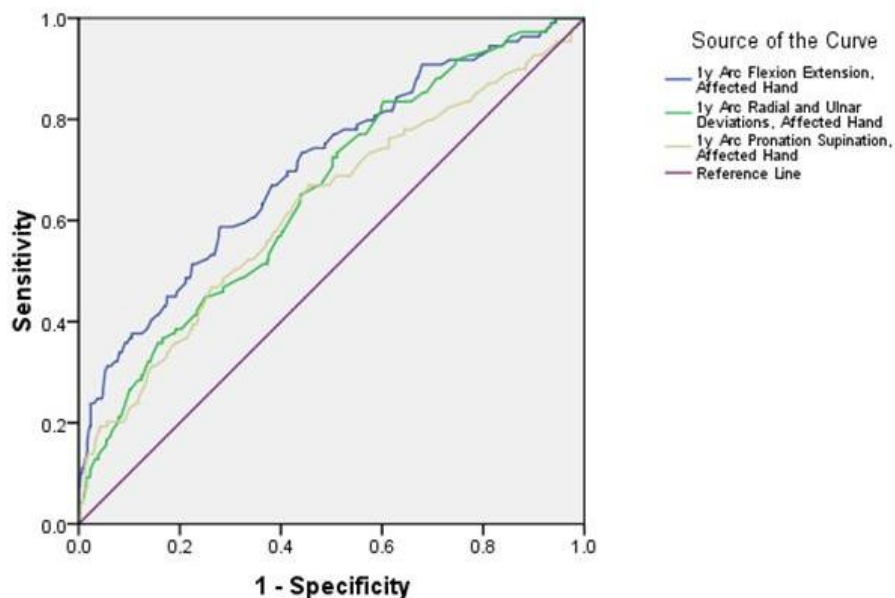
Figure 4.1: Receiver operating characteristic curve using arcs of motion to distinguish between good and suboptimal functional outcomes one year after distal radius fracture.
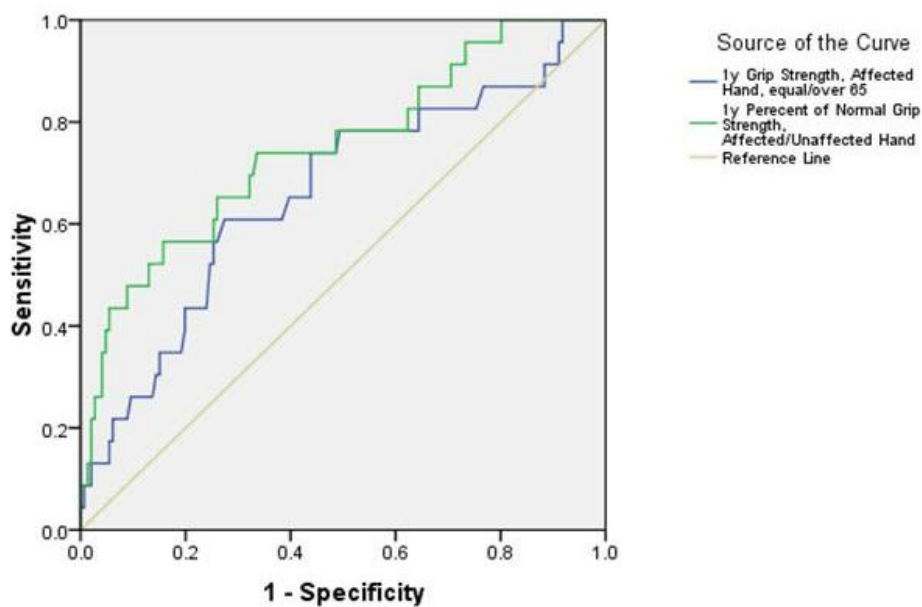
Figure 4.2: Receiver operating characteristic curve using the grip strength of injured hand and injured/uninjured percentage to distinguish between good and suboptimal functional outcome one year after distal radius fracture.

The stratified results of ROC analysis based on the participant's gender identified that the best cut off points of arcs of motion were similar for female and male participants. The AUC calculation identified that grip strength was best outcome measure to differentiate good versus suboptimal functional outcomes in both women and men (AUCs 0.67 vs 0.74) (Table 4.3). The strongest discriminators of good or suboptimal function for both women and men were the injured/uninjured percentage of wrist flexion/extension arc (0.72 vs 0.77) and also grip strength (0.73 vs 0.77) (Table 4.4).

Figure 4.3: Receiver operating characteristic curve using the grip strength of injured hand and injured/uninjured percentage to distinguish between good and suboptimal functional outcome one year after distal radius fracture.

(A)
Participants equal or over 65 years old

(B)
Participants less than 65 years old
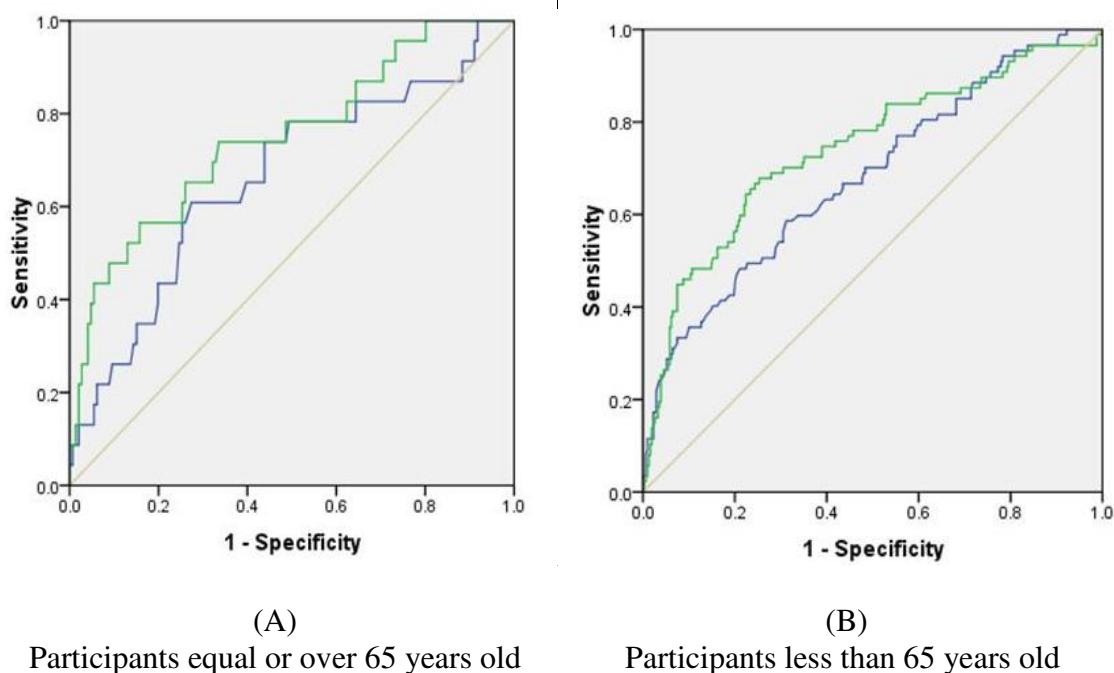
Source of the Curve

— Grip strength, injured hand

— Grip strength, injured/uninjured hands

— Reference line

The relative risk calculation showed that the participants with a grip strength of at least 64% of uninjured hand were three times more likely to report a good functional outcome in comparison to those who had <64% grip strength. The older participants with the grip strength of 65% of uninjured hand were two times more likely to report good functional outcome. This rate for participants younger than 65 with the same grip strength was four times compare to those who had lesser amounts of grip strength. Women with the grip strength of equal/greater 65% and men with the grip strength of equal/greater 69% of uninjured hand were more likely to report good functional outcome after DRF (Tables 4.3, 4.4, and Figures 4.3, 4.4).

Figure 4.4: Receiver operating characteristic curve using the grip strength of injured hand and injured/uninjured percentage to distinguish between good and suboptimal functional outcome one year after distal radius fracture.

(A) Female   (B) Male
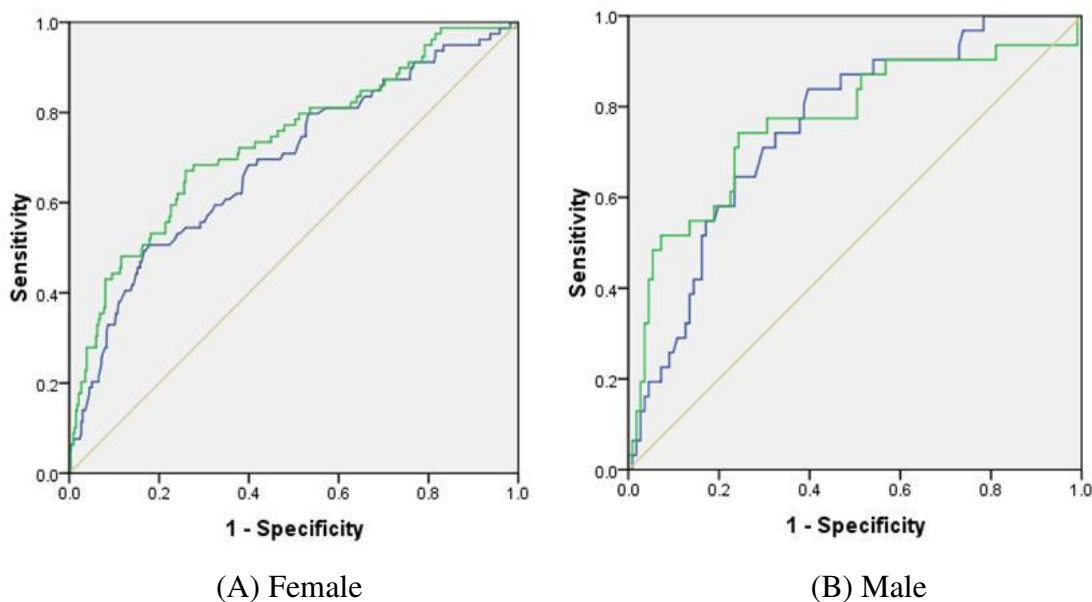
Source of the Curve

— Grip strength, injured hand

— Grip strength, injured/uninjured hands

— Reference line

4.5 Discussion

This study demonstrates that the objective physical impairments of the wrist (ROMs and grip strength) are moderately correlated to functional outcomes as measured by the PRWE at two, three, six, and 12 months after the DRF (with the exception of pronation). Furthermore, patients require a greater restoration of their normal range of motion to report a positive functional outcome in comparison to grip strength; achieving a satisfactory level of grip strength recovery was a more discriminating characteristic of achieving a good functional outcome. Finally, summary impairment measures like arcs of motion and percent recovered grip strength are stronger correlates of function as compared to the individual measures that comprise them.

Rating scales for correlation are a controversial case. There is no absolute number guide for correlation coefficient that identify two variables have low to high degree of relationship; however some statisticians have suggested that r <0.40 could be considered as low value for Pearson correlation.[36] It is necessary to know that correlation coefficients are very sensitive to sample size.[34] It means the strength of the association between two variables must be interpreted in the context of the problem.[37] With considering of our large sample size, we did consider Pearson correlation of r <0.30, between 0.30-0.50, and >0.50 as low, moderate and high values for the relationship between physical impairment measures and patient-rated pain and function.[32,33]

The low to moderate correlations in our study between physical impairment measures and wrist pain and function score were in agreement with previous studies.[11,12,38,39] Previous studies correlating outcomes and pain and function after the DRF have mostly focused at first six months after injury.[11, 12] The only study which reported correlation of functional outcomes one year after DRF focused on different methods of measurement for pain and function (wrist outcome measure, PRWE pain, PRWE specific, PRWE usual, SF-36 physical health).[38]

The PRWE score is also affected by a series of outcome measures including pain, sensation disturbances, ability to do usual activities and ability to do specific activities of daily living. Level of education and compensatory status can also affect the functional status.[11] We did consider the wrist ROM measures and grip strength for wrist function, but did not consider the other potential influences might affect the outcome. Low correlation between wrist pronation ROM measures and PRWE scores might be explained through the fact that pronation was regained most quickly after the DRF.[13] Although pronation is very important in functional activities, most of the usual and specific activities on the PRWE do not need absolute raw pronation. The specific activities on the PRWE which may need pronation are: turn a door knob and use a bathroom tissue with affected hand. Lack of forearm pronation on these specific activities can be compensated by patient shoulder abduction, forward flexion and internal rotation.[40]

Our results have strong concordance with findings by Chung et al.[12] who reported people with DRF needed to regain 95% of the flexion/extension arc of motion to be satisfied with their wrist function. Although satisfaction and functional outcome are different perspectives, we determined that people with DRF needed 81, 82, 94% of arcs of wrist flexion/extension, radial/ulnar deviations, and pronation/supination respectively, to report a good functional outcome on the PRWE. The small differences between arcs of motion needed for good function and the arcs were needed for satisfaction after DRF may relate to patient expectations. People may not be satisfied with minimum arcs of ROM needed for function and may expect to regain full motion of their wrist after injury. This expectation refers to the healthy people who get a wrist or hand injury and want to come back in their normal function. The question arises is what will be the expectation of people who have restricted motion before the fracture? Chung measured patients satisfaction based on two questions in the satisfaction domain of the Michigan Hand Outcomes Questionnaire (MHQ), which consisted of 37 questions that reflected self assessment in the areas of overall hand function, activities daily living, pain, work performance, aesthetics, and satisfaction with function.[41] The differences between measurement methods for wrist function or satisfaction (the PRWE versus the MHQ)

might be other possible reason for small differences between arcs of motion needed for good versus satisfied wrist function.

All of the arcs of motion and grip strength measures had a moderately high AUC with the patient function, indicating that good function and arcs of flexion/extension, radial/ulnar deviations, and pronation/supination were positively correlated (negatively related to the PRWE scores). The AUC calculation for grip strength in our study was in concordant with the Chung results (0.74 vs 0.77), indicating that discriminatory ability of grip strength for functional outcome or satisfaction was similar. The discriminating ability of the arc of wrist flexion/extension was slightly higher in the study by Chung et al (0.81 vs. 0.74) indicating the differences between good function and satisfaction concepts.[12]

We found that percentage of grip strength restored, as indicated by internal comparison with the uninjured side, was the physical impairment measure that best distinguished between good and suboptimal function after DRF (AUC 0.74). This distinguishing ability was not significantly different between younger and older participants (0.74 vs. 0.76) or women and men (0.73 vs. 0.77), indicating that age and gender did not affect people expectations of grip strength recovery after the DRF. Another physical impairment measure which distinguished between good and suboptimal wrist function was the percentage of wrist flexion/extension arcs restored. It was slightly higher for the younger participants compare to older participants (0.75 vs. 0.70), and men compared to women (077 vs. 0.72). These differences might refer to the higher expectations and functional demands of males and younger participants.

We found that people need to regain 64% of their contralateral grip strength in order to rate themselves has having good wrist function after DRF. Our results confirm Sarmiento's[42] estimation of 60% and Chung's[12] estimation of 65% of grip strength recovery for good function after DRF. There is an interesting contradiction in our findings. Grip strength is more important in differentiating functional outcomes; but does not need to achieve the same level of recovery compare to the uninjured hand to perform optimal functional outcome. The reasons for this are unclear. Perhaps patients require

full range of motion to perform routine tasks of daily life and notice small losses of motion as being barriers to completion of important tasks, but are able to accommodate this. Patients may be more aware of their motion loss in comparison to their alternative side because they have visual feedback about the loss. Conversely, many activities of daily life can be performed without maximum grip strength and therefore the loss of some strength may not compromise as many tasks of daily life. Since self-report measures focus on pain and tasks of daily life, full grip strength may not be necessary to achieve success on many of these tasks. Further investigations that look at the role of range of motion and grip strength in higher level performance tasks or return to work would be warranted. It should be considered that lower levels of grip strength recovery are sufficient in terms of goal setting for hand therapy programs.

4.6 Study Limitations

Although our cohort study allowed us to analysis several outcomes, it had a number of limitations that should be considered when interpreting our results. The measurement bias should be considered, because at least three different raters were used as independent evaluators over the measurement time. It is possible this issue induced measurement error which would have tended to reduce the significance level of observed correlations. However, standardized methods were used to assess physical impairment and function. These methods have previously been shown to be reliable.[23,24,27,29] Moreover, it was not possible to categorize the patients based on their function before the injury, since there were no data available for the participants before the fractures. So, the authors could not compare the participants function before and after injury.

Therapists need to set long-term functional goals that consider the individual perspectives of the patient; and the applications of this and other studies addressing the relative importance of motion and strength impairments in functional recovery. It appears that range of motion only moderately correlates to overall functional outcomes but, in order to optimize outcomes, therapy should attempt to achieve almost normal range motion in comparison to the patient's other side. Conversely, grip strength is a stronger contributor

to functional outcomes; particularly in younger patients. However, grip strength does not need to be as close to the uninjured comparator in order for patients to achieve functional outcomes.

4.7 Conclusion

Most physical impairment measures of the wrist are moderately correlated with wrist pain and function after the DRF. The ROM measures of wrist flexion, extension, supination, pronation, grip strength, age and sex, contribute significantly with the patient-rated wrist pain and function score in early and late stages after the DRF. Patients with DRF need to regain 81-94% of the wrist arcs of flexion/extension, radial/ulnar deviations, pronation/supination and 64% of grip strength.

4.8 Disclosure

The study presented here was funded in part by the Graduate Thesis Research Award – The internal grant at the University of Western Ontario. The first and second authors were funded through the Joint Motion Program (SBT), and New Investigator Award (JCM) – The Canadian Institutes of Health Research (CIHR). The scientific committee and medical ethical board at the University of Western Ontario approved the protocol. The authors declare that they have no conflict of interest.

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CHAPTER 5

General Discussion and Future Direction

5.1 Overview of Thesis

The focus of this thesis was to examine how to optimize fracture outcomes; with a focus on wrist fractures. This included determining whether physical modalities could stimulate fracture healing, as well methods to assess the reliability and accuracy of range of motion impairments, and finally the role of the physical impairments as contributors to function following distal radius fracture.

This thesis demonstrated that low-power laser therapy improved the biomechanical properties of bone following fracture healing in animal models. Although there is still insufficient evidence to establish the optimal dosage, the available results suggested that low-power laser irradiation improved the strength of healing bones in animal models. In a systematic review on humans conducted by these authors (as part of the comprehensive process), similar effects were found for ultrasound in humans.[1] Thus, the role of physical agents as facilitators of bone healing within rehabilitation was supported.

In the next phase of this work, the focus was on physical impairments, in particular joint motion. The first issue addressed was the clinical measurement of joint motion. We determined that digital goniometry reliably measured range of motion in both wrist and (index) finger PIP joints in patients with limited motion. This method was highly reliable for all measures across occasions and raters, using various instruments, despite a lack of consistent use of force across raters. This study also determined that measured physical impairment moderately correlated with rated pain and function in patients with distal radius fracture. This suggested that wrist motion was a contributor to function- although other factors must also contribute as important additional components.

In the final phase of this thesis, the focus was on the amount of motion and grip strength required for optimal functional outcome. Most physical impairment measures of the wrist were moderately correlated with wrist pain and function after distal radius fracture. Range of motion as measured for wrist flexion, extension, supination, pronation and also the levels of grip strength, age and sex contribute significantly with the patient-rated wrist pain and function both in early and late stages of distal radius fracture. Patients with

distal radius fracture needed to regain near normal (81%-94%) arcs of wrist flexion/extension, radial/ulnar deviation, pronation/supination and 64% of grip strength to achieve optimal functional outcomes.

5.2 Implications of Thesis Findings on Practice, Policy and Future Research

5.2.1 Low-power Laser Irradiation

In chapter 2, we found that collation of results from the relevant studies using a systematic review process and meta analysis revealed low-power laser, effectively stimulated bone healing in animal models. Specifically it increased the mechanical strength of bone in fracture models. Since this work has only been proven in an animal model, it cannot yet move into clinical practice or policy. Rather, the implications are for future research needed. In order to establish the effects of low level lasers on bone healing, additional studies should be performed using biomechanical measures, which are the optimal indicator for bone strength for this question.[2,3] Studies that define optimal dosage in animal models closer to human should be the next step. Then randomized studies are needed to determine if the same bone healing stimulation effects occurring in animals may also be seen in human. A low power He-Ne laser has been suggested for a trial in a large clinical study, since this type of laser was commonly used in all relevant studies on connective tissue healing and seemed to have positive effects on healing process.[2] Although it is still early to recommend low-power laser therapy in humans, the available body of evidence is promising and warrants conducting clinical trials in humans to evaluate the effectiveness of this modality in promoting bone healing. Results from such clinical trials may be compared with those of placebo and to other noninvasive modalities that have been shown to affect bone healing (e.g., ultrasound) and may lead to the development of new protocols for the treatment of human bone fractures.

5.2.2 Range of Motion Measurement

In chapter 3, we demonstrated that reliable measurement of range of motion in patients with wrist and hand limitations can be obtained using different digital instruments across different occasions or raters. The results confirmed the reliability and accuracy of the data for range of motion derived from digital goniometers. Few studies compared different computerized goniometers, included torque assessments or examined both hand and wrist movements within the same study. Other studies that examined digital goniometers focused on healthy subjects[4,5,6], or used subjects with either normal range of motion[7], or with specific limited wrist movements[6,8]. Our results support goniometric assessments across raters and devices as a method, to determine limitations in wrist and hand joint motion. It was evident that raters tend to use more consistent force on re-application compared than forces applied by different raters for similar measure. This evidence suggests that the application force may make a small contribution to lower inter-rater reliability. Until now rater force application during goniometry has been a concern; but few studies have addressed this issue quantitatively. We demonstrated that raters tend to reproduce similar torque application upon repeated testing; but that different raters were significantly different in their force application. Although the ICCs were still high, suggesting this did not substantially impair the ability to discriminate between people in a group, it undoubtedly contributes to the absolute amount of error in any given score. This evidence makes it harder to know whether a patient is different when examined by a different person.

There are several options to deal with this issue. One is to include torque calibration in training of goniometry. Methods for calibrating force across raters might be included when teaching goniometry. There are a variety of ways to calibrate force applied whether it is measure quantitatively or done subjectively by joint resistance. Although the torque goniometer we used is not routinely available for clinical practice, the cost of producing such devices is not that high and may be a direction for development of new commercial devices. It is reassuring that despite the differences in torque that range of motion score still provides a reliable measure for use in clinical practice. However, our study provided

an area where enhanced precision might be pursued. Future reliability studies may be conducted to compare the results from digital instruments used for this thesis project with data derived from mechanical goniometers in specific groups of patients.

The moderate relationship between individual joint motion measurements, obtained from digital goniometers, and data from self-reported pain and function questionnaires suggests that joint motion impairments contribute to functional disability. This moderate correlations are in concordance with the findings has been found in a variety of other musculoskeletal conditions.[9,10] This suggests that measurement of motion is an important impairment to consider in clinical practice, but should not be the only impairment measure used to make clinical decisions. Policies that include loss of joint motion in impairment ratings or disability assessment have been supported by this finding. This finding contributed to the decision to study the extent of motion needed for function carried out in this thesis.

5.2.3 Physical Impairment Outcome Measures, Pain and Function

In chapter 4, we demonstrated that patients needed to regain high level of wrist arcs of motion (flexion/extension, radial/ulnar deviations, pronation/supination) to achieve optimal functional outcomes after distal radius fracture. Interestingly, a moderate level of grip strength (compared to the normal side) was enough for these patients to achieve optimal function based on patient-rated pain and function scores. Former studies have quantified level of physical impairments for wrist function focused on healthy people[11], or used the specific functional activities[12], or specific limited wrist movements[13], or early stages after distal radius fracture[13]. Our results confirmed the former findings of required moderate grip strength for optimal functional outcomes after distal radius fracture.[13,14] We also agree that a more normal arc of motion is required for function; although in our study this was a little lower than the finding of the previous researchers (0.81 vs. 0.95)[13] who evaluated satisfaction as the outcome of interest.

These results show that many activities of daily life (based on specific and usual activities of the PRWE) may not need maximum grip strength and therefore loss of some grip

strength may not affect function. Conversely, high level of wrist arcs of motion is necessary to achieve optimal function in these activities of daily life. These findings can be also very useful to determine how much therapy would be necessary to achieve optimal functional outcome. A study by Michlovitz et al.[15] reported that physical impairment measures were used much more frequently than functional outcome questionnaires in assessing progress during treatment. Therefore, it is important to be able to relate these to function. On the other side, patients are clearly more interested in having optimal function than improvements in physical impairment. So, the gap between measurement of physical impairment measures and functional level is a real concern.[15] The findings of our study can fill this gap and the clinician can compare data from their patients with these "benchmarks" to identify the functional impairment and recovery after distal radius fracture. The clinicians should aware that their patients may have optimal wrist function when they regain high levels of wrist arc of flexion/extension, radial/ulnar deviation and pronation/supination, and at least moderate level of grip strength. Our further investigation about level of contribution of physical impairments to patient-rated pain and function can help the clinicians to know the required physical impairments for optimal functional outcomes after distal radius fracture. Our study did not take into consideration occupational or personal demands and expectations; so these would be considered when applying this evidence to patients.

Since joint motion is important, fracture rehabilitation must incorporate interventions that will maximize ROM. There is evidence for a number of physical therapy interventions that can improve joint motion either specifically for fractures, or for stiff joints.[16] A systematic review of therapy interventions for improving range of motion has shown that joint mobilization, a supervised exercise program, and splinting can effectively increase joint range of motion.[16] Further investigation of therapy practice patterns identified that more than 90% of therapists included range of motion exercises, and about 80% included mobilization and splinting in their treatment plan through immobilization phase after distal radius fracture.[15] These rates of preferred practice patterns were decreased to 80% for range of motion exercises and less than 40% for mobilization and splinting during the immobilization phase.[15] These findings suggest the importance of range of motion exercise, mobilization and splinting in treatment plan after distal radius fracture. Our

results support the focus on regaining motion that is evident in practice analysis. It also provides therapists with targets that might help achieve more effective treatment plan to regain optimal function for the patients with distal radius fracture.

Taken together these studies suggest that physical therapy programs should consider the use of physical agents where there is a concern about the quality of bone healing. Since fracture union rates vary by fracture and a variety of clinical circumstances, the need for this intervention will be variable. The nonunion rates are low in distal radius fracture, so this use may be infrequent in this fracture. Conversely, the thesis suggests that joint motion must be restored and therapists should routinely incorporate interventions to improve joint motion into rehabilitation programs. This is supported by current practice patterns.[15] Joint motion should be routinely measured in fracture rehabilitation and efforts to be consistent with testing methods including positioning, instruments, landmarks and force application should be considered. The thesis findings support the need for physical therapy involvement in fracture recovery and provide some direction on how to optimize it.

5.3 Limitations

Although this thesis addressed some gaps in the literature, many remain. Further the thesis had limitations which affected the extent to which it addressed these gaps. The study of laser effectiveness was limited by the small number of available studies and lack of clinical data to represent the effects of laser on bone healing in humans. The results of animal studies cannot be extrapolated to humans. Further, since we did not perform systematic reviews for all potential physical modalities that might be used on fracture healing, we do not know if laser is more or less promising than other physical agents. We did perform another systematic review and meta analysis on effects of low-intensity pulsed ultrasound on human fracture healing[1], which also supported that physical agent assists bone healing. However, there were other alternative physical agents which might have been effective on fracture healing. It would be necessary to perform a comprehensive systematic search to find clinical effectiveness of all potential physical

agents on fracture healing, and to compare the results (common outcome measures) of different modalities at some point in the future to answer this question. Further since nonunion, delayed union and malunion are all adverse outcomes, these aspects of fracture healing should all be addressed. That was not possible in this thesis.

We also had limitations in the manner in which we studied the role of joint motion in fracture recovery. Although we studied the reliability and validity of range of motion measures in patients with wrist and hand limitation, we did not perform reliability measurements specifically for the patients who had distal radius fracture. Although it made sense to study reliability in the larger group of patients that might be tested using goniometry to make our findings more broadly generalizable, this made them less specific to our primary target-distal radius fracture. However, since 73% of the study contained patients with distal radius fracture, the results of the reliability study can be considered for the range of motion measures after this fracture.

Finally, our cohort study was a retrospective cohort and so we had restrictions on data availability. For example we might have been able to ask patients what amount of recovery they expected, or required for function to cross reference our Receiver Operating Characteristics (ROC) findings if the study had been a prospective cohort design. The study was based on self-reported function so we do not know if the amount impairment recovery needed to achieve a good PRWE score actually did provide for sufficient capability for performance of tasks and roles e.g. return to work. Further, the cut-off for optimal functional outcome is not precisely defined and may vary across people.

5.4 Recommendations for Future Studies

Studies toward understanding effective mechanisms to promote better healing for human bone fractures, using physical agents are currently underway. We have initiated a comprehensive and systematic review of literature to examine the effectiveness of electrical stimulation and electromagnetic fields. The effect of low-level laser irradiation

on human fracture healing is a novel question that should be examined in human randomized trials as the next step of relevant clinical research. Future studies that enhance our ability to understand the contribution of physical impairment outcome measures in various musculoskeletal disorders, and the role of self-report functional surveys and scales on clinical decision making and outcomes may lead to more effective patient-centered treatment protocols.

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Appendix A

The Patient Rated Wrist Evaluation

PATIENT RATED WRIST EVALUATION

Name_____

Date_____

*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.

Sample scale ◆   0 1 2 3 4 5 6 7 8 9 10
                          No Pain   Worst Ever

RATE YOUR PAIN:

At rest	0 1 2 3 4 5 6 7 8 9 10
When doing a task with a repeated wrist movement	0 1 2 3 4 5 6 7 8 9 10
When lifting a heavy object	0 1 2 3 4 5 6 7 8 9 10
When it is at its worst	0 1 2 3 4 5 6 7 8 9 10

How often do you have pain?	0 1 2 3 4 5 6 7 8 9 10
	Never Always

Please turn the 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 ◆   0 1 2 3 4 5 6 7 8 9 10
No   Difficulty   Unable To Do

Activity	Scale
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.*

Activity	Scale
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

The Disabilities of the Arm, Shoulder and Hand

DISABILITIES OF THE ARM, SHOULDER AND HAND

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

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND

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

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

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

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

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

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

A DASH score may <u>not</u> be calculated if there are greater than 3 missing items.

DISABILITIES OF THE ARM, SHOULDER AND HAND

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including home-making if that is your main work role).

Please indicate what your job/work is:_____

☐ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

		NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1.	using your usual technique for your work?	1	2	3	4	5
2.	doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3.	doing your work as well as you would like?	1	2	3	4	5
4.	spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_____

☐ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

		NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1.	using your usual technique for playing your instrument or sport?	1	2	3	4	5
2.	playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3.	playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4.	spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may **not** be calculated if there are any missing items.

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Appendix C

The Short Version of the Disabilities of the Arm, Shoulder and Hand

*Quick*DASH

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

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

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

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

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

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

*Quick*DASH DISABILITY/SYMPTOM SCORE = $\left(\left[\dfrac{\text{sum of n responses}}{n}\right] - 1\right) \times 25$, where n is equal to the number of completed responses.

A *Quick*DASH score may <u>not</u> be calculated if there is greater than 1 missing item.

*Quick*DASH

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including homemaking if that is your main work role).

Please indicate what your job/work is:_____

☐ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week.

Did you have any difficulty:	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_____

☐ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week.

Did you have any difficulty:	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may **not** be calculated if there are any missing items.

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Appendix D

The Quality of Animal/Tissue Research Scale

The Quality of Animal/Tissue Research Scale

Item	Rating		
	Yes (2)	Partial (1)	No (0)
1. Animals /tissue samples were randomly allocated to groups.			
2. The animals/tissue samples were similar across comparison groups.			
3. The tissue/animal model study was appropriate for the biological properties/questions being evaluated.			
4. The animal model used was appropriate to make inferences in terms of human application? (Tissue similar to, or is human tissue).			
5. Objective measurements were performed using sufficient standardization of measurement techniques and appropriate instrumentation.			
6. Reliability of measurements was reported or referenced to indicate sufficient consistency of the outcomes analyzed.			
7. All animals entered into the study accounted for? (All were analyzed or reasons for withdrawal noted).			
8. 90% of the animals entered were included in the data analysis.			
9. The between group/time statistical comparisons used appropriate statistical methods.			
10. Measures of variability and confidence intervals were provided to indicate the range/size of the effects observed.			
Total score (/20)			

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Appendix E

Ethics Approval Forms
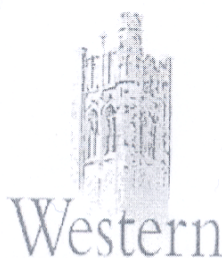
Office of Research Ethics

The University of Western Ontario
Room 4180 Support Services Building, London, ON, Canada N6A 5C1
Telephone: (519) 661-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. J.C. MacDermid
Review Number: 16168E **Review Level:** Expedited
Review Date: May 20, 2009

Protocol Title: Reliability and validity of J-Tech and NK digital measurements of wrist and fingers movement in patients with wrist/hand ROM limitations

Department and Institution: Hand and Upper Limb Centre, St. Joseph's Health Care London
Sponsor:

Ethics Approval Date: July 29, 2009 **Expiry Date:** September 30, 2010
Documents Reviewed and Approved: UWO Protocol, Letter of Information and Consent
Documents Received for Information:

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 study 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 ou must request it using the UWO Updated Approval Request Form.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:

a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
b) all adverse and unexpected experiences or events that are both serious and unexpected;
c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

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.

Chair of HSREB: Dr. Joseph Gilbert

Ethics Officer to Contact for Further Information			
☐ Janice Sutherland (jsutherl@uwo.ca)	☐ Elizabeth Wambolt (ewambolt@uwo.ca)	☑ Grace Kelly (grace.kelly@uwo.ca)	☐ Denise Grafton (dgrafton@uwo.ca)

This is an official document. Please retain the original in your files. cc: ORE File
LHRI

LAWSON HEALTH RESEARCH INSTITUTE

CLINICAL RESEARCH IMPACT COMMITTEE

RESEARCH OFFICE REVIEW NO.:   R-09-326

PROJECT TITLE: Reliability and validity of J-Tech and NK digital measurements of wrist and fingers movement in patients with wrist/hand ROM limitations

PRINCIPAL INVESTIGATOR: Dr. J MacDermid

DATE OF REVIEW BY CRIC: August 20, 2009

Health Sciences REB#:   16168E

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and the project:

Was Approved

PLEASE INFORM THE APPROPRIATE NURSING UNITS, LABORATORIES, ETC. BEFORE STARTING THIS PROTOCOL. THE RESEARCH OFFICE NUMBER MUST BE USED WHEN COMMUNICATING WITH THESE AREAS.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

All future correspondence concerning this study should include the Research Office Review Number and should be directed to Sherry Paiva, CRIC Liaison, LHSC, Rm. C210, Nurses Residence, South Street Hospital.

cc: Administration

Western Research

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
File Number: 102762
Review Level: Delegated
Approved Local Adult Participants: 400
Approved Local Minor Participants: 0
Protocol Title: Definition of Risk Recovery Cutoffs in Wrist Motion for Poor Functional Outcomes after Distal Radius Fracture; and Effects of Age and Gender
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,Western University
Sponsor:
Ethics Approval Date: August 07, 2012 **Expiry Date:** March 31, 2013
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Western University Protocol		

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

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

a) Name: Siamak Bashardoust Tajali

  Address: Dep. Health & Rehab. Sciences
Physical Therapy Program
The University of Western Ontario
1201 Western Road
London, ON
N6G 1H1

b)

Degree	University	Department	Year
Ph.D. (PT)	Univ. Western Ontario	Physical Therapy	2012 (Aug.)
M.Sc. (PT)	Iran Univ. Medical Sciences	Physical Therapy	1999
B.Sc. (PT)	Iran Univ. Medical Sciences	Physical Therapy	1992

c) Relevant Employment History

Date	Rank & Position	Department	Institution
2006-Present	Graduate Research Asst.	Physical Therapy	U. Western Ontario
2006-2010	Graduate Teaching Asst.	Physical Therapy	U. Western Ontario
2009-2011	Health & Safety Officer	Teaching Asst. Union	U. Western Ontario
1999-2006	Academic Board Member	Physical Therapy	Iran U. Med. Sc.
1994-2006	Founder, Partner, Physical Therapist	Physical therapy	Health, Sport Medicine Institute, Tehran-Iran
1994-2000	Lecturer	Physical Therapy	Iran U. Med. Sc., Sh. Beheshti U. Med. Sc.
1992-1994	Teaching Assistant	Physical Therapy	Sh. Beheshti U. Med. Sc.

d) Academic Honors *(not research grants)*

 2008   Appreciation award of CHRW-Univ. Western Ontario.*"co-chair and executive member in Rumi Seminar; the universal poet, mysticism and modernism"*

 2006   Appreciation award of Physical Therapy Research Group (Jehad Daneshgahi), Iran Univ. Med. Sc. *"Excellence as an academic board researcher"*

2004   Appreciation award of Physical Therapy Research Group (Jehad Daneshgahi), Iran Univ. Med. Sc. *"Excellence as an academic board researcher"*

2003   Appreciation teaching award, Iranian Physiotherapy Association, Lecturer in workshop: *"Evidence based practice - advanced"*

2002   Appreciation teaching award, Iranian Physiotherapy Association, Lecturer in workshop: *"Evidence based practice – basic"*

2001   Recipient of award for best presentation, 14th International Congress of Physiology & Pharmacology, Tehran-Iran.

1999   Appreciation teaching award of, Amirkabir Uni. Technology, Lecturer in workshop: *"Biological effects of low power lasers"*

1999   Appreciation teaching award, Dep. Physical Therapy, Iran Univ. Med. Sc., Award of 5 years cooperation as an instructor and researcher.

1998   Recipient of appreciation award of graduation, Iran Univ. Med Sc. Honors ranking first (highest GPA: 19.6/20), in M.Sc. physiotherapy.

1996   Appreciation award of cooperation, Iran National Olympic Committee, physical therapy treatment for Iran national wrestling team.

1996   Recipient of appreciation teaching award, Dep. Physical Therapy, Sh Beheshti Univ. Med. Sc. Excellence in teaching as clinical instructor.

1996   Recipient of award for best presentation, 1st Nationwide Iranian Physiotherapy Students Congress, March 1996.

e) Scholarly and Professional Activities

2010-present Peer reviewer, Journal of Health Science Inquiry, Toronto-Canada.
2010-present Peer reviewer, Journal of Physical Therapy, Manipal-India.
2010   Invited reviewer, Journal of Advances in Medical Science, Balystok-Poland.
2008   Abstract reviewer, London Interprofessional Healthcare Conference, London-Ontario, Canada.
2005-2006   Invited Reviewer, Journal of Iran Univ. Med. Sc., Tehran-Iran.
2005-2006   Invited Reviewer, Journal of Kashan Univ. Med. Sc. (Feyz), Kashan-Iran.
2003-2006   Invited Reviewer, Journal of Jehad Iran Univ. Med. Sc. (Yakhteh), Tehran-Iran.
1996   Abstract reviewer & chair of two scientific sessions, 1st Congress of Iranian Physiotherapy Students, Tehran-Iran.

f) Significant University Duties

2006-Present   Research and Teaching Assistant; *Physical Therapy Dep., Univ. Western Ontario.*

Major Research Titles:

1. "Biomechanical effects of low power lasers on bone healing in animal models; a Meta analysis"
2. "Effect of low intensity pulsed ultrasound on bone healing; a systematic review approach"
3. "Reliability and validity of electro goniometric ROM measurements in patients with limited wrist and hand motion"
4. "Definition of risk recovery cut offs in wrist motion for poor functional outcomes After distal radius fracture; effects of age and gender"
5. "Effect of electrical stimulation on bone healing; a systematic review approach" *(In Progress)*

Teaching Assistant of the courses:

1. Foundations of Physical Therapy Practice – PT9511 (for three years)
2. Physical Therapy in Acute Care Setting – PT9526 (for one year)
3. Physical Therapy in Rehabilitation Setting II – PT9535 (help to TA for one semester)
4. Exercise in Special Populations – PT9547 (help to TA for one semester)

1999-2006   Full-time Academic Board Researcher*, Physical Therapy Research Group, Jehad Daneshgahi, Iran Univ. Med. Sc., Tehran-Iran.*

Major Research Titles:

1. "The Comparative Research of Effects of High and Low Frequency Ultrasound Therapy in Chronic Low Back Pain"
2. "Effects of Ultrasound Therapy on Bone Healing in Rabbits from Histological and Biomechanical Points of View"
3. "Changes of Histological Specialties of Bone Follow Low Power He-Ne Laser Radiation after Partial Osteotomy in Rabbits"
4. "Effects of Low Power He-Ne Laser Radiation on Bone Healing from Healing from Radiological Point of View"
5. "Effects of Low Power He-Ne Laser on Survival of Skin Flap in Rats"
6. "Study of Biomechanical Behavior of Tibia Bone in Rabbits"
7. "Effects of Low Power He-Ne Laser Radiation in Healing of Open Skin Rat Wound"
8. "Effects of Low Power Ga-As Laser Radiation in Healing of Open Skin Rat Wound"

1994-2000   Part-time Instructor, Consultant and Researcher, *Physiotherapy Department, Faculty of Rehabilitation, Shahid Beheshti Univ. Med. Sc.; & Iran Univ. Med. Sc., Tehran-Iran.*

Major Research Titles:

1. "Effects of McQueen Technique at Increase of Quadriceps Muscle Power in Athletics and Non Athletics (A Comparative Study)"
2. "Comparative Study between Electrical Stimulation and Isometric Contraction on Increasing of Isometric Muscle Power"
3. "Effects of Diadynamic Current on Pain Tolerance-Comparison of Different Bernard's Currents"
4. "Effects of High Voltage Current on Pain Tolerance"
5. "Comparative Study of Maximum Voluntary Contraction of Quadriceps Muscle in Amateur Soccer's players"

Instructor of the courses:

1. Clinical Practice and Training *(Placement of orthopedic and surgical disorders).*
2. Clinical Practice and Training *(Placement of burn and surgical disorders).*
3. Physical Therapy in Medical Conditions I *(Cardiopulmonary and vascular Diseases).*
4. Measurement and Evaluation *(Muscle Testing).*

1992-1994   Teaching Assistant, *Physiotherapy Department, Faculty of Rehabilitation, Shahid Beheshti Univ. Med. Sc. (Clinical Practice & Training, Measurement & Methods).*

1997-2006   Graduate Supervisions**:**
           (Supervisor of 8 Bachelor + Advisor of 3 Master Theses in Physical Therapy)

 Titles of Theses for Bachelor Degree in Physical Therapy:

1. Khajavi F, Asadi A. Effects of McQueen Technique at Increase of Quadriceps Muscle Power in Athletics and Non Athletics (A Comparative Study).

2. Jamali E. Comparative Study between Electrical Stimulation and Isometric Contraction on Increasing of Isometric Muscle Power.

3. Bidmeshk M, Bayatlo A, Khazraye A. Effects of Ultrasound Therapy on Bone Healing in Rabbits from Biomechanical Points of View.

4. Fayzi M, Ghafari A. Effects of Diadynamic Current on Pain Tolerance-Comparison of Different Bernard's Currents.

5. Ebrahimi M. "Effects of High Voltage Current on Pain Tolerance.

6. Hosieni M. Comparative Study of Maximum Voluntary Contraction of Quadriceps Muscle in Amateur Soccer's players.

7. Darioush Farahi. Capacitivie Coupled Electrical Stimulation and Electrical Magnetic Fields in Bone Healing. A Litreature Review.

8. Nayeni H. Transcutaneous Electrical Stimulation, An Overview from Theory to Practice.

Titles of Theses for Master Degree in Physical Therapy:

1. Tabatabye M. Effects of Low Power He-Ne Laser on Survival of Skin Flap in Rats.

2. Solimani M. Histological Study of Low Power He-Ne Laser Irradiation in Bone Healing.

3. Heidar Abadi A. Effects of Ga-As Laser Irradiation on Trigger Points.

g) Major Academic Grants & Awards

2012   The SOGS 125th Scholarship, Society of Grad. Students, U. Western Ontario.

2012   Graduate Thesis Research Award, Dept. Health & Reh., U. Western Ontario.

2011-2012 CIHR Travel Award, Canadian Institutes of Health Research (CIHR).

2010-2011   Joint Motion Program (JuMP) – Canadian Institutes of Health Research (CIHR) Training Program in Musculoskeletal Health Research and Leadership.

2010-2011   Ontario Graduate Scholarship (OGS).

2010   Ontario Student Bursary Award, Society of Grad. Students, U. Western Ontario.

2009   Graduate Thesis Research Award, Dept. Health & Rehab, U. Western Ontario.

2009   Parsana Doctoral Scholarship, Grad. Teaching Assistant Union, U. Western Ontario.

2006-2010 Full Doctoral Funding in Physical Therapy Program, U. Western Ontario.

1998   Best Master Research Project in the Graduation Year, Iran U. of Med. Sc.

1998   Best Research Project of the Year, Jehad Daneshgahi, Iran U. of Med. Sc.

h) Published Articles in Refered Journals

1. **Bashardoust Tajali S,** MacDermid J, Grewal R. "Definition of Risk Recovery Cut offs in Wrist Motion for Poor Functional Outcomes after Distal Radius Fracture; and Effects of Age and Gender", (in press).

2. **Bashardoust Tajali S,** MacDermid J, Grewal R. Young C. "Intrarater and Interrater Reliability of Electrogoniometric Measurements in Patients with Hand and Wrist Limitations", (in press).

3. **Bashardoust Tajali S,** Houghton P, MacDermid J, Grewal R. "Effects of Low Intensity Pulsed Ultrasound Therapy on Fracture Healing; A Systematic Review and Meta Analysis" published paper in American Journal of *Physical Medicine and Rehabilitation, 2012; 91(4):349-367.*

4. **Bashardoust Tajali S,** MacDermid J, Houghton P, Grewal R. "Effects of Low Power Laser Irradiation on Bone Healing in Animals; A Meta Analysis" published paper in *Journal of Orthopaedic Surgery & Research, 2010; 5(1): 1-22.*

5. **Bashardoust Tajali S,** Ebrahimi E, Kazemi S, Bayat M, Azari A, Hosseinian M, Azordegan F, Kamali M. "Effects of He-Ne Laser Irradiation on Osteosynthesis" published paper in *Osteo Trauma Care*, 2003; 11: S17-S20.

6. Kazemi S, Jamali Zavare A, **Bashardoust Tajali S.**"Effects of 1 MHz Frequency Ultrasound on Bone Tissue after Partial Osteotomy in Rabbits: A Histological Study" published paper in *Yakhteh (The Cell), 2003; 5(17): 29-34.*

7. **Bashardoust Tajali S,** Kazemi S, Azari A, Shahverdi A, Jabal Ameli M. "Effects of Ultrasound Therapy on Bone Healing in Rabbits" published paper in *Feyz Medical Journal, Spring 2000; 13(6): 29-35.*

8. **Bashardoust Tajali S,** Bayat M, Ebrahimi E, Azari A, Hosseinian M, Azordegan F, Kamali, M. "Effect of Low Power Helium-Neon Laser Radiation on Healing of Minor Bone Deformation of Rabbit Tibia" in *Feyz Medical Journal, Fall 1998; 7(3): 9-15.*

9. **Bashardoust Tajali S.** "Physiotherapy in AIDS" in *Journal of the Iranian Physiotherapy Association (JIPA), Autumn 1996; 2(6): 14-21.*

i) Major Presentations in Refered Conferences

1. "Reliability of Electro-Goniometric ROM Measurements in Patients with Hand and Wrist Limitations", Combined Meeting of The Canadian Society for Surgery of the Hand & The Canadian Society of Hand Therapists (CSHT), Toronto-Canada. May 2012.

2. "Intrarater and Interrater Reliability of Electrogoniometric Measurements in Patients with Hand and Wrist Limitations", American Society of Hand Therapists (ASHT), Nashville-USA, Sep 2011.

3. "Effects of Low Intensity Pulsed Ultrasound Therapy on Fracture Healing; A Systematic Review Approach", 16th International World Confederation of Physical Therapy (WCPT) Congress, Amsterdam-Netherlands, June 2011.

4. "Low Intensity Pulsed Ultrasound Therapy improves Fracture Healing; A Systematic review and Meta Analysis", Western Research Forum 2011, London-Canada, Feb 2011.

5. "Prevalence of Low Back Pain among Physical Therapists", International Association for the Study of Pain, 3rd International Congress on Neuropathic Pain (IASP/NeuPSIG), Athens-Greece, May 2010.

6. "Effects of Low Power Laser Irradiation on Bone Healing in Animals: A Meta Analysis", Annual Meeting of American Society for Surgery of the Hand and American Society of Hand Therapist (ASSH & ASHT), San Francisco-USA, Sep 2009.

7. "The Clinical Effects of High and Low Frequency Ultrasound Therapy on Chronic Low back Pain", 5th World Congress World Institute of Pain, New York-USA, Mar 2009.

8. "Effects of Ultrasound Therapy on Bone Healing in Patients at Risk of Compromised or Delay Bone Healing", 2009 Western Research Forum, The University of Western Ontario, London-Canada, Feb 2009.

9. "Effects of Low Power Laser Irradiation on Bone Healing in Animals; A Meta-Analysis", Health and Rehabilitation Sciences Graduate Research Forum, The University of Western Ontario, London-Canada, Feb 2009.

10. "Effects of Ultrasound Therapy on Bone Healing in Patients at Risk of Compromised or Delay Healing", Health and Rehabilitation Sciences Graduate Research Forum, The University of Western Ontario, London-Canada, Feb 2009.

11. "Effects of High and Low Frequency Ultrasound Therapy on Bone Healing", 14th Congress of the World Confederation for Physical Therapy, Barcelona-Spain, June 2003.

12. "The Comparative Study of High and Low Frequency Ultrasound Therapy on Bone Regeneration", 10th Congress of the World Federation for Ultrasound in Medicine and Biology, Montreal-Canada, June 2003.

13. "Effects of Low Power He-Ne Laser Irradiation on Bone Healing", 1st Kuwait International Physical Therapy Conferences, Ministry of Health of Kuwait, Kuwait City-Kuwait, Nov 2002.

14. "Effects of He-Ne Laser Irradiation on Osteossynthesis", Osteosynthese International Congress, Rethymno-Greece, Sep 2002.

15. "Effects of Diadynamic Currents on Pain Threshold", 10th World Congress on Pain International Association for the Study of Pain, San Diego-California, Aug 2002.

16. Presentation a Training Course entitles: "Evidence-Based Practice", 13th Congress of Iranian Physical Therapy, Tehran-Iran, May 2002.

17. "Effects of Superficial Galvanofaradic Currents on Pain Tolerance", 1st International Congress of Pain and Physical Medicine and Rehabilitation, Tehran-Iran, Apr 2002.

18. "Effects of Electrical Stimulation on Maximum Voluntary Isometric Contraction of Healthy Muscle Power", 3rd International Mediterranean Sport Sciences Congress, Antalya-Turkey, Nov 2001.

19. "Effects of Low Power He-Ne Laser Radiation on Bone Regeneration in Rabbits from Biomechanical and Histological Points of View", 14th World Congress of the International Society for Laser in Surgery and Medicine, Chennai-India, Aug 2001.

20. "Effects of High Voltage Current on Pain Threshold", 1st Congress of Pain Study and Research, Tehran-Iran, May 2001.

21. "Effects of He-Ne Radiation on Collagen Synthesis of Fibroblast Cells", 6th International Congress of Dermatology, Isfahan-Iran, May 2001.

22. "Effects of Low Power He-Ne Laser Radiation on Skin Flaps in Rats", 6th International Congress of Dermatology, Isfahan-Iran, May 2001.

23. "Effects of Low Power He-Ne Laser Radiation in Healing of Open Skin Rat Wound", 6th International Congress of Dermatology, Isfahan-Iran, May 2001.

24. "Effects of Low Power Ga-As Laser Radiation in Healing of Open Skin Rat Wound", 6th International Congress of Dermatology, Isfahan-Iran, May 2001.

25. "The Compensatory Study of Electrical Stimulation and Isometric Contraction Effects on Increasing Isometric Muscle Power", 12th Congress of Iranian Physical Therapy, Tehran-Iran, May 2001.

26. "Effects of 3MHz Ultrasound Therapy on Bone Healing, A Biomechanical Study", 11th Congress of Iranian Physical Therapy, Tehran-Iran, May 2000.

27. "Study of Biomechanical Behaviour of Tibia Bone in Rabbits", 9th Congress of Iranian Medical Engineering, Tehran-Iran, Mar 2000.

28. "Effects of Ultrasound Therapy on Bone Healing Acceleration", 9th Congress of Iranian Medical Engineering, Tehran-Iran, Mar 2000.

29. "Biomechanical Study of Tibia Bone Behaviour", 1st Congress of Students of Medical Engineering, Tehran-Iran, Nov 1999.

30. "The Histological Study of the Effects of Low Power He-Ne Laser Irradiation on Bone Regeneration", 4th Congress of Iranian Anatomy Sciences, Tehran-Iran, Nov1999.

31. "Can We Use Low Power Lasers to Accelerate Bone Regeneration?", 4th Countrywide Medical-Sport Congress, Tehran-Iran. Oct 1999.

32. "Effects of Low Power Laser Radiation on Bone Regeneration in Rabbits from Biomechanical Point of View", 14th Iranian Congress of Physiology and Pharmacology, Tehran-Iran, May1999. *(The article was selected as one of the best congress articles).*

33. "The Biomechanical Study of the Effects of Low Power Laser on Bone Regeneration", International Symposium Biomechanics in Sports, National Olympic Committee of Iran, Tehran-Iran, Aug 1998.

34. "Effects of Low Power He-Ne Laser irradiation on Bone Healing", 9th Congress of Iranian Physical Therapy, Tehran-Iran, May 1998.

35. "Physiotherapy in AIDS", 1st Congress of Iranian Physiotherapy Students, Tehran-Iran, Feb 1996 *(The article was selected as the best congress article).*

36. "Analysis of Human Movement by Computer", 5th Congress of Iranian Physical Therapy, Tehran-Iran, May 1994.

37. "Physiotherapy of Blood and Lymphatic Vessels Disease", 1st Congress of Iranian Physical Therapy, Tehran-Iran, May 1990.

j)   Continuing Education

2012   JuMP Summer Research Symposium, JuMP-CIHR Program, UWO, London.
2012   Inflammation in Chronic Disease, JuMP-CIHR Program, UWO, London.

2012 How to get Ahead in Science, Brain & Mind Institute, JuMP-CIHR Program, UWO, London.
2012 Team Building Excellence Windsor, MITACS Training Program, Windsor.
2012 Effective Networking, MITACS Training Program, Windsor.
2011 Annual Strategic Research Planning Meeting & Retreat, JuMP-CIHR Program, UWO, London.
2011 JuMP Summer Research Symposium, JuMP-CIHR Program, UWO, London.
2011 Innovation Takes Leadership: Ivey Global Health Innovation, JuMP-CIHR Program, Toronto.
2010 Connecting Leadership Education & Research, JuMP-CIHR Program, UWO, London.
2010 11th Annual Strain Injury Seminar, Occupational Health Clinics for Ontario Workers, Sudbury.
2009 Workplace Healthy Environments, Public Service Alliance of Canada (PSAC), National Health & Safety Conference, Montreal.
2009 Laser Safety, UWO, London.
2009 Workplace-Specific Hazard Training (Advanced Certification), Edu. Safety Ass. Ontario, Toronto.
2009 Laboratory – Environmental Waste Management Safety Training, UWO, London.
2009 Workplace Safety & Insurance Board (Basic Certification), Edu. Safety Ass. Ontario, Toronto.
2009 Teaching Assistant Training Program, UWO, London.
2009 18th Annual Coalition of Graduate Employee Unions (CGEU), UOT, Toronto.
2009 5th Annual Canadian Coalition Employee Unions (CCGEU) Conference, UOT, Toronto.
2009 Biosafety Training, UWO, London.
2009 Radiation Safety Training, UWO, London.
2009 Standard First Aid CPR Level HCP, Emerg. Response Team (UWO) & Canadian Red Cross.
2008 Business Conduct Excellence, MITACS Training Program, Kitchener.
2008 Practice Your Presentation Skills, MITACS Training Program, Kitchener.
2007 Summer Publication and Grant Workshop, McMaster University, Hamilton.
2007 Outcome Measures in Musculoskeletal Practice, McMaster University, Hamilton.
2006 24th Annual Western Homecoming Sport Medicine Symposium, UWO, London.
2005 Minimally Interventional Spinal Treatment (MIST), Iranian Academic Center for Education, Culture & Research (ACECR), Tehran.
2003 Movement, Stability and Low Back Pain, ACECR, Tehran.
2001 Expert Meeting: Evidence Based Practice. World Confed. Physical Therapy, London (UK).
2001 Evidence_Based Practice. Tehran Univ. Med. Sc., Tehran.
2001 Curriculum Design and Development. Tehran Univ. Med. Sc., Tehran.
2001 Problem-Based Learning Method. Tehran Univ. Med. Sc., Tehran.
2000 Biochemistry of Exercise. Tehran Univ. Med. Sc., Tehran.
2000 Biology Connective Tissues. Tehran Univ. Med. Sc., Tehran.
2000 Effect of Exercise on the Immune System. Tehran Univ. Med. Sc., Tehran.
2000 Pharmacology on Rehabilitation. Tehran Univ. Med. Sc., Tehran.
1998 Computer for Med. & Paramed. Shahid Beheshti Univ. Med. Sc., Shohada Hosp. Tehran.

1997   Modern Physiotherapy of Sport's Injury. Medical Sport Federation of Iran, Tehran.

1996   Understanding & Management of Chronic Pain. Iranian Physiotherapy Ass., Tehran.

1996   Sport in Specific Diseases. Iranian Physical Medicine and Rehab. Society, Tehran.

K)   Volunteer Contribution Activities

1. Member of Health Plan and International Graduate Students Issues Committees; Society Grad. Students (SOGS). *(June 2009 – Present)*
2. The UWO Councillor, Dep. Health & Rehab. Sciences; Society Grad. Students (SOGS). *(May 2010 – Present)*
3. The CHRW (Radio Navaye Iran); UWO. *(Sep 2006 - Feb 2009; Sep 2010 – March 2012)*
4. Chair of Health & Safety Committee; Member of Negotiating, TA Needs Bursary and Food Bank Committees; Grad. Teaching Assistant Union, UWO. *(June 2009– May 2011)*
5. Certified Member of Joint Occupational Health & Safety Com., UWO. *(June 2009– May 2011)*

Signature: ._____.

Date: ._____.