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Physical Therapy after Triangular Fibrocartilage Injuries and Ulnar Wrist Pain

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by

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A Dissertation submitted in partial satisfaction of
the requirements for the degree
Doctor of Science in Physical Therapy

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Each person whose signature appears below certifies that this dissertation in his/her opinion is adequate, in scope and quality, as a dissertation for the degree Doctor of Science.

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ABBREVIATIONS

ANOVA	Analysis of Variance
APTA	American Physical Therapy Association
ASHT	American Society of Hand Therapists
CI	Confidence Interval
CID	Clinically Important Difference
CONSORT	Consolidated Standards of Reporting Trials
DASH	Disability of The Arm, Shoulder, and Hand Questionnaire
DRF	Distal Radius Fracture
DRUJ	Distal Radio-Ulnar Joint
ECU	Extensor Carpi Ulnaris
ICC	Interclass Correlation Coefficient
ICF	International Classification of Functioning, Disability, and Health
ICF-CY	International Classification of Functioning, Disability, and Health-Children and Youth
IRB	Institutional Review Board
LT	Lunotriquetral
MHQ	Michigan Hand Questionnaire
MDC	Minimal Detectable Change
MRI	Magnetic Resonance Imaging
PRWE	Patient-Rated Wrist Evaluation
QoL	Quality of Life

RCT	Randomized Controlled Trial
SAHP	School of Allied Health Professions
SE	Standard Error
SF-36	Short Form-36
TFCC	Triangular Fibrocartilage Complex
WHO	World Health Organization

ABSTRACT OF THE DISSERTATION

Physical Therapy after Triangular Fibrocartilage Injuries and Ulnar Wrist Pain

by

Mohamed A. Abdelmegeed

Doctor of Science, Graduate Program in Physical Therapy,
Loma Linda University, September 2015
Dr. Everett Lohman III, Chairperson

Background: The ulnar side of the wrist has been referred to as the "black box" of the wrist because of its complex structures and sophisticated anatomy, disorders at this anatomical site have been compared to those of low back pain

Purposes: The purpose of this study was to apply the Brief International Classification of Functioning (ICF) Core Set for Hand Conditions to the physical therapy outcome measures, and to evaluate the contribution of these measures to overall health in subjects with ulnar wrist pain. A secondary purpose was to investigate the effect of wrist orthotics and strengthening exercise on subjects with ulnar wrist pain.

Methods: Thirty five subjects with ulnar wrist pain were recruited to receive orthotics and strengthening exercises. Investigators measured pain, function using the Patient-Rated Wrist Evaluation (PRWE) questionnaire, grip strength using the Jamar dynamometer, at baseline, two and four weeks post randomization. Regression analysis was used to investigate the effect of these variables on overall health represented by the Short Form (SF-36) questionnaire. A mixed Analysis of Variance (ANOVA) modeling was used to investigate the effect of the intervention over time.

Results: Fifty three percent of the variability in SF-36 physical health summary scores was explained by the studied variables with grip strength predicting 31% of the

variability. There were statistical significant differences between the two intervention groups and the control group, while there were no statistical significant differences between the two intervention groups over the three measurement occasions.

Conclusions: The Brief ICF Core Set for Hand Conditions can be a useful abridged list of categories relevant to functioning and health in subjects with ulnar wrist pain. Also, orthotics intervention is as effective as orthotics plus strengthening exercises in improving pain, function, and grip strength in subjects with ulnar wrist pain.

Key words: Ulnar wrist pain, Triangular Fibrocartilage Complex, Brief International Classification of Functioning Core Set, ulnar-based orthotics, Physical Therapy.

CHAPTER ONE

INTRODUCTION AND REVIEW OF THE LITERATURE

The ulnar side of the wrist has been referred to as the "black box" of the wrist because of its complex structures and sophisticated anatomy, disorders at this anatomical site have been compared to those of low back pain.[1]

Sources of ulnar-sided wrist pain are numerous. The triangular fibrocartilage complex (TFCC) injuries are on top of the list, other common causes are lunotriquetral ligaments injuries and ulanr impaction syndrome.[1] Brukner and Khan[2]; Crosby and Greenberg[3] also reported that the TFCC is a common site of ulnar wrist pain

The TFCC is located between the ulna and ulnar carpus, it is the major stabilizer of distal radioulnar joint (DRUJ). This complex anatomical structures of the ulnar side of the wrist contribute to the stability and dynamic movements and to produce powerful grip.[4] Axial loads at the wrist accompanied with ulnar deviation may tear the central portion of the complex.[2]

Anatomical Background

The TFCC encompasses the articular disk (called the triangular fibrocartilage proper), the volar and dorsal radioulnar ligaments, the meniscus homologue, the ulnar collateral ligament, and the extensor carpi ulnaris tendon's sub-sheath.[2,3,5] The base of ulnar styloid process gives origin to the ulnar collateral ligament which is considered a poorly defined capsular structure. The meniscus homologue spans from the dick portion of TFCC to triquetrum, lunate, and the fifth metacarpal bones.[6]

The triangular fibrocartilage complex (TFCC) gives origin or receives insertion to many ligaments and important stabilizing structures of the ulnar side of the wrist. The extrinsic ligaments fibers originate mainly from the volar aspect of the TFCC and partly from ulnar styloid. They are inserted into the palmar part of lunate, triquetrum, and lunotriquetral ligament. These extrinsic ligaments act as a stabilizers of ulna with the ulnar carpus.[1]

The TFCC gets its blood supply from the terminal branches of the anterior and posterior interosseous arteries. Only the peripheral portion of the complex is nourished with blood, while the central part has poor blood supply.[6]

Palmer[7] has classified TFCC injuries into traumatic and degenerative. Traumatic injuries have four subtypes, while the degenerative has five subtypes. This classification system has been endorsed in the literature as the standard classification of injuries of TFCC, and has aided in the diagnosis and management of TFCC injuries.[8]

Injuries to the Structures of the Ulnar Side of the Wrist

As the forearm moves from supination to pronation, it produces variable amount of torque depending on the power of movement, and this stresses the TFCC structures with repeated overuse, which can leads to damage of the structure. This is more obvious in sports requiring forceful rotation of the forearm.[3]

Injury to the TFCC is the most common concomitant soft tissue injuries with distal radius fractures (DRF) and accounts for 39% to 84% of unstable DRF.[9, 10] In other studies, an incidence of 43% to 78% has been reported.[11, 12] Other than TFCC injuries, Lindau et al.[9] has indicated that the common soft tissue injuries associated with DRF

include scapholunate, lunotriquetral interosseous ligament tears. These soft tissue injuries contribute to wrist pain, weakness of hand grip, and motion restriction.[9, 13]

The extensor carpi ulnaris (ECU) tendon represents the sixth dorsal compartment of the wrist. The tendon subsheath fixes the tendon to the distal 1.5 to 2 cm of the ulna.[14, 15] The ECU tendon pathology is a major source of ulnar-sided wrist pain16 that produces dorso-ulnar pain predominantly during supination, wrist flexion and ulnar deviation[17], or wrist flexion with pronation and subjects may have pain symptoms at night.[16]

Injuries occur predominately in sport overuse syndromes, commonly those involving rowing and racquet sport activities, and in non-dominant wrists of tennis players because of double backhand hit.[18] Less commonly, it may occur as a result of low-energy traumatic events, such as twisting injury. ECU pathologies can coexist with other sources of ulnar wrist pain including TFCC injuries.[16]

If the ECU tendon's sub-sheath is torn with overuse in sports, ECU tendon become unstable and will be susceptible to subluxation or dislocation. Subjects with ECU tendons symptomatic instability may present with audible crepitus on rotating the forearm and can be easily inspected by observation.[19] Clinicians can reproduce the symptoms by applying resistance to wrist extension and ulnar deviation which will reproduce pain. Clicking with swelling may be also present along the tendon sub-sheath. Traditionally, diagnosis of ECU tendonitis is clinical based on presented signs and symptoms. However, Magnetic Resonance Imaging (MRI) is often used for diagnosis.[16]

Examination of Ulnar Wrist Pain

Because of the complex anatomy at the wrist, examination can be challenging. Brukner and Khan[2] reported that examination of subjects with TFCC injuries reveals tenderness, swelling over dorso-ulnar aspect, pain on resisted wrist extension and ulnar deviation, clicking with wrist movement, and decreased grip strength. Lester et al.[20] described a provocative maneuver to reproduce ulnar wrist pain in subjects with TFCC injuries. They used a simple "press test" where the clinician asks the individual with suspected TFCC injury to lift him/ herself off the chair using the affected writ by pressing down on the chair. Positive findings include localized ulnar wrist pain reported by the subject, reluctance to perform the test and/or apprehension when performing it.

Among the physical impairments listed in the literature, grip strength may be the most studied health measure used by hand therapists. The American Society of Hand Therapists (ASHT) [21] has published standard guidelines for testing grip strength. The patients is seated with elbow flexed 90 degrees, the forearm in neutral position, and the patient grip the Jamar dynamometer at the second handle position.[21] Grip strength testing is a valid and reliable method and reliability is well-documented in literature.[22-27] Grip and pinch strength testing should be accomplished using the guidelines published by the American Society of Hand Therapists.[28]

Physical Therapy Treatment for Ulnar Wrist Pain

Brukner and Khan[2] addressed some principles for managing hand and wrist injuries. They reported that for the hand to be functional, it requires stability, mobility, preserved sensation, and must be pain-free. To obtain mobility and long-term pain-free

hand, rehabilitation after injuries is necessary. Conservative management of TFCC injuries may include protective bracing, strengthening (if tolerated), heat, and/or electrotherapy modalities for pain.[2]

During inflammatory phase of injury, pain and swelling is common in wrist and hand, therapist must target edema control and pain reduction. During regenerative phase where proliferation of scar tissues take place, therapists should opt to use supportive splints and active exercises to maintain the range of motion. During remodeling phase, therapists can progress to use serial splints, active and active assistive exercises, with heat, stretching and electrotherapy modalities when appropriate.[2]

The pisiform splint can be used for treatment of ulnar wrist pain. The aim with pisiform boost splint is to create coupling force at the ulno-carpal region. The distal part of the splint provides a posteriorly directed force to the pisotriquetral region coupled with an anteriorly directed force by the proximal part of the splint applied to the distal one third of the ulnar shaft. Straps hold the splint to the affected part at, proximal, and distal to the wrist.[29]

Self-Reported Outcome Measures

Patient-reported outcome measures are ubiquitously available in literature.[30] These questionnaire/ scales can be joint-specific[31, 32], condition-specific[33, 34], or global outcome measure of function.[35, 36]

The patient-rated wrist evaluation (PRWE) questionnaire was first developed by MacDermid in 1996 to address pain and disability in subjects with DRF.[32] The questionnaire consists of two subscales with total of 15 questions. Five questions address

pain intensity and frequency, ten questions address function by evaluating specific and usual activities.[37] Pain and function sub-scores can be reproduced separately in addition to total PREW score. Pain sub-scale's score ranges from 0 (no pain) to 50 (worst pain), while function sub-scale score ranges from 0 (no difficulty performing specific or usual activities) to 100 (unable to perform specific or usual activities).[38]

Numerous studies has viewed PRWE questionnaire as a valid, reliable, and responsive tool for subjects with DRF and other wrist and hand injuries. Interclass correlation coefficient (ICC) reported value of reliability ranged from 0.78 to 0.94, suggesting good reliability.[32, 39-44] MacDermid[37] reported that the construct, convergent validity as well as responsiveness of PRWE have been studied in various populations of wrist-related disorders such as DRF, carpal fractures, osteoarthritis, rheumatoid arthritis, and Kienbock's disease

Although its total score has been strongly associated with the disability of the arm, shoulder, and pain (DASH) questionnaire's score[45], the PRWE questionnaire has been reported to be superior to the DASH questionnaire in terms of validity and responsiveness in subjects with related hand/ wrist injuries.[46-48] PRWE also has been shown to have moderate to poor strength association with impairments (e.g. grip strength, wrist motion, dexterity)[46], general health[32,45], age[49,50], and radiological findings.[49,51] The smallest change in the total PRWE score that reliably reflects change in disability rather than measurement error is 12 points, whereas the smallest difference in the PRWE score which patients perceive as benefit is 24 points.[41]

Originally developed in English language, PRWE questionnaire is now available in many other languages, it has been translated and validated to Swedish[52], German[42,43], Chinese[53], Dutch[54], Japanese[44], and Hindi[30] languages.

The International Classification of Functioning, Disability, and Health

Back in 2001, the World Health Organization (WHO) [57] addressed activity limitation, participation restriction, and impairments, and encouraged finding relationships between these measurements. Little is still known about the relationship between measurement of impairment and activity limitation in subjects with hand and wrist pathologies.[55]

The association between impairment and disability is continuously identified by the American Physical Therapy Association (APTA) as an exceedingly prominent question in physical therapy research56. According to the international classification of functioning, disability, and health (ICF), Impairment is defines as "problem in body function or structure such as a significant deviation or loss" and activity limitation as "difficulties in executing a task or action".[57]

A brief ICF model pertinent to hand conditions was published in 2009 by the WHO. This model was named "ICF Core Sets for Hand Conditions" after a consensus agreement on the model at a meeting held in Switzerland with representation from over twenty countries.[58] This model has been used in scientific literature on different hand conditions like hand osteoarthritis[59], tendon and nerve repair[60], rheumatoid arthritis[61], to predict different health outcomes, with recommendation to be further investigated and validated.[62]

The ICF Core Set for Hand Conditions was derived from the main ICF classification to describe and include functional limitation and participation restriction relevant to hand conditions. It is considered the standardized framework to identify and classify functioning and impairment of subjects with hand conditions. Therefore, it can be a useful tool in clinical practice and research.[63]

The WHO identifies two ICF models for hand conditions; the comprehensive and the brief ICF Core Sets. The comprehensive model lists broader, multi-facets to entails functioning and disability relevant to hand conditions. The Brief ICF Core Set details the functioning and disability and works as the minimal standards for classification of hand conditions.[63]

The ultimate goal in physical therapy practice is to restore functioning to patients.[64, 65] Optimal functioning covers all body functions, activities and social participation.[57]

According to Maitland, assessment and treatment in musculoskeletal physical therapy practice are based on measurement of impairment, such as pain, loss of range of motion.[66] The ICF incorporated these measures into their classification model of functioning, disability and health. It does make sense to correlate activity limitation and participation restriction to these measures of impairments.[57]

CHAPTER TWO

APPLICATION OF PHYSICAL THERAPY OUTCOME MEASURES TO THE BRIEF INTERNATIONAL CLASSIFICATION OF FUNCTIONING CORE SET FOR HAND CONDITIONS IN SUBJECTS WITH ULNAR WRIST PAIN

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Abstract

Purpose: The purpose of this study was to apply the Brief International Classification of Functioning (ICF) Core Set for Hand Conditions to the physical therapy outcome measures, and to evaluate the contribution of these measures to overall health in subjects with ulnar wrist pain.

Methods: Thirty five subjects with ulnar wrist pain received a 4-week home-based treatment program including orthotics and strengthening exercises. Investigators measured pain, function, grip strength, and overall health four weeks post-intervention. Regression analysis was used to investigate the effect of these variables on overall health represented by the Short Form (SF-36) questionnaire.

Results: Fifty three percent of the variability in SF-36 physical health summary scores was explained by the studied variables with grip strength predicting 31% of the variability.

Conclusions: The Brief ICF Core Set for Hand Conditions can be a useful abridged list of categories relevant to functioning and health in subjects with ulnar wrist pain.

Study Design: Prospective Cohort, correlation study.

Level of Evidence: 2b individual Cohort, quantitative research.

Key words: Ulnar wrist pain, Brief International Classification of Functioning Core Set, Hand conditions, Physical Therapy.

Introduction

The World Health Organization (WHO) in 2001 addressed activity limitation, participation restriction, and impairment in research, and encouraged finding relationships among these constructs.[1] Likewise, The American Physical Therapy Association (APTA) continues to identify the association between impairment and disability as a prominent question in physical therapy research.[2] Still little is known how impairment measures and activity limitation interrelate in subjects with hand and wrist pathologies.[3]

The aim of establishing the International Classification of Functioning, Disability, and Health (ICF) framework was to provide a common language using a scientific base to describe functioning and health. ICF multidimensional language helped in understanding health and health related domains. The ICF provides a framework for describing functioning and disability by including different perspectives of health. [1] The WHO defines impairment as a "problem in body function or structure such as a significant deviation or loss" and activity limitation as "difficulties in executing a task or action".[1]

The WHO in 2009 published a brief ICF abridged list of categories pertinent to hand conditions. This list was named "The Brief ICF Core Set for Hand Conditions" after a consensus agreement on the model during a meeting held in Switzerland with representation from over twenty countries.[4] Research studies have investigated this model on different hand conditions such as hand osteoarthritis, [5] tendon and nerve repair, [6] rheumatoid arthritis, [7] to predict different health outcomes, with recommendations to be further investigated and validated.[8]

The ICF Core Set for Hand Conditions was derived from the main ICF classification to describe and include functional limitation and participation restriction relevant to hand conditions. The Brief ICF Core Set for Hand Conditions elaborates functioning and works as a useful tool in clinical practice and research.[9] Therefore, the purpose of this study was to apply the Brief ICF Core Set for Hand Conditions to physical therapy outcome measures, and to evaluate the contribution of these measures to overall health in subjects with ulnar-sided wrist pain.

Methods

This study was part of another study performed to examine the effect of physical therapy on subjects with ulnar wrist pain. Because of the nature of the study which was a randomized controlled trial, we adjusted the design of this study to a correlation design so it fits the purpose. In doing so, participants received their treatment on different time intervals so that each participant received ulnar-based orthosis and strengthening exercises by the end of his or her participation.

The Institutional Review Board (IRB) of Loma Linda University approved the study prior to the recruitment of subjects. We conducted the study between March 2014 and February 2015 at the physical therapy laboratory of the School of Allied Health Professions (SAHP), Loma Linda University.

Participants

The principal investigator screened subjects for eligibility to participate in the study. Subjects were included if they have/ had ulnar wrist pain due to traumatic injuries

of the triangular fibrocartilage complex (TFCC), extensor carpi ulnaris (ECU) tendon, and/or lunotriquetral (LT) ligament within the past three months. We excluded subjects if they have/ had non-traumatic conditions of wrist and hand, concomitant distal radius fractures (DRF), radial-sided wrist pain, surgery(ies) of the affected upper extremity within the past six months.

Thirty five subjects underwent the baseline evaluation. Five subjects did not meet the inclusion criteria and two never retuned beyond the baseline evaluation session due to scheduling conflicts. Data analysis was based on the remaining 28 participants who provided written consent to continue with the study.

Procedure

Following procurement of patient informed consent, the investigators obtained information about the demographic characteristics of the participants. Researchers then assessed: (1) subjective wrist pain and function using the Patient-Rated Wrist Evaluation (PRWE) questionnaire; (2) grip strength using Jamar hand-held dynamometer; and (3) overall health and quality of life (QoL) using the Short Form (SF-36) questionnaire. We also administered some clinical tests to document the possible source of ulnar wrist pain. These tests were: piano key test, piano key sign, TFCC compression test, ulna fovea sign, press test, and LT compression test.

By the end of their participation, subjects received ulnar-based orthosis, guided wrist and hand strengthening exercises. The treatment program was home-based for four weeks. Investigators performed the evaluation at baseline and at the end of the fourth week. The principal investigator demonstrated the proper way of applying the orthotic

material and performing the strengthening exercises. Subjects were then asked to demonstrate the exercises and application of the orthosis before they went home with the wrist exercise and orthosis log sheet. We gave each participant a printed copy of the strengthening exercise guidelines with illustrated pictures for each exercise.

Researchers followed up with participants twice a week by phone and asked them if they had any question or concern. We also asked them to bring the log sheet at the end of the fourth week. The principal investigator conducted a post-intervention evaluation at the end of the fourth week.

Outcome Measures

The Patient-Rated Wrist Evaluation (PRWE) Questionnaire

The PRWE questionnaire includes pain and function parameters. The questionnaire consists of two subscales with total of 15 questions. Five questions address pain intensity and frequency while ten questions address function by evaluating specific and usual activities. Pain sub-scale's score ranges from 0 (no pain) to 50 (worst pain), while function sub-scale's score ranges from 0 (no difficulty performing specific or usual activities) to 100 (unable to perform specific or usual activities).[10-12] Investigators calculated pain and function sub-scores separately.

Participants were asked to rate their pain intensity and level of functional limitation over the past week on an 11-point scale ranging from 0 (no pain/ no difficulty) to 10 (worst pain ever experienced/ unable to perform activity). If any of the questions was not applicable to the subjects, they were asked to try to provide their best estimate of pain or functional activity limitations.[11] Previous studies showed that the PRWE

questionnaire was a reliable tool for subjects with DRF and other wrist and hand injuries. Interclass correlation coefficient (ICC) value ranged from 0.78 to 0.94, suggesting a very good reliability.[10-18] Moreover, it has been shown to be the most responsive outcome measure in subjects with DRF.[14]

Jamar hand-held dynamometer

The Jamar Hand Dynamometer (range 0–900 N; accuracy 5% full scale or less), JAMAR® Dynamometer (Sammons Preston; Bolingbrook, IL, USA) measures the isometric grip force exerted on an adjustable handle placed in a grip position.[19, 20] Investigators measured grip strength using Jamar dynamometer according to the guidelines of the American Society of Hand Therapists' strength assessment recommendation.[21] Researchers recorded the mean of three trials of maximum grip force for each subject.

Short Form (SF-36) Questionnaire

The SF-36 questionnaire is a widely accepted generic health outcome measure. It consists of eight sub-scales that cover different health facets including physical health, bodily pain, vitality, general health, emotional role, mental health, and social roles. Each of these subscales can be scored out of 100 maximum, with higher score indicating better outcomes.[22-24]

Since the ICF is a classification system, not a health measurement tool, it has to be represented by a quantifiable outcome measure in order to be statistically scrutinized. The literature showed that the SF-36 is superior to other health measures in assessing

overall health.[22-24] Therefore, we used the SF-36 in this study to represent health condition of ulnar wrist pain and overall QoL. The scores of the eight subscales of the SF-36 were aggregated into the two main component of health, physical and mental health. These scores were then used as the outcome variables and were correlated with PRWE sub-scores of pain, function, and grip strength scores, which were used as the predictor variables.

We used the ICF-classification's underlying model of functioning and disability to describe the lived experience of people with ulnar wrist pain. Authors of this study developed their own model (figure 1) adapted from Harris et al.[25] and MacDermid.[6] Researchers did not consider the contextual factors of the environmental domain of the ICF in this study, and none of the studied variables belonged to body structure domain (anatomical body parts). Age and gender were included to capture relevant contextual, personal factors that may influence the change in SF-36 health scores. PRWE and Jamar dynamometer measured impairment in body function, activity limitation, and participation restriction domains. A summary of the studied variables and corresponding ICF domains can be found in Table 1.

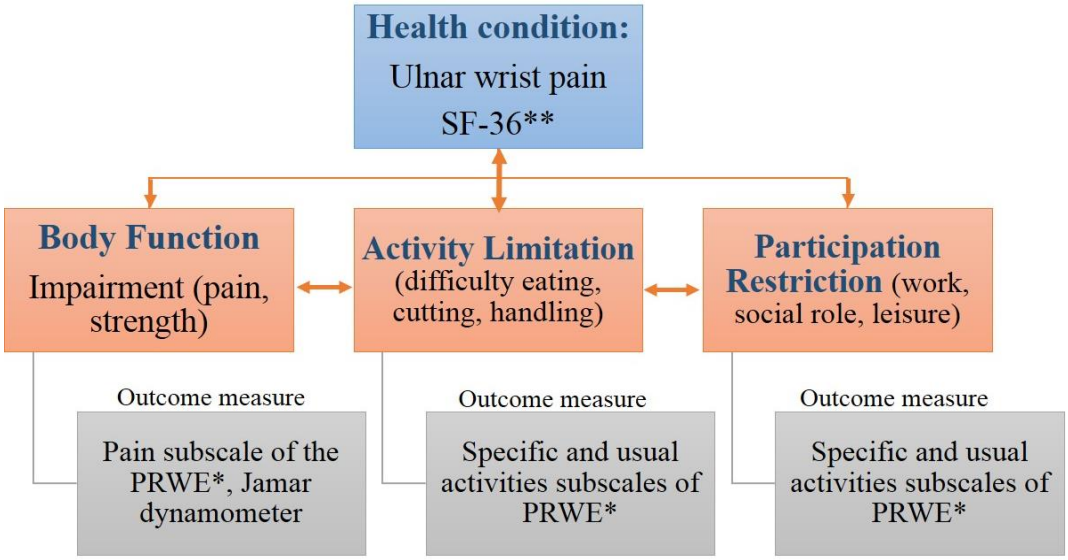

Figure 1. The International Classification of Functioning (ICF) model applied to ulnar wrist pain (*adapted from Harris et al.*[25] *and MacDermid* [6])

**SF-36: Short form-36 questionnaire, which was used to represent the health condition of ulnar wrist pain
*PRWE: Patient-rated wrist evaluation questionnaire

Table 1. Studied variables and corresponding ICF§ domains

ICF domains	Studied variables
Health condition (ulnar wrist pain)	SF-36* physical and mental health summary sub-scores
Personal domains	Age (years) Gender
Body functions	Pain subscale of the PRWE** Grip strength (lbs.)
Activity and participation	Specific and usual activity subscales of PRWE**

**SF-36: Short form 36 questionnaire*
***PRWE: patient-rated wrist evaluation*
§ ICF: International classification of Functioning, Disability, and Health

Data Analysis

Data was analyzed using IBM SPSS Statistics Grad Pack 22.0 PREMIUM for windows. Descriptive statistics was used to summarize the data. Data was reported as mean ± SD for quantitative variables and frequency distribution (%) for categorical variables. The normality of the measures was examined using Kolmogorov Smirnov test. Researchers examined the data for homogeneity and violation of model assumption using histogram, box, and scatter plots. The relationship among variables four weeks post-intervention was examined using Pearson's Correlation Coefficient.

Researchers used multivariate analysis of variance to examine different regression models among the variables of interest four weeks post-intervention. SF-36 physical and mental health aggregated scores were used as the outcome variables, and the scores of pain, function, and grip strength were used as the predictor variables. Through hierarchical multiple regression modeling, age and gender were controlled for by blocked entry into the model and then the predictor variables were added using stepwise entry method. Previous studies suggested that the confounding variables such as age and gender need to be entered in the model in a specific sequence to control for their effect.[8,26] The F to enter was 0.05 and the F to remove was 0.10. Significance was set at 0.05.

Results

Participant characteristics are presented in Table 2. Data analysis was based on the twenty eight eligible subjects, age ranged from 18-53 years (mean 34.61 ± 9.47). Sixty four percent of the participants were males, 92.9 % right handed, and right hand

injury was depicted in 53.6%. By screening participants for possible sources of pain, we found isolated TFCC injuries in eight subjects (28.6%), isolated ECU tendonitis in five (17.9%), isolated LT ligament injury in four (14.3%), combined TFCC and ECU injury in five (17.9%), combined TFCC and LT ligament injury in five (17.9%), and combined TFCC, ECU, LT injuries in one subject (3.6%).

Table 2: Sample characteristics (N=28)

Variable	n (%)
Gender:	
Male	18 (64.3)
Female	10 (35.7)
Dominancy:	
Right hand	26 (92.9)
Left hand	2 (7.1)
Injured hand:	
Right	15 (53.6)
Left	13 (46.4)
Source of pain*:	
TFCC only	8 (28.6)
ECU tendonitis only	4 (14.3)
LT ligament only	5 (17.9)
TFCC and ECU	5 (17.9)
TFCC and LT ligament	5 (17.9)
TFCC, ECU, and LT	1 (3.6)

**TFCC= triangular fibrocartilage complex, ECU= extensor carpi ulnaris, LT= lunotriquetral*

Pearson correlation coefficient results are reported in table 3. The highest correlation was between grip strength and SF-36 physical health component measured at four weeks post-intervention (r=.70, p< .001). A significant negative correlation existed between pain and physical component of the SF-36 (r= -.57, p= .002). Also, there was a significant negative correlation between the usual, specific function subscales of the PRWE questionnaire and the physical health component of the SF-36 (r= -.52, p= .004).

There were significant correlations between the predictor variables themselves four weeks post-intervention (see table 3). The highest correlation existed between pain and function (r=.92, p<.001). On the other hand, there was no significant correlation between pain, function, grip strength and the mental health component of the SF-36 (p> .05). None of the personal factors (age, gender) correlated significantly with either physical or mental health scores of the SF-36 (p>.05).

Table 3: Pearson Correlation Coefficient (r) between the predictor and outcome variables at the end of the fourth week.

		Strength	Pain	Function	SF-36 Physical health	SF-36 Mental health
Strength	r			**-.699****	**.697****	.218
	p-value			**.000**	**.000**	.266
Pain	r	**-.707****			**-.570****	.001
	p-value	**.000**			**.002**	.999
Function	r		**.923****		**-.523****	-.006
	p-value		**.000**		**.004**	.976
Age	r				-.357	-.154
	p-value				.062	.433
Gender	r				-.199	-.327
	p-value				.311	.090

** *Correlation is significant at the 0.01 level (2-tailed).*

Results from hierarchical multiple regression analysis can be found in Table 4. Researchers checked the assumptions of normality and linearity of variances and they were all met. Blocked entry of gender and age in the regression model revealed moderate prediction of the change in SF-36 physical health scores, $F_{2, 25} = 3.48$, $p = .047$, $R^2 = 22\%$. When the other predictor variables were entered in a stepwise fashion, strength by itself contributed to 31% of added variance, and significantly improved the predicted capacity of the model $R^2 = 53\%$ $p = .001$.

In the final model, only grip strength significantly predicted the change in SF-36 physical health summary scores. The final model included gender, age, and strength and it was a significant model of prediction $F_{3, 24} = 8.88$, $p < .001$. Grip strength measured four weeks post-intervention was the most significant predictor of SF-36 physical health scores, while pain and function were excluded from the model.

Table 4: Hierarchical multiple regression summary, predicting SF-36 physical health scores

Model	R^2(ΔR^2; p-value*)	Predictors	Coefficient	SE§	p-value**
1 (constant), gender, age	.22(.22; .047)	Gender	-9.8	5.7	.10
		Age	-.7	.3	.025
2 (constant), gender, age, strength four weeks	.53(.31; .001)	Gender	-5.4	4.7	.25
		Age	-.3	.3	.27
		strength	.4	.1	.001

*Testing the significant change in R^2.
**Testing for significance of each variable in the model.
§ SE: standard error.

Discussion

In the current study, we examined the relationship between overall health and QoL represented by SF-36 questionnaire and certain functioning aspects based on an adapted version of the ICF model of functioning and disability, assessed by using the PRWE questionnaire and Jamar Hand Dynamometer. This study indicated a strong linkage between the physical health component of the SF-36 and physical therapy outcome measures, specifically grip strength, in subjects with ulnar wrist pain.

Association between Predictors and Outcome Variables

There was a significant association between grip strength and the physical health component of SF-36 measured after four weeks of the intervention. The grip strength by itself predicted 31% of the variability in the physical health component of the SF-36. This strong association between grip strength and physical health is logical, considering that grip strength is an integral component of body physical function and it is an important hand function. On the other hand, we identified weak associations between SF-36 scores of physical and mental health with pain and function as measured with PRWE questionnaire.

Among the physical impairments listed in the literature, grip strength is used extensively to represent impairment in different hand pathologies[27], and it may be the most studied health measure used by hand therapists.[28] Strength is incorporated in the Brief ICF Core Set for Hand Conditions (Appendix 1) in different categories, either directly such as in category *b730 muscle power functions*, or embedded in other categories to allow different functions to take place (*b710 mobility of joint functions,*

b760 control of voluntary movement functions, d230 carrying out daily routine, d430 lifting and carrying objects, d445 hand and arm use, and d840-d859 work and employment). This may explain the high capacity of grip strength in predicting changes in physical health in subjects with ulnar wrist pain.

According to LaStayo, [29] orthotic intervention is the mainstay of conservative treatment and strengthening is not always a priority is subjects with TFCC injuries. Most of study's participants had traumatic acute and sub-acute TFCC injuries. We believe that the ulnar-based orthotic device reduced pain associated with TFCC injuries and enabled regaining of strength which contributed the most to the variability in SF-36 physical health sub-scores.

Strong associations among the predictor variables after four weeks of therapy indicated the strong linkage between reduction in pain severity and improvement in function and grip strength. The regression model, however, excluded pain and function although there were strong associations between the predictor variables themselves and between the predictor variables and the SF-36 physical health summary sub-scores when performing Pearson Correlation analysis. Exclusion of pain and function from the regression model may be due to the major improvement in grip strength which may have superimposed the improvement in pain and function, or because the PRWE questionnaire was not able to identify the actual improvement in pain and function.

Although the PRWE questionnaire has been used extensively in literature as a valid and reliable outcome measure after wrist and hand injuries[10-18], we found that it had a low capacity of predicting significant changes in SF-36 scores in subjects with ulnar wrist pain. This relatively low predictive capacity has been documented in another study.

Harris et al.[25] found that PRWE explained only 13% and 33% of the variability in SF-36 physical health measured at one week and three months respectively after DRF. Moreover, only 10% and 8% of the variability in SF-36 mental component were explained by its relationship to PRWE scores measured at three months and one year respectively. This contradicted the findings of Changulani et al.[14] who reported a variable correlation between the PRWE and SF-36 scores (ranged from 0.33 and 0.73), and they identified the PRWE as the most responsive outcome measure in subjects with DRF.

Probably due to the low predictive capacity of the PRWE and its relationship to SF-36 physical and mental aspects of health, Squitieri et al.[8] used another patient-reported measures to explain the variability in health outcome measures. They used Michigan Hand Outcome questionnaire (MHQ) as a measure of health status, and correlated it with other physical therapy outcome measures (Jebsen Taylor test, range of motion measurements, different functioning domains of MHQ), and patient demographic factors. They found that these variables predicted 93%, 98%, and 97% of the variability in MHQ measured at six weeks, three, and six months respectively in subjects with DRF.

SF-36 Mental Health and ICF Environmental Factors

There was no significant correlation between the mental component of the SF-36 and the predictor variables. Regression models excluded all the predictor variables when it was correlated with mental health component of the SF-36 scores. There may be possible reasons explaining the lack of this association. First, we had a small sample size that might not be representative of the overall population and perhaps the time frame was too short to trigger influence response in mental health scores. Second, we did not

consider the environmental aspect of the ICF as a contextual factor contributing to the change observed in study's outcomes.

In contrast, Kus et al.[30] documented the importance of the mental function in subjects with hand conditions. They reported that ICF category such as *b134 sleep function* and *b152 emotional function* should not be overlooked in subjects with hand conditions as they contributed to subjects' general health. They indicated that emotional function was not only important to the subjects' perceived health as measured by self-reported measures, but also for rating of health outcomes by healthcare professionals. Their participants, however, had more serious hand conditions than those in the present study. They recruited subjects who suffered from diseases such as Dupuytren's disease, or if they had general conditions affecting the hand such as Parkinson's disease or brachial plexus injuries.

Various researches also documented the importance of mental aspect of health in subjects with hand conditions.[30-36] Most of the studied conditions were more challenging than those in the present study such as Dupuytren's disease, [31] systemic sclerosis, [32] cold sensitivity, [33] carpal tunnel syndrome, [34] and hand osteoarthritis.[35] Moreover, William et al.[36] found that posttraumatic stress disorders and depression negatively impacted general health in subjects with severe hand injuries.

In a study by Squitieri et al.[8], the environmental factors slightly contributed to the change in satisfaction level of subjects with DRF. They found as little as 3%, 1%, and 7% contribution to the change in satisfaction scores as measured at six weeks, three, and six months respectively. Our perspective is that environmental factors could be of a significant predictive value in more challenging health conditions that may have a

broader impact on function such as stroke, lower limb disability, or in life-threatening diseases such as cancers or terminal illnesses, or in conditions with psychosocial impact such as depression.

Kus et al.[30] conducted a multicenter study of a large sample size (260) on subjects with different hand conditions. They were able to validate 12 out of the 23 categories of the Brief ICF Core Set for Hand Conditions. They identified those 12 categories as the major contributors to the variance in patients' self and proxy-reported measures based on multiple regression analyses. Although half of the identified variables belonged to the activity and participation domains, their results highlighted the significant contribution of the environmental factors. They recommended consideration of the identified environmental factor such as *e225 climate, e410 individual attitude of immediate family members, e460 social attitudes* and other relevant factors when dealing with subjects with hand pathologies. They concluded that the Brief ICF Core Set for Hand Conditions should be used as the standard tool in addressing functioning in subjects with hand conditions.

A broader understanding of health-related quality of life (QoL) facets and how they relate with functioning in ICF domains is important in clinical practice. Patients' estimation of the perceived satisfaction has been ubiquitously highlighted in literature.[37-42] Perceived satisfaction reflects subjective point of view of life condition using patient's own eyes.[43, 44] A modified ICF model by McDougall et al.[45] suggested that perceived satisfaction of QoL should be incorporated as codes in the personal domain of both the ICF and the modified ICF model for children and youth, namely, the International Classification of Functioning, Disability, and Health- Children and Youth (ICF-CY).

Limitations

This study had several limitations. First, the sample size was small. Because of the scarce nature of the targeted conditions, we were able to recruit a sample of 35 subject with ulnar wrist pain over a year. Our interest was directed to a specific source of wrist pain, therefore, generalizability of the results to other wrist injuries can be used with caution. Future studies may take into consideration other possible sources of ulnar wrist pain, and to recruit subjects from different centers and settings for more accurate representation.

Second, only 53% of the variance in the SF-36 physical health scores was explained by the predictor variables, and the regression models excluded all the predictor variables when they were correlated with the mental health scores of the SF-36. A large unexplained variability in general health may be due to other factors not investigated in this study. We did not consider the environmental factors which might have explained more variability in the two facets of health, physical and mental.

Third, we only used PRWE questionnaire and grip strength measurement to represent the functioning component of the ICF. Although PRWE has been identified as a reliable measure[14-20], it was excluded from the regression models. Other measures of functioning such as MHQ may be used. The MHQ covers broader aspects of functioning and health and has high validity, reliability, and responsiveness.[46-49] For future studies, we may recommend the use of MHQ in conjunction with PRWE questionnaire to examine the relationship between functioning and overall health.

Conclusion

Proper understanding of the ICF model opens up a wide range of research studies in physical therapy and rehabilitation, and provides a template for evidence based practice regarding physical therapy in clinical settings. Our aim in this study was to crosswalk the physical therapy outcome measures to the Brief ICF Core Set for Hand Conditions. We think that the use of the Brief ICF Core Set for Hand Conditions is an integral part of the clinical language that should be endorsed by clinicians and therapists. It enables a useful systemic process for identifying, documenting, and communicating health status. This study may serve as an addendum to link health related QoL to functioning in subjects with ulnar wrist pain.

Investigators of the present study attempted to make a transition from just describing a bodily injury (ulnar wrist pain) using the Brief ICF Core Set for Hand Conditions framework to measuring of the health outcomes utilizing the Brief ICF Core Set for Hand Conditions as a conceptual framework. Although it might seem challenging, researchers should try to link physical therapy instruments to the ICF in different settings (e.g. assessment, treatment) for different health conditions.

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Appendix 1

The Brief ICF Core Set for Hand Conditions*

ICF Domains	ICF Code	ICF Category
Body function	b152	Emotional functions
	b265	Touch function
	b270	Sensory functions related to temperature and other stimuli
	b280	Sensation of pain
	b710	Mobility of joint functions
	b715	Stability of joint functions
	b730	Muscle power functions
	b760	Control of voluntary movement function
	b810	Protective functions of the skin
Body structure	s120	Spinal cord and related structures
	s720	Structure of shoulder region
	s730	Structure of upper extremity
Activities and participation	d230	Carrying out daily routine
	d430	Lifting and carrying objects
	d440	Fine hand use
	d445	Hand and arm use
	d5	Self-care
	d6	Domestic life
	d7	Interpersonal interactions and relationships
	d840-d859	Work and employment
Environmental factors	e1	Products and technology
	e3	Support and relationships
	e5	Services, systems, and policies

*Adapted from Rudolf et al.[4]

CHAPTER THREE

EFFECT OF ORTHOTICS AND STRENGTHENING EXERCISES ON SUBJECTS WITH TRIANGULAR FIBROCARTILAGE COMPLEX (TFCC) INJURIES AND ULNAR WRIST PAIN

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Abstract

Purpose: The purpose of this study was to investigate the effect of wrist orthotics and strengthening exercise on subjects with ulnar wrist pain.

Methods: Thirty five subjects with acute and sub-acute ulnar wrist pain were randomized to receive either ulnar-based orthotics, ulnar-based orthotics plus strengthening exercises, or placebo intervention. We measured pain and function using the Patient-Rated Wrist Evaluation (PRWE) questionnaire, and grip strength using the Jamar dynamometer, at baseline, two and four weeks post randomization. A mixed Analysis of Variance (ANOVA) modeling was used to investigate the effect of the intervention over time.

Results: There were statistical significant differences between the two intervention groups and the control group, while there were no statistical significant differences between the two intervention groups over the three measurement occasions.

Conclusion: Based on the results, orthotics intervention is as effective as orthotics plus strengthening exercises in improving pain, function, and grip strength in subjects with ulnar wrist pain.

Study design: Prospective randomized controlled trial.

Level of evidence: Therapy, level 2b individual RCT.

Key words: Ulnar wrist pain, ulnar based orthotics, Physical Therapy.

Introduction

The complex anatomical structure of the ulnar side of the wrist invited some authors to refer it to as the "black box". Authors have identified disorders at ulnar side of the wrist as having close resemblance to those of low back pain.[1, 2] Sources of ulnar-sided wrist pain are numerous, with triangular fibrocartilage complex (TFCC) injuries at top of the list. Other common causes are lunotriquetral ligaments injuries[1-3] and extensor carpi ulnaris tendon and tendon sheath.[2, 3]

The complex anatomical structures of the ulnar side of the wrist contribute to the stability, dynamic movements, and the production of a powerful grip.[5, 6] The TFCC is located between the ulna and ulnar carpus, it is the major stabilizer of the distal radioulnar joint (DRUJ). Axial loads at the wrist accompanied with ulnar deviation may tear the central portion of the complex.[2, 3]

The TFCC helps stabilize the distal radioulnar joint (DRUJ). It encompasses the articular disk (called the triangular fibrocartilage proper), the volar and dorsal radioulnar ligaments, the meniscus homologue, the ulnar collateral ligament, and the sub-sheath of extensor carpi ulnaris tendon**.**[2, 3, 6, 7] The base of ulnar styloid process gives origin to the ulnar collateral ligament which is considered a poorly defined capsular structure. The meniscus homologue spans from the dick portion of TFCC to triquetrum, lunate, and the fifth metacarpal bones.[8]

The extensor carpi ulnaris (ECU) tendon represents the sixth dorsal compartment of the wrist. The tendon sub-sheath fixes the tendon to the distal 1.5 to 2 cm of the ulna.[9, 10] The ECU tendon pathology is a major source of ulnar-sided wrist pain[3, 11] that produces

dorso-ulnar pain predominantly during supination, wrist flexion and ulnar deviation[4], or wrist flexion with pronation. Subjects may have pain symptoms at night.[11]

Injuries occur predominately in sport-related overuse syndromes[3, 4], commonly those involving rowing and racquet sport activities[3, 12], and in non-dominant wrists of tennis players because of double backhand hit.[12] Less commonly, it may occur as a result of low-energy traumatic events, such as twisting injury. ECU pathologies can coexist with other sources of ulnar wrist pain including TFCC injuries**.**[11]

Because of the complex anatomy at the wrist, examination can be challenging. Brukner and Khan[2] reported that examination of subjects with TFCC injuries reveals tenderness, swelling over dorso-ulnar aspect, pain on resisted wrist extension and ulnar deviation, clicking with wrist movement, and decreased grip strength. Lester et al.[13] described a provocative maneuver to reproduce ulnar wrist pain in subjects with TFCC injuries. They used a simple "press test" where the clinician asks the individual with suspected TFCC injury to lift him/ herself off the chair using the affected wrist by pressing down on the chair. Positive findings include localized ulnar wrist pain reported by the subject, reluctance to perform the test, and/or apprehension when performing the procedure.

Brukner et al.[2] addressed some principles for managing hand and wrist injuries. They reported that for the hand to be functional, it requires stability, mobility, preserved sensation, and must be pain-free. To obtain mobility and a long-term pain-free hand, rehabilitation after injuries is necessary. Conservative management of TFCC injuries may include protective bracing, strengthening (if tolerated), heat, and/or electrotherapy

modalities for pain[2]. Crosby and Greenberg[3] reported that tenosynovitis and subluxations of ECU tendon can heal with a period of immobilization for several weeks.

Methods

This was a prospective, randomized, controlled, single-blinded, parallel groups, clinical trial, designed to investigate the effect of orthotics intervention and strengthening exercises in subjects with ulnar wrist pain. The Institutional Review Board (IRB) of Loma Linda University approved the study prior to the recruitment of subjects. We conducted the study between March 2014 and February 2015 at the physical therapy research laboratory of the School of Allied Health Professions (SAHP), Loma Linda University.

Participants

Thirty five subjects with ulnar wrist pain were referred for therapy from Loma Linda Medical Center, the Hand Clinic of the Outpatient Center of Loma Linda University, and primary care physicians. Subjects were further screened at baseline for eligibility to participate in the study. Inclusion criteria was delimited to subjects with ulnar wrist pain due to acute or sub-acute injuries of the TFCC, ECU tendon, and/or lunotriquetral (LT) ligament. Subjects were excluded if they have/had non-traumatic conditions of wrist and hand, concomitant distal radius fractures (DRF), radial-sided wrist pain, surgery(ies) of the affected upper extremity within the past six months.

Thirty subjects met the inclusion criteria and two dropped out after the baseline evaluation. We analyzed the data based on the remaining 28 eligible participants. A flow

diagram according to the Consolidated Standards of Reporting Trials (CONSORT) statement[14] illustrates the progression of study participants through the trial (Figure 2).

Procedure

Due to the nature of the study, we followed a single blinded, three parallel groups design where participants could not be completely blinded to intervention type, but they were blinded to group assignments and to participants in other groups. Investigators were neither blinded to group assignment nor the intervention type.

After eligible participants signed the consent form to participate in the study, they were asked to pick a sealed number from an envelope. Numbers were generated using random table number generator and each number was pre-assigned to one of the three groups. Subjects in group 1 received ulnar-based orthotic device, subjects in groups 2 received the same orthotic device as in group 1 plus a program of home-based strengthening exercises, while subjects in group 3 received a placebo tennis elbow strap and served as control. The principal investigator conducted the evaluation at baseline, two weeks of the start of the treatment, and a post-intervention evaluation after four weeks.

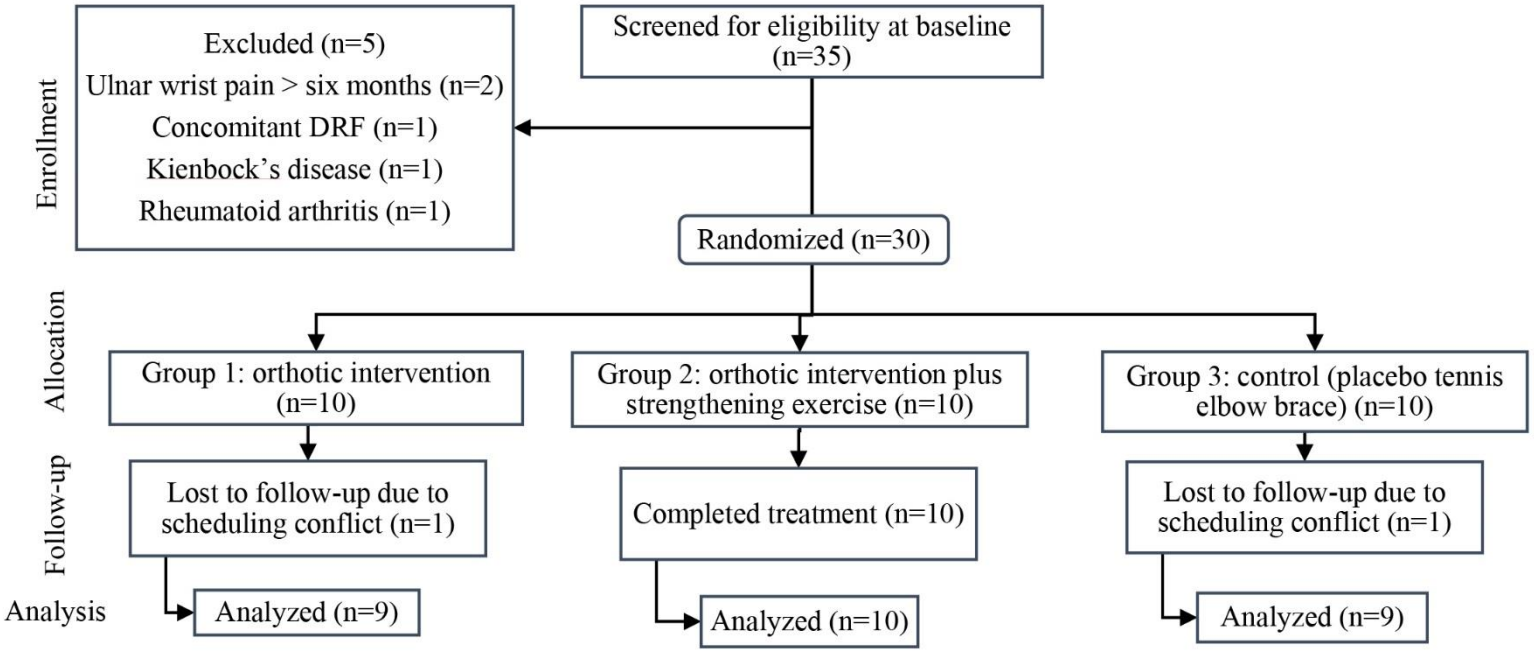

Figure 2. Flowchart outlining the progression of participants in the clinical trial

The investigators obtained participant's demographic characteristics at baseline, and then conducted the measurement of (1) pain and function using of the wrist joint using the PRWE questionnaire, and (2) grip strength using Jamar hand-held dynamometer. Provocative testing has increased the accuracy of diagnosis following injury to the distal end of ulna.[6] In almost all of the provocative tests, tenderness to palpation is the most informative sign of a positive findings.3 Therefore, we further screened subjects for the possible source of ulnar wrist pain with the following provocative maneuvers at baseline:

1. Piano Key Test:

   The patients was sitting with elbow flexed at 90 degrees and forearm flat and pronated on the table. The investigator supported the distal radius with one hand and moved the distal ulna by applying dorso-volar pressure with the other hand. The test is considered positive with pain and tenderness is elicited distal to the ulnar styloid process with or without increased mobility of the distal radio ulnar joint (DRUJ).[1, 3, 15-17]

2. Piano Key Sign:

   We asked the subject to push the pronated ulna against the table. Test is considered positive when pain is felt in the ulnar side of the wrist distal to the ulnar styloid

   process[1, 15]

3. The TFCC Compression Test (also known as Ulno-Carpal Stress Test, Ulnar Impingement Test):

   The test is analogous to the McMurray test of the knee. With the patient sitting with the elbow flexed 90 degree, the investigator grasped the subject's hand and applied pressure against the distal ulna by deviating the hand into ulnar deviation and rotating the hand into supination and pronation against the fixed forearm. The test is considered positive when pain or clicking is reproduced on the ulnar side of the wrist distal to the ulnar styloid.[1, 3, 15-18]

4. Ulna Fovea Sign:

   The examiner applied pressure over the area between the ulnar styloid process and the ulnar carpus. The test is positive when pain and tenderness is elicited in that area. The test has 95.2% sensitivity and 86.5% specificity in detecting ulnotriquetral ligament injuries and ulnar wrist pain.[19]

5. Press Test (Also known as Sitting Hand Test):

   The subject was seated in a chair and we asked him/her to push him/herself off the seat using the affected wrist with the intention to load the body weight against the affected wrist. The test was positive if the ulnar wrist pain and tenderness was reproduced by this maneuver.[2, 13, 17] The test has 100% sensitivity in detecting TFCC tears.[13]

6. Lunotriquetral Compression Test:

   The investigator stabilized the lunate with one hand while applying dorso-volar pressure on the triquetrum with the other hand, with the hand of the subject is in

pronation. Test is considered positive if pain or clicking was elicited at the lunotriquetral interval.[1, 15, 17, and 20]

Intervention

The intervention was ulnar-based orthosis plus or minus strengthening exercises according to group assignment. At day one, investigators demonstrated the proper way of wearing the orthotics and performing the strengthening exercises. Subjects were then asked to demonstrate the exercises and application of the orthosis before they went home with the wrist exercise and orthosis log sheet. We gave each participant a printed copy of the strengthening exercise guidelines with illustrated pictures for each exercise. The researchers followed up with participants twice a week by phone and asked them if they had any question or concern. We also asked them to bring the log sheet at the end of the second and the fourth week for follow up.

Ulnar-Based Orthosis

We used a prefabricated ulnar-based orthotic device (Figure 3). The orthotic device that was used in this study was the Bauerfeind ManuLoc Wrist Support by Bauerfeind AG® (Zeulenroda-Triebes, Thuringia, Germany). Subjects were instructed to wear the brace as much as they can during the day and night, only remove it for hygiene and for performing the exercises. The average wearing time for the brace was 13 hours per day.

Figure 3. Bauerfeind ManuLoc Wrist Support® that was used in the study

Strengthening Exercises

Strengthening exercises were performed within the pain tolerance which was mandatory to maximize the healing process and prevent symptoms provocation. Exercise progression occurred when there was no adverse response from supination to neutral forearm position and finally into pain free full pronation.[21] Tools that were used to perform strengthening exercises were soft, racquet, tennis balls, Thera-Band® and Thera-band FlexBar® with variable resistances (Sammon Preston Inc, Chicago, IL).

Exercise progressed from soft ball squeeze in the first week of therapy, to racquet ball squeeze, dynamic wrist flexion-extension Thera-Band® strengthening in the second week, to tennis ball squeeze, dynamic wrist flexion-extension, supination-pronation, radial-ulnar deviation strengthening exercises using variable resistance of Thera-Band®, and Thera-Band FlexBar® resistance training in the third and fourth week. In each of the exercises, contraction was held for six seconds, repeated ten times, and performed three

times per day. Exercises were performed three times per week for four weeks. Subjects were given exercise log sheet that was checked during each visit.

Outcome Measures

The Patient-Rated Wrist Evaluation (PRWE) Questionnaire

The PRWE questionnaire includes pain and function parameters. The questionnaire consists of two subscales with total of 15 questions. Five questions address pain intensity and frequency while ten questions address function by evaluating specific and usual activities. Pain sub-scale's score ranges from 0 (no pain) to 50 (worst pain), while function sub-scale's score ranges from 0 (no difficulty performing specific or usual activities) to 100 (unable to perform specific or usual activities).[22-24] Investigators calculated pain and function sub-scores separately.

Participants were asked to rate their pain intensity and level of functional limitation over the past week on an 11-point scale ranging from 0 (no pain/ no difficulty) to 10 (worst pain ever experienced/ unable to perform activity). If any of the questions was not applicable to the subjects, they were asked to try to provide their best estimate of pain or functional activity limitations.[23] Previous studies showed that the PRWE questionnaire was a reliable tool for subjects with DRF and other wrist and hand injuries. Interclass correlation coefficient (ICC) value ranged from 0.78 to 0.94, suggesting a very good reliability.[22-30] Moreover, it has been shown to be the most responsive outcome measure in subjects with DRF.[26]

Jamar hand-held dynamometer

The Jamar Hand Dynamometer (range 0–900 N; accuracy 5% full scale or less), JAMAR® Dynamometer (Sammons Preston; Bolingbrook, IL, USA) measures the isometric grip force exerted on an adjustable handle placed in a grip position.[31, 32] Investigators measured grip strength using Jamar dynamometer according to the guidelines of the American Society of Hand Therapists' strength assessment recommendation.[33] Researchers recorded the mean of three trials of maximum grip force for each subject.

Data Analysis

Data was analyzed using SPSS Statistics Grad Pack 22.0 PREMIUM for Windows. Descriptive statistics was generated to present the data. Data was reported as mean ± SD for quantitative variables and frequency (%) for categorical variables. Normality of quantitative data was checked using Kolmogorov Smirnov test and box plots. To compare means of age, strength, pain, and function in the three groups at baseline, one way analysis of variance (ANOVA) was conducted.

To compare gender, hand dominancy, and the hand injury distributions among groups, Chi-squared test of independence was performed. To investigate the effect of the intervention on the outcome measures over time, a three by three mixed factorial ANOVA model was conducted. Post hoc analysis was performed using Bonferroni correction test. Significance level was set at .05.

Results

Participants' characteristics are presented in Table 5. Data analysis was based on the twenty eight eligible subjects, age ranged from 18-53 years (mean 34.6 ± 9.5). By screening participants for possible sources of pain, we found isolated TFCC injuries in eight subjects (28.6%), isolated ECU tendonitis in five (17.9%), isolated LT ligament injury in four (14.3%), combined TFCC and ECU injury in five (17.9%), combined TFCC and LT ligament injury in five (17.9%), and combined TFCC, ECU, LT injuries in one subject (3.6%).

Table 5. Participants' characteristics

Variable	Group 1: Orthotics (n=9)	Group 2: Orthotics plus strengthening (n=10)	Group 3: Control (n=9)
Age, mean ± SD	30.22 ± 8.0	34.10 ± 7.2	39.56 ± 11.4
Gender, n(%)	Male: 6 (66.7%) Female: 3 (33.3%)	Male: 6 (60%) Females: 4 (40%)	Male: 6 (66.7%) Female: 3 (33.3%)
Dominancy, n(%)	Right: 9 (100%) Left: 0 (0%)	Right: 9 (90%) Left: 1 (10%)	Right: 8 (88.9) Left: 1 (11.1)
Injured hand, n(%)	Right: 5 (55.6) Left: 4 (44.4)	Right: 4 (40%) Left: 6 (60%)	Right: 6 (66.7) Left: 3 (33.3)

Chi-squared test revealed no statistical significant differences among groups regarding gender (p=.94), hand dominancy (p=.60), and whether the right or left hand is injured (p=.50). There was no significant difference among groups regarding age of the participants ($F_{2, 25}$= 2.4, p= .10), and at baseline, there were no significant differences among groups regarding strength ($F_{2, 25}$= 2.9, p=.07), pain ($F_{2, 25}$= 2.5, p=.11), and function ($F_{2, 25}$= .9, p=.42).

Strength

There was a significant difference in mean strength across the three times points ($F_{2, 50}$= 203.6, p<.001) and among groups ($F_{2, 25}$= 12.8, p<.001). In addition, there was a significant interaction between time and groups ($F_{4, 50}$= 19.6, p<.001). To further examine the differences among groups, we conducted a pot hoc comparison using Bonferonni test. Results revealed no significant difference in mean strength between the orthotics group (group1) and the orthotics plus strengthening group (group 2) at the three assessment times (p>.05), however, there was a significant difference in mean strength between the orthotics group and the control group (group 3) at the three measurement times (p<.01), and a significant difference between the orthotics plus strengthening group and the control group at the three measurement occasions (p<.001).

Pain

There was a significant difference in mean pain across the three times points ($F_{2, 50}$= 92.3, p<.001) and among groups ($F_{2, 25}$= 13.8, p<.001). In addition, there was a significant interaction between time and groups *(*$F_{4, 50}$= 6.3, p<.001). Post hoc comparison using Bonferonni test revealed no significant difference in mean pain between the orthotics group and the orthotics plus strengthening group at the three assessment times (p>.05), however, there was a significant difference in mean pain between the orthotics group and the control group at the three measurement times (p<.05), and a significant difference between the orthotics plus strengthening group and the control group at the three measurement occasions (p<.001).

Function

There was a significant difference in mean function across the three times points ($F_{2, 50}$= 121.8, p<.001) and among groups ($F_{2, 25}$= 7.32, p<.05). In addition, there was a significant interaction between time and groups ($F_{4, 50}$= 11.58, p<.001). Post hoc comparison using Bonferonni test revealed no significant difference in mean function between the orthotics group and the orthotics plus strengthening group at the three assessment times (p>.05), however, there was a significant difference in mean function between the orthotics group and the control group at the three measurement times (p<.05), and a significant difference between the orthotics plus strengthening group and the control group at the three measurement occasions (p<.001).

A summary of the outcome variables over the three measurement occasions can be found in table 6.

Table 6: Summary of mean (SE*) of the outcome variables across groups over time.

	Strength (lb)	95% CI**	Pain (PRWE)	95% CI**	Function (PRWE)	95% CI**
			Baseline			
Orthotics (n=9)	46.9 (3.1)	40.5-53.3	28.3 (2.7)	22.8- 33.9	53.3 (5.0)	43- 63.7
Orthotics plus strengthening (n=10)	52.0 (3.0)	46- 58.1	34.4 (2.6)	29.1- 39.7	58.4 (4.8)	48.6- 68.2
Control (n=9)	41.7 (3.1)	35.3- 48	36.4 (2.7)	30.9- 42	62.9 (5.0)	52.5- 73.3
			Two weeks			
Orthotics (n=9)	65.3 (4.8)	55.4- 75.3	16.4 (2.5)	11.3- 21.6	27.1 (6.9)	12.9- 41.4
Orthotics plus strengthening (n=10)	73.9 (4.6)	64.4- 83.3	23.2 (2.4)	18.3- 28.1	35.10 (6.6)	21.6- 48.6
Control (n=9)	50.7 (4.9)	40.7- 61	32.8 (2.5)	27.6- 38	53.9 (6.9)	39.6- 68.1
			Four weeks			
Orthotics (n=9)	92.6 (4.4)	83.6- 101.6	8.1 (2.0)	4.1- 12.2	9.8 (4.0)	1.5- 18.1
Orthotics plus strengthening (n=10)	98.4 (4.2)	90- 107	9.3 (1.9)	5.5- 13.1	12.6 (3.8)	4.8- 20.5
Control (n=9)	55.3 (4.4)	46.3- 64.4	27.0 (2.0)	23- 31.1	49.8 (4.0)	41.5- 58.1

**SE: standard error.*

***CI: confidence interval.*

Discussion

Statistical Versus Clinical Significance

This study investigated the effect of orthotic intervention with or without strengthening exercises in subjects with ulnar wrist pain. In this study, we obtained a consistent result in the outcome variables over the three measurement times. There were no statistical significant differences between the two treatment groups regarding improvement in pain, function, and grip strength, while there were significant differences between the treatment and control groups over time.

Although the was no statistical significant difference between the two intervention groups regarding improvement in strength, subjects in the group that received orthotic intervention plus strengthening exercises showed a slightly better improvement in mean strength scores 73.9(4.6 lb.) as compared to the group who received orthotic intervention only with mean of 65.3(4.8 lb.) after two weeks of therapy. This was the case also after four weeks of therapy with orthotic plus strengthening group had a mean strength score of 98.4(4.2 lb.), while subjects who received only orthotic intervention had a mean score of 92.6(4.4 lb.).

The lack of the statistical differences between the two intervention groups may be due to the duration of the strengthening exercises that was used in this study. We used a home-based four weeks strengthening program that addressed all muscle groups around the wrist and the distal radioulnar joint and it was progressive in nature, however, perhaps the time frame was not adequate to trigger a statistical significance between the two intervention groups.

On the other hand, subjects who received orthotic intervention only showed a slightly better improvement in their mean scores of pain and function over time as compare to subjects who received orthotic intervention plus strengthening exercises (see Table 2), although there was no statistical significant difference. It is always important to address the clinical significance even if the statistical significance is absent, and to weigh our statistical results against the importance of the improvement in the outcome measures of a clinical condition. Regarding pain and function, it is important to note that, the lower the score, the better the improvement in pain and function, as this was the construct of the PRWE.

This study yielded no significant differences between groups at baseline, however, both intervention groups showed a significant difference over time in comparison to the control group. Most of the subjects in the control group reported no improvement in their pain and functional level. They reported inability to perform their duties as efficient as they were before the injury. Investigators assured that subjects in control groups did not utilize any intervention for their condition during the study period and that they were compliant with the placebo tennis elbow usage.

The Use of Orthotics

According to LaStayo[21], ulnar gutter orthoses do not prevent forearm rotation, however, they provides enough support for pain relief for subjects with ulnar wrist pain. Ulnar gutter orthoses are the mainstay of the conservative management of central tear of the TFCC. According to Crosby and Greenberg[3]**,** bracing is the first line of treatment of ulnar wrist pain. They reported that compression of distal radioulnar joint for several

weeks can be a non-operative option for stable TFCC injury and ECU tendonopathy. They documented that the non-operative treatment of TFCC varies by patients' functional goals and level of activities.

In his algorithmic approach for treatment of ulnar writs pain, LaStayo[21], portrayed the sequence of treatment for different sources of ulnar wrist pain. Conservative treatment of TFCC articular disc tears and wrist tendonitis was centered on the use of ulnar gutter orthotics plus or minus strengthening exercises. Therefore, our focus was on these two intervention to try to substantiate their use in clinical practice and to document an evidence for their use.

Before the start of the study, we tested thermoplastic ulnar-gutter orthoses and we surveyed the market for a good orthotic device that will achieve the best support for the ulnar side of the wrist. Because of the nature of the weather in California, due to the availability of the braces, and the time constraints, we opted to use a prefabricated ulnar-based orthotic that is durable and breathable, yet achieves the maximum support needed. Most of the other braces were either universal wrist supports or did not achieve the support needed.

In this study, we used the Bauerfeind® ManuLoc Wrist Support (Figure 2), and to the authors' knowledge, this orthotic has not been used before in literature. The brace uses a German technology that allows moderate to maximum support to the ulnar side of the wrist thanks to the two metal stays and three laced straps. One metal stay was positioned on the dorso-ulnar side of the wrist and another one volary. The brace leaves the fingers and the radial side of the wrist free for function while providing a comfortable

pressure over the ulna during rotation of the forearm. The orthosis was deemed to be comfortable, reliable, and easy to use.

Strength

LaStayo[21] reported that strengthening is not always a priority in subjects with ulnar wrist pain and therapists must weigh overstressing the structures to gain better function against status and stage of healing**.** The goal of strengthening exercise performed in this study was to restore muscle strength that was decreased secondary to pain and/or inflammation. Our exercises were progressive in nature over a period of four weeks, making sure that there is no increase in symptoms. Grip strengthening results in light isometric strength of hand and wrist muscles.[17] In this study, we used a mixture of isometric and dynamic strengthening for subjects with ulnar wrist pain

Thera-band® are elastic bands with variable resistance levels as identified by their color and thickness. In the present study, we used two color-coded bands, yellow and red for strength training. Yellow band has the most easy resistance level and the red one provides a moderate resistance. Ozkaya and Nordin[34], explained that the resistance offered by the elastic bands has the same resistance properties of a spring, in that they both have a length for force application, elastic material, and cross-sectional area to determine the magnitude of resistance.

There is paucity in research regarding the use of different resistance of elastic bands in strength training. And there is no documentation whether different resistance of Thera-band® affects different types of contraction. In other words, we do not know if the elastic bands are contraction-specific, and whether higher resistance will affect concentric

or eccentric strength. Also, nothing is mentioned about the norms or the recommended length and the level of resistance of the band for different conditions.[35, 36]

Page et al.[35] proposed that the resistance offered by the elastic bands is accommodating, because resistance can change by the length of the Thera-band® and the lever arm. Hughes et al.[36] indicated the elastic bands are not considered isotonic form of resistance since the resistance can change, and they are not a form of isokinetic exercise as well since there is non-uniformity in the stretch properties of the bands. Unsubstantiated strength training protocols shed some light on the need for future research in exploring the appropriate regimen for different stages of injury.

Thera-band® has been used empirically with good results for strengthening despite the lack of evidence about how much resistance is provided by the band and what are the criteria of choosing and standardizing the protocol of treatment using the bands.[36] Despite this lack of evidence, Hughes et al.[36] tried to investigate the elastic properties of elastic tubing using the tube for shoulder abduction exercise. They found a strong relationship between the tension of the tube and the percentage of length change during exercises, however, they could not standardize the resistance level provided by the elastic tubing.

Camci et al.[37] Indicated that the length of the band and the level of resistance are patient-specific. They used Borg CR10 scale to determine the perceived resistance offered by the bands during shoulder elevation and lowering exercises. They used all the available color-coded bands and asked the participants to perform the exercises and to rate the perceived resistance from each band on the Borg CR10 scale until level of perceived effort reached 5 or 6, then they used the band with resistance of two color level below that band for rehabilitation.

The Patient-Rated Wrist Evaluation (PRWE) Questionnaire

The use of patient-reported outcome measures is ubiquitously available in literature. There is an increasing need to address the patients' conditions according to patients' perspectives[38]. In the current study, we used the PRWE questionnaire as self-reported measure to address pain and function in subjects with ulnar wrist pain. The scale has been used extensively in literature for evaluating pain and function across many hand/wrist pathologies with strong evidence that the questionnaire is valid, reliable, and responsive [22-30, 38]

Maciel et al.[39] used the PRWE questionnaire as their outcome measure in subjects with DRFs. They reported some limitations in using the questionnaire with their subjects as the questionnaire did not address the compensatory mechanisms that patients may use to compensate for functional limitations and/or participation restrictions. They argued, however, that these compensatory strategies may not be as meaningful to subjects and they will not reflect a usual or a specific activity that is routinely performed, and hence, they are not important to be addressed in the questionnaire.

We found the questionnaire comprehensive enough in subjects with ulnar wrist pain. In the specific activities subscale of the PRWE, we found activities like *"turning a door knob using my affected hand",* and *"cut meat using a knife in my affected hand"* very relevant to the condition of ulnar wrist pain as they directly address limitation in supination- pronation and ulnar deviation range of motion. Moreover, activities like *"use my affected hand to push up from a chair"* is directly correlated with a test we performed in the clinical exam "press test", which has 100% sensitivity for detecting TFCC

injuries.[13] We found that the questionnaire user-friendly, easy to be explained to subjects, and take few minutes to be filled.

A recent article by Mehta et al.[38] described the different psychometric properties of the PRWE in a systematic review design. They highlighted the superiority of the PRWE questionnaire over other upper extremity self-reported outcome measures. They explained that the PRWE is a region- specific outcome measure that directly address pain and disability pertinent to hand/wrist conditions and that it is more comprehensive to use in clinical practice. They concluded that the PREW is a reliable, valid, responsive tool for measuring pain and function in subjects with different hand/wrist pathologies. They recommended future research to be performed to estimate the minimal detectable change (MDC) and clinically important difference (CID) of the PRWE questionnaire for different wrist/ hand pathologies.

On the other hand, they reported a gap in literature regarding comparing the questionnaire to other hand/wrist outcome measures such as Michigan Hand Questionnaire (MHQ) and Boston Carpal Tunnel Questionnaire. In their systematic review, Mehta et al.[38] identified weak to moderate association between the PRWE questionnaire and objective measures such as strength and range of motion. Moreover, they reported low to moderate association between PRWE questionnaire and outcome measure assessing behavioral factors, giving the fact that pain, functional limitation and behavioral elements of health are different constructs.

In a letter to the editor, Brink et al.[40] concluded that future studies is needed to compare and correlate the PRWE to objective measures such as strength and hand function tests. Brink et al. reported a high internal consistency of the Dutch version of the

PRWE as indicated by Cronbach's alpha score of .89 for pain subscale, .91 for the function subscale, and .923 for the total questionnaire. Their result suggested a high internal consistency and strong structural validity of the questionnaire.

Limitations

This study may be viewed within the context of several limitations. First, the sample size was small. A larger sample may be needed to further document the effect of orthotic and strengthening intervention in subjects with ulnar wrist pain. More representative sample is needed also for better generalizability of the results.

Second, the duration of strength training used in this study might have been less efficient in providing an increase in strength. We only used four weeks strength training, and it can be argued that, longer duration of strength training may have a different results in mean strength scores among groups.

Third, we used only one type of pre-fabricated ulnar-based orthotic device. It is possible that a custom-made orthotic may better suit subjects with ulnar wrist pain. Further research are needed to investigate different types of orthotic interventions.

Conclusion

The distal ulna is a complex area in the field of hand surgery and therapy.[6] Based on the results, clinicians should consider the use of ulnar-based orthotics as a priority treatment in subjects with ulnar wrist pain. Although grip strength is always important to assess in subjects with different wrist/hand pathologies, strength training may not be a priority all the time. Therapists should weigh implementing strength training against the

use of appropriate support of wrist in subjects with ulnar wrist pain. In the current study, we can conclude that the orthotic intervention is as effective as the combined effect of orthotic intervention and strengthening exercises in subjects with acute and sub-acute ulnar wrist pain.

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CHAPTER FOUR

DISCUSSION

In the current study, we examined the relationship between overall health and QoL represented by SF-36 questionnaire and certain functioning aspects based on an adapted version of the ICF model of functioning and disability, assessed by using the PRWE questionnaire and Jamar Hand Dynamometer. This study indicated a strong linkage between the physical health component of the SF-36 and physical therapy outcome measures, specifically grip strength, in subjects with ulnar wrist pain.

This study also investigated the effect of orthotic intervention with or without strengthening exercises in subjects with ulnar wrist pain. In this study, we obtained a consistent result in the outcome variables over the three measurement times. There were no statistical significant differences between the two treatment groups regarding improvement in pain, function, and grip strength, while there were significant differences between the treatment and control groups over time.

Relationship between Predictors and Outcome Variables

There was a significant association between grip strength and the physical health component of SF-36 measured after four weeks of the intervention. The grip strength by itself predicted 31% of the variability in the physical health component of the SF-36. This strong association between grip strength and physical health is logical, considering that grip strength is an integral component of body physical function and it is an important hand function. On the other hand, we identified weak associations between SF-36 scores

of physical and mental health with pain and function as measured with PRWE questionnaire.

Among the physical impairments listed in the literature, grip strength is used extensively to represent impairment in different hand pathologies[67], and it may be the most studied health measure used by hand therapists.[21] Strength is incorporated in the Brief ICF Core Set for Hand Conditions in different categories, either directly such as in category *b730 muscle power functions*, or embedded in other categories to allow different functions to take place (*b710 mobility of joint functions, b760 control of voluntary movement functions, d230 carrying out daily routine, d430 lifting and carrying objects, d445 hand and arm use, and d840-d859 work and employment*). This may explain the high capacity of grip strength in predicting changes in physical health in subjects with ulnar wrist pain.

According to LaStayo, [29] orthotic intervention is the mainstay of conservative treatment and strengthening is not always a priority is subjects with TFCC injuries. Most of study's participants had traumatic acute and sub-acute TFCC injuries. We believe that the ulnar-based orthotic device reduced pain associated with TFCC injuries and enabled regaining of strength which contributed the most to the variability in SF-36 physical health sub-scores.

Strong associations among the predictor variables after four weeks of therapy indicated the strong linkage between reduction in pain severity and improvement in function and grip strength. The regression model, however, excluded pain and function although there were strong associations between the predictor variables themselves and between the predictor variables and the SF-36 physical health summary sub-scores when

performing Pearson Correlation analysis. Exclusion of pain and function from the regression model may be due to the major improvement in grip strength which may have superimposed the improvement in pain and function, or because the PRWE questionnaire was not able to identify the actual improvement in pain and function.

Although the PRWE questionnaire has been used extensively in literature as a valid and reliable outcome measure after wrist and hand injuries[32, 38-44, 68] , we found that it had a low capacity of predicting significant changes in SF-36 scores in subjects with ulnar wrist pain. This relatively low predictive capacity has been documented in another study. Harris et al.[69] found that PRWE explained only 13% and 33% of the variability in SF-36 physical health measured at one week and three months respectively after DRF. Moreover, only 10% and 8% of the variability in SF-36 mental component were explained by its relationship to PRWE scores measured at three months and one year respectively. This contradicted the findings of Changulani et al.[40] who reported a variable correlation between the PRWE and SF-36 scores (ranged from 0.33 and 0.73), and they identified the PRWE as the most responsive outcome measure in subjects with DRF.

Probably due to the low predictive capacity of the PRWE and its relationship to SF-36 physical and mental aspects of health, Squitieri et al.[62] used another patient-reported measures to explain the variability in health outcome measures. They used Michigan Hand Outcome questionnaire (MHQ) as a measure of health status, and correlated it with other physical therapy outcome measures (Jebsen Taylor test, range of motion measurements, different functioning domains of MHQ), and patient demographic factors. They found that these variables predicted 93%, 98%, and 97% of the variability in MHQ measured at six weeks, three, and six months respectively in subjects with DRF.

SF-36 Mental Health and ICF Environmental Factors

There was no significant correlation between the mental component of the SF-36 and the predictor variables. Regression models excluded all the predictor variables when it was correlated with mental health component of the SF-36 scores. There may be possible reasons explaining the lack of this association. First, we had a small sample size that might not be representative of the overall population and perhaps the time frame was too short to trigger influence response in mental health scores. Second, we did not consider the environmental aspect of the ICF as a contextual factor contributing to the change observed in study's outcomes.

In contrast, Kus et al.[70] documented the importance of the mental function in subjects with hand conditions. They reported that ICF category such as *b134 sleep function* and *b152 emotional function* should not be overlooked in subjects with hand conditions as they contributed to subjects' general health. They indicated that emotional function was not only important to the subjects' perceived health as measured by self-reported measures, but also for rating of health outcomes by healthcare professionals. Their participants, however, had more serious hand conditions than those in the present study. They recruited subjects who suffered from diseases such as Dupuytren's disease, or if they had general conditions affecting the hand such as Parkinson's disease or brachial plexus injuries.

Various researches also documented the importance of mental aspect of health in subjects with hand conditions.[70-76] Most of the studied conditions were more challenging than those in the present study such as Dupuytren's disease, [71] systemic sclerosis, [72] cold sensitivity, [73] carpal tunnel syndrome, [74] and hand osteoarthritis.[75] Moreover, William et

al.[76] found that posttraumatic stress disorders and depression negatively impacted general health in subjects with severe hand injuries.

In a study by Squitieri et al.[62], the environmental factors slightly contributed to the change in satisfaction level of subjects with DRF. They found as little as 3%, 1%, and 7% contribution to the change in satisfaction scores as measured at six weeks, three, and six months respectively. Our perspective is that environmental factors could be of a significant predictive value in more challenging health conditions that may have a broader impact on function such as stroke, lower limb disability, or in life-threatening diseases such as cancers or terminal illnesses, or in conditions with psychosocial impact such as depression.

Kus et al.[70] conducted a multicenter study of a large sample size (260) on subjects with different hand conditions. They were able to validate 12 out of the 23 categories of the Brief ICF Core Set for Hand Conditions. They identified those 12 categories as the major contributors to the variance in patients' self and proxy-reported measures based on multiple regression analyses. Although half of the identified variables belonged to the activity and participation domains, their results highlighted the significant contribution of the environmental factors. They recommended consideration of the identified environmental factor such as *e225 climate, e410 individual attitude of immediate family members, e460 social attitudes* and other relevant factors when dealing with subjects with hand pathologies. They concluded that the Brief ICF Core Set for Hand Conditions should be used as the standard tool in addressing functioning in subjects with hand conditions.

A broader understanding of health-related quality of life (QoL) facets and how they relate with functioning in ICF domains is important in clinical practice. Patients' estimation of the perceived satisfaction has been ubiquitously highlighted in literature.[77-82] Perceived satisfaction reflects subjective point of view of life condition using patient's own eyes.[83, 84] A modified ICF model by McDougall et al.[85] suggested that perceived satisfaction of QoL should be incorporated as codes in the personal domain of both the ICF and the modified ICF model for children and youth, namely, the International Classification of Functioning, Disability, and Health- Children and Youth (ICF-CY).

Statistical Versus Clinical Significance

Although the was no statistical significant difference between the two intervention groups regarding improvement in strength, subjects in the group that received orthotic intervention plus strengthening exercises showed a slightly better improvement in mean strength scores 73.9(4.6 lb.) as compared to the group who received orthotic intervention only with mean of 65.3(4.8 lb.) after two weeks of therapy. This was the case also after four weeks of therapy with orthotic plus strengthening group had a mean strength score of 98.4(4.2 lb.), while subjects who received only orthotic intervention had a mean score of 92.6(4.4 lb.).

The lack of the statistical differences between the two intervention groups may be due to the duration of the strengthening exercises that was used in this study. We used a home-based four weeks strengthening program that addressed all muscle groups around the wrist and the distal radioulnar joint and it was progressive in nature, however, perhaps

the time frame was not adequate to trigger a statistical significance between the two intervention groups.

On the other hand, subjects who received orthotic intervention only showed a slightly better improvement in their mean scores of pain and function over time as compare to subjects who received orthotic intervention plus strengthening exercises, although there was no statistical significant difference. It is always important to address the clinical significance even if the statistical significance is absent, and to weigh our statistical results against the importance of the improvement in the outcome measures of a clinical condition. Regarding pain and function, it is important to note that, the lower the score, the better the improvement in pain and function, as this was the construct of the PRWE.

This study yielded no significant differences between groups at baseline, however, both intervention groups showed a significant difference over time in comparison to the control group. Most of the subjects in the control group reported no improvement in their pain and functional level. They reported inability to perform their duties as efficient as they were before the injury. Investigators assured that subjects in control groups did not utilize any intervention for their condition during the study period and that they were compliant with the placebo tennis elbow usage.

The Use of Orthotics

According to LaStayo[29], ulnar gutter orthoses do not prevent forearm rotation, however, they provides enough support for pain relief for subjects with ulnar wrist pain. Ulnar gutter orthoses are the mainstay of the conservative management of central tear of

the TFCC. According to Crosby and Greenberg[3], bracing is the first line of treatment of ulnar wrist pain. They reported that compression of distal radioulnar joint for several weeks can be a non-operative option for stable TFCC injury and ECU tendonopathy. They documented that the non-operative treatment of TFCC varies by patients' functional goals and level of activities.

In his algorithmic approach for treatment of ulnar writs pain, LaStayo[29], portrayed the sequence of treatment for different sources of ulnar wrist pain. Conservative treatment of TFCC articular disc tears and wrist tendonitis was centered on the use of ulnar gutter orthotics plus or minus strengthening exercises. Therefore, our focus was on these two intervention to try to substantiate their use in clinical practice and to document an evidence for their use.

Before the start of the study, we tested thermoplastic ulnar-gutter orthoses and we surveyed the market for a good orthotic device that will achieve the best support for the ulnar side of the wrist. Because of the nature of the weather in California, due to the availability of the braces, and the time constraints, we opted to use a prefabricated ulnar-based orthotic that is durable and breathable, yet achieves the maximum support needed. Most of the other braces were either universal wrist supports or did not achieve the support needed.

In this study, we used the Bauerfeind® ManuLoc Wrist Support, and to the authors' knowledge, this orthotic has not been used before in literature. The brace uses a German technology that allows moderate to maximum support to the ulnar side of the wrist thanks to the two metal stays and three laced straps. One metal stay was positioned on the dorso-ulnar side of the wrist and another one volary. The brace leaves the fingers

and the radial side of the wrist free for function while providing a comfortable pressure over the ulna during rotation of the forearm. The orthosis was deemed to be comfortable, reliable, and easy to use.

Strength

LaStayo[29] reported that strengthening is not always a priority in subjects with ulnar wrist pain and therapists must weigh overstressing the structures to gain better function against status and stage of healing. The goal of strengthening exercise performed in this study was to restore muscle strength that was decreased secondary to pain and/or inflammation. Our exercises were progressive in nature over a period of four weeks, making sure that there is no increase in symptoms. Grip strengthening results in light isometric strength of hand and wrist muscles.[86] In this study, we used a mixture of isometric and dynamic strengthening for subjects with ulnar wrist pain

Thera-band® are elastic bands with variable resistance levels as identified by their color and thickness. In the present study, we used two color-coded bands, yellow and red for strength training. Yellow band has the most easy resistance level and the red one provides a moderate resistance. Ozkaya and Nordin[87], explained that the resistance offered by the elastic bands has the same resistance properties of a spring, in that they both have a length for force application, elastic material, and cross-sectional area to determine the magnitude of resistance.

There is paucity in research regarding the use of different resistance of elastic bands in strength training. And there is no documentation whether different resistance of Thera-band® affects different types of contraction. In other words, we do not know if the

elastic bands are contraction-specific, and whether higher resistance will affect concentric or eccentric strength. Also, nothing is mentioned about the norms or the recommended length and the level of resistance of the band for different conditions.[88, 89]

Page et al.[88] proposed that the resistance offered by the elastic bands is accommodating, because resistance can change by the length of the Thera-band® and the lever arm. Hughes et al.36 indicated the elastic bands are not considered isotonic form of resistance since the resistance can change, and they are not a form of isokinetic exercise as well since there is non-uniformity in the stretch properties of the bands. Unsubstantiated strength training protocols shed some light on the need for future research in exploring the appropriate regimen for different stages of injury.

Thera-band® has been used empirically with good results for strengthening despite the lack of evidence about how much resistance is provided by the band and what are the criteria of choosing and standardizing the protocol of treatment using the bands.[89] Despite this lack of evidence, Hughes et al.[89] tried to investigate the elastic properties of elastic tubing using the tube for shoulder abduction exercise. They found a strong relationship between the tension of the tube and the percentage of length change during exercises, however, they could not standardize the resistance level provided by the elastic tubing.

Camci et al.[90] Indicated that the length of the band and the level of resistance are patient-specific. They used Borg CR10 scale to determine the perceived resistance offered by the bands during shoulder elevation and lowering exercises. They used all the available color-coded bands and asked the participants to perform the exercises and to rate the perceived resistance from each band on the Borg CR10 scale until level of

perceived effort reached 5 or 6, then they used the band with resistance of two color level below that band for rehabilitation.

The Patient-Rated Wrist Evaluation (PRWE) Questionnaire

The use of patient-reported outcome measures is ubiquitously available in literature. There is an increasing need to address the patients' conditions according to patients' perspectives.[91] In the current study, we used the PRWE questionnaire as self-reported measure to address pain and function in subjects with ulnar wrist pain. The scale has been used extensively in literature for evaluating pain and function across many hand/wrist pathologies with strong evidence that the questionnaire is valid, reliable, and responsive [32, 39-44]

Maciel et al.[92] used the PRWE questionnaire as their outcome measure in subjects with DRFs. They reported some limitations in using the questionnaire with their subjects as the questionnaire did not address the compensatory mechanisms that patients may use to compensate for functional limitations and/or participation restrictions. They argued, however, that these compensatory strategies may not be as meaningful to subjects and they will not reflect a usual or a specific activity that is routinely performed, and hence, they are not important to be addressed in the questionnaire.

We found the questionnaire comprehensive enough in subjects with ulnar wrist pain. In the specific activities subscale of the PRWE, we found activities like *"turning a door knob using my affected hand",* and *"cut meat using a knife in my affected hand"* very relevant to the condition of ulnar wrist pain as they directly address limitation in supination- pronation and ulnar deviation range of motion. Moreover, activities like *"use*

my affected hand to push up from a chair" is directly correlated with a test we performed in the clinical exam "press test", which has 100% sensitivity for detecting TFCC injuries.[20] We found that the questionnaire user-friendly, easy to be explained to subjects, and take few minutes to be filled.

A recent article by Mehta et al.[91] described the different psychometric properties of the PRWE in a systematic review design. They highlighted the superiority of the PRWE questionnaire over other upper extremity self-reported outcome measures. They explained that the PRWE is a region- specific outcome measure that directly address pain and disability pertinent to hand/wrist conditions and that it is more comprehensive to use in clinical practice. They concluded that the PREW is a reliable, valid, responsive tool for measuring pain and function in subjects with different hand/wrist pathologies. They recommended future research to be performed to estimate the minimal detectable change (MDC) and clinically important difference (CID) of the PRWE questionnaire for different wrist/ hand pathologies.

On the other hand, they reported a gap in literature regarding comparing the questionnaire to other hand/wrist outcome measures such as Michigan Hand Questionnaire and Boston Carpal Tunnel Questionnaire. In their systematic review, Mehta et al.[91] identified weak to moderate association between the PRWE questionnaire and objective measures such as strength and range of motion. Moreover, they reported low to moderate association between PRWE questionnaire and outcome measure assessing behavioral factors, giving the fact that pain, functional limitation and behavioral elements of health are different constructs.

In a letter to the editor, Brink et al.[54] concluded that future studies is needed to compare and correlate the PRWE to objective measures such as strength and hand function tests. Brink et al.[54] reported a high internal consistency of the Dutch version of the PRWE as indicated by Cronbach's alpha score of .89 for pain subscale, .91 for the function subscale, and .923 for the total questionnaire. Their result suggested a high internal consistency and strong structural validity of the questionnaire.

Limitations

This study had several limitations. First, the sample size was small. Because of the scarce nature of the targeted conditions, we were able to recruit a sample of 35 subject with ulnar wrist pain over a year. Our interest was directed to a specific source of wrist pain, therefore, generalizability of the results to other wrist injuries can be used with caution. Future studies may take into consideration other possible sources of ulnar wrist pain, and to recruit subjects from different centers and settings for more accurate representation. A larger sample may be needed to further document the effect of orthotic and strengthening intervention in subjects with ulnar wrist pain

Second, only 53% of the variance in the SF-36 physical health scores was explained by the predictor variables, and the regression models excluded all the predictor variables when they were correlated with the mental health scores of the SF-36. A large unexplained variability in general health may be due to other factors not investigated in this study. We did not consider the environmental factors which might have explained more variability in the two facets of health, physical and mental.

Third, we only used PRWE questionnaire and grip strength measurement to represent the functioning component of the ICF. Although PRWE has been identified as a reliable measure[32, 38-44, 68], it was excluded from the regression models. Other measures of functioning such as MHQ may be used. The MHQ covers broader aspects of functioning and health and has high validity, reliability, and responsiveness.[99-102] For future studies, we may recommend the use of MHQ in conjunction with PRWE questionnaire to examine the relationship between functioning and overall health.

Fourth, the duration of strength training used in this study might have been less efficient in providing an increase in strength. We only used four weeks strength training, and it can be argued that, longer duration of strength training may have a different results in mean strength scores among groups.

Lastly, we used only one type of pre-fabricated ulnar-based orthotic device. It is possible that a custom-made orthotic may better suit subjects with ulnar wrist pain. Further research are needed to investigate different types of orthotic interventions.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATION

Conclusions

ICF and Ulnar Wrist Pain

Proper understanding of the ICF model opens up a wide range of research studies in physical therapy and rehabilitation, and provides a template for evidence based practice regarding physical therapy in clinical settings. Our aim in this study was to crosswalk the physical therapy outcome measures to the Brief ICF Core Set for Hand Conditions. We think that the use of the Brief ICF Core Set for Hand Conditions is an integral part of the clinical language that should be endorsed by clinicians and therapists. It enables a useful systemic process for identifying, documenting, and communicating health status. This study may serve as an addendum to link health related QoL to functioning in subjects with ulnar wrist pain.

Investigators of the present study attempted to make a transition from just describing a bodily injury (ulnar wrist pain) using the Brief ICF Core Set for Hand Conditions framework to measuring of the health outcomes utilizing the Brief ICF Core Set for Hand Conditions as a conceptual framework. Although it might seem challenging, researchers should try to link physical therapy instruments to the ICF in different settings (e.g. assessment, treatment) for different health conditions.

Physical Therapy for Subjects with Ulnar Wrist Pain

The distal ulna is a complex area in the field of hand surgery and therapy.[103] Based on the results, clinicians should consider the use of ulnar-based orthotics as a

priority treatment in subjects with ulnar wrist pain. Although grip strength is always important to assess in subjects with different wrist/hand pathologies, strength training may not be a priority all the time. Therapists should weigh implementing strength training against the use of appropriate support of wrist in subjects with ulnar wrist pain. In the current study, we can conclude that the orthotic intervention is as effective as the combined effect of orthotic intervention and strengthening exercises in subjects with acute and sub-acute ulnar wrist pain.

Recommendations

The authors of the this study would recommend the following fur future research in the context of ICF, Brief ICF Core Set for Hand Conditions, and physical therapy for subjects with ulnar wrist pain

1. Further studies should be performed to deeply study, apply, and operationalize the ICF and the Brief ICF Core Set for Hand Conditions.
2. Future studies may consider the other categories of the Brief ICF Core Set for Hand Conditions that were not studied in this research
3. Other outcome measures can be used to further scrutinize the relationship between physical therapy clinical tools and the ICF and the Brief ICF Core Set for Hand Conditions
4. Further similar research may include the environmental component of the ICF in the research and find if the results would be different. Environmental aspect of health is an important construct of bio-psychosocial understanding of the ICF

5. A larger sample may be considered in future research to further document the effect of orthotic and strengthening intervention in subjects with ulnar wrist pain
6. A longer duration of strength training may be necessary to trigger a different response for strength gain in subjects with ulnar wrist pain
7. Different types of orthotic interventions can be tried on subjects with ulnar wrist pain

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APPENDIX A

THE PATIENT RATED WRIST EVALUATION QUESTIONNAIRE

Name: _____ Date: _____

PATIENT RATED WRIST EVALUATION

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

1. PAIN

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

RATE YOUR PAIN: Sample Scale ☞	0 No Pain	1	2	3	4	5	6	7	8	9	10 Worst Ever
At rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with a repeated wrist movement	0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object	0	1	2	3	4	5	6	7	8	9	10
When it is at its worst	0	1	2	3	4	5	6	7	8	9	10
How often do you have pain?	0 Never	1	2	3	4	5	6	7	8	9	10 Always

2. FUNCTION

A. SPECIFIC ACTIVITIES

*Rate the **amount of difficulty** you experienced performing each of the items listed below - over the past week, by circling the number that describes your difficulty on a scale of 0-10. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do it at all.*

Sample scale →	0 No Difficulty	1	2	3	4	5	6	7	8	9	10 Unable To Do
Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Cut meat using a knife in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

B. USUAL ACTIVITIES

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

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

APPENDIX B

THE SHORT FORM (SF-36) QUESTIONNAIRE

SF-36 QUESTIONNAIRE

Name:_____ **Ref. Dr:**_____ **Date:** _____

ID#: _____ **Age:** _____ **Gender: M / F**

Please answer the 36 questions of the **Health Survey** completely, honestly, and without interruptions.

GENERAL HEALTH:
In general, would you say your health is:
○ Excellent ○ Very Good ○ Good ○ Fair ○ Poor

Compared to one year ago, how would you rate your health in general now?
○ Much better now than one year ago
○ Somewhat better now than one year ago
○ About the same
○ Somewhat worse now than one year ago
○ Much worse than one year ago

LIMITATIONS OF ACTIVITIES:
The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
○ Yes, Limited a lot ○ Yes, Limited a Little ○ No, Not Limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Lifting or carrying groceries
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Climbing several flights of stairs
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Climbing one flight of stairs
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Bending, kneeling, or stooping
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Walking more than a mile
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Walking several blocks
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Walking one block
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Bathing or dressing yourself

○Yes, Limited a Lot ○Yes, Limited a Little ○No, Not Limited at all

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Cut down the amount of time you spent on work or other activities

○Yes ○No

Accomplished less than you would like

○Yes ○No

Were limited in the kind of work or other activities

○Yes ○No

Had difficulty performing the work or other activities (for example, it took extra effort)

○Yes ○No

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Cut down the amount of time you spent on work or other activities

○Yes ○No

Accomplished less than you would like

○Yes ○No

Didn't do work or other activities as carefully as usual

○Yes ○No

SOCIAL ACTIVITIES:

Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

○Not at all ○Slightly ○Moderately ○Severe ○Very Severe

PAIN:

How much bodily pain have you had during the past 4 weeks?

○None ○Very Mild ○Mild ○Moderate ○Severe ○Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

○Not at all ○A little bit ○Moderately ○Quite a bit ○Extremely

ENERGY AND EMOTIONS:
These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

Did you feel full of pep?
- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

Have you been a very nervous person?
- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

Have you felt so down in the dumps that nothing could cheer you up?
- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

Have you felt calm and peaceful?
- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

Did you have a lot of energy?
- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

Have you felt downhearted and blue?

- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

Did you feel worn out?

- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

Have you been a happy person?

- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

Did you feel tired?

- ○ All of the time
- ○ Most of the time
- ○ A good Bit of the Time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

SOCIAL ACTIVITIES:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfer your social activities (like visiting with friends, relatives, etc.)?

- ○ All of the time
- ○ Most of the time
- ○ Some of the time
- ○ A little bit of the time
- ○ None of the Time

GENERAL HEALTH:
How true or false is each of the following statements for you?

I seem to get sick a little easier than other people
○Definitely true ○Mostly true ○Don't know ○Mostly false ○Definitely false

I am as healthy as anybody I know
○Definitely true ○Mostly true ○Don't know ○Mostly false ○Definitely false

I expect my health to get worse
○Definitely true ○Mostly true ○Don't know ○Mostly false ○Definitely false

My health is excellent
○Definitely true ○Mostly true ○Don't know ○Mostly false ○Definitely false

APPENDIX C

WRIST STRENGTHENING GUIDELINES

Subject's name: _____ Date: _____

Wrist Strengthening Exercises

Subjects' guidelines

The following exercises are designed to strengthen muscles of your wrist and hand as part of the study you are enrolled in. these exercises should be performed when you do not have any pain or within your pain-free range. If you have any question or concern, please feel free to contact Mohamed Abdelmegeed at 9095834966 or mabdelmegeed@llu.edu

Please follow the following guidelines:

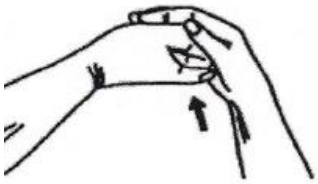
Week 1

1. **Soft ball squeeze**
   When comfortable, please perform this exercise as shown in the picture. Hold each squeeze for 6 seconds, release and relax for another 6 seconds. Repeat 10 times and do three sets daily.

2. **Dynamic self-resistance wrist movement:**
   A. **Wrist flexion:** sit on a chair and support your elbow on your thigh so that your palm faces forward as shown in the picture. Move your wrist upward against the resistance of the other hand.
   B. **Wrist extension:** Make a fist with your hand with palm down. Move wrist in an upward direction and resist with opposite hand
   C. **Wrist radial deviation:** Make a fist with involved hand with thumb upward and facing ceiling. Move wrist in an upward direction and resist with opposite hand.

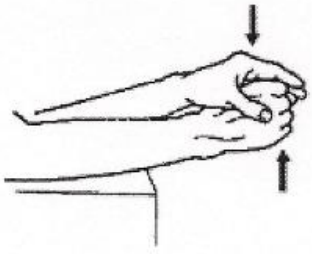
   For each movement, perform the contraction for 6 seconds, repeat 10 times and perform 3 sets daily.

Flexion



Extension

Radial deviation



Week 2:

1. **Racquet ball squeeze:**
   When comfortable, please perform this exercise as shown in the picture. Hold each squeeze for 6 seconds, release and relax for another 6 seconds. Repeat 10 times and do three sets daily.

2. **Dynamic self-resistance supination and pronation:**
   A. **Supination:** Make a fist with involved hand with thumb downward. Rotate forearm slight toward a palm upward position. Resist with opposite hand.
   B. **Pronation:** Make a fist with involved hand with thumb upward. Rotate forearm slightly toward a palm down position. Resist with opposite hand

   Perform each contraction for 6 seconds. Repeat 10 times for each movement and do three sets daily

Supination

Pronation

3. **Resistance band exercises flexion-extension:**
   When comfortable, please perform the following exercises as shown in the pictures for the flexion, extension wrist movements (up, down). You can perform them in sitting or standing position. You can secure the resistance band to the leg of the chair or under your foot. Hold each contraction for 6 seconds. Repeat 10 times for each movement and do three sets daily.

Flexion

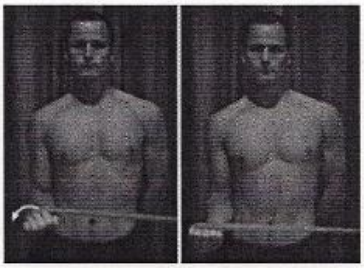
Extension

Week 3 and week 4:

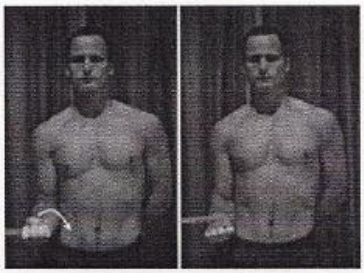
1. **Tennis ball squeeze**
   Squeeze the ball as hard as is comfortable as shown in the picture. Hold each squeeze for 6 seconds, release and relax for another 6 seconds. Repeat 10 times and do three sets daily.

2. **Towel wringing exercise:**
Grip a dry towel with both hands and twist them in opposite directions. You can assume four different grips; both hands facing up, both hands facing down, right hand up and left down, and left up and right down. You can grip the towel with hands side by side or slightly apart.
In week 3, perform each wringing movement for 6 seconds, repeat 10 times daily for 3 sets. Gradually progress to 20 repetitions for 3 sets daily in week 4

3. **Resistance band- supination, pronation:**
Supination: sit on a chair beside a table or a door with elbow bent 90 degree at your side. Anchor one end of theraband to the table or the door, hold the other end of theraband and wrap it around your hand so that your palm faces down as shown in the picture. Slowly rotate your forearm so that your palm faces up against the resistance of theraband.
Pronation: wrap theraband around your hand as shown in the picture so that your palm is facing up, slowly rotate your forearm so that your palm faces down against the resistance of theraband.
In week 3, perform each movement for 6 seconds, repeat 10 times daily for 3 sets. Gradually progress to 20 repetitions for 3 sets daily in week 4



Supination



Pronation

4. **Resistance band- radial, ulnar deviation:**
Radial deviation: secure the theraband under your foot, support your elbow on your thigh, and hold the band with your hand so that the thumb is pointing upward as shown in the picture. Slowly move your wrist upward toward the ceiling hold and slowly return
Ulnar deviation: secure the theraband under your feet. With your elbow at your side, grasp the theraband so that the thumb faces forward as shown in the picture. Keep your elbow steady and slowly move your wrist backward, hold and slowly return. No movement should occur at the elbow.
In week 3, perform each movement for 6 seconds, repeat 10 times daily for 3 sets. Gradually progress to 20 repetitions for 3 sets daily in week 4

Radial deviation

Ulnar deviation

APPENDIX D

WRIST EXERCISE AND SPLINTING LOG SHEET

Subject's name: _____ Date: _____

Activity / **Week 1**	Splint wearing time	Soft ball squeeze	Self-resistance wrist flexion	Self-resistance wrist extension	Self-resistance wrist radial dev.		
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							
Activity / **Week 2**	Splint wearing time	Racquet ball squeeze	Self-resistance supination	Self-resistance pronation	Theraband flexion	Theraband extension	
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							
Activity / **Week 3**	Splint wearing time	Tennis ball squeeze	Towel wringing	Theraband supination	Theraband pronation	Theraband radial deviation	Theraband ulnar deviation
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							
Activity / **Week 4**	Splint wearing time	Tennis ball squeeze	Towel wringing	Theraband supination	Theraband pronation	Theraband radial deviation	Theraband ulnar deviation
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							

APPENDIX E

INFORMED CONSENT FORM

LOMA LINDA UNIVERSITY
School of Allied Health Professions

Informed Consent to Participate In Research

"LINKING PHYSICAL THERAPY OUTCOME MEASURES TO THE INTERNATIONAL CLASSIFICATION OF FUNCTION AFTER TRIANGULAR FIBROCARTILAGE INJURIES AND ULNAR WRIST PAIN"

You are invited to take part in a research study. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. Before you agree, you need to take time to carefully read and understand what your participation would involve. To decide whether or not you want to be part of this research, the purpose, procedures, risks, and possible benefits of the study are described in this form so you can make an informed decision.

1. WHY IS THIS STUDY BEING DONE?

This study is being conducted by Mohamed Abdelmegeed, a doctoral student, and Dr. Everett B. Lohman, faculty at the department of physical therapy, Loma Linda University. The ulnar side of the wrist has been referred to as the "black box" of the wrist because of its complex structures. There are many causes of ulnar-sided wrist pain; one of the most common causes is injury to an articular structure called "Triangular Fibrocartilage Complex" or the TFCC which is located between your ulna and carpal bones. There are also other ligaments and tendons that attach to this complex and can be sources of pain at your ulnar side of the wrist. Ulnar wrist pain causes motion restriction in performing regular activities, weak hand grip.

No previous study has attempted to study the effect of splinting and strengthening exercises in subjects with ulnar wrist pain. The purposes of this study are (1) to investigate the effect of splinting and strengthening exercises after TFCC injuries and ulnar wrist pain, (2) to link physical therapy outcomes measures to the International Classification of Functioning (ICF) in subjects with ulnar wrist pain, and (3) to develop a clinical prediction rule that can guide clinical

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decision making in subjects with ulnar wrist pain who likely to benefit from splinting and strengthening.

Sixty subjects with ulnar wrist pain is expected to participate in this study. You are being asked to participate because you have been diagnosed with, or have symptoms of ulnar wrist pain.

2. HOW WILL I BE INVOLVED?

- All evaluation and treatment procedures will take place at room A620 Nichol Hall, Loma Linda University.
- Each participant will have to come for one baseline evaluation session, and two follow up sessions, for a total of three visits within one month. These visits will be part of scheduled research visits necessary to conduct the study.
- After the post intervention evaluation is performed on all participants (at day 30), subjects in the control group will receive a four-week program of splinting and strengthening exercises and will require them to come for two more visits after the first month for follow up of their treatment, for a total of five visits within two months period.
- A summary of the study's activities can be found at the last page of this document: **(please refer to the attachment at the end of this document)**

Day 1: Informed consent, evaluation including history taking, screening with ultrasound, pain and function assessment, measurement of grip strength, range of motion, and overall quality of life. Also, exercise prescription and splint instructions will be provided (will take approximately 30 minutes of your time).

- The investigator will collect background information including your age, gender, onset and duration of symptoms, activity level (athletic or non-athletic), involved side (right or left), and relieving and aggravating factors. This will take approximately 5 minutes.
- The investigator will then perform a baseline evaluation which will include the following:
    - Your grip strength will be measured using a hand-held dynamometer.
    - Severity of pain and functional limitation will be checked by completing a subject –rated questionnaire that address pain and function.
    - Wrist range of motion will be measured with a goniometer.

- The principal investigator will determine, using an ultrasonography imager, which structure causes your pain.
- Overall quality of life and health status will be assessed by filling a questionnaire.

- Once the baseline evaluation is completed, the investigator will randomly assign you into one of three groups; splinting group 1, splinting and home-based strengthening exercise group 2, or a control group 3. All subjects will perform their assigned intervention for four weeks in their assigned groups.
- Splinting is a support that is intended to take some load off the painful area. An ulnar-sided wrist support will be used in this study to take some load off the ulnar side of the wrist, while allowing your normal daily activities. It is not intended to restrict or limit wrist movement completely.
- Splints and exercise tools will be provided by the study investigators.
- A written explanation of home exercises program, duration and frequency of exercises, splint wearing time, and other relevant program's instruction will be provided to all subjects.

Day 14: Midpoint through the research study (after 2 weeks of the intervention) you will be required to come again for a follow up session. Follow up evaluation will be conducted including pain and function assessment, measurement of grip strength, range of motion, and overall quality of life, follow up for exercise performance and splint compliance (will require approximately 30 minutes).

Day 30: Post intervention evaluation (after four weeks of intervention) will include: screening with ultrasound, pain and function assessment, measurement of grip strength, range of motion, and overall quality of life. Global rating of change scale will be conducted as well (will take approximately 30 minutes).

3. WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MIGHT HAVE?

Participation in this study may yield minimal risk to you. Although there are no potential risks or adverse effects reported regarding splinting and exercises if they are performed properly, general

adverse effects can result from improperly performing exercises and/or wearing splints. Over doing or improperly performing exercises can result in increased pain and/or discomfort. Improper splint fitting can result in localized skin irritation, discomfort, limitation of movement. The study's investigators will closely monitor subjects in their progression, making sure that the splints are comfortable, exercises are performed accurately with proper dosage. The investigators will ask the participants to report any adverse effect, or concern about the therapy.

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

4. WILL THERE BE ANY BENEFIT TO ME OR OTHERS?

You will not directly benefit from the study. Data obtained from this study will serve to establish a treatment consensus and a clinical decision making for those with ulnar wrist pain. This will benefit other subjects with similar conditions in the future and will advance the research in this particular area of ulnar wrist pain.

5. WHAT ARE MY RIGHTS AS A SUBJECT?

Participation in this study is voluntary. You may leave the study at any time. If at any time during a procedure you decide to stop, just inform the person conducting the procedure. This decision will NOT affect your present or future relationship with those conducting the study or loss of benefits to which you are otherwise entitled to.

- If you decide to withdraw from the study, you should notify the research team immediately. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.
- If you withdraw or are removed from the study, the researcher may ask you to return for a final close-out visit or complete an exit telephone interview.
- Likewise, your participation in this study may be stopped by the study staff/investigator for any reason without your agreement.

6. WHAT OTHER CHOICES DO I HAVE?

Ulnar wrist pain can be treated with or without surgical interventions. This study is intended to address symptoms associated with ulnar wrist pain without surgical intervention. Also, you can take prescribed medications to treat symptoms associated with ulnar wrist pain. Your physician or primary care doctor can discuss these options with you. Moreover, you can receive splinting and strengthening exercises to treat symptoms associated with ulnar wrist pain anywhere else outside this research study.

7. HOW WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

To ensure that confidentiality of any information obtained about you during this research study is maintained, data associated with your participation in this study will be passcode protected. Your identity on these records will be indicated by a unique three-digit code assigned to your name. Information linking your code to your identity will be accessible only to the investigators and will be stored in separate file which will be passcode protected.

8. WHAT COSTS ARE INVOLVED?

Study's investigators will be responsible for providing exercise tools and splints necessary for the intervention. Evaluation procedure, follow up exam and any necessary tools related to the study will be provided by the investigators. Neither you nor your insurance provider will be responsible for any charges associated with procedures performed for purposes of this research study.

9. WILL I BE PAID IF I TAKE PART IN THIS RESEARCH STUDY?

A one-time gift card of $25 will be given to you upon completion of your participation in this study. If you are in group 1 or 2, you will complete your participation at the end of a month of intervention and follow up (total of three visits). If you are in the control group, you will come for total of five visits within 2 months period for completion of your participation.

10. WILL STUDY STAFF RECEIVE PAYMENT?

Investigators conducting this research won't receive any payment for performing evaluation and/or therapy pertinent to this study.

Linking Physical Therapy Outcome Measures to the International Classification of Function after Triangular Fibrocartilage Injuries and Ulnar Wrist Pain

11. RESEARCH RELATED INJURY:

To report any injury related to participation in the study, you should call the principal investigator, Dr. Everett Lohman at (909) 558-83171, during daytime hours (8:00 am- 5:00 pm PST). If you require medical assistance, your personal physician or local emergency room should be contacted. If you experience any undue stress or discomfort, or injury occurred, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare.

12. WHO DO I CALL IF I HAVE QUESTIONS?/ IMPARTIAL THIRD PARTY

If you wish to contact an impartial third party not associated with this study regarding questions about your rights pertinent to this study, or to report a complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, (909) 558-4647, or e-mail patientrelations@llu.edu for information and assistance.

13. SUBJECT'S STATEMENT OF CONSENT

I have read the contents of the consent form and have listened to the verbal explanation provided by the investigators. My questions concerning this study have been answered to my satisfaction. I have been given a copy of the consent form. Signing this consent document does not waive my rights nor does it release the investigators, institution, or sponsors from their responsibilities associated with the study. I have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me. I may call and leave a voice message for the principal investigator, Dr. Everett Lohman, during routine office hours at (909) 558 83171 or e-mail him at elohman@llu.edu, if I have additional questions or concerns.

Linking Physical Therapy Outcome Measures to the International Classification of Function after Triangular Fibrocartilage Injuries and Ulnar Wrist Pain

I hereby give voluntary consent to participate in this study. By signing this form I agree to participate in this research study.

Signature of Subject

Printed Name of Subject

Date

14. INVESTIGATOR'S STATEMENT

I have reviewed the contents of the consent form with the person signing above. I attest that the requirements for informed consent for the medical research project described in this form have been satisfied- that the subject has been provided with a copy of the California Experimental Subject's Bill of Rights, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered. I will provide the subject with a signed and dated copy of this consent form.

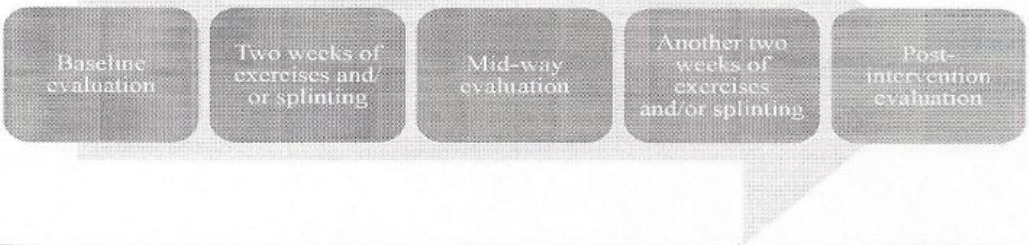
Signature of Investigator

Printed Name of Investigator

Date

Linking Physical Therapy Outcome Measures to the International Classification of Function after Triangular Fibrocartilage Injuries and Ulnar Wrist Pain

Attachment 1: Study Flow Chart:



Days/ visits / Tasks	Day 1 Visit 1	Day 14 Visit 2	Day 30 Visit 3
Informed consent	×		
Baseline evaluation	×		
Mid-way evaluation		×	
Post-intervention evaluation			×
History	×		
Pain and function questionnaire	×	×	×
Quality of life questionnaire	×	×	×
Grip strength measurement	×	×	×
Range of motion measurement	×	×	×
Screening with ultrasound	×		×
Prescription of exercises	×		
Application of splint	×		
Follow up		×	×
Global Rating of Change scale			×

APPENDIX F

AUTHORIZATION FOR USE PROTECTED HEALTH INFORMATION

INSTITUTIONAL REVIEW BOARD
Authorization for Use of
Protected Health Information (PHI)
Per 45 CFR §164.508(b)
RESEARCH PROTECTION PROGRAMS
LOMA LINDA UNIVERSITY | Office of the Vice President of Research Affairs
24887 Taylor Street, Suite 202 Loma Linda, CA 92350
(909) 558-4531 (voice) / (909) 558-0131 (fax)/e-mail: irb@llu.edu

TITLE OF STUDY:	"LINKING PHYSICAL THERAPY OUTCOME MEASURES TO THE INTERNATIONAL CLASSIFICATION OF FUNCTION AFTER TRIANGULAR FIBROCARTILAGE INJURIES AND ULNAR WRIST PAIN"
PRINCIPAL INVESTIGATOR:	Everett B. Lohman III, DSc, PT, OCS.
Others who will use, collect, or share PHI:	Mohamed Abdelmegeed, PT, MSc, DSc-c

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: Name, gender, address, diagnosis, telephone number, and date of birth. This information will be obtained with your permission from your physician.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not be required to follow national and international "protected health information" (PHI) regulations such as the federal privacy rule.

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Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

- This authorization does not expire, and will continue indefinitely unless you notify the researchers that you wish to revoke it.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at 909-583-4966.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient *or* Patient's Legal Representative	Date
Printed Name of Legal Representative (if any)	Representative's Authority to Act for Patient
Signature of Investigator Obtaining Authorization	Date

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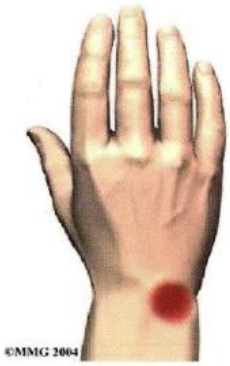
IRB 1/23/2013

APPENDIX G

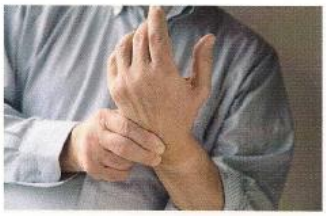
FLYER FOR RECRUITING PARTICIPANTS

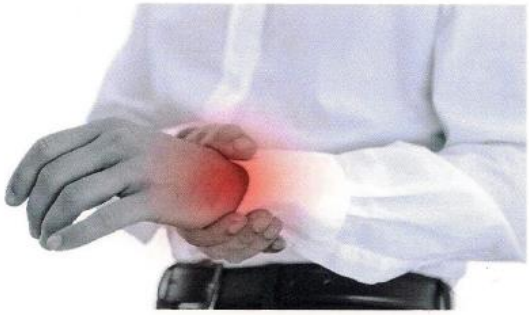


LOMA LINDA UNIVERSITY

School of Allied Health Professions

Research Opportunity





"LINKING PHYSICAL THERAPY OUTCOME MEASURES TO THE INTERNATIONAL CLASSIFICATION OF FUNCTION AFTER TRIANGULAR FIBROCARTILAGE INJURIES AND ULNAR WRIST PAIN"

The Department of Physical Therapy of the School of Allied Health Profession, Loma Linda University is conducting a research study examining the effect of physical therapy on subjects with ulnar (medial) wrist pain.

PARTICIPANTS ARE NEEDED

You may qualify to participate in this study if:

- You have pain at the medial (ulnar) side of your wrist.
- Your age is between 18-50

If you are eligible to participate, you will be evaluated at baseline, two weeks, and four weeks of the intervention. You will be screened at baseline for sources of your pain and then you will receive treatment for your condition assigned by study's investigators

Neither you nor your health insurance provider will be charged for the cost of any evaluation or treatment provided for the purposes of this study. After completing the intervention, you will receive a gift card as an expression of our thanks for your participation

If you are interested to participate or would like to know more about the study, please contact **Mohamed Abdelmegeed** at **909-583-4966** or email at **mabdelmegeed@llu.edu**

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APPENDIX H

PHONE SCRIPT FOR SUBJECTS' REFERRAL

Phone Script for Subjects' Recruitment

- Hello. My name is Mohamed Abdelmegeed. I am a doctor of science, physical therapy student at Loma Linda University. May I speak to (name of the eligible participant)?
- Your name has been given to me by your physician _____
- I would like to tell you about our research study that will be conducted by the physical therapy department of Loma Linda University
- Would it be convenient for me to talk to you about this study right now? (If not, I will set time for re-call)
- The purpose of this study is to investigate the effect of strengthening exercises and splinting in subjects with medial wrist pain.
- You are being invited to participate in our study based on your eligibility of having been diagnosed with ulnar wrist pain, and your age is between 18-50 years
- If you agree to participate in this research study, as part of your scheduled research visit, you will undergo a baseline evaluation which will include the measurement of your pain severity, functional level, grip strength, wrist joint range of motion, and overall quality of life. You will be also screened for the source of your pain with ultrasonography imaging with no harm to you. You will be then randomly assigned into one of three groups for intervention for four weeks. Group 1 will receive splinting, group 2 will receive splinting combined with home-based strengthening exercises. Group 3 will serve as control in the first month and will receive splinting and home-based strengthening exercises after the first month of intervention for four weeks.
- You will be given a detailed instructions for home-based strengthening exercise, and wearing time for splinting. A third group will be a control and will receive no treatment

for the first four weeks, however, if you are in this group, you will get treatment for your condition after the post intervention evaluation is conducted by the end of the fourth week of your participation

- Three evaluations will be performed throughout the study; baseline, two weeks, and four weeks after the start of the therapy. Each evaluation session will take approximately 30-45 minutes of your time
- By the end of your participation, you will receive a $25 gift card. If you are in group 1 or 2, you will complete your participation at the end of a month of intervention and follow up (total of three visits). If you are in the control group, you will come for total of five visits within 2 months period for completion of your participation.
- Your participation in this study yields no to minimal risk to you. General adverse effects can result from improperly performing exercises and/or wearing splints. Over doing or improperly performing exercises can result in increased pain and/or discomfort. Improper splint fitting can result in localized skin irritation, discomfort, limitation of movement. We will closely monitor you to make sure that everything is correct and comfortable to you.
- Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law
- You will not directly benefit from the study. Data obtained from this study will serve to establish a treatment consensus and a clinical decision making for those with ulnar wrist pain.
- Do you have any questions?

- Would you like to participate in our study? If yes, is it convenient to schedule an appointment for baseline evaluation?
- You can contact the study's principal investigator Dr. Everett Lohman during regular office hours at (909)558- 83171 or email him at elohman@llu.edu
- Participation in this study is voluntary. Your decision whether or not to participate or deciding to terminate your participation at any time will not affect the quality of care you receive. Moreover, you can receive splinting and strengthening exercises to treat symptoms associated with ulnar wrist pain anywhere else outside this research study
- If you would like to contact me, don't hesitate to call my cellphone number (909)5834966 or email me at mabdelmegeed@llu.edu
- Thank you for your time.

APPENDIX I

LETTER FOR SUBJECTS' REFERRAL

LOMA LINDA UNIVERSITY
School of Allied Health Professions

Letter for Patient Referral

Dr._____;

My name is Everett Lohman, DSC, PT, OCS. I am a faculty at the Department of Physical Therapy School of Allied Health, Loma Linda University. My DSC graduate student, Mohamed Abdelmegeed and I are conducting a research study on subjects with ulnar-sided wrist pain. The purpose of this study is to investigate the effect of physical therapy, specifically, splinting and strengthening exercises on subjects with ulnar wrist pain due to either triangular fibrocartilage injuries, Lunotriquetral ligament, and/or extensor carpi ulnaris tendon injuries. Our inclusion criteria included subjects diagnosed with ulnar wrist pain due to the aforementioned causes, and age between 18-50 years.

If you have subjects who you feel would qualify for or may benefit from participation in our study, we would appreciate it if you would inform them about our study and check if they are interested in learning more about it. If the patient expresses interest, we will contact them with details about the study. However we need the patient's permission to do so. Thus, we would appreciate if you provide him/her with enclosed Authorization for Use of Protected Health Information (PHI) form to read and sign. This form will allow his or her name, diagnosis, phone number (home, cellular), date of birth, and gender to be forwarded to the study investigator. After the form is signed please contact Mohamed Abdelmegeed, PT, MsPT at (909)583-4966 or email at mabdelmegeed@llu.edu to arrange for initial visit, to obtain the signed PHI form, and relevant patient information form.

Thank you for referring subjects for participation in our study.

Sincerely,

Everett Lohman, DSC, PT, OCS.

24951 North Circle Drive, Nichol Hall

Loma Linda, CA 92350

Phone: (909) 558 Ext 83171

E- mail: elohman@llu.edu