12-17-2012 12:00 AM

Properties and Applications of Sensory Outcome Measures in Carpal Tunnel Syndrome

Derek KM Cheung
The University of Western Ontario

Supervisor
Dr. Joy C MacDermid
The University of Western Ontario

Graduate Program in Health and Rehabilitation Sciences
A thesis submitted in partial fulfillment of the requirements for the degree in Master of Science

PROPERTIES AND APPLICATIONS OF SENSORY OUTCOME MEASURES IN CARPAL TUNNEL SYNDROME

(Spine title: Properties of Sensory Outcome Measures in CTS)

(Thesis format: Integrated Article)

by

Derek Ka Ming Cheung

Graduate Program in Health and Rehabilitation Science (Physical Therapy)

A thesis submitted in partial fulfillment
of the requirements for the degree of
Degree Masters of Science

The School of Graduate and Postdoctoral Studies
The University of Western Ontario
London, Ontario, Canada

THE UNIVERSITY OF WESTERN ONTARIO
School of Graduate and Postdoctoral Studies

CERTIFICATE OF EXAMINATION

Supervisor

Dr. Joy C. MacDermid

Supervisory Committee

Dr. Ruby Grewal

Dr. Dave Walton

Examiners

Dr. Dave Walton

Dr. Trevor Birmingham

Professor Dave Humphreys

The thesis by

Derek Ka Ming Cheung

entitled:

PROPERTIES AND APPLICATIONS OF SENSORY OUTCOME MEASURES IN CARPAL TUNNEL SYNDROME

is accepted in partial fulfillment of the
requirements for the degree of
«Master's of Health and Rehabilitation Science (Physical Therapy)»

Date

Chair of the Thesis Examination Board

Abstract

This thesis aimed to determine the psychometric properties and applications of sensory threshold tools and outcome measures in patients with Carpal Tunnel Syndrome (CTS). The first chapter is a psychometric study that defines clinically important difference (CID), construct validity and responsiveness of touch and vibration threshold tools and in the Symptoms Severity Scale (SSS). The study found the CID for the Pressure Specified Sensory Device (PSSD) and for the SSS was $0.15 g/mm^2$ and 0.50 respectively. The study also found that the Vibrometer was more representative of hand function and responsive compared PSSD. The second objective of this thesis was to determine the feasibility of recruiting patients with CTS to test the effects of cell phone texting on sensory and functional outcome measures. The recruitment rate was 73% and touch threshold was most influenced by texting for patients. Further research is required on the process of clinical decision making based on sensory tool evaluations.

Keywords

Carpal Tunnel Syndrome, sensation, Clinical Important Difference (CID), construct validity, responsiveness, feasibility, cell phone.

Co-Authorship Statement

I am the primary author of this thesis. I completed the development of the research topics, development of protocol, completion of ethics forms, data collection, writing of this thesis, and revisions of this thesis. My supervisor, Dr. Joy MacDermid, has provided substantial guidance in the development of the research topics, development of protocols, ethics submission process, guidance in data collection, provided the necessary equipment for data collection, and support in revisions of this thesis.

Advisory Committee:

Dr. Ruby Grewal provided assistance in protocol development, guidance in data collection, referral of patients for the second part of the thesis, ethics submission, revisions of the thesis, and practical guidance.

Dr. Dave Walton provided assistance in protocol development and guidance in scientific writing.

.

Acknowledgments

I feel blessed to have such a strong research team behind me through this Master's experience. It has been very rewarding experience to guide me in my career path! I would like to thank my supervisor Dr. Joy MacDermid for her guidance and wisdom for this Master's thesis. Her expertise and dedication has made this Master's experience worthwhile. I would like to thank Dr. Ruby Grewal for providing a patient population for this study and her expertise/mentorship during patient recruitment for my research. I'd like to thank Dr. Dave Walton for his guidance through developing this thesis. Special thanks to Kate Kelly, Chris Young, Kristie Millman and my lab mates for their instrumental and technical support throughout my data collection period and work on side projects. Thank you to Dr. Douglas Ross and Dr. Bing Gan for providing a patient population for my thesis. As well, a special acknowledgment goes to Linda Shanahan, Susan Malecki, and Nancy Bowes for coordinating patient recruitment. Thanks to Dr. Andrew Johnson who has provided assistance with clarifying statistical concepts. Thanks to George Kramer from Wheelsbridge for his technical support with TIVI. Thanks to Lynn Stewart for helping with recruiting healthy controls. I would like to thank my lab mates Siamak, Shaguftha, Vanitha, and Joshua during the pilot testing phase of the TIVI equipment used in Chapter 3. I'd like to thank Chandni and Emily for their assistance in formatting the final thesis. I'd like to also thank Raja (co-op student) for his assistance during pilot testing for equipment in Chapter 3. Thanks to the staff at the hand therapy department for sharing valuable clinical information. Thanks to Ellen (librarian) for helping to find archived resources for my thesis. Thanks to the patients and people who volunteered their time to be part of my study. I hope you enjoyed the Tim Horton gift cards! Lastly I'd like to thank my parents, my family, and my friends for their consistent support during my studies. God bless.

Table of Contents

CERTIFICATE OF EXAMINATION ii

Co-Authorship Statement iv

Acknowledgments v

Table of Contents vi

List of Tables x

List of Figures xi

Chapter 1 1

1 Background 1

1.1 Epidemiology 2

1.2 Clinical Presentation of CTS 3

1.3 Treatment 5

1.4 Clinical Outcome Measures and Properties 5

Pressure specified sensory device (PSSD). 5

The Vibrometer. 6

Symptom severity scale (SSS). 7

1.5 Changes to Blood Flow 8

1.6 Applications of Sensory Tools in Hand Activity: Cell Phone Use 8

1.7 Summary of Limitations in Current Knowledge 9

1.8 Purpose of this Thesis 10

1.9 Thesis Overview 10

1.10 References 12

Chapter 2 20

2 The Construct Validity, Clinically Important Differences, and Responsiveness of Symptom Severity Scores, and Sensory Tests in Patients with Carpal Tunnel Syndrome.....20

2.1 Introduction..... 21

2.2 Methods..... 23

Sample size justification. 24

2.3 Outcome measures. 24

Pressure specified sensory device (PSSD). 24

The vibrometer. 24

The symptom severity scale (SSS). 25

Disability of the arm, shoulder, and hand (DASH) questionnaire. 25

NK dexterity small objects test. 25

2.4 Procedure 26

2.5 Analysis..... 26

Cross-sectional convergent validity..... 27

Calculating clinically important difference (CID) for SSS..... 27

Calculating clinically important difference (CID) for the vibrometer and PSSD. 28

Responsiveness. 28

2.6 Results..... 29

2.7 Discussion..... 39

2.8 Conclusion 43

2.9 References..... 44

Chapter 3..... 53

3 A Pilot Study to Determine the Effect of Cell Phone Texting on Patients with Carpal Tunnel Syndrome (CTS)..... 53

3.1 Introduction..... 54

3.2 Hypotheses:..... 55

3.3 Materials and Methods:..... 56

3.4 Outcome Measures: 57

TIVI (Tissue Viability Imaging) 600 polarization spectroscopy camera (version 7.4 Wheelsbridge AB, Linköping, Sweden):..... 57

Pressure Specified Sensory Device (PSSD) (NK Biotechnical Corporation, Minneapolis, MN, USA):..... 59

Numeric Rating Scale for Pain: 59

Numeric Rating Scale for Numbness:..... 59

Numeric Rating Scale for Fatigue: 60

Symptom Severity Scale (SSS):..... 60

Texting Performance:..... 61

3.5 Procedure: 61

3.6 Intervention:..... 62

3.7 Analysis: 63

Objective 1: Sample Size Calculation for Feasibility Study..... 63

Objective 2 and 3: Determining Differences within and between Patients and Healthy Controls..... 64

3.8 Results:..... 64

Objective 1: Feasibility of the Research Study..... 64

Objective 2:..... 66

Superficial Red Blood Cell Concentration. 66

Touch Threshold 67

Pain. 68

Numbness..... 68

Fatigue69

Objective 3: Performance differences between Patients and Controls. 69

3.9 Discussion 84

3.10 Conclusion and Implications: 89

3.11 References 90

4 Overview of this Thesis 97

4.1 What is Already Known on This Topic 97

4.2 What This Thesis Adds to Our Knowledge Base 98

4.3 Implications 98

4.4 Limitations 99

4.5 Future Research Directions and Recommendations 99

4.6 Recommendations and Future Research Directions for Pilot Studies: 99

4.7 References 101

List of Tables

Table 1.1: Categories of Nerve Injury Classification 3

Table 2.1: Demographic information of patients 31

WSIB = Workplace Safety Insurance Board Table **2.2: Baseline descriptive data** 31

Table 2.3: Spearman correlation between sensory and symptoms severity scores and their functional measures 33

Table 2.4: Information on the ROC curves produced 34

Table 2.5: Change scores for the SSS and responsiveness based on proceeding to surgery 35

Table 2.6: Responsiveness for the PSSD, and vibrometer based on CID of change score SSS = 0.5 36

Table 3.1: Cell Phone Specification 63

Table 3.2: Descriptive Data of Outcome Measures for Measuring Effects of Texting 73

Table 3.3: Descriptive Data of Texting Performance 74

Table 3.4: Comparison of Sample Sizes Required for a Full Study 81

Table 3.5: Comparison of Exclusion Criteria, Sample Size, and Outcome Measures for Pilot and Full Study 83

List of Figures

2.1: Receiver Operating Characteristic Curve for Determining the Cut-off Point to Determine Responder and Non Responder Subgroups Based on the SSS 37

Figure 2.2: Receiver Operating Characteristic Curve for Determining the Cut-off Point to Determine a Clinical Important Change for the PSSD based on the CID of 0.5 for the SSS..... 38

Figure 3.1: Flow Chart Detailing the Recruitment of Patient Participants 75

Figure 3.2: Changes in Red Blood Cell Concentration in Patients over Time 76

Figure 3.3: Changes in PSSD over Time for Patients and Controls 77

Figure 3.4: Changes over time with Pain..... 78

Figure 3.5 Changes over time with Numbness 79

Figure 3.6: Change over Time with Fatigue 80

Appendix A 1

Appendix A 2 – Screen Tool for Chapter 3 103

Appendix A 3 – Numeric Rating Scale for Pain, Fatigue, and Numbness 106

Appendix A 4 – Script 109

Appendix A 5 - Symptom Severity Scale 117

Appendix A 6: DASH questionnaire 119

Appendix A 7 Ethics Approval Forms..... 124

Chapter 1

1 Background

Carpal Tunnel Syndrome (CTS) is one of the most common neuropathies to the upper extremity. In general, the presenting symptoms associated to CTS are the result of the compression of the median nerve beneath the transverse retinaculum. [1] Common signs and symptoms in diagnosed CTS are: numbness, tingling, and pain in the hand, and nocturnal symptoms. [2] The cause of CTS is controversial, as it can be caused by a multitude of physiological changes to the nerve, surrounding structures within the carpal tunnel structure, or vascular changes. Some reasons for the cause of CTS include: edema causing increase pressure within the carpal tunnel, [1] fibrosis, [1] or the entrapment of blood resulting in ischemia by surrounding tissue. [3] Chronic compression of the nerve has been thought to result in decreased blood flow to large fibers and result in demyelination. [4] One of the common symptoms to CTS are sensory changes, and in the ability for patients to perceive specific stimuli, particularly touch and vibration threshold.

Vibration threshold changes occur early in neuropathy, while pressure thresholds tend to change in later stages of CTS. [5] Sensory recovery is an important part of the rehabilitation process for patients with CTS. During the evaluative process of patients with CTS, it is important that sensory tools provide useful information to inform clinicians on the status of the patients' sensory recovery and to make decisions [6]on whether to proceed with different treatment or to end treatment. Tools should be validated for construct validity, [6] be responsive to treatment, [6] and have a defined clinically important difference.

Furthermore, beyond clinical use, the application of sensory tools could be used in testing novel day to day activities which patients may come across. It is possible that specific activities may alter sensation and aggravate symptoms patients currently experience. With these concepts in mind, this thesis is intended to explore the psychometric properties and specific applications of sensory tools and outcome measures. We will briefly summarize the epidemiology, clinical background on sensory changes, properties

of the Pressure Specified Sensory Device (PSSD) and Vibrometer, summary of limitations in current literature, and an overview of the objectives for this thesis.

1.1 Epidemiology

Within the province of Ontario in Canada, CTS occurred at rate of 29 out of 100,000 workers in 1997. [7] More than half of the persons affected are women (54%) and generally occur between 35- 54 years of age. [7, 8] In 1997, the injury was highest among the textile, fur and leathers, machine operation, and transportation. [7] In the United States of America, occupational surveys from data in 2010 reported that the lifetime prevalence of clinician diagnosed CTS was 6.7% of the population. [9]

The risk factors or potential causes of CTS within workplaces have been studied extensively. Potential reasons for the cause of CTS are: nature of the job demands, gender differences, elevated body mass index, [10] medical history (previous fracture or mechanical neck problem), [10] individual characteristics (caffeine consumption and diabetes). [11, 12] For professions requiring highly repetitive movement involving awkward postures of the upper extremity, mechanical pressure on finger tips, and twisting of the wrist have been documented to have a higher risk of workers developing CTS than jobs not requiring such tasks[13]. Other reasons that may cause CTS are pregnancy [14-19] and recent injury to the upper extremity. [20] Recent injury to the upper extremity may cause carpal tunnel syndrome because of potential impingement of the median nerve in cases with distal radius fractures. [20] There is controversy about the extent to which CTS is work-related or a result of genetic factors, and how these are reflected in health conditions with co-morbidities.

1.2 Clinical Presentation of CTS

When nerve injury occurs, there is first intermittent paraesthesia that is experienced. [21] As neuropathy progresses, patients experience constant paraesthesia, and weakness in the hand. [21] In late stages, there is numbness and potential paralysis in the hand. [21] Sensation is altered and an increase in touch and vibration threshold occurs during early stages of nerve injury. [4] There are five classes of nerve injury, where the severity is rated from 1 to 5. Carpal tunnel syndrome is a compression neuropathy that crosses categories 1 to 3 because categories 4 and 5 involve transection of the nerve (Table 1). [4, 5, 22] Each category of CTS presents itself with different presentation of alterations to sensation from physiological changes to the median nerve and associated structures (motor and sensory) to the median nerve.

Table 1.1: Categories of Nerve Injury Classification

	Neuropraxia	**Axonotmesis**	
Sunderland Categories of Nerve Injury Classification and Presentation	Category 1 (early stage of CTS): Conduction block, Axon remained normal. Initial sensation of parathesia. Focal demyelination	Category 2 – axon loss. Intact endoneurium. Wallerian degeneration of distal nerver and myelin sheath.	Category 3 (late stage CTS) – loss of continuity of axons and endoneurium. Perineurium intact. Wallerian degeneration At distal end. Endoneural scarring. Chance of recovery dependent on content in fascicles.

	Mild	**Moderate**	**Severe**
Symptomology [4, 22, 23]	Mild symptoms of tingling, pain, and numbness Mainly nocturnal symptoms Day symptoms – wrist in flexed position at 1min No abnormal findings +/- Tinel and Phalen's	Persistent symptoms Decreased tactile sensation Loss of dexterity Weak grip and pinch Symptoms increase at night Burning pain, swelling or tightness in hand Varied degree of thenar weakness/atrophy Skin changes Decreased protective sensation Greater 2PD values Definite +ve Tinel's and Phalen's Decreased nerve conduction on EMG	Prolonged neuropraxia Marked by decreased 2PD Decreased tactile gnosis Impaired dexterity and function Weakness of 2 lumbricals and thenar muscles. Atrophic skin changes +/- Tinel's and Phalen's Severely decreased nerve conduction on EMG

PD = point discrimination. EMG = Electromyography

Categories 4 and 5 of Sunderland Categories of Nerve Injury Classification do not represent CTS because they involve complete transaction of the nerve. Nerve transection is not a characteristic of CTS.

1.3 Treatment

The initial treatment process of non severe cases of CTS usually involves non surgical treatment, often involving orthotic intervention (splinting). [24] If orthotic intervention fails, surgery is the next level of treatment. [25] The decision to proceed to surgery is based on patient's concerns, and/or based on the clinician's decision from a number of clinical outcome measures. The clinician's decision to send a patient on towards surgery or to end treatment is based on whether the changes in outcome measures from follow up appointment presented a clinically important difference. Ozyurekoglu et al [26]calculated the minimal clinically important difference (MCID) for the Symptom Severity Scale (SSS) in a group of patients with CTS after conservative treatment with steroid injection. They found that the MCID was 1.04 on the SSS. [26] However, we are unaware from previous literature on the clinically important difference for orthotic intervention. Likewise, clinicians use a battery of sensory tests, such as touch threshold and vibration threshold, to evaluate sensory threshold. We are uncertain of previous literature which has documented the clinically important difference of the SSS and sensory threshold tools after orthotic intervention. A study is needed to address this gap in literature.

1.4 Clinical Outcome Measures and Properties

Pressure specified sensory device (PSSD). The Pressure Specified Sensory Device (PSSD) is a sensory threshold tool used commonly within research settings. The PSSD can measure static one point (1PS), static two point (2PS), moving one point discrimination (1PM), and moving two point discrimination (2PM). The purpose of these tests are to measure cutaneous pressure threshold on the surface of skin to detect pressure (1 point testing) and to discriminate one prong from two prongs (2 point testing), targeting sensory receptors for measuring

both static and dynamic stimuli. [27] The PSSD has demonstrated construct validity in relation to the nerve conduction studies, [28, 29] with object identification with 2PD, [30] and valid to be used for groups with neuropathy caused by diabetes. [31] The PSSD has shown to be a reliable tool, [27] and shows expected physiological relationships between pressure threshold and the distance between stimuli. [32] Although there are many sensory tools, the PSSD cannot be compared to other measurement tools for sensation, such as Semmes Weinstein monofilament (SWMF) because poor correlations have been shown between the two tools (r = 0.21 - .29). [33] Thus, previous psychometric properties determined for the SWMF should not be used as evidence to support the PSSD, although they both measure the construct of touch threshold, 1 point and 2 point testing for both static and dynamic. The PSSD has been extensively studied using 2 point discrimination, [30] but 1 point static testing has not been validated for construct validity in relation to symptom severity, self reported hand function, and dexterity for patients with CTS. The PSSD values have been shown to significantly change after carpal tunnel release, [34] but a study on responsiveness of the PSSD has not been examined. Quantifying the responsiveness would allow the responsiveness of the PSSD to be compared to other sensory measures. An examination of the psychometric properties would be required to justify the utility of touch threshold testing with 1 point of the PSSD in patients with CTS.

The Vibrometer**.** The Vibrometer measures vibration threshold or the minimum amount of stimulus that is required to elicit a response (with the vibration amplitude usually measured in micrometers (um). The Vibrometer is commonly used for diagnostic purposes to detect for impairments to the peripheral nerve [35, 36] because the fibers responsible for detecting vibration threshold are affected early during neuropathy. [4] The Vibrometer has been found to have low construct validity with nerve conduction studies, [35, 37-40] but mixed findings on whether it is more sensitive to detect neuropathy compared to standard nerve conduction testing. [37] The Vibrometer has demonstrated moderate correlation with dexterity testing (r = -0.62). [30] The tool has also been found to be reliable. [41, 42] However,

the construct validity of the tool has not been assessed in relation to self reported measures of function and symptom severity. There is a disproportional amount of research focus on relating performance based tools (i.e. electromyography) to represent function, rather than determining the association of vibration threshold to the symptoms (for example, pain or numbness) that patients experience. An examination of self reported symptoms in relation to vibration threshold would allow clinicians to make more informed decisions by understanding how vibration threshold is associated to patients' hand function. In addition, there is no clear cut point to indicate a clinically important difference for the Vibrometer for evaluating patients with CTS who undergo orthotic intervention to determine whether they should continue to proceed with surgery or to end treatment.

Symptom severity scale (SSS). The Symptom Severity Scale (SSS) is a questionnaire with 11 questions [43, 44] specifically designed to assess the symptom severity experienced by patients with CTS. [43] The tool has demonstrated construct validity, [43] and reliability. [43, 45] The SSS has also been shown to be responsive after treatment for surgery, [44, 46-48] and after steroid injection. [26] The minimal clinically important difference has been demonstrated for surgery, [48] and after steroid injection. [26] However, the cut point for clinically important difference is for the SSS after orthotic intervention has not been established. The clinically important difference may help clinicians discriminate whether patients should proceed to surgery or not after orthotic intervention. When testing for clinical properties of sensory tools, in theory, the SSS should demonstrate a correlation with overall hand function and dexterity. However, previous research has not shown the association between the SSS to other measures of hand function. It is not clear how symptoms are correlated to hand function. A psychometric study should be performed to establish the cut point for the clinically important difference and the construct validity of the SSS in relation to self reported measures of hand function.

1.5 Changes to Blood Flow

In a patient affected with CTS, there is a breakdown of the blood nerve barrier of the median nerve from elevated pressure, resulting in inflammation within the tissue. [49] Previous research has found that patients have impaired control of blood flow. [50-55] Previous in-lab and clinical testing has found that the sympathetic response is slower and recovery is delayed before and after exercise in patients with CTS. [50-55] Patients with CTS have also been shown to have slower blood flow velocities compared to people without CTS. [50, 52, 53] One study indicated that blood flow was faster in patients with CTS compared to healthy participants. [52] These previous studies [50, 52, 53] have utilized Doppler system and thermography to measure vascular performance in patients with CTS.

However, one of the limitations of these tools is that they cannot measure red blood cell concentration specifically at one instantaneous point time, and can only measure blood flow. Focusing on an instantaneous red blood cell concentration would be advantageous to describe the influence of CTS on blood circulation in areas where sensation is altered. In addition, we can see how specific activities with the hand would influence blood flow. This information would be useful for understanding how blood circulation is affected by CTS.

1.6 Applications of Sensory Tools in Hand Activity: Cell Phone Use

Cell phone texting is an increasingly popular method of communication,[56] and research describing the physiological changes from texting is fairly novel among different populations. Most research on describing physiological changes from cell phone texting [57-59]has primarily focused on university student populations with and without musculoskeletal symptoms. Gustafsson et al [57] found that subjects with musculoskeletal symptoms had lower muscle activity in the thumbs but higher activity in the trapezius compared to those participants without symptoms. [57] In a preliminary study, Lin and Peper [58] found that texting increases respiratory rate, heart rate, and self reported stress levels. [58] Research studies have also suggested that cell phone texting may result in pain experienced on the upper extremity. [59] To our knowledge, no research has examined the

effect of cell phone texting on a patient population with clinically diagnosed CTS. Postures, motions, and forces obtained during cell phone texting by patients with CTS may result in an increase in sensory thresholds, altered blood flow, and aggravated symptoms. Understanding the sensory, vascular, and symptomatic changes that may occur with texting might allow clinicians or ergonomists to understand the impact of texting on clinical outcome measures in a patient population with CTS. The first stage of research should be to determine the immediate impact of texting in patients and in age matched controls to determine if there are immediate changes in physiological function in responses to clinical tools. The findings from this pilot study would inform the feasibility of completing a larger future study on the long-term effects of texting. A feasibility study should be performed to determine the influence of texting on clinical outcome measures in patients with CTS on this novel topic.

1.7 Summary of Limitations in Current Knowledge

Sensory evaluation is an important part of the treatment process to evaluate the severity of CTS that patients have. It is important that tools can discriminate patients with CTS who have undergone treatment and to determine the next step in the treatment process, specifically whether patients with CTS going through orthotic intervention should continue towards surgery or not. It would be equally important to know the responsiveness of sensory tools and construct validity of sensory tools to determine which sensory tools are more representative of hand function. However, we could not locate these psychometric properties in previous literature on the PSSD and the Vibrometer. In addition, the application of sensory tools to measure sensory and functional changes in patients with CTS under conditions after newly emerging hand activity, such as texting on a cell phone. These findings would provide insight into how patient populations are affected by texting activity and their performance are impacted by CTS.

1.8 Purpose of this Thesis

The central question of this thesis was to determine the physiological response to (potentially risky) exposures and intervention in patients with CTS and its potential impact on sensory improvement.

This thesis attempted to identify the following objectives in patients with CTS:

- The psychometric properties of two sensory threshold devices (the Pressure Specified Sensory Device (PSSD) and Vibrometer), and the Symptom Severity Scale (SSS), in terms of the clinically important difference, construct validity to functional outcome measures, and responsiveness after orthotic intervention

- The potential differences in sensory measures and outcome measures between patients and healthy individuals after texting on a cell phone through a pilot study

1.9 Thesis Overview

This thesis is composed of 2 manuscripts. The first manuscript is located in Chapter 2 and the second manuscript is located in Chapter 3.

The aim of the manuscript in Chapter 2 was to determine a number of the psychometric properties of the Pressure Specified Sensory Device (PSSD), the Vibrometer and the Symptom Severity Scale (SSS). Specifically, the primary objective of this study was to determine the CID of the sensory tools and in the SSS to discriminate patients who were successfully treated with orthotic intervention and patients who needed to proceed further with surgery. The secondary objective of this study was to determine the construct validity and responsiveness of sensory threshold tools and in the SSS. This study was able to identify differences in properties between the PSSD and the Vibrometer, suggest rational for these properties, and which tool would be more useful in discriminating patients with CTS after orthotic intervention and representative of overall hand function.

Chapter 3 was dedicated to determining the feasibility of recruiting patients with CTS, and to describe the effects of cell phone texting on their touch threshold, superficial blood flow, and self reported symptom ratings. The objective of the study was to determine differences between a group of patients with CTS to an age-and-gender matched control group. We determined that a full study to determine the effects of cell phone texting was feasible to perform over the recruitment period and a full study could be completed in the future. We were able to identify factors which reduced the number of eligible patients in the study. We also found that patients experienced more symptoms throughout the study compared to age and gender matched controls and symptoms worsened from texting. Patients experienced a significant increased in touch threshold and fatigue compared to baseline levels after texting. Since studies the physiological effects of cell phone texting are limited, this study serves as an early effort to describe potential adverse effects of cell phone texting in a patient population with CTS and in healthy age and gender matched controls.

In summary, this thesis is intended to bridge specific gaps in literature behind the measurement properties of sensory tools for evaluating patients with CTS in clinical and non clinical environments.

1.10 References

1. Werner RA, Andary M. Carpal tunnel syndrome: pathophysiology and clinical neurophysiology. *Clinical Neurophysiology*. 2002;113:1373-1381.

2. Rempel D, Evanoff B, Amadio PC, et al. Consensus criteria for the classification of carpal tunnel syndrome in epidemiologic studies. *Am J Public Health*. 1998;88:1447.

3. Sunderland S. The nerve lesion in the carpal tunnel syndrome. *J Neurol Neurosurg Psychiatry*. 1976;39:615-626.

4. MacDermid JC, Wessel J. Clinical diagnosis of carpal tunnel syndrome: a systematic review. *Journal of Hand Therapy*. 2004;17:309-319.

5. Maggi SP, Lowe 3rd J, Mackinnon SE. Pathophysiology of nerve injury. *Clin Plast Surg*. 2003;30:109.

6. Finch E, Dina. Brooks, Stratford PW. Physical rehabilitation outcome measures. . 2002.

7. Zakaria D. Rates of carpal tunnel syndrome, epicondylitis, and rotator cuff claims in Ontario workers during 1997. *Chronic Dis Can*. 2004;25:32-39.

8. Ibrahim T, Majid I, Clarke M, Kershaw CJ. Outcome of carpal tunnel decompression: The influence of age, gender, and occupation. *Int Orthop*. 2009;33:1305-1309.

9. Luckhaupt SE, Dahlhamer JM, Ward BW, Sweeney MH, Sestito JP, Calvert GM. Prevalence and work-relatedness of carpal tunnel syndrome in the working population, United States, 2010 national health interview survey. *Am J Ind Med*. 2012.

10. Ferry S, Hannaford P, Warskyj M, Lewis M, Croft P. Carpal tunnel syndrome: a nested case-control study of risk factors in women. *Am J Epidemiol*. 2000;151:566-574.

11. Atcheson SG, Ward JR, Lowe W. Concurrent medical disease in work-related carpal tunnel syndrome. *Arch Intern Med*. 1998;158:1506.

12. Nathan PA, Keniston RC, Lockwood RS, Meadows KD. Tobacco, caffeine, alcohol, and carpal tunnel syndrome in American industry: a cross-sectional study of 1464 workers. *Journal of occupational and environmental medicine*. 1996;38:290.

13. Burt S, Crombie K, Jin Y, Wurzelbacher S, Ramsey J, Deddens J. Workplace and individual risk factors for carpal tunnel syndrome. *Occup Environ Med*. 2011;68:928-933.

14. Jurjevic A, Bralic M, Antoncic I, Dunatov S, Legac M. Early onset of carpal tunnel syndrome during pregnancy: case report. *Acta Clin Croat*. 2010;49:77-80.

15. Padua L, Di Pasquale A, Pazzaglia C, Liotta GA, Librante A, Mondelli M. Systematic review of pregnancy-related carpal tunnel syndrome. *Muscle Nerve*. 2010;42:697-702.

16. Mondelli M, Rossi S, Monti E, et al. Long term follow-up of carpal tunnel syndrome during pregnancy: a cohort study and review of the literature. *Electromyogr Clin Neurophysiol*. 2007;47:259-271.

17. Tejerizo LC, Moro J, Sanchez MM, et al. Carpal tunnel syndrome in pregnancy. *Progresos en Obstetricia y Ginecologia*. 1999;42:659-668.

18. Ekman-Ordeberg G, Salgeback S, Ordeberg G. Carpal tunnel syndrome in pregnancy. A prospective study. *Acta Obstet Gynecol Scand*. 1987;66:233-235.

19. Seror P. Carpal tunnel syndrome during pregnancy. *J Gynecol Obstet Biol Reprod*. 1997;26:148-153.

20. Dyer G, Lozano-Calderon S, Gannon C, Baratz M, Ring D. Predictors of Acute Carpal Tunnel Syndrome Associated With Fracture of the Distal Radius. *J Hand Surg*. 2008;33:1309-1313.

21. Mackinnon SE. Pathophysiology of nerve compression. *Hand Clin*. 2002;18:231-241.

22. Berger RA, Weiss APC. Basic pathology of the hand, wrist, and forearm: Nerve. In: Mackinnon SE, Dvali L, eds. *Hand Surgery.* Vol 1. Lippincott Williams & Wilkins; 2004.

23. Dellon AL. *Evaluation of Sensibility and Re-Education of Sensation in the Hand.* Williams & Wilkins Baltimore; 1981.

24. Kaplan SJ, Glickel SZ, Eaton RG. Predictive factors in the non-surgical treatment of carpal tunnel syndrome. *J Hand Surg*. 1990;15 B:106-108.

25. Shi Q, MacDermid JC. Is surgical intervention more effective than non-surgical treatment for carpal tunnel syndrome? a systematic review. *Journal of orthopaedic surgery and research*. 2011;6:1-9.

26. Ozyurekoglu T, McCabe SJ, Goldsmith LJ, LaJoie AS. The minimal clinically important difference of the Carpal Tunnel Syndrome Symptom Severity Scale. *J Hand Surg Am*. 2006;31:733-8; discussion 739-40.

27. Dellon AL, Keller KM. Computer-assisted quantitative sensorimotor testing in patients with carpal and cubital tunnel syndromes. *Ann Plast Surg*. 1997;38:493.

28. Slutsky DJ. Use of nerve conduction studies and the pressure-specified sensory device in the diagnosis of carpal tunnel syndrome. *J Hand Surg Eur Vol*. 2009;34:60-65.

29. Tassler P, Dellon A. Correlation of measurements of pressure perception using the pressure-specified sensory device with electrodiagnostic testing. *Journal of Occupational and Environmental Medicine*. 1995;37:862.

30. Novak CB, Mackinnon SE, Kelly L. Correlation of two-point discrimination and hand function following median nerve injury. *Ann Plast Surg*. 1993;31:495.

31. Siemionow M, Zielinski M, Sari A. Comparison of clinical evaluation and neurosensory testing in the early diagnosis of superimposed entrapment neuropathy in diabetic patients. *Ann Plast Surg*. 2006;57:41.

32. Aszmann OC, Dellon AL. Relationship between cutaneous pressure threshold and two-point discrimination. *J Reconstr Microsurg*. 1998;14:417-421.

33. Dellon ES, Crone S, Mouery R, Dellon AL. Comparison of the Semmes-Weinstein monofilaments with the pressure-specifying sensory device. *Restorative Neurol Neurosci*. 1993;5:323-326.

34. Macdermid JC, Richards RS, Roth JH, Ross DC, King GJ. Endoscopic versus open carpal tunnel release: a randomized trial. *J Hand Surg Am*. 2003;28:475-480.

35. Cherniack MG, Moalli D, Viscolli C. A comparison of traditional electrodiagnostic studies, electroneurometry, and vibrometry in the diagnosis of carpal tunnel syndrome. *J Hand Surg Am*. 1996;21:122-131.

36. Dellon AL. The vibrometer. *Plast Reconstr Surg*. 1983;71:427.

37. Gerr F, Letz R, Harris-Abbott D, Hopkins LC. Sensitivity and specificity of vibrometry for detection of carpal tunnel syndrome. *Journal of occupational and environmental medicine*. 1995;37:1108.

38. Lundborg G, Lie-Stenstrom AK, Sollerman C, Stromberg T, Pyykko I. Digital vibrogram: a new diagnostic tool for sensory testing in compression neuropathy. *J Hand Surg Am*. 1986;11:693-699.

39. SZABO RM, Gelberman R, Dimick M. Sensibility testing in patients with carpal tunnel syndrome. *Journal of bone and joint surgery.American volume*. 1984;66:60-64.

40. Szabo RM, Gelberman RH, Dimick MP. Sensibility testing in patients with carpal tunnel syndrome. *J Bone Joint Surg Am*. 1984;66:60-64.

41. Hubbard MC, MacDermid JC, Kramer JF, Birmingham TB. Quantitative vibration threshold testing in carpal tunnel syndrome: analysis strategies for optimizing reliability. *J Hand Ther*. 2004;17:24-30.

42. Novak CB, Kelly L, Mackinnon SE. Sensory recovery after median nerve grafting. *J Hand Surg*. 1992;17:59-68.

43. Levine DW, Simmons BP, Koris M, et al. A self-administered questionnaire for the assessment of severity of symptoms and functional status in carpal tunnel syndrome. *JOURNAL OF BONE AND JOINT SURGERY-AMERICAN VOLUME-*. 1993;75:1585-1585.

44. Mondelli M, Ginanneschi F, Rossi S, Reale F, Padua L, Giannini F. Inter-observer reproducibility and responsiveness of a clinical severity scale in surgically treated carpal tunnel syndrome. *Acta Neurol Scand*. 2002;106:263-268.

45. Greenslade JR, Mehta RL, Belward P, Warwick DJ. Dash and boston questionnaire assessment of carpal tunnel syndrome outcome: What is the responsiveness of an outcome questionnaire? *J Hand Surg*. 2004;29 B:159-164.

46. Katz JN, Gelberman RH, Wright EA, Lew RA, Liang MH. Responsiveness of self-reported and objective measures of disease severity in carpal tunnel syndrome. *Med Care*. 1994;32:1127-1133.

47. Jerosch-Herold C, Shepstone L, Miller L, Chapman P. The responsiveness of sensibility and strength tests in patients undergoing carpal tunnel decompression. *BMC Musculoskeletal Disorders*. 2011;12:244.

48. Kim JK, Jeon SH. Minimal clinically important differences in the Carpal Tunnel Questionnaire after carpal tunnel release. *J Hand Surg Eur Vol*. 2012.

49. MacDermid JC, Doherty T. Clinical and electrodiagnostic testing of carpal tunnel syndrome: a narrative review. *J Orthop Sports Phys Ther*. 2004;34:565-588.

50. Galea LA, Mercieca A, Sciberras C, Gatt R, Schembri M. Evaluation of sympathetic vasomotor fibres in carpal tunnel syndrome using continuous wave Doppler ultrasonography. *J Hand Surg Br*. 2006;31:306-310.

51. Pritchard MH, Pugh N, Wright I, Brownlee M. A vascular basis for repetitive strain injury. *Rheumatology (Oxford)*. 1999;38:636-639.

52. Soejima O, Iida H, Naito M. Measurement of median nerve blood flow during carpal tunnel release with laser Doppler flowmetry. *Minim Invasive Neurosurg*. 2001;44:202-204.

53. Yayama T, Kobayashi S, Awara K, et al. Intraneural blood flow analysis during an intraoperative Phalen's test in carpal tunnel syndrome. *J Orthop Res*. 2010;28:1022-1025.

54. Ozcanli H, Coskun NK, Cengiz M, Oguz N, Sindel M. Definition of a safe-zone in open carpal tunnel surgery: a cadaver study. *Surg Radiol Anat*. 2010;32:203-206.

55. Özcan HN, Kara M, Özcan F, et al. Dynamic Doppler Evaluation of the Radial and Ulnar Arteries in Patients With Carpal Tunnel Syndrome. *Am J Roentgenol*. 2011;197:W817-W820.

56. CTIA (International Association for the Wireless Telecommunications Industry). CTIA (International Association for the Wireless Telecommunications Industry).

Available at: http://www.ctia.org/consumer_info/service/index.cfm/AID/10323. Accessed June/20, 2012.

57. Gustafsson E, Johnson PW, Hagberg M. Thumb postures and physical loads during mobile phone use - A comparison of young adults with and without musculoskeletal symptoms. *Journal of Electromyography and Kinesiology*. 2010;20:127-135.

58. Lin I-, Peper E. Psychophysiological patterns during cell phone text messaging: A preliminary study. *Applied Psychophysiology Biofeedback*. 2009;34:53-57.

59. Berolo S, Wells RP, Amick 3,Benjamin C. Musculoskeletal symptoms among mobile hand-held device users and their relationship to device use: A preliminary study in a Canadian university population. *Appl Ergon*. 2011;42:371-378.

Chapter 2

2 The Construct Validity, Clinically Important Differences, and Responsiveness of Symptom Severity Scores, and Sensory Tests in Patients with Carpal Tunnel Syndrome

A version of this chapter has been submitted for publication

Cheung DKM, MacDermid JC, Grewal R. The Construct Validity, Clinically Important Differences, and Responsiveness of Symptom Severity Scores, and Sensory Tests in Patients with Carpal Tunnel Syndrome. J Hand Ther. 20XX; XX: XX - XX

2.1 Introduction

Carpal Tunnel Syndrome (CTS) is a common compression neuropathy with an annual prevalence ranging between 2.7% in Sweden [1] to 6.7% in the United States of America. [2] Incidences of Carpal Tunnel Syndrome can vary depending on the type of the occupation. In 1988 and 2010, industry related jobs (for example, manufacturing and food services), contributed to the majority of work related CTS cases in the United States of America based on National Health Surveys. [2, 3] For workers employed within educational institutions, a lower prevalence of CTS injury was found. [2] CTS is a major contributor to occupational upper extremity disorders, [4, 5] and is associated with considerable health care costs. [6]

Typical sensory symptoms experienced by patients with CTS are tingling, pain, and numbness at night or throughout the day; with advanced stages of the disease affecting motor function and dexterity. [7-12, 12-14] A number of clinical tests are performed to evaluate hand function in patients with CTS, [15-20] such as sensory tests, [21] or disease specific questionnaires. [22] These clinical tests can help clinicians determine if a patient responded to treatment; and if carpal tunnel release is required. [15] The Clinically Important Difference (CID) is a measurement property for responsiveness that indicates the change scores on an outcome measure that is considered to provide important information for a clinician or patient for deciding the next step in a treatment protocol. This CID could be used to discriminate patients who make clinically important changes; indicating a clinical improvement following treatment. Studies that identify CID must divide patient responses as clinically important versus clinically unimportant to determine the optimal cut-off. Thus, an external criterion on another outcome measure must be used to make this judgment. A variety of methods can be used as an external criterion to determine whether a patient has made a clinically important change. As for patients with CTS, if symptoms resolve with conservative treatment, this could be considered an external criterion for demonstrating clinical improvement. If symptoms continue despite

conservative treatment, the patient did not experience a clinical important change, and surgery would be the next treatment option. The Symptom Severity Scale (SSS) is a commonly used self-reported questionnaire designed specifically for evaluating symptoms in CTS. [22] The CID of the SSS is equal to 1.04 or 1.14, depending whether the treatment method is by steroid injection [23, 24] or with carpal tunnel release [25] respectively. However, the CID for orthotic intervention has not been identified in literature or identified for clinical practice.

In addition, sensation is an important component of hand function, [19, 26] and is typically impaired in CTS. Sensory testing is important to assist clinicians in the diagnosis of CTS; to determine severity; or to monitor improvements with treatment. A variety of tools can provide quantitative measures of sensory threshold for different modalities, including touch and vibration threshold. [15-17, 19] Two sensory tools which are often used in clinical studies to measure sensory characteristics are the Pressure Specified Sensory Device (PSSD) (NK Biotechnical Corporation, Minneapolis, MN, USA) and the Vibrometer (Z tech Medical, Salt Lake City, UT, USA). Some clinical measurement properties of the PSSD and Vibrometer have been reported. The PSSD has been shown to have high reliability (r= 0.95) and interrater reliability in healthy persons for one point static testing (r= 0.99). [27] The Vibrometer has excellent test-retest reliability in patients with CTS with intraclass correlation coefficients (ICCs) ranging from 0.86 to 0.89. [28] However, there is limited evidence about the discriminative and evaluative properties of sensory measures - in particular to touch and vibration threshold tools. There is a specific deficit of knowledge about the CID of sensory tools, which is a substantial gap in clinical knowledge since this is the measure that would be relevant for clinical decision making regarding whether patients have made clinically relevant improvements.

The purpose of this study was to evaluate the clinical measurement properties of the Vibrometer and the PSSD and self-reported measures of symptoms severity in patients with CTS, in terms of the following:

1. The convergent construct validity in relation to measures of self-reported and performance-based hand function (DASH and NK Dexterity).

2. The CID of the SSS (established by comparison to the external criterion of failure to achieve symptom relief as indicated by progression to surgery).

3. The CID of the Vibrometer and PSSD.

4. The responsiveness of the Vibrometer and PSSD in patients who achieved a clinically important improvement in symptoms.

2.2 Methods

All patients were recruited from a tertiary care center specializing in upper limb disorders. Patients were diagnosed with CTS based on a clinical diagnosis made by the treating hand surgeons and confirmed by electromyography (EMG) based on the latest version of the American Association of Electrodiagnostic Medicine criteria as outlined by consensus criteria by Rempel et al. [14] Patients were included in the study if they had mild CTS, as conservative management is appropriate for this particular category of the disease. [29] Patients were excluded from the study if they met any of the following criteria:

Exclusion Criteria:

- Urgent or severe CTS requiring early operative intervention;
- Pregnancy [30-32];
- Concurrent injury to the upper extremity including recent trauma (i.e. fracture, amputation, tumor, or nerve compression);
- Wrist arthritis, rheumatoid arthritis, diabetes mellitus, or thyroid disease;
- Inability to complete study forms/assessments; and
- Neurological conditions

This study was approved by the university research ethics board and informed consent was obtained from each patient.

Sample size justification. The sample size was determined for the correlation between sensory tools and SSS, DASH, and Dexterity to achieve significance using G*Power version 3.1.4 software

(http://www.psycho.uni-duesseldorf.de/abteilungen/aap/gpower3/download-and-register) at a power of 80% with a correlation of 0.5 with a bivariate normal model. Alpha was set at 0.05 using a 2 tail test. The minimum sample size required was 29 patients. Statistical significance was considered if $p<0.05$.

2.3 Outcome measures.

Pressure specified sensory device (PSSD). The PSSD is a computerized touch threshold device, which can measure the minimum amount of pressure required to elicit a response from a subject (g/mm^2), as well as spatial discrimination (2 Point Discrimination) (2PD). It has a range of 0.1 to 100 g/mm^2. Each hemispheric prong has an area of $0.90mm^2$. This study tested touch threshold only with the PSSD. For touch threshold of a single point, the tester applied an individual metallic prong from the PSSD device into the distal pulp of the long finger in the affected hand while the participant sat with eyes closed. Participants were instructed to push a trigger held in the opposite hand, to identify when they perceived the stimulus. The PSSD has been shown to have high reliability (r= 0.95) and intertest reliability in patients with neuropathy for one point static testing (r= 0.99). [27] For each visit, a total of five repetitions were taken; the lowest and highest scores were dropped and the remaining three were averaged as recommended by the manufacturer. A total of three visits were required.

The vibrometer. The Vibrometer is a sensory modality which measures vibration perception threshold. [33] The Vibrometer used in this study is a 50 Hz computer-controlled ramped protocol where the vibration stimuli are applied through a 2mm diameter aperture with a 1mm diameter vibrating post. Subjects were required to

identify when they felt a stimulus by squeezing a handheld trigger with their eyes closed. The minimum score is 1 um and the maximum score is 180um. A ramped protocol is regulated by the device supplying sufficient repetitions of test stimuli; to achieve a stable estimate of vibration threshold. The Vibrometer has shown excellent test retest reliability in patients with CTS with ICCs ranging from 0.86 to 0.89. [28] The Vibrometer was tested once at each follow up point and for a total of 3 times.

The symptom severity scale (SSS). The SSS is a disease specific questionnaire composed of 11 questions each rated 1 through 5 that measures symptoms experienced in a typical 24 hour period within the past 2 weeks. Respondents rate the severity of CTS-related symptoms and disability with scores ranging from 1 (no symptoms) to 5 (worst). [22] The final score for the SSS is calculated as a mean of 11 questions. It has been assessed and found to be valid for face, content, and construct validity in measuring clinically relevant change in patients with Carpal Tunnel Syndrome. [22, 34-36] It has also been shown to be reliable for test-retest reliability. [22, 37] The questionnaire was completed once per visit and patients were required to complete the questionnaire a total of 3 times.

Disability of the arm, shoulder, and hand (DASH) questionnaire. The DASH is a self–report measure which allows patients to rate the disability of their arm, shoulder and hand. [38] Responses range from 1 to 5, with a higher score indicating higher levels of pain and disability. The questionnaire has been shown to be responsive after Carpal Tunnel Release surgery. [39] The convergent, construct, and discriminatory validity has been supported for distal upper extremities, including Carpal Tunnel Syndrome. [40] DASH has also been found to be responsiveness to clinical change. [40] The questionnaire was completed once per visit and patients were required to complete the questionnaire a total of 3 times.

NK dexterity small objects test. The NK Dexterity Small Objects Test (referred to as "Dexterity" for short) is a test of manual dexterity which measures the amount of time (in seconds) that is required for a patient to move objects on a

plastic board. [41, 42] Sizes of the objects are classified as small, medium, or large. It consists of plastic and metal objects that need to be moved with the affected hand and placed into another location. Timing was initiated from the moment the hand moved from the starting position towards the first object until subjects removed their hand from the final object. For this study, dexterity testing was done with the small objects only because fine motor function is expected to be most affected in CTS. [41] In addition, the small object subtest has been shown to have the best correlation to hand function with r = 0.47-0.87; and also has high reliability (ICC = 0.53-0.86). [41, 42] The time recorded for the patient to complete the dexterity task was the mean of 3 trials at each follow up point.

2.4 Procedure

Each patient was treated with night orthotic intervention of the wrist in neutral position for 12 weeks; and had assessments at baseline, 6 weeks, and 12 weeks later. If patients and surgeons felt that orthotic intervention was not reducing symptoms, then surgery was offered. Patients were monitored for a year following the intervention to determine whether they proceeded to surgery.

At baseline and at each follow up visit, patients completed the following assessments: PSSD, Vibrometer, SSS, DASH, and Dexterity. Data for the PSSD and Vibrometer were collected by having each patient seated with their affected arm supported on a table. For the PSSD, the wrist was supported by a piece of foam, such that the wrist was in neutral position and the palm was facing upwards. Data for the Vibrometer was collected by having the arm rest directly on the table with the hand in pronated position. The long finger was used for testing sensation in both PSSD and Vibrometer testing. Testing was done on the affected hand if CTS was affecting only one side; otherwise, the hand with more severe symptoms was tested for subjects who had CTS in both hands.

2.5 Analysis

All analyses were performed using SPSS software version 19. Data were checked for normality [43, 44] by checking the skewness ratio for each outcome measure were between ±

2. [44, 45] The Shapiro-Wilk test was also evaluated to determine if data were normal as a verification process. If $p>0.05$, the data are normally distributed. Otherwise, if $p<0.05$, the data are not normally distributed. [44] The data were not normally distributed ($p<0.05$), thus non-parametric statistics were used for correlations.

Cross-sectional convergent validity. Cross Sectional Convergent Validity assesses the extent to which a measure's result agrees with another measure that is believed to be assessing the same or similar attribute. [46] The correlation between the PSSD and the Vibrometer to measures of hand function were determined using Spearman's correlation (r_s) since the data were not normally distributed. Interpretation was based on the guidelines that Spearman' correlation are considered poor if $r_s< 0.25$, considered moderate if $r_s = 0.25 - 0.50$, considered good if $r_s = 0.50 - 0.75$ and considered excellent if $r_s > 0.75$. [43]

Calculating clinically important difference (CID) for SSS. The CID was determined using Receiver Operating Characteristic (ROC) curves to determine the cutoff point to dichotomize and categorize the sample into 2 groups. The first criterion to determine if an important change occurred was based on patients proceeding toward surgery. The SSS was used to determine a cut-off score to discriminate clinically important change. The patients were categorized either as *responders* (those who responded to orthotic intervention and did not proceed to surgery) or *non-responders* (those who did not respond to orthotic intervention and proceeded to surgery).

The final follow-up visit was based on scores at 12 weeks. For patients ($n = 21$ for the PSSD and $n = 22$ for the Vibrometer) who did not return for their final follow-up, the score at 6 weeks was carried forward as it represented the last known status; and our previous studies have shown that patients who are going to respond to treatment will do so within the first six weeks. [24] ROC curves were used to establish the discriminative ability of the cut-off score; and to determine the optimized cut-off. ROC curves plotted sensitivity (y-axis) versus 1 – specificity (x-axis). For the ROC curves for the SSS, sensitivity is defined as the

number of patients who achieved a change score that was less than the cut off divided by all those who proceeded to surgery. Specificity refers to the number of patients who achieved a change greater than the cut-off score divided by those did not proceed to surgery. Whereas for the sensory tools, sensitivity is defined as the number of patients who did not achieve an important change divided by those who achieved a change score less than the cut off on the SSS. Specificity refers to the number of patients who achieved an important change divided by those who had scored more than the cut off on the SSS. The most efficient cut off score is the point closest to the top left corner of the ROC curve. If the area under the curve (AUC) is equal or less than 0.50, this would mean the curve is no better than chance to discriminate patients. Generally, an area under the curve > 0.75 is considered to be clinically useful. [47]

Calculating clinically important difference (CID) for the vibrometer and PSSD. Once the CID was calculated for the SSS, this cut score was used to determine the CID of the two sensory tools. ROC curves were used to establish the discriminative ability of the cut score and the optimized cut off. If the area under the curve (AUC) is equal or less than 0.50, this would mean has no better than chance ability to discriminate.

Responsiveness. Responsiveness is the ability of a tool to measure a clinically important change that is noticeable to the patient or the clinician. [48] There are two broad methods of determining clinically meaningful change: anchor and distribution-based approaches. Both were used in this study.

Anchor based methods define clinically important change based on an external anchor, [49] which can be based on a subjective opinion (from a clinician's or patient's perception) or from an objective measures (such as a disease specific tool). [49] The anchor must be clearly defined and be able to show clinically important difference between groups at one instant (cross sectional approach) or over a period of time (longitudinal approach). [50] Often, a global rating of change is used to determine subjective change. Although this method is easy to apply, it

is subject to recall bias. The use of a disease specific tool is more accurate to measure important change because it is a standardized tool in clinical practice. This study used the SSS as the external anchor.

Distribution based methods focus on statistical properties of a tool for measuring clinically important change. [50] There are three approaches of distribution based methods (statistical significance, sample variation, and measurement precision), but only sample variation will be explained for the case of this paper. One of the more common methods of measuring sample variation are Effect Size (ES) and Standardized Response Mean (SRM). These are the two distribution based methods used in this study. The ES was calculated by dividing the mean change by the standard deviation of baseline scores. [51] The SRM was calculated by dividing the mean difference of the change scores by the standard deviation of change. [52]

The SRM and ES were calculated for both the responder group and the non-responder groups for the SSS, the PSSD, and the Vibrometer based on the CID's established in this study for the SSS. The change scores were calculated in the same way when determining the CID for the SSS, PSSD, and Vibrometer. Responsiveness was defined as low if SRM and ES were < 0.5, moderate if SRM and ES were between 0.5 to 0.8 and large responsiveness if ≥ 0.8. [53, 5437]

2.6 Results

A total of 73 patients (20 men and 53 women) were eligible for inclusion in this study. Patients were between the ages of 29 to 74 years (mean age of 49 ± 9 years). The duration of the symptoms ranged from 1 month – 30 years (mean 4 ± 6 years) (See Table 1). Tables with baseline and follow up scores for PSSD, Vibrometer, DASH, SSS, and Dexterity are shown in Table 2. Only 63 patients out of 73 patients completed the SSS. From this group of 63 patients, 38 patients completed the PSSD, and 22 completed testing with the Vibrometer for both baseline and final follow up. The SSS, PSSD, and

the Vibrometer had 2, 1, and 5 patients respectively who had their scores at 6 weeks carried forward to 12 weeks.

The Vibrometer demonstrated moderate correlations to symptoms and dexterity at most follow-up assessments; and was more strongly related to these tools than was the PSSD (Table 3). The Vibrometer had low to moderate correlations with the SSS ($r = 0.22 – 0.41$) and moderate correlations with Dexterity ($r = 0.36 – 0.41$) (Table 3). The PSSD demonstrated low correlation to both SSS ($r = 0.22 – 0.32$) and Dexterity ($r < 0.32$) (Table 3). Neither sensory measure correlated significantly to the DASH ($r = 0.09 – 0.30$) (Table 3). The SSS demonstrated moderate correlation to dexterity; and a large correlation to the DASH (0.63 – 0.76) (Table 3).

The CID for the change in the SSS that best differentiated response to orthotic intervention was 0.5 points (86% sensitivity; and 54% specificity); with an area under the curve of 0.73 (0.60, 0.86) (Figure 1 and Table 4). The CID for the PSSD was equal $0.15 g/mm^2$ (60% sensitivity; and 39% specificity) with an area under the curve of 0.46 (0.27, 0.64) (Figure 2). The ROC curve for the Vibrometer could not be graphed because all 22 individuals improved at least 0.5 points on the SSS and the cut-off point did not provide any values for the x axis for 1-specificity (Table 5).

The SSS demonstrated expected large responsiveness for responders (SRM= 2.18 (±0.42) and ES = 1.40 (±0.42)) and low responsiveness for non responders (SRM = 0.15(±0.31) and ES = 0.08 (±0.25)) (Table 5). The PSSD demonstrated low responsiveness for both responder (SRM = 0.09 and ES = 0.08) and non responder (SRM = 0.04 and ES = 0.06) (Table 6). The Vibrometer demonstrated moderate responsiveness for responders (SRM= 0.61 and ES = 0.46) to treatment and low responsiveness for non responders (SRM = 0.18 and ES = 0.12) (Table 6).

Table 2.1: Demographic information of patients

Total Number of Participants	73
Number of Males	20
Number of Females	53
Mean Age and Range	49 ± 9 years (29 – 74 years)
Symptoms Duration	4 ± 6 years (1 month – 30 years)
Left Hand Affected:	10
Right Hand Affected	25
Both Hand Affected	38
Heart Problems	7
Diabetes	5
Arthritis:	26
WSIB Compensation cases:	18 with 4 pending

WSIB = Workplace Safety Insurance Board

Table **2.2: Baseline descriptive data**

	PSSD	**Vibrometer**	**DASH**	**SSS**	**Dexterity Small Objects Test**
Mean (SD)	**6.36 (7.62)**	**28.16 (28.66)**	**35.63 (18.25)**	**3.04 (0.75)**	**49.17 (15.74)**
Median (25th and 75th percentile)	**4.40 (3.38, 5.90)**	**19.00 (10.75, 39. 25)**	**33.33 (23.33, 47.29)**	**3.00 (2.45 , 3.64)**	**44.00 (40.00, 53.00)**
Skewness (Standard Error)	**4.02 (0.38)**	**2.56 (0.31)**	**0.66 (0.28)**	**-0.027 (0.29)**	**2.35 (0.31)**
Kurtosis (Standard Error)	**17.65 (0.75)**	**8.03 (0.62)**	**0.282 (0.56)**	**-0.64 (0.60)**	**6.62 (0.61)**

Table 2.3: Spearman correlation between sensory and symptoms severity scores and their functional measures

Tools	Time	PSSD r_s (95%CI)	Vibrometer r_s (95%CI)	SSS r_s (95%CI)
DASH	Baseline	0.09±0.32	0.13±0.25	0.63±0.14*
	6 weeks	0.31±0.30	0.21±0.27	0.74±0.14*
	12 weeks	0.10±0.27	0.22±0.27	0.76±0.13*
SSS	Baseline	0.22±0.31	0.41±0.25*	1.0
	6 weeks	0.32±0.30*	0.22±0.27	
	12 weeks	0.25±0.27	0.35±0.27*	
Dexterity	Baseline	0.20±0.31	0.36±0.25*	0.32±0.25*
	6 weeks	0.32±0.30*	0.41±0.27*	0.53±0.21*
	12 weeks	-0.02±0.27	0.39±0.27*	0.59±0.20*

PSSD = Pressure Specified Sensory Device. DASH = Disability of the Arm, Shoulder, and Hand. SSS = Symptom Severity Scale.

* Correlation is significant at $p<0.05$

Confidence intervals were calculated with http://vassarstats.net/rho.html.

Table 2.4: Information on the ROC curves produced

	Figure1: ΔSSS **n = 62**	**Figure 2: ΔPSSD** **n=38**	**ΔVibrometer** **n=55**
External Criterion	Failed to sufficiently resolve symptoms- proceed to surgery	Failed to sufficiently resolve symptoms – based on ΔSSS = 0.5	
Cut point for CID	0.50	0.15	undefined
Area under the curve	0.73 (0.60 – 0.86)	0.46 (0.27-0.64)	n/a
Sensitivity	0.86	0.60	0%
Specificity	0.54	0.39	100%

ROC = Receiver Operating Characteristic. CID = Minimally Clinically Important Difference. ΔSSS = change in SSS scores. ΔPSSD = change in PSSD scores. ΔVibrometer = change in Vibrometer scores. CID for Vibrometer was undefined because all who completed both Vibrometer and SSS did not proceed to surgery. Non responders for Vibrometer were because they did not complete SSS.

Table 2.5: Change scores for the SSS and responsiveness based on proceeding to surgery

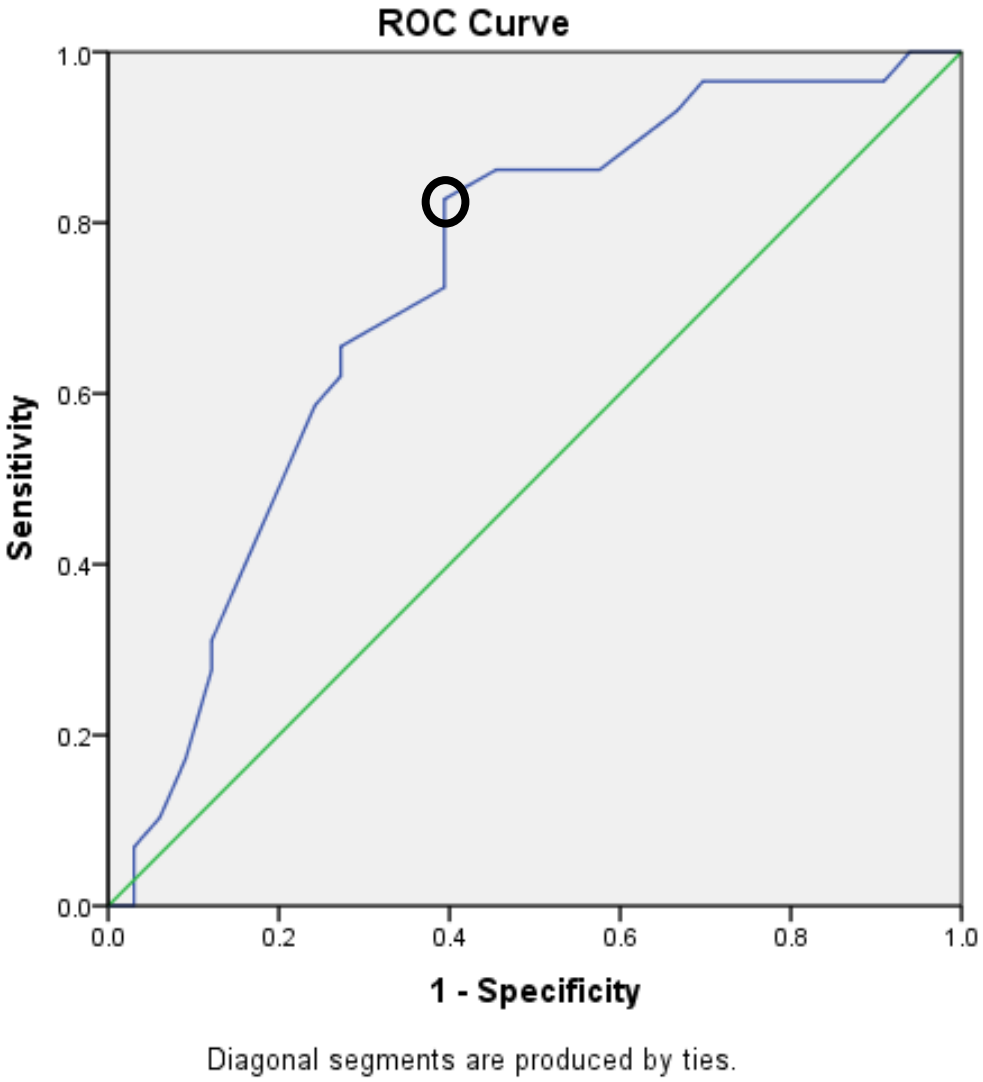
	N	Mean Baseline Score (SD)	Mean Post Treatment Score (SD)	Mean Change (SD)	SRM (95%CI)	ES (95%CI)
SSS Score Overall	62	3.03 (0.75)	2.70 (0.89)	0.32 (0.64)	0.50 (±0.24)	0.67 (±0.24)
SSS Score Responders (Δ ≥ 0.50)	22	3.03(0.70)	2.05(0.73)	0.98(0.45)	2.18 (±0.42)	1.40 (±0.42)
SSS Score Non Responders (Δ < 0.50)	39	3.02 (0.79)	3.08 (0.759)	0.06(0.39)	0.15 (±0.31)	0.08 (±0.31)

SD = Standard Deviation. PSSD = Pressure Specified Sensory Device. DASH = Disability of the Arm, Shoulder, and Hand. SSS = Symptom Severity Scale. CI = Confidence Interval

Table 2.6: Responsiveness for the PSSD, and vibrometer based on CID of change score SSS = 0.5

	N	Mean Baseline Score (SD)	Mean Post Treatment Score (SD)	Mean Change (SD)	SRM (95%CI)	ES (95%CI)
PSSD Responder	15	4.13 (1.99)	3.83 (3.53)	0.30 (3.26)	0.09 (±0.51)	0.08 (±0.51)
PSSD Non Responder	23	7.82(9.47)	7.30(15.29)	0.53(13.48)	0.04 (±0.41)	0.06 (±0.41)
Vibrometer Responder	22	25.55(19.51)	16.64(14.46)	8.91(14.70)	0.61 (±0.41)	0.46 (±0.41)
Vibrometer Non Responder	33	27.39 (32.10)	23.39 (29.89)	4.00 (21.81)	0.18 (±0.34)	0.12 (±0.34)

SD = Standard Deviation. SRM = Standardized Response Mean. ES = Effect Size. PSSD = Pressure Specified Sensory Device. DASH = Disability of the Arm, Shoulder, and Hand. SSS = Symptom Severity Scale. CI = Confidence Interval. The overall ES of all patients was calculated to indicate the overall response to orthotic intervention; SRM and ES were determined for responders and non-responders to indicate responsiveness.



2.1: Receiver Operating Characteristic Curve for Determining the Cut-off Point to Determine Responder and Non Responder Subgroups Based on the SSS

Circle represents cut point for Clinically Important Difference.

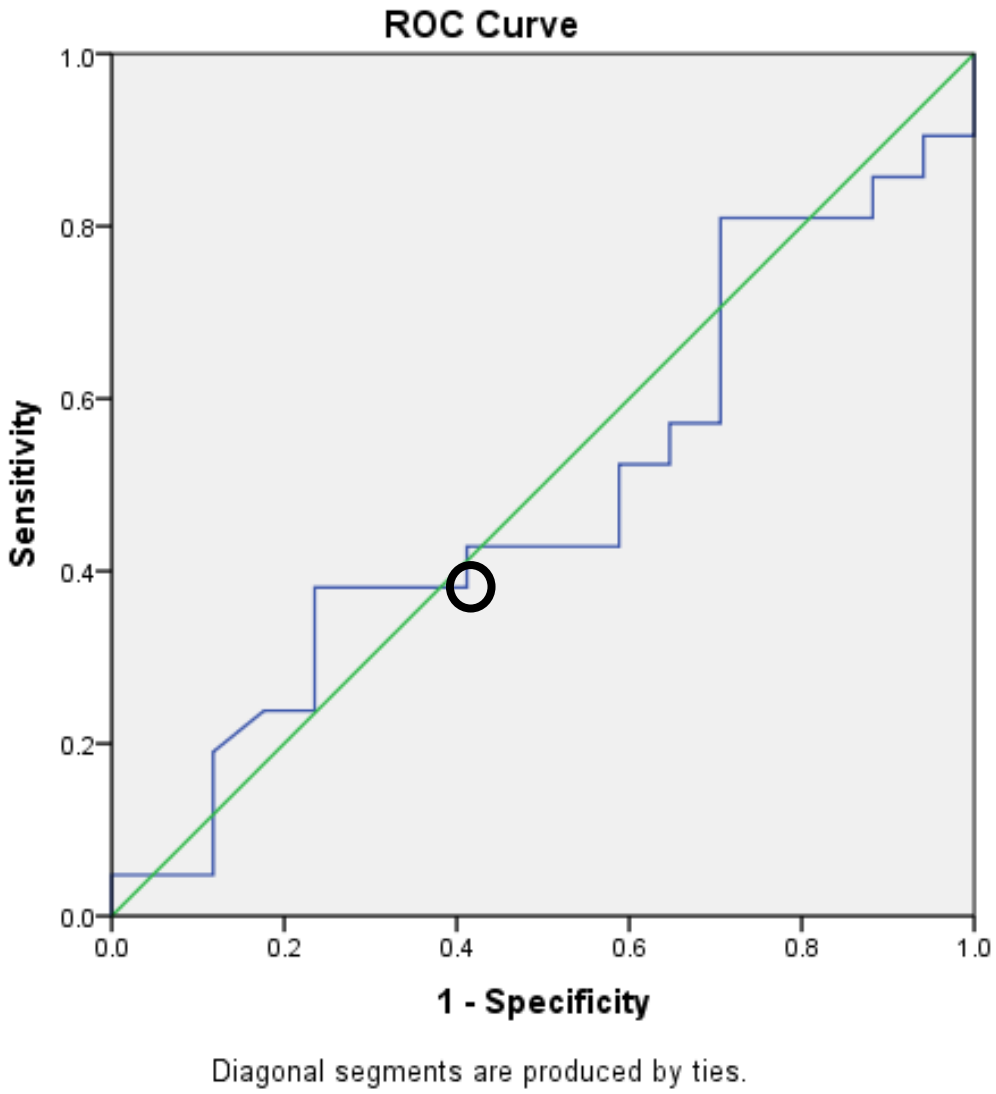


Figure 2.2: Receiver Operating Characteristic Curve for Determining the Cut-off Point to Determine a Clinical Important Change for the PSSD based on the CID of 0.5 for the SSS.

Circle represents cut point for Clinically Important Difference.

2.7 Discussion

The current study provides estimates of self-report and sensory measures used in outcome assessment of CTS that support the use of the SSS and Vibrometry. This current study demonstrated that the CID of the symptom severity scale is smaller than has been previously established with reference to a surgical intervention. [25] Previous studies have suggested that a one-point difference [23, 25] was clinically important; whereas our study suggested that a 0.50 change was clinically important. Since the SSS is a five point scale; a one-point difference represents a 20% improvement; whereas 0.5 represents a 10% improvement. These differences can be partially attributed to differences in the effect size of the two interventions since we know that surgery provides greater change in symptoms compared to conservative management. [55] For this reason, it is important to establish a CID for conservative management that could be used by therapists when assessing the response to orthotic intervention.

The ROC curve in Figure 1 has shown that the CID for the SSS is 0.5. However, this value is much lower than the CID determined by Ozyurekoglu et al, [23] which was 1.04. Potential differences between the studies may stem from differences in treatment type and the severity of cases in both studies. This current study used orthotic intervention for chronic cases of CTS, whereas in Ozyurekoglu et al's study, [23] cortisone injections were used for treatment and the patients were suffering from acute cases of CTS. In terms of the method of reported change, our study used the SSS to measure patient self -reported change after determining whether they should proceed to surgery or not. Ozyurekoglu et al [23] calculated the CID for the SSS based on a global rating of change as the external anchor for patients to determine improvement. The Global Rating of Change has been criticized because of recall bias from the patient, [56] which may overestimate or underestimate the effect of the treatment. Our study determined the CID for the SSS based on the anchor of proceeding to surgery which combines a shared decision by both clinician and patient. We also used distribution-based methods to illustrate responsiveness, which has shown that the SSS is responsive to clinical change (Table 5).

This study supports the discriminative ability of the SSS, although there are limitations inherent in the measurement properties of the SSS, and in this study. The estimate of CID at 0.5 is subject to imprecision as the lower end of the interval is below 0.75, [47] although the confidence interval indicates discrimination may be as high as 0.86. The AUC indicates that the SSS would be more useful than the PSSD or the Vibrometer for discriminating patients with a CID. In practice, it would be useful to set treatment goals to achieve a CID of 0.5 on the SSS or greater. However, since the specificity of this cut-off was lower than sensitivity, therapists should expect some patients who improve more than 0.5 and would still proceed to surgery despite having improved symptoms (Table 5 and Table 6). The tool's CID has a higher probability to send a patient toward surgery rather than not.

Our study also had used the external criteria of proceeding to surgery rather than using a global rating of change [23] compared to Ozyurekoglu et al's study. The external criterion of proceeding to surgery was decided by a clinician on the presentation of symptoms which patients still experienced despite orthotic intervention. However, patients may still choose not to go for surgery despite when a clinician is in favour of surgery. The SSS was used as an external criteria for the PSSD because the SSS is a self -reported and disease specific outcome measure, which would a patient to have a role within the decision making process of deciding or not to proceed to surgery under a standardized process. The global rating of change is subject to recall bias and variability [57, 58] by the patient, and it may not accurately determine the best clinical decision for the patient. The SSS overcomes the issues of reliability and recall bias that the global rating of change may have. This study incorporates both clinician's and patient's input in the treatment process of determining the clinically important difference on the SSS.

Comparing the performance of our two sensory tests, we suggest that the Vibrometer scores provided more clinically useful indicators than did the PSSD. The Vibrometer was more responsive based on both anchor and distribution based estimates of responsiveness. The correlations between measures were more consistent with the expected relationships of sensory function to hand function for the Vibrometer in comparison to the PSSD. The PSSD and Vibrometer did not discriminate to the extent

thought useful in clinical practice; in fact the PSSD was no better than chance because the area under the ROC curve was crossing the 0.5 mark (Table 5 and 6). The Vibrometer did not provide a defined cut score, as all patients had improved at least 0.5 on the SSS. A larger sample size of patients could be recruited for future studies to increase the number of failures from orthotic intervention to allow for a cut score to be determined. Clinicians should be aware that the PSSD and Vibrometer may not be useful for clinical decisions about whether their patients have made clinically important improvements. Since that the Vibrometer shows more promise, the next steps would be to perform more detailed analysis about the use of Vibrometer scores in clinical decision-making. Although we did not find the PSSD useful for evaluating clinical change, others have reported it useful in diagnosis of nerve entrapment syndromes. [59] The PSSD is a very sensitive tool for diagnosing CTS, cubital tunnel syndrome, tarsal tunnel syndrome, and common peroneal nerve entrapment, all having highest sensitivity possible (100%), but low specificity ranging from 0 – 33%. [59] The PSSD was reported to be more sensitive than standard electrodiagnosis, which is a standard method for diagnosing neuropathy (which had sensitivity ranging between 37% - 89% depending on the type of neuropathy.) [59] The PSSD would be able to detect neuropathies even when the standard method cannot in patients suspected of having neuropathy.

The correlation between the sensory measures and the DASH did not match our a priori expectations. We expected that sensory function should contribute to hand function and be reflected in this measure because the DASH has questions specifically regarding numbness and tingling, and it has been validated for the CTS population. [60] Correlations were generally higher with the SSS which suggest that the SSS is a better indicator of sensory nerve function than the DASH. In addition, the DASH does not contain specific questions on touch or vibration threshold, so this may contribute to the low correlations between sensory threshold tests and DASH.

The SSS was found to have moderate correlations with dexterity small objects test, and good to excellent correlations [61] with DASH. Our correlation between the SSS and DASH is similar to the results found in a study on the validation of the Turkish version of the Quick DASH to the SSS in patients with CTS. [60] This paper found that the Quick

DASH had a high correlation between the disability/symptom and work subscales with the SSS (r = 0.63-0.68). Our current study and the study by Dogan et al [60] both reinforce that the DASH is a valid tool for the evaluating patients with CTS. In terms of the correlation between dexterity and symptom severity, the moderate correlation indicates a proportional relation between symptoms severity and the impairment to hand dexterity. Our study had similar findings to a kinematic study [61] comparing the variability in the precision of pinching tasks in 16 age and gender matched patients with CTS and healthy controls. Gehrmann et al [61] found that patients with CTS had more variability in their pinching movements compared to the controls. Regardless of methodology, both our studies suggest that CTS impairs hand dexterity.

Our study results had some limitations. Most important of these is that the sensory tests were performed by a trained experienced independent evaluator, not by a hand therapist. Independent evaluators may have been less skilled than hand therapists in sensory testing. However, even experienced hand therapists do not always agree on touch threshold measures in CTS patients. [16, 17] The PSSD is a hand-held device and may be more subject to error than the Vibrometer. Brakel et al [62] found that evaluator experience in sensory testing can influence inter-tester reliability. The study examined the inter tester reliability in sensory testing between five physiotechnicians and nurse/paramedical workers in a sample of patients with leprosy. Physiotechnicians had significantly higher weighted kappa values with touch threshold testing (kappa = 0.98 versus 0.89) compared to whole group. [62] This difference might be explained because physiotechnicians were more experienced in sensory testing than nurse/paramedical workers. [62] In contrast, the Vibrometer is an automated ramped protocol and uses multiple applications of a vibrating stimulus. Hence, skill may have been less importance for this tool, so that the random error may be reduced. Our study also had small groups tested for each sensory tool as a limitation to the study. We had some tests which were not completed for each patient when they came for their visit. These small sample sizes may have resulted in increased type II error of the correlations found between the sensory tools and functional measures. For example, the PSSD was unable to achieve a significant correlation with other tools. We would need to be more consistent during data collection to complete outcome measures for all patients coming into the study.

2.8 Conclusion

This study suggests that the Vibrometer is a better choice for evaluating sensation to represent overall hand function. The CID of 0.5 on the SSS from orthotic intervention may be useful for setting treatment goals. Sensory tools should not be used in isolation to make decisions about clinical improvement in CTS. Despite the common use of sensory evaluation, there remains a large gap in our knowledge of the clinical measurement properties of different tools and test protocol variations. Future studies should address how clinical decisions are made based on sensory measures and whether sensory tools are important measures in evaluating the prognosis of patients.

2.9 References

1. Atroshi I, Gummesson C, Johnsson R, Ornstein E, Ranstam J, Rosén I. Prevalence of carpal tunnel syndrome in a general population. *JAMA: the journal of the American Medical Association*. 1999;282:153.

2. Luckhaupt SE, Dahlhamer JM, Ward BW, Sweeney MH, Sestito JP, Calvert GM. Prevalence and work-relatedness of carpal tunnel syndrome in the working population, United States, 2010 national health interview survey. *Am J Ind Med*. 2012.

3. Tanaka S, Wild DK, Seligman PJ, Halperin WE, Behrens VJ, Putz-Anderson V. Prevalence and work-relatedness of self-reported carpal tunnel syndrome among U.S. workers: Analysis of the Occupational Health Supplement data of 1988 National Health Interview Survey. *Am J Ind Med*. 1995;27:451-470.

4. Zakaria D. Rates of carpal tunnel syndrome, epicondylitis, and rotator cuff claims in Ontario workers during 1997. *Chronic Dis Can*. 2004;25:32-39.

5. Zakaria D, Robertson J, MacDermid J, Hartford K, Koval J. Work-related cumulative trauma disorders of the upper extremity: Navigating the epidemiologic literature. *Am J Ind Med*. 2002;42:258-269.

6. Feuerstein M, Miller VL, Burrell LM, Berger R. Occupational upper extremity disorders in the federal workforce: prevalence, health care expenditures, and patterns of work disability. *Journal of Occupational and Environmental Medicine*. 1998;40:546.

7. Werner RA, Andary M. Carpal tunnel syndrome: pathophysiology and clinical neurophysiology. *Clinical Neurophysiology*. 2002;113:1373-1381.

8. Kerwin G, Williams CS, Seiler 3rd J. The pathophysiology of carpal tunnel syndrome. *Hand Clin*. 1996;12:243.

9. Gerritsen AAM, de Vet HCW, Scholten RJPM, Bertelsmann FW, de Krom MC, Bouter LM. Splinting vs surgery in the treatment of carpal tunnel syndrome. *JAMA: the journal of the American Medical Association*. 2002;288:1245.

10. Gerritsen AA, de Krom MC, Struijs MA, Scholten RJ, de Vet HC, Bouter LM. Conservative treatment options for carpal tunnel syndrome: a systematic review of randomised controlled trials. *J Neurol*. 2002;249:272-280.

11. Gerritsen AA, de Vet HC, Scholten RJ, van Tulder MW, Bouter LM. Enabling meta-analysis in systematic reviews on carpal tunnel syndrome. *J Hand Surg Am*. 2002;27:828-832.

12. Gerritsen AA, Uitdehaag BM, van Geldere D, Scholten RJ, de Vet HC, Bouter LM. Systematic review of randomized clinical trials of surgical treatment for carpal tunnel syndrome. *Br J Surg*. 2001;88:1285-1295.

13. Gerritsen AAM, De Vet HCW, Scholten RJPM, Bertelsmann FW, De Krom MCTFM, Bouter LM. Greater clinical effects on carpal tunnel syndrome with surgery than with splinting; results of a randomised clinical trial. *Ned Tijdschr Geneeskd*. 2002;146:2153-2156.

14. Rempel D, Evanoff B, Amadio PC, et al. Consensus criteria for the classification of carpal tunnel syndrome in epidemiologic studies. *Am J Public Health*. 1998;88:1447.

15. MacDermid J. Accuracy of clinical tests used in the detection of carpal tunnel syndrome: a literature review. *Journal of Hand Therapy*. 1991;4:169-176.

16. MacDermid JC, Kramer JF, Roth JH. Decision making in detecting abnormal Semmes-Weinstein monofilament thresholds in carpal tunnel syndrome. *J Hand Ther*. 1994;7:158-162.

17. MacDermid J, Kramer J, McFarlane R, Roth J. Inter-rater agreement and accuracy of clinical tests used in diagnosis of carpal tunnel syndrome. *Work*. 1997;8:37-44.

18. MacDermid JC, Doherty T. Clinical and electrodiagnostic testing of carpal tunnel syndrome: a narrative review. *J Orthop Sports Phys Ther*. 2004;34:565-588.

19. MacDermid JC, Wessel J. Clinical diagnosis of carpal tunnel syndrome: a systematic review. *Journal of Hand Therapy*. 2004;17:309-319.

20. Thonnard JL, Saels P, den Bergh PV, Lejeune T. Effects of chronic median nerve compression at the wrist on sensation and manual skills. *Experimental brain research*. 1999;128:61-64.

21. Bell-Krotoski J, Weinstein S, Weinstein C. Testing sensibility, including touch-pressure, two-point discrimination, point localization, and vibration. *Journal of hand therapy: official journal of the American Society of Hand Therapists*. 1993;6:114.

22. Levine DW, Simmons BP, Koris M, et al. A self-administered questionnaire for the assessment of severity of symptoms and functional status in carpal tunnel syndrome. *JOURNAL OF BONE AND JOINT SURGERY-AMERICAN VOLUME-*. 1993;75:1585-1585.

23. Ozyurekoglu T, McCabe SJ, Goldsmith LJ, LaJoie AS. The minimal clinically important difference of the Carpal Tunnel Syndrome Symptom Severity Scale. *J Hand Surg Am*. 2006;31:733-8; discussion 739-40.

24. Boyd KU, BING SGAN, Ross DC, Richards RS, Roth JH, MacDermid J. Outcomes in carpal tunnel syndrome: symptom severity, conservative management and progression to surgery. *Clinical and investigative medicine*. 2005;28:254-260.

25. Kim JK, Jeon SH. Minimal clinically important differences in the Carpal Tunnel Questionnaire after carpal tunnel release. *J Hand Surg Eur Vol*. 2012.

26. Thonnard JL, Saels P, den Bergh PV, Lejeune T. Effects of chronic median nerve compression at the wrist on sensation and manual skills. *Experimental brain research*. 1999;128:61-64.

27. Dellon AL, Keller KM. Computer-assisted quantitative sensorimotor testing in patients with carpal and cubital tunnel syndromes. *Ann Plast Surg*. 1997;38:493.

28. Hubbard MC, MacDermid JC, Kramer JF, Birmingham TB. Quantitative vibration threshold testing in carpal tunnel syndrome: analysis strategies for optimizing reliability. *J Hand Ther*. 2004;17:24-30.

29. Alfonso C, Jann S, Massa R, Torreggiani A. Diagnosis, treatment and follow-up of the carpal tunnel syndrome: a review. *Neurol Sci*. 2010;31:243-252.

30. Massey EW. Carpal tunnel syndrome in pregnancy. *Obstet Gynecol Surv*. 1978;33:145-148.

31. Mondelli M, Rossi S, Monti E, et al. Prospective study of positive factors for improvement of carpal tunnel syndrome in pregnant women. *Muscle and Nerve*. 2007;36:778-783.

32. Stolp-Smith K, Pascoe MK, Ogburn P, J. Carpal tunnel syndrome in pregnancy: frequency, severity, and prognosis. *Arch Phys Med Rehabil*. 1998;79:1285-1287.

33. Tucker AT, White PD, Kosek E, et al. Comparison of vibration perception thresholds in individuals with diffuse upper limb pain and carpal tunnel syndrome. *Pain*. 2007;127:263-269.

34. Leite J, Jerosch-Herold C, Song F. A systematic review of the psychometric properties of the Boston Carpal Tunnel Questionnaire. *BMC musculoskeletal disorders*. 2006;7:78.

35. Katz JN, Gelberman RH, Wright EA, Lew RA, Liang MH. Responsiveness of self-reported and objective measures of disease severity in carpal tunnel syndrome. *Med Care*. 1994;32:1127-1133.

36. Chatterjee JS, Price PE. Comparative responsiveness of the Michigan Hand Outcomes Questionnaire and the Carpal Tunnel Questionnaire after carpal tunnel release. *J Hand Surg Am*. 2009;34:273-280.

37. Greenslade JR, Mehta RL, Belward P, Warwick DJ. Dash and boston questionnaire assessment of carpal tunnel syndrome outcome: What is the responsiveness of an outcome questionnaire? *J Hand Surg*. 2004;29 B:159-164.

38. McConnell SG, Beaton DE, Bombardier C. *The DASH Outcome Measure User's Manual* First ed. Toronto, Ontario: Institute for Work & Health; 1999.

39. Kotsis SV, Lau FH, Chung KC. Responsiveness of the Michigan Hand Outcomes Questionnaire and physical measurements in outcome studies of distal radius fracture treatment. *J Hand Surg Am*. 2007;32:84-90.

40. Beaton DE, Katz JN, Fossel AH, Wright JG, Tarasuk V, Bombardier C. Measuring the whole or the parts? Validity, reliability, and responsiveness of the Disabilities of the Arm, Shoulder and Hand outcome measure in different regions of the upper extremity. *J Hand Ther*. 2001;14:128-146.

41. MacDermid JC, Mulè M. Concurrent validity of the NK hand dexterity test. *Physiotherapy Research International*. 2001;6:83-93.

42. Turgeon TR, MacDermid JC, Roth JH. Reliability of the NK dexterity board. *J Hand Ther*. 1999;12:7-15.

43. Portney LG, Watkins MP, eds. *Foundations of Clinical Research Applications to Practice* Second Edition ed. Upper Saddle River, New Jersey: Prentice Hall Health; 2000.

44. Stern LD. *A Visual Approach to SPSS for Windows.* 2nd ed. Pearson; 2010.

45. Gardner RC. *Psychological Statistics using SPSS for Windows.* Prentice Hall Upper Saddle River, NJ; 2001.

46. Finch E, Dina. Brooks, Stratford PW. Physical rehabilitation outcome measures. . 2002.

47. Worster A, Fan J, Upadhye S. Understanding receiver operating characteristic (ROC) curves. *CJEM*. 2006;8:19-20.

48. Liang H-, Wang Y-, Pan S-, Wang T-, Huang T-. Asymptomatic Median Mononeuropathy Among Men With Chronic Paraplegia. *Arch Phys Med Rehabil*. 2007;88:1193-1197.

49. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR. Methods to explain the clinical significance of health status measures. Mayo Foundation; 2002;77:371-383.

50. Yost KJ, Eton DT. Combining distribution-and anchor-based approaches to determine minimally important differences. *Eval Health Prof*. 2005;28:172-191.

51. Kazis LE, Anderson JJ, Meenan RF. Effect sizes for interpreting changes in health status. *Med Care*. 1989:178-189.

52. Liang MH, Larson MG, Cullen KE, Schwartz JA. Comparative measurement efficiency and sensitivity of five health status instruments for arthritis research. *Arthritis & Rheumatism*. 2005;28:542-547.

53. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* Lawrence Erlbaum; 1988.

54. Cohen J. Statistical power analysis for the behavioral sciences. . 1977.

55. Shi Q, MacDermid JC. Is surgical intervention more effective than non-surgical treatment for carpal tunnel syndrome? a systematic review. *Journal of orthopaedic surgery and research*. 2011;6:1-9.

56. Chung KC. The Minimal Clinically Important Difference of the Carpal Tunnel Syndrome Symptom Severity Scale. *J Hand Surg*. 2006;31:739-740.

57. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *The Journal of manual & manipulative therapy*. 2009;17:163-170.

58. Herrmann D. Reporting Current, Past, and Changed Health Status: What We Know about Distortion. *Med Care*. 1995;33:AS89-AS94.

59. Tassler P, Dellon A. Correlation of measurements of pressure perception using the pressure-specified sensory device with electrodiagnostic testing. *Journal of Occupational and Environmental Medicine*. 1995;37:862.

60. Dogan SK, Ay S, Evcik D, Baser O. Adaptation of Turkish version of the questionnaire Quick Disability of the Arm, Shoulder, and Hand (Quick DASH) in patients with carpal tunnel syndrome. *Clin Rheumatol*. 2011;30:185-191.

61. Gehrmann S, Tang J, Kaufmann RA, Goitz RJ, Windolf J, Li Z-. Variability of Precision Pinch Movements Caused by Carpal Tunnel Syndrome. *J Hand Surg*. 2008;33:1069-1075.

62. Van Brakel W, Khawas I, Gurung KS, Kets C, Van Leerdam M, Drever W. Intra-and inter-tester reliability of sensibility testing in leprosy. *International journal of leprosy and other mycobacterial diseases: official organ of the International Leprosy Association*. 1996;64:287.

Chapter 3

3 A Pilot Study to Determine the Effect of Cell Phone Texting on Patients with Carpal Tunnel Syndrome (CTS)

Cheung DKM, MacDermid JC, Grewal R

3.1 Introduction

Text messaging is a common method of communication. Between the years 2001 to 2011, there was a substantial increase in the number of cell phone subscribers and text messages sent in the United States of America. [1] A recent study examined the nature of cell phone usage over 2001-2011 and found at that in 2001, there were128.4million cell phone subscribers and 252.8 million text messages sent per month in U.S. [1] Ten years later, the number of cell phone subscribers has increased to 331.6 million and 193.1billion text messages were sent per month. In 2011, an average of 20 text messages were sent per day per user; although there is wide variability in usage. [1]

Case studies have reported that many adolescents and adults have suffered from injuries sustained from prolonged thumb texting activity. [2, 3] Case studies and observational studies have indicated injuries such as joint arthritis, tendonitis in the thumb, [4] and tenosynovitis suggesting a link to excessive texting. [3] A biomechanical study has indicated that people suffering from pain and numbness in the upper extremity (neck, arm, or hand) had lower muscle activity in the trapezius, but higher muscle activity in the thumb during a texting activity compared to non-symptomatic individuals. [5] This suggests an etiologic basis for hand pathology with excessive texting. Other studies have also indicated physiological changes from texting in healthy individuals, such as increased trunk stability, and changes in breathing patterns. [6] However, it is not clear how patient populations such as people with Carpal Tunnel Syndrome (CTS) are affected by texting. It might be assumed that pre-existing pathology increases the potential for adverse effects of texting. It is also unclear how the performance of patients with CTS might be impaired or different from individuals without CTS.

Carpal Tunnel Syndrome (CTS) is a common neuropathy associated with vascular, sensory, and motor impairments in the hand and the wrist. [7, 8] Classical symptoms for the diagnosis of CTS include: altered sensation, numbness, tingling, and occasionally pain in the hand. [7, 8] Studies suggest that these symptoms are aggravated from the increase in

carpal tunnel pressure within the carpal tunnel structure, [9-11] which compresses anatomical structures [12] against the median nerve. Carpal tunnel pressure varies depending on the posture of the wrist (flexion, extension, radial deviation, or ulnar deviation), forearm posture (pronated, semi-pronated, or supinated), and the finger posture (closed, pinch, straight, or relaxed). [7 9] Carpal tunnel pressures are the highest at extreme ranges of motion for the wrist depending on the postures of the fingers, and forearm. [13] Cell phone texting is commonly performed with the thumbs and may be characterized by both wrists in ulnar deviation and the fingers are in a closed or pinching position around the cell phone device. The thumbs perform repetitive motion of pressing against keys, while the other digits are flexed and grip the device.

Understanding the impact of texting on a patient population with CTS would inform our understanding about the nature of patients' symptoms with activity; and help clinicians make recommendations about the use of cell phones. Therefore the purposes of this study were:

1. To determine the feasibility of conducting a large cohort study examining long-term risks of texting in patients with CTS and normal age-matched controls

2. To establish the potential immediate effects that might be anticipated on superficial blood flow, sensory threshold and symptoms in response to texting

3. To determine difference in texting performance between patients with CTS and normal age-matched controls

3.2 Hypotheses:

1. We anticipate that feasibility will be demonstrated:
    a. If outcome measure variability suggests that a long–term cohort study could be conducted with less than 300 subjects in total
    b. If exclusion rates did not exceed 60%
    c. If participation rates exceeded 20%

   d. The rate of withdrawal does not exceed 20%
2. Patients with CTS will have significantly lower superficial blood flow, higher touch threshold, and worse symptoms than healthy controls. Significant changes will occur to measurement outcomes immediately after texting for patients only.
3. Patients with CTS will text significantly fewer characters, shorter duration, and slower average texting speed compared to healthy controls.

3.3 Materials and Methods:

Patients with known CTS were recruited from a tertiary health care setting was confirmed by one of three hand surgeons using clinical tests and results from electrodiagnostic studies. Patients were informed about the study either through the treating surgeon or through administrative staff. Patients were excluded from the study if they had one of the following exclusion criteria:

- Received previous surgery for CTS
- Insulin dependent Diabetes
- Younger than 18 years old or older than 65 years old
- Recent or current injury to the upper extremity, including neck – muscle, bone, or nerve injury (within the past year)
- Osteoarthritis
- Heart Condition
- Ongoing cancer
- CTS with ongoing pregnancy
- Vascular problems with the hands or arms (i.e. Raynaud's Syndrome)

Age and gender matched persons without CTS were also recruited as controls for the study. The controls were recruited through posters advertisement in the hospital and through word of mouth to hospital staff (physiotherapists, occupational therapists, and administrative staff), and graduate students. When controls were recruited by word of mouth, the primary investigator explained the study at staff meetings to inform and guide staff to decide whether they would be interested and/or eligible for the study. Exclusion criteria were explained to staff to advise them to whether they were eligible for the study or not. Hard copies describing the study, contact information, and a sign-up sheet were given to staff. Patients were matched with controls recruited for the study within an age range of ± 5 years. Persons who were 65 years old were matched with a control between ages 60 to 65 years old to stay within the age bracket of the study. Patients were matched to age and gender matched controls to allow for matched comparisons and improve statistical power. Recruitment of the controls was based on the same exclusion criteria as patients with CTS to participate in the study. Only one visit was required for the study for each participant. Each participant was asked not to consume any caffeine (i.e. tea or coffee) 4 hours before the study. All participants who participated in the study understood the letter of information and provided signed consent to participate in the study.

3.4 Outcome Measures:

TIVI (Tissue Viability Imaging) 600 polarization spectroscopy camera (version 7.4 Wheelsbridge AB, Linköping, Sweden): TIVI software was used to quantify red blood cell concentration on the palmar side of the hand using a digital camera (Canon Rebel EOS model 450D, Japan) with a polarization lens. The camera was supported by a multi-jointed metal arm provided by Wheelsbridge and the arm was secured to a desk. The camera was adjusted to point downwards towards the surface of the desk. A royal blue coloured file folder was placed under the camera to fill the camera view. An outline was drawn on the blue folder to standardize hand positioning for the left and right hand. Each participant was required to place their hand in line with the outline with hand(s) in

supinated position with the skin grooves for each interphalangeal joint of the fifth phalange in line with specific markings on the hand outline. The participants were asked to keep their palms in an open position with all fingers and their thumb in line with each other. Each image was captured with the polarized lens set at the cross polarization setting and the camera was positioned at a distance between 200mm to 300mm from the participant's hand. Image quality was set to medium normal. One photo was taken every 5 seconds and uploaded into the attached laptop computer. The camera has a light penetration depth between 400 to 500 micrometers. [14]

Once the images were captured, the TIVI images were processed using the TIVI software. For each participant, one image at baseline and at each follow up point (0, 2, 5, and 10 minute(s) after texting) were used for processing and analysis, for a total of 5 images per participant. If the participant had bilateral CTS, only one hand (left or right) was processed and analyzed for this study. For patients with bilateral CTS, the hand with more severe symptoms as defined by the SSS was used for processing and analyzed. If only one side was affected with CTS, that hand would be used. The same sided hand was processed for matched controls. Regions of Interest (ROI's) were selected at the distal pulps of each finger and the sum of the ROI's represented total blood flow in the hand. Curve tracker was used to produce a spread sheet categorizing the magnitudes of red blood cell concentration by the selected ROI's. Values for the TIVI are measured by Arbitrary Units (A.U.). Data was exported from the TIVI software into Microsoft Excel 2007 spreadsheets via Curve Tracker and then imported into SPSS version 19.0 for analysis. The TIVI has been validated for construct validity to measure superficial red blood cell concentration with in vitro fluid models and computer simulations. [14, 15] The models performed in vitro demonstrated that the TIVI software was able to accurately calculate the oxygen saturation level of 91.5%, which is within the physiological range of oxygen saturation within blood. [14] The TIVI has been shown to be sensitive to change during blood occlusion testing, [15] and drug testing on skin. [16] The TIVI has demonstrated inter-laboratory reliability. [17] When 4 TIVI units were tested in two different sites with identical protocols, the average systematic drift was <1.02% for all 4 units under the same protocol. [17] When the same protocol was repeated 2 months later, TIVI

demonstrated test retest reliability. [17] The maximum percentage deviation ranged from 0.74% to 1.7%. [17]

Pressure Specified Sensory Device (PSSD) (NK Biotechnical Corporation, Minneapolis, MN, USA): This computerized tool measures touch threshold or the amount of pressure required to elicit a response on the distal pulp of the thumb. The PSSD was collected with the participant seated at the testing station and with the participant resting his hand in a supinated position on a piece of foam and asked to close his eyes. The tester would gently touch the pulp of the thumb at 5 different points with the PSSD device and the participant would respond when they detected the stimuli by pushing a trigger in the other hand. The highest and lowest values were discarded and the average of three values was recorded as the measure of touch threshold. The PSSD has been evaluated for reliability (r= 0.95) and inter-rater reliability in patients with neuropathy for one point static testing (r= 0.93 - 1.00). [18]

Numeric Rating Scale for Pain: This scale allowed patients to rate their measured pain in the hand at a specific point in time. The numeric rating scale ranges from 0 to 10. Participants were asked to first rate their pain between 0 (not experiencing the symptom at all) to 10 (worst possible rating) verbally. The first author (DC) would mark down the rating to the corresponding scale. For bilateral CTS cases, the hand chosen for analysis was the side which had greater symptom severity based on the patient's concern, and from patient lists. For unilateral cases, the affected side was tested. For controls, the side tested was matched to the patient's same side. The numeric pain rating scale has been validated for examining changes in pain qualities in CTS after treatment. [19]

Numeric Rating Scale for Numbness: Numeric rating scales for measuring numbness have been suggested to be valid for measuring the severity of Carpal Tunnel Syndrome. [20, 21] The numeric rating scale ranges from 0 to 10. Participants were asked to first rate the amount of numbness they experienced in their hand between 0 (not experiencing the symptom at all) to 10 (worst possible rating) verbally. The first author (DC) would mark down the rating to the corresponding scale. For bilateral CTS cases, the hand chosen for analysis was the side which had greater symptom severity based on the patient's concern,

and from patient lists. For unilateral cases, the affected side was tested. For controls, the side tested was matched to the patient's same side. The numeric rating scale for numbness is a component of the PQAS (Pain Quality Assessment Scale), and measures sensibility impairment, similar to the Ten test. The PQAS is a 20 item scale which allows the patient to rate various components of pain between 1 (none) to 10 (worst). The numeric rating scale for numbness in the PQAS has been shown to be a responsive tool for measuring change in numbness (ES = 1.27) after treatment for CTS with injection and lidocaine patch, separately. [19] The Ten test is a sensory test where patients rate the extent of sensory impairment between 1 (impaired) to 10 (normal or best sensibility). The test retest reliability of the numeric rating scale for numbness has not been verified, but the Ten test [22] has been verified to show inter-rater reliability (ICC = 0.91) for 49 patients with peripheral nerve disorders.

Numeric Rating Scale for Fatigue: The purpose of the numeric rating of fatigue is to rate perceived fatigue after an activity. The numeric rating scale ranges from 0 to 10. Participants were asked to first rate the amount of fatigue they experienced in their hand between 0 (not experiencing the symptom at all) to 10 (worst possible rating) verbally. The first author (DC) would mark down the rating to the corresponding scale. For bilateral CTS cases, the hand chosen for analysis was the side which had greater symptom severity based on the patient's concern, and from patient lists. For unilateral cases, the affected side was tested. For controls, the side tested was matched to the patient's same side. The numeric rating scales for fatigue and numbness have been used in new patients with cancer receiving chemotherapy [23] for rating fatigue and numbness affecting the whole body. We are uncertain if the numeric rating scale for fatigue is valid and reliable for patients with CTS after performing an activity because this application has not been tested, but numeric rating of pain and other symptoms have been consistently high across numerous contexts.

Symptom Severity Scale (SSS): The SSS is a self-report questionnaire designed for measuring symptoms experienced by patients with CTS. [24] The SSS is composed of 11 questions each rated 1 through 5 that measures symptoms experienced in a typical 24 hour period within the past 2 weeks. Respondents rate the severity of CTS-related

symptoms and disability where a rating of 1 indicated that there was no symptom at all, and 5 represented the worst symptom experienced. [24] Rating the scale was done for both the left and right hand to determine which hand was worse. The mean score was calculated for each hand and the hand with the higher score was used as the final score for calculations in this study. The SSS has been assessed and found to be valid for face, content, and construct validity in measuring clinically relevant change in patients with CTS. [24] The SSS was used to determine which hand had more severe symptoms in bilateral cases. The SSS has also been shown to be reliable [24, 25] and responsive. [26, 27]

Texting Performance: For texting performance, we wanted to observe the number of characters texted, duration texted (seconds), and the texting speed (characters/second). The number of characters texted was counted for each participant. This value was the sum of the number of characters and the number of spaces entered into the cell phone during the visit for each participant. Each text message was sent to an email account and then copied to a word processing software (Microsoft Office 2010). The number of characters was counted using a count feature within word processing software to count all characters and spaces in the text messages. The duration each participant was able to text was timed with a digital timer in seconds. The timer counted down from 15 minutes. The duration of texting recorded was when the time was up or if the patient requested to stop texting early because of symptoms; whichever was first. The texting speed was calculated by dividing the number of characters and spaces entered into the cell phone it by the duration in seconds which the participant was texting.

3.5 Procedure:

The letter of information was explained to each participant and consent was provided. Then, each participant provided the following demographic information: age, gender, duration of symptoms (for patients only), which hand was affected (for patients only), hand dominance (left or right), whether the injury was involving Workplace Safety and Insurance Board (WSIB), and familiarity with texting on a QWERTY phone (yes or no). Then the SSS was completed. Data for the TIVI, the numeric rating scale for pain, fatigue, and numbness, and the PSSD were collected at rest (in this order).

Participants were then asked to perform a standardized texting task. Immediately after texting, data for the TIVI, PSSD, and the Numeric Rating Scale for Pain, Fatigue, and Numbness were collected. These outcome measures were measured again at 2 minutes, 5 minutes, and 10 minutes after texting.

3.6 Intervention:

During the texting activity, patients and controls were asked to text with a cell phone while seated and to use only their thumbs to text in their response to questions from a questionnaire. The same cell phone was used for all the participants and all participants used the QWERTY key pad on the cell phone. The questionnaire was composed of 60 questions which allowed for open ended responses. The questionnaire asked patients general questions regarding how participants learn about the study, or where did they plan to go after the study. The questionnaire was designed for this study and is not a standard part of patient care. Participants were asked to place a space between each word they entered. After each question, participants were asked to place a period and then proceed to the next question. This period was used by the authors to separate each response in the questionnaire. Since the cell phone had a limit of 600 characters per text message, once text message reached 600 characters, each text message was sent to the first author's email account. After each message was successfully sent, the participant continued texting from the questionnaire. Each participant performed the texting activity for a maximum time of 15 minutes. If the activity was too uncomfortable, the time of pain free typing was recorded. If participants completed answering the entire questionnaire, the participants were asked to complete the questionnaire again until 15 minutes had elapsed from the start of the texting activity. The cell phone was set to prevent word prediction to complete the replication of the script.

Cell Phone Model: The cell phone that was used for the study was a LG Rumour 2 (LG Corp, Seoul, South Korea) which has a sliding QWERTY touch key pad for entering text message. A QWERTY key pad is type of key pad interface where the top left letter row read from left to right is Q-W-E-R-T-Y. Only the QWERTY key pad was used in this study. A T9 key pad which was also available on the phone (but not used for this study)

is a key pad with 9 keys which has a predictive feature for letters or numeric characters. The predictive word feature for the phone was turned off.

Table 3.1: Cell Phone Specification

Company and Model	LG Rumour 2
Dimensions (height x width x depth)	11.2 x 5.3 x 1.8 cm in QWERTY mode)
Weight	120g
Resolution	240 x 320 pixels
Keyboard Input Text	QWERTY or T9
Maximum character and space storage per text message	600

3.7 Analysis:

Objective 1: Sample Size Calculation for Feasibility Study. Sample size for future cohort studies was calculated based on the observed variability of the measures in this study trial. The sample size was determined using a sample size calculator based on a 2 sided test to determine a significant difference between the patient and control group as independent variables [28] from http://stat.ubc.ca/~rollin/stats/ssize/n2.html at a power of 80% with $\alpha = 0.05$. The value for x_1 was a pooled score of patient and control scores at baseline, and x_2 was the sum of x_1 and 20% [29] of x_1 for each outcome measure, to account for clinically important change. The standard deviations for the calculator were derived from each of the 6 outcome measure based on x_1 (Table 2). The minimum sample size required for a full study ranged between 16 to 120 patient participants per group depending on the outcome measure (Table 4). The sample size for a full study would

depend on which outcome measure(s) will be used. Statistical significance was considered if $p<0.05$.

Objective 2 and 3: Determining Differences within and between Patients and Healthy Controls. Generalized Linear Model (GLM) [30] was used to determine if patients have different measures of blood flow, sensory threshold, and symptoms compared to controls at baseline (compare SSS, TIVI, PSSD, and NRS for pain, fatigue, and numbness) at rest and at each follow-up point after texting. Interactions were examined for significance between group and time. Post hoc analyses were performed using Bonferroni Correction for non significant interactions to determine between group differences. Pair wise comparisons [30] were used to perform within-group comparisons to compare between baseline scores to each of the follow-up scores.

An analysis of covariance (ANCOVA) [30] was performed to compare texting performances between patients and controls for the number of characters texted, time texted, and texting speed. Experience with texting was controlled as a covariant.
Data was checked for normal distribution for each follow up point. Differences were considered significant with $p<0.05$.

3.8 Results:

Seventy one patients were screened for the study using patient lists for 8 months from mid January to mid September 2012. The data were considered normally distributed because sample sizes were equal in both groups. [3132] Data had minor violations of the assumption of circularity and adjustments were made with the Greenhouse-Geisser epsilon to the degrees of freedom to correct for this violation. [32, 33] No data were missing. Demographic information of participants is presented in Table 1.

Objective 1: Feasibility of the Research Study. We had a 21% accrual rate for acquiring patients from the potential pool of available subjects, as we successfully recruited 15 out of 71 eligible patients. Thirty nine patients (55% of potential patient

participants) were excluded because they did not meet the inclusion criteria (Table 1b) (Figure 1). Twenty two potential patient participants were approached (31%). Six patients refused to participate when approached (Table 1c). Ten patients were not approached (Table 1d). Sixteen patients were recruited for the study, indicating a 73% recruitment rate. One patient withdrew from the study, indicating a withdrawal rate of 6% (Table 1c). Thus, fifteen patient participants completed the study. Fifteen healthy age and gender matched controls were also recruited as controls. The 3 main exclusion criteria for excluding patients was because of age (patients were over 65 years old), from co-morbidities to upper extremity, or from diabetes (Table 1b) The main reason potential patients refused to participate in the study because they were not interested in the study, as they had other commitments after their appointments. Ten potential patient participants were not approached (Figure 1). The most common reason for not approaching potential patient participants were the first author (DC) or administrative staff missed the opportunity to approach the study to patients (Table 1d). Surgeons found most patients were willing to participate in the study, unless patients did not have time before or after the study to participate because of personal commitments. The study took a maximum of 40 minutes to complete for each participant. For a full study to be completed, the sample size per group will range between 16 to 120 patients or between 32 to 240 participants in total depending on the outcome measure (Table 4). In regarding recruitment, recruitment was slow in the spring and summer months between May to August. Only one patient came in during that time period. During the spring and summer months were when most patients refused to participate because they had other time commitments after their medical appointment.

In terms of methodological concerns, equipment and protocol was straight forward to follow and complete. Training took 2 weeks for the evaluator at the laboratory to become familiarized with using the five measurement outcomes. The evaluator required the most time learning how to operate the TIVI system properly, as it was a new addition to the existing laboratory. Learning to capture photos and analyze the data took 10 working days. Two experienced research assistants trained the evaluator to use the PSSD for two 30 minute sessions.

Objective 2: Impact of Texting on Touch Threshold, Superficial Red Blood Cell Concentration, and Symptoms. Prior to texting, patients demonstrated significantly higher touch threshold (4.04g/mm^2 versus 2.62 g/mm^2) ($p = 0.014$) (Table 2 and Figure 3) and higher ratings on symptoms (all $p<0.05$)(See Table 2 and Figures 4,5, and 6). Patients had on average 3 points higher for pain and fatigue, and 4 points higher for numbness than controls. There were no significant differences in superficial red blood cell concentration between groups at baseline; although patient scores were on average 15 A.U. higher, but was not statistically significant (736 A.U. versus 682 A.U.) ($p = 0.29$).

After texting, touch threshold increased significantly for patients, and touch threshold values did not return to baseline levels at 10 minutes after texting (Table 2 and Figure 3). There were gradual increases in symptoms of pain, and numbness after texting for the patient group, but the increases were not significantly different from baseline. Fatigue increased significantly only immediately after texting Table 2 and Figure 6). All outcome measures for the control group did not change significantly from texting.

3.8.1.1 Description of Outcome Measures at Baseline, Immediately after Texting, 2 minutes, 5 minutes, and 10 minutes after Texting

Superficial Red Blood Cell Concentration. At baseline before texting, patients had 8% more superficial red blood cell concentration compared to controls (736.08 A.U. versus 682.20 A.U. for patients and controls respectively), but was not significantly higher than baseline ($p=0.29$). After texting, patients had a decrease of 0.3% from baseline following texting, and controls had a decrease of 2.2% from baseline superficial red blood concentration immediately following texting. No significant changes were found over time ($p=1.00$).

Red blood cell concentration remained relatively constant throughout the study ($p=1.00$), and patients had higher red blood cell concentration compared to controls, but was not significantly higher ($p = 1.00$) (Figure 2). For patients, red blood cell concentration decreased from 736.08 at baseline to 733.88 immediately

after texting (0.3% decrease from baseline). Patients had a decrease immediately after texting from 733.88 A.U. to 704.49 A.U. at 2 minutes (4.3% decrease from baseline), 751.45 A.U. at 5 minutes (2% increase from baseline), and 705.54 A.U. at 10 minutes after texting (4% decrease from baseline). Controls had a decrease immediately after texting from 682.2 A.U. to 667 A.U. (2% decrease from baseline). The red blood cell concentration for controls decreased from baseline at 682.20 A.U. to 667 A.U. at 2 minutes,(0.7% decrease from baseline), then decreased to 675.16 A.U. at 5 minutes (1% decrease from baseline), and then decreased to 644 A.U. at 10minutes after texting (5.6% of baseline).

Touch Threshold. Patients had 53% higher touch threshold values compared to controls at baseline before texting (4.04g/mm^2 versus 2.62g/mm^2 for patients and controls respectively). Patients' touch threshold significantly increased by 66% from baseline immediately after texting (4.04 to 6.71g/mm^2) ($p = 0.008$), whereas the touch threshold for controls increased by 14% (2.62g/mm^2 to 3.00g/mm^2) ($p=1.00$).

After texting, touch threshold values for patients remained higher than baseline, and did not return towards baseline at 2, 5, or 10 minutes after texting. After texting, touch threshold for patients decreased from 6.71g/mm^2 to 5.51g/mm^2 at 2 minutes (136% of baseline value)($p=0.09$), increased to 6.19 g/mm^2 at 5 minutes (153% of baseline value)($p=0.02$), and decreased to 5.51g/mm^2 at 10 minutes after texting (136% of the baseline magnitude)($p=0.035$)(Figure 2). The touch threshold value at 5 minutes and 10 minutes after texting were significantly higher than the baseline value, but not the touch threshold value at 2 minutes after texting. After texting, the control group experienced a decrease in touch threshold from 3.00g/mm^2 to 2.27g/mm^2 at 2 minutes (87% of baseline value), then increased to 2.48 g/mm^2 at 5 minutes (95% of baseline value), and then increased to 2.45g/mm^2 at 10 minutes after texting (94% of baseline value). No significant differences were found between baseline and follow up values for the control group ($p = 1.00$).

Pain. At baseline before texting, patients had pain ratings 3 points higher than controls (2.73 versus 0.07 points for patients and controls respectively) at baseline (Table 2). Patients experienced significantly more pain than controls ($p<0.05$). After texting, patients experienced an increase of 1 point more pain (2.73 and 3.87 points before and after texting respectively), although not significantly higher than baseline ($p=0.152$), whereas the controls did not experience substantial change in pain ratings after texting (0.07 to 0.13 points before and after texting respectively) ($p=1.00$).

After texting, pain ratings decreased towards scores at baseline for patients and pain scores were not significantly different from baseline ($p=0.15$ -1.00). Pain ratings remained relatively unchanged for controls ($p=1.00$) (Table 2 and Figure 4). Differences on pain ratings were +0.07, -0.2, and +0.2 point between baseline and follow up scores at 2 minutes, 5 minutes, and 10 minutes respectively after texting for patients. The differences in pain ratings for controls between baseline and follow up points at 2, 5, and 10 minutes after texting were 0, +0.13, and -0.07 point respectively. Pain scores after texting did not differ significantly from the baseline pain score ($p = 1.00$).

Numbness. Patients had numbness ratings which were on average 4 points higher than controls at rest, which was significantly higher ($p<0.05$). Patients experienced an increase of 0.6 point in numbness after texting, whereas controls had increase of 0.21 point in numbness ratings. Neither group experienced a significant change in numbness after texting ($p=1.00$).

After texting, rating score for numbness decreased towards baseline for the patient group. Differences on ratings for numbness were +0.27, -0.33, and 0 point between baseline and follow up scores at 2 minutes, 5 minutes, and 10 minutes respectively after texting for patients. The differences in ratings for numbness between baseline and follow up points at 2, 5, and 10 minutes after texting were

+0.07, +0.14, and 0 point respectively for controls, which were not significantly different from the baseline value (p=1.00) (Table 2 and Figure 5).

Fatigue. Patients had fatigue ratings which was 3 points higher than controls at baseline. Patients had fatigue ratings 2 points higher than controls ($p<0.05$). Patients experienced a significant increase of 2 points in fatigue rating immediately after texting (p=0.016), whereas controls had a 1 point increase in fatigue immediately after texting, although the change was not significant from baseline (p=0.33).

After fatigue increased from texting, fatigue ratings decreased towards scores at baseline for patients and controls (Table 2 and Figure 6). Differences on ratings for fatigue were +0.4, -0.06, and +0.14 point between baseline and follow up scores at 2 minutes, 5 minutes, and 10 minutes respectively after texting for patients. No significant differences were found between baseline and follow up points for patients (p=1.00). The differences in ratings for fatigue between baseline and follow up points at 2, 5, and 10 minutes after texting were +0.6, +0.33, and +0.13 point respectively. No significant differences were found between baseline and follow up points for controls (p=1.00).

Objective 3: Performance differences between Patients and Controls. When experience was controlled for in texting performance, patients with CTS texted fewer characters [$F(1,27) = 19.81$ ($p<0.05$), $\eta^2 = 0.42$] (Table 3) and had a slower texting speed than controls [$F(1,27) = 22.63$ ($p<0.05$), $\eta^2 = 0.46$)] (Table 3). No difference was found in the duration of time patients and controls were able to text ($F(1,27) = 2.50$ ($p=0.13$), $\eta^2 = 0.085$) (Table 3). All 15 controls performed 15 minutes of texting, but only 12 out of 15 patients completed the full 15 minutes.

Table 3.1a 1 Sample Characteristics

Characteristics	Patients (mean ± SD) (median)	Controls (mean ± SD) (median)
Age(years)	48 years old ± 11 years (50)	46 years old ± 11 years (49)
Men: Women	7:8	7:8
Symptom Duration (weeks) (±SD)	266 ± 425.75 (112)	Does not apply
right: left hand ratio	10:5	10:5
Ratio of participants familiar with texting on QWERTY keypad: Not familiar with texting on QWERTY keypad	10:5	10:5
SSS	3.04	1

SD = Standard Deviation. SSS = Symptom Severity Scale

Table 3.1b 1: Reasons for Lack of Eligibility Based on Exclusion Criteria

Exclusion Criteria	Description of Exclusion Criteria	Number of Patients Excluded from Study	Percentage of Total Potential Patient Participants
Diabetes	Diabetes can impair sensation in the hand. Did not discriminate for patients who are insulin dependent. Patients who are not dependent on insulin may not have impairments to sensation.	7	9.9%
Too old (>65 years old)	N/A	16	23%
Injury to Upper Extremity (Co-morbidity)	Trigger finger, swelling, elbow injury, and osteoarthritis	10	14%
Surgery has been done previously	Surgery was performed previously by surgeons at this site. Certain health conditions may be the cause of patients to come in for second surgery.	2	2.8%
Heart Condition	Patients had abnormal	2	2.8%

	heart beat which may influence TIVI values.		
CTS was not confirmed by surgeon on site	Patients were suggested to have CTS by their family physician	2	2.8%
Total		39	55%*

*value has small degree of rounding error

Table 3.1c 1: Reasons for Refusal to Participate

Reason for Not Participating in Study	Number of Participants	Percentage of Total Potential Patient Participants
Not Interested	5	7.0%
Language barrier (i.e. did not understand English)	1	1.4%
Withdrew from study (to attend appointment with surgeon)	1	1.4%
Total	7	10%*

*value has small degree of rounding error

Table 3.1d 1 Reasons for Not Approaching Potential Participants

Reason for Not Participating in Study	Number of Participants	Percentage of Total Potential Patient Participants
Timing (i.e. secretaries felt it was too early in the morning for patients and commute to hospital)	2	2.8%
Missed opportunity to recruit patient (i.e. illness)	5	7.0%
Patient Missed Appointment with Surgeon	3	4.2%
Total	10	14%*

*value has small degree of rounding error

Descriptive Data of Outcome Measures for Measuring Effects of Texting

Tool	Group		Baseline	Immediately after Texting	2 min after Texting	5 min after Texting	10 min after Texting
PSSD	Patient	Mean (SD)	4.04 (3.36)	6.71 (5.94)	5.51 (3.51)	6.19 (5.58)	5.51 (3.91)
		Median	3.00	4.70	5.20	5.20	4.70
	Control	Mean (SD)	2.62 (1.84)	3.00 (2.10)	2.27 (1.60)	2.48 (1.66)	2.45 (1.64)
		Median	1.80	2.00	1.70	1.70	1.90
TIVI	Patient	Mean (SD)	736.08 (154.43)	733.88 (149.90)	704.49 (129.79)	751.45 (133.00)	705.54 (104.69)
		Median	714.82	730.00	690.23	778.93	677.94
	Control	Mean (SD)	682.20 (185.54)	667.00 (16.20)	683.00 (180.00)	675.16 (182.48)	644.00 (147.71)
		Median	664.04	662.50	648.33	649.56	646.64

Tool	Group		Baseline	Immediately after Texting	2 min after Texting	5 min after Texting	10 min after Texting
Pain	Patient	Mean (SD)	2.73 (2.01)	3.87 (2.77)	2.80 (2.83)	2.53 (3.00)	2.93 (2.88)
		Median	3.00	3.00	2.00	1.00	2.00
	Control	Mean (SD)	0.07 (0.26)	0.13 (0.35)	0.07 (0.26)	0.20 (0.56)	0.00
		Median	0.00	0.00	0.00	0.00	0.00
Fatigue	Patient	Mean (SD)	2.93 (2.31)	4.80 (2.98)	3.33 (2.91)	2.87 (2.85)	3.07 (2.60)
		Median	3.00	5.00	2.00	2.00	2.00
	Control	Mean (SD)	0.07 (0.26)	1.27 (1.44)	0.67 (1.11)	0.40 (0.63)	0.20 (0.41)
		Median	0.00	1.00	0.00	0.00	0.00

Tool	Group		Baseline	Immediately after Texting	2 min after Texting	5 min after Texting	10 min after Texting
Numb -ness	Patient	Mean (SD)	4.00 (3.02)	4.60 (3.22)	4.27 (3.10)	3.67 (3.72)	4.00 (2.95)
		Median	3.02	3.22	3.10	3.18	2.95
	Control	Mean	0.00	0.21 (0.77)	0.07 (0.27)	0.14 (0.36)	0.00
		Median	0.00	0.00	0.00	0.00	0.00

Table 3.2: Descriptive Data of Outcome Measures for Measuring Effects of Texting

SD = standard deviation. Min = minutes

Characteristic of Texting Performance	**Patients**	**Controls**
Number of Characters Texted (mean)(SD)	631 (246)	993 (209)**
Duration of Texting (seconds) (SD)	809.87	900
Average Texting Speed (characters/second) (SD)	0.76 (0.19)	1.10(0.23) **
% Completed Texting Task	80%	100%

Table 3.3: Descriptive Data of Texting Performance

** = significantly higher
SD = Standard Deviation

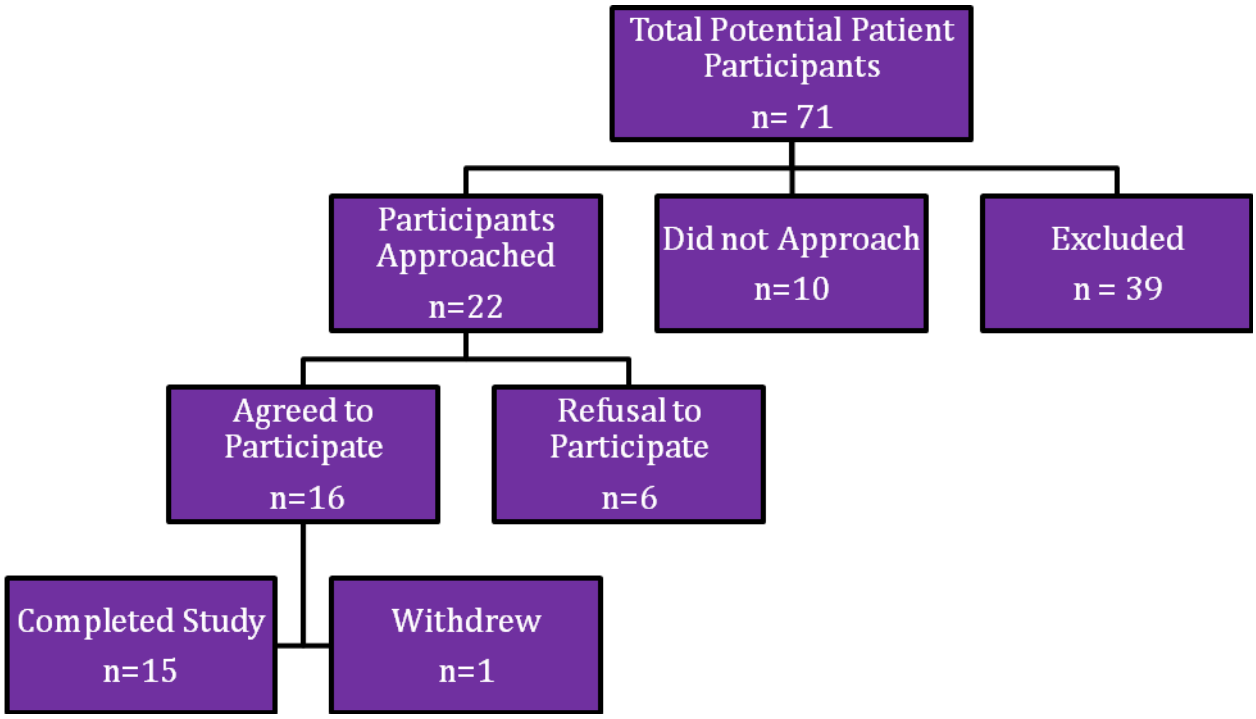


Figure 3.1: Flow Chart Detailing the Recruitment of Patient Participants

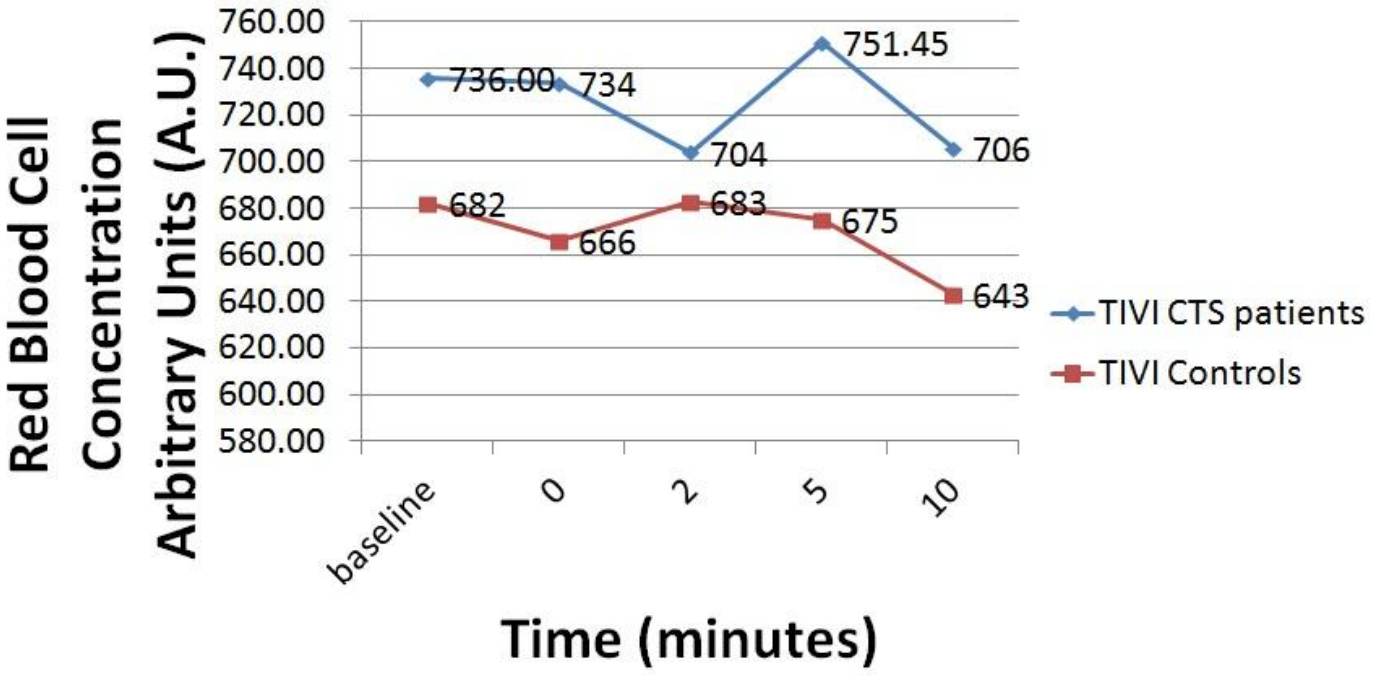


Figure 3.2: Changes in Red Blood Cell Concentration in Patients over Time

TIVI = Tissue Viability Imaging

Min post = minutes post texting

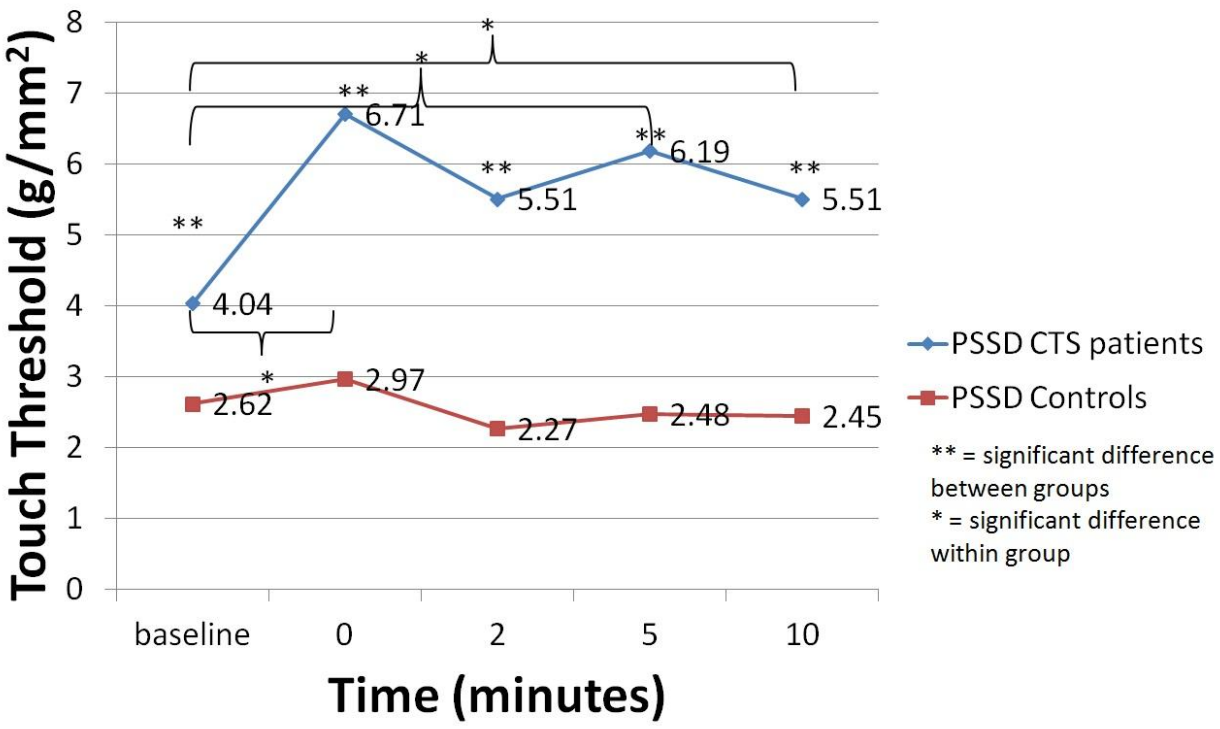


Figure 3.3: Changes in PSSD over Time for Patients and Controls

PSSD = Pressure Specified Sensory Device

Min post = minutes after texting

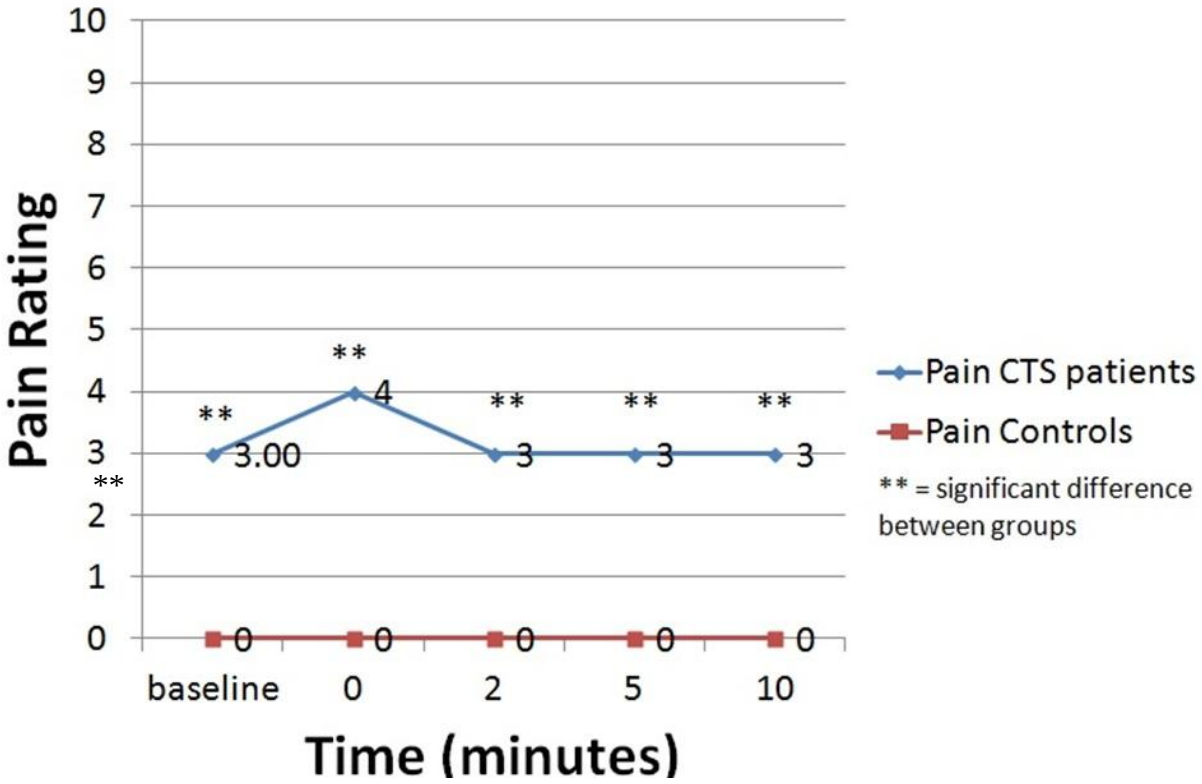


Figure 3.4: Changes over time with Pain

Min post = minutes after texting

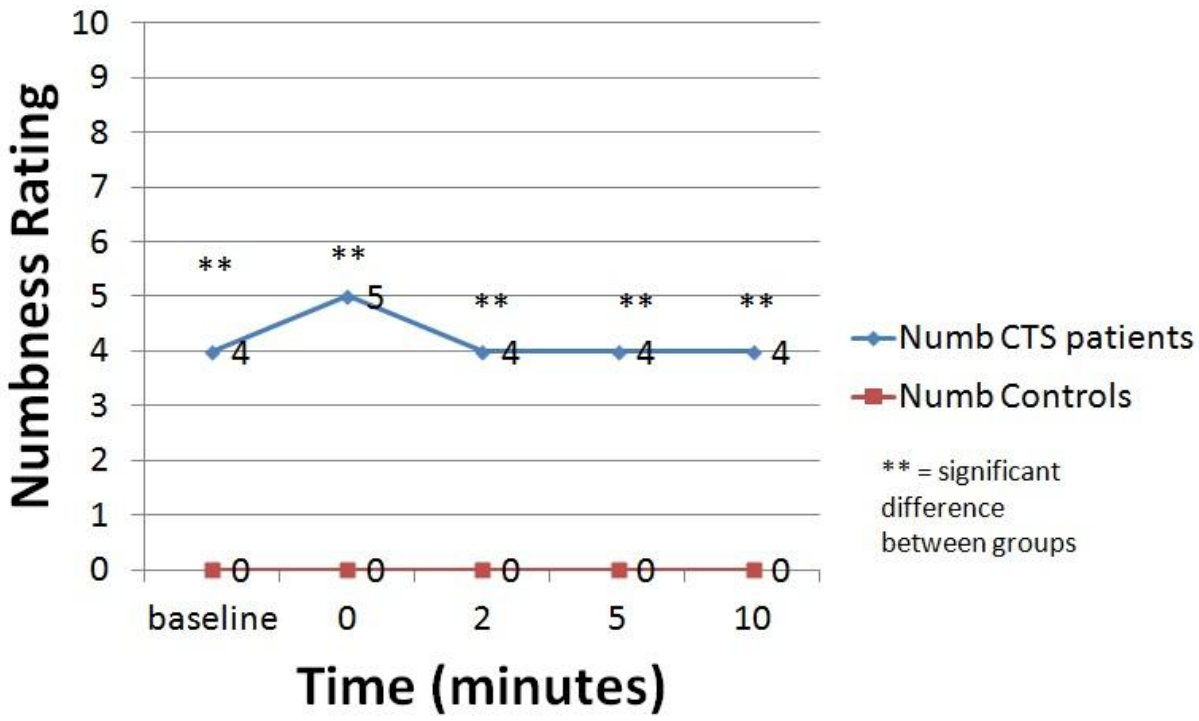


Figure 3.5 Changes over time with Numbness

Min post = minutes after texting

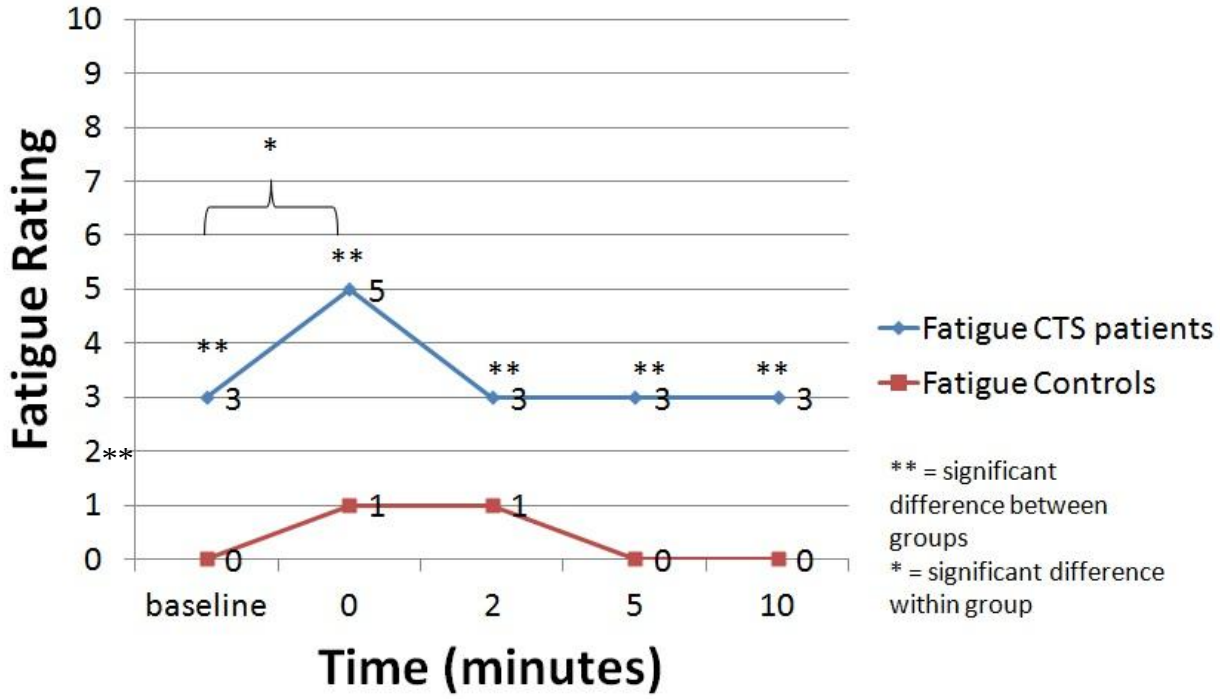


Figure 3.6: Change over Time with Fatigue

Min post = minutes after texting

Measurement outcome	Sample Size Required per group	Patients to be Screened Based on Accrual Rate of 21%	Total Number of Participants
PSSD	120	571	240
TIVI	23	110	46
Pain NRS	16	76	32
Fatigue NRS	36	171	72
Numbness NRS	36	171	72

Table 3.4: Comparison of Sample Sizes Required for a Full Study

PSSD = Pressure Specified Sensory Device, TIVI = Tissue Viability Imager, NRS = Numeric Rating Scale

	Pilot	Full Study	Rational for Changes to Pilot Study
Study Design	Test Retest study	Test Retest study	Appropriate for methodology
Exclusion Criteria	• Received previous surgery for CTS • Diabetes • Younger than 18 years old or older than 65 years old • Recent or current injury to the upper extremity, including neck – muscle, bone, or nerve injury (within the past year) • Osteoarthritis • Heart Condition • Ongoing cancer • CTS with ongoing pregnancy • Vascular problems with the hands or arms (i.e. Raynaud's Syndrome)	• Received previous surgery for CTS • Diabetes without altered sensation from diabetes. • Younger than 18 years old and under 65 years old • Injury to the hand or wrist (i.e. fracture, osteoarthiritis, amputation) (within the past year) • CTS with ongoing pregnancy • Vascular problems with the hands or arms (i.e. Raynaud's Syndrome)	The exclusion criteria on recent injury eliminated 14% potential candidates from the study. It was the 2nd top reason patients were excluded and too conservative. Patient with recent minor injuries should be allowed to participate. Although some patients have diabetes, they may not have impaired sensation. Diabetics who do not require insulin injection should not be excluded from this study. Aging is known to be factor to result in peripheral nerve degeneration and touch threshold increases with age. [34, 35 36-38]
Sample Size	15 per group	Depends on outcome measure (Table 4)	http://stat.ubc.ca/~rollin/stats/ssize/n2.html [28]
Study Intervention	Texting on cell phone for 15 minutes from questionnaire	Texting on cell phone for 15 minutes from questionnaire. Cell phone models and type should be chosen carefully.	Some participants were more familiar with their own cell phone rather than the one provided. Index finger could also be used for texting.

Pilot	Full Study	Rational for Changes to Pilot Study	Pilot
Setting	Research laboratory at tertiary health care setting specializing in upper extremity	Research laboratory at tertiary health care setting specializing in upper extremity	Environment is suitable for recruiting patients with CTS.
Measurement Outcomes	• TIVI • PSSD • Numeric Rating Scale for Pain • Numeric Rating Scale for Numbness • Numeric Rating Scale for Fatigue	• TIVI • PSSD • Numeric Rating Scale for Pain • Numeric Rating Scale for Numbness • Numeric Rating Scale for Fatigue	All tools were straight forward to operate. Testing took maximum of 40 minutes to complete.

Table 3.5: Comparison of Exclusion Criteria, Sample Size, and Outcome Measures for Pilot and Full Study

TIVI = Tissue Viability Imaging, PSSD = Pressure Specified Sensory Device

3.9 Discussion

In this pilot study, we examined the differences between and within a group of patients with CTS and a group of age and gender matched controls after completing a texting task. This study found that patients with CTS experienced more symptoms and had more impairment to sensation compared to age and gender matched controls at all time points. In terms of texting performance, patients also performed worse than controls.

Study Feasibility:

This pilot study can be expanded into a full study with some changes to the exclusion criteria. Our primary focus for this study was to examine the feasibility of recruiting patients for this study. We were able to determine a sample size that was under 300 subjects, have an exclusion criteria rate less than 60%, participation rate greater than 20%, and have a withdrawal rate of less than 20%. Recruitment of patient participants by surgeons seems to be the most optimal method, as most patients were willing to participate. Our exclusion criteria for excluding any potential patient with other recent hand injuries were too conservative at times. We felt that hand injuries occur commonly and we were limiting our recruitment to patients with CTS and no other injuries. For example, a patient who has a minor bruise or cut on the palms could be recruited. In addition, diabetics who are not insulin dependent could be included in this study. Those with diabetes were originally excluded from this study was because they were assumed to all suffer from neuropathy and have altered sensation caused by diabetes. However, not all diabetics suffer from peripheral neuropathy [39] and patients with diabetes without neuropathy could be recruited for the study. These considerations may help increase the recruitment of patient participants by changing the exclusion criteria to be more liberal. The age range was appropriate, as we captured the age range of working adults and the ages when most patients suffer from CTS. Aging has been associated to age related changes to sensory threshold [34, 35 36-38] and it seemed appropriate to exclude adults over 65 years of age.

Recruiting controls was not an issue for this pilot study, as many healthy hospital workers were available for the study, and were willing to participate. Candidates who would qualify for the control group would be considered anyone without CTS and any other injury to the upper extremity. A total of 20 controls were recruited for the study, but only 15 controls were analyzed. During the recruitment process of healthy controls, no records were made to document how many hospital staff were asked to participate in the study. Controls were invited to be part of the study by word of mouth and announcements made at the staff meetings at the hand therapy and physiotherapy department of the tertiary center. Nineteen controls were recruited by word of mouth and would probably be the best way to approach controls for a larger study. As for posters posted in the hospital hallways, only one control was recruited. Overall, the best strategy for recruiting controls seems to be by word of mouth and announcements.

As hypothesized, patients experienced more classical symptoms of CTS compared to controls at baseline in this study. However, pain and numbness were not significantly different after texting for the patient group, but scores did increase gradually during texting and decreased after texting. Pain and numbness may have increased from wrist posture, combined with constant gliding of the tendons in the carpal tunnel with repetitive forces, which could increase the pressure exerted against the median nerve, and associated structures, aggravating symptoms. Kier et al [9] did a biomechanical study examining the changes in carpal tunnel pressure from changes in wrist posture (extension versus flexion and radial versus ulnar deviation) and with finger posture (0, 45, or 90 degrees flexion). The study found that carpal tunnel pressure increased the most with wrist extension with straight fingers. Radial and ulnar deviations also increased carpal tunnel pressures. [9] This study suggested that the increased pressure could aggravate symptoms in patients with CTS based on hand postures. [9]In addition, since the texting activity required force application on the distal pulp of the thumbs, it is possible the force could also aggravate the symptoms during texting. Rempel et al [40] performed a biomechanical study, and found that the application of a force at the tip of the digits increased carpal tunnel pressure. In our study, posture and forces at the pulps of the thumbs were not measured, but could be performed in future studies to track changes to these variables throughout texting. Most patients in our study needed to shake their injured hand(s), or have the forearm point downwards with the wrist in neutral position to minimize the numbness the patient participants were experiencing

after texting. The neutral wrist posture and having the forearm pointing downwards may have helped to alleviate symptoms by decreasing carpal tunnel pressure.

However, it is important to note that the gradual increase in pain and numbness lacked potential power to conclude results on the effects of cell phone texting within groups. The small sample size of 15 participants is not large enough to say this did not happen by chance. The sample size calculation for each measurement outcome demonstrated that the sample size of 15 participants per group was too small (Table 4). A future study should be performed to determine the sample size required for more conclusive results for within group comparisons.

Patients also demonstrated a significant increase in touch threshold after texting, and also at 5 and 10 minutes after texting (Figure 2). It has been established in previous literature that patients with CTS have higher touch threshold levels than healthy individuals.[10, 11] Compression of the median nerve may decrease the nerve conduction velocity and magnitude of signals from the Merkel disks and Pacinian corpuscles, resulting in a higher touch threshold in the thumbs. Thus, more pressure was required for patients to detect touch stimuli. In a study by Gelberman et al, [41] the researchers tested the influence of different carpal tunnel pressures on touch threshold, nerve conduction tests, and functional tests in 12 healthy individuals. The participants had their carpal tunnel pressure increased with a catheter, and outcome measures were taken at baseline and after carpal tunnel pressure were increased. [41] They found that as carpal tunnel pressure increased, touch threshold values with the Semmes Weinstein monofilament also increase. [41] There was an increase in self-reported parathesia with increased carpal tunnel pressure. [41] This may suggest that texting on a cell phone increases carpal tunnel pressures for patients with CTS, and results in increased touch threshold values. Even after the testing, PSSD scores for patients did not return back to levels at baseline for patients. However, the PSSD may have high measurement error, as the confidence intervals are fairly wide. The PSSD might be a very sensitive tool for detecting abnormal sensation, as it has high sensitivity for detecting diseases, such as neuropathies caused by diabetes, [42] and CTS. [43] Its sensitive nature might be demonstrated in its ability to measure change after texting activity.

Both controls and patients experienced fatigue after texting. A study that supports our findings on fatigue examined the occurrence of muscle fatigue in the forearms of computer users after prolonged typing. Lin et al [44] used electromyography to quantify forearm muscles in 30 female typists who typed for 2 hours continuously. They found that 74% of the measured forearm muscles manifested fatigue, and that extensor digitorum communis presented more fatigue than forearm flexor muscles. [44] The sensation of fatigue may have resulted from lactic acid accumulation in the thenar and forearm muscles, as a result of contraction of muscles in the hand during texting activity. Fatigue was present in the computer typing tasks requiring long term dynamic contractions with forces less than 10% of maximum voluntary contractions. [44] Future research should be done to verify the mechanisms behind fatigue in low level hand activity and in patient populations requiring cell phone texting as part of their daily activity.

Red blood cell concentration values from the TIVI remained relatively stable throughout the study for both patients and controls. Patients had higher red blood cell concentration than the controls throughout the study. This finding is similar to results a study by Gelberman et al, [41] where arterial and venous blood flow did not change by increases in carpal tunnel pressure among healthy individuals. [41] Previous studies have found that patients with CTS have slower blood flow compared to controls. [45, 46] The differences in findings in our study and previous studies may be due to the penetration ability of the light used in quantifying blood flow between different methods of examining blood flow. Other studies had used Laser Doppler Systems, which examines deep into tissue and provide a more precise measurement of blood flow. The TIVI software only measures red blood cell concentration on the superficial skin level, so deeper blood flow was not measured. This study is one of the initial studies on measuring superficial blood flow in patients with CTS. We suggest there should be more studies on this topic in the future.

As expected, patients typed fewer characters and had slower texting speed. Patients may have performed worse than controls because the texting activity may have aggravated their symptoms, so the patients texted fewer characters and texted slower to reduce the symptoms. We had 3 patients who stopped texting early before the 15 minute mark because the numbness was too bothersome, and interfered with their ability to text. This was not the same found from

Guftasson et al, where young adults were asked to text on a cell phone and had electromyography and performance measurements (i.e. texting duration) taken. [5] In a subgroup analysis of the group with hand/arm symptoms, they required less time to perform the texting task compared to individuals without symptoms. [5] Despite this difference, our study had a specific patient population which was clinically diagnosed and did not have comorbidities.

This study has a number of strengths and novel findings. It evaluated patients and controls using self-reported measures which would accurately measure their symptoms which they feel and how these symptoms changed over time. The tools used in this study are commonly used within clinical and ergonomic settings and these tools would be highly accessible. This study also compared patients with CTS to an age and gender matched control group. Our study had patients between the age ranges of 29 to 65 years of age. Women between 35 to 44 years of age have the highest rates of CTS claims from work, and for men between ages 35 to 54 years of age in Canada. [47] Previous studies examining texting have primarily focused on younger adults in university settings, [6, 48 49] , but did not report the ages of the participants. Additionally, university students would not accurately represent the general working adult population between 35 to 65 years old. The texting activity was designed to simulate an environment outside of a laboratory. The task allowed participants to choose a posture that was comfortable to them, to accommodate for variability in hand, and trunk postures while in seated position. The questionnaire used for the texting intervention also contained open ended questions, which allowed for variability in responses according to the participants' preferences.

Our study also had some potential weaknesses. We recruited a small sample size of patient participants and controls. A larger sample of patient participants would be required to have sufficient power in multivariate calculations, and decrease the probability of potential type II error to allow for more conclusive results on between and within group differences. In addition, we used only one model of cell phone for our study. The nature of the texting activity in this study was restricted to texting with only the thumbs. Performance may vary depending on the specific digits used for texting and on the model of cell phone used for texting. We recommend future studies to use different models of cell phones.

3.10 Conclusion and Implications:

This pilot study provides valuable information on how cell phone texting affect patients with CTS. The study found that patients experienced more symptoms than controls after texting. Patients with CTS also performed worse than age and gender controls in texting. However, the results were under powered to make conclusive statements. This pilot study also provides important information for future studies involving patients with CTS and cell phone texting.

3.11 References

1. CTIA (International Association for the Wireless Telecommunications Industry). CTIA (International Association for the Wireless Telecommunications Industry). Available at: http://www.ctia.org/consumer_info/service/index.cfm/AID/10323. Accessed June/20, 2012.

2. Williams IW, Kennedy BS. Texting tendinitis in a teenager. *J Fam Pract*. 2011;60:66-7, 1 p following 67.

3. Ashurst JV, Turco DA, Lieb BE. Tenosynovitis caused by texting: an emerging disease. *J Am Osteopath Assoc*. 2010;110:294-296.

4. Ming Z, Pietikainen S, Hänninen O. Excessive texting in pathophysiology of first carpometacarpal joint arthritis. *Pathophysiology*. 2006;13:269-270.

5. Gustafsson E, Johnson PW, Hagberg M. Thumb postures and physical loads during mobile phone use - A comparison of young adults with and without musculoskeletal symptoms. *Journal of Electromyography and Kinesiology*. 2010;20:127-135.

6. Lin I-, Peper E. Psychophysiological patterns during cell phone text messaging: A preliminary study. *Applied Psychophysiology Biofeedback*. 2009;34:53-57.

7. Werner RA, Andary M. Carpal tunnel syndrome: pathophysiology and clinical neurophysiology. *Clinical Neurophysiology*. 2002;113:1373-1381.

8. Kerwin G, Williams CS, Seiler 3rd J. The pathophysiology of carpal tunnel syndrome. *Hand Clin*. 1996;12:243.

9. Keir PJ, Bach JM, Rempel DM. Effects of finger posture on carpal tunnel pressure during wrist motion. *J Hand Surg*. 1998;23:1004-1009.

10. Gelberman RH, Hergenroeder PT, Hargens AR, Lundborg GN, Akeson WH. The carpal tunnel syndrome. A study of carpal canal pressures. *J Bone Joint Surg Am*. 1981;63:380-383.

11. Rojviroj S, Sirichativapee W, Kowsuwon W, Wongwiwattananon J, Tamnanthong N, Jeeravipoolvarn P. Pressures in the carpal tunnel. A comparison between patients with carpal tunnel syndrome and normal subjects. *Journal of Bone and Joint Surgery - Series B*. 1990;72:516-518.

12. Phalen GS. The Carpal-Tunnel Syndrome: SEVENTEEN YEARS'EXPERIENCE IN DIAGNOSIS AND TREATMENT OF SIX HUNDRED FIFTY-FOUR HANDS. *The Journal of Bone and Joint Surgery*. 1966;48:211.

13. Werner R, Armstrong TJ, Bir C, Aylard MK. Intracarpal canal pressures: The role of finger, hand, wrist and forearm position. *Clin Biomech*. 1997;12:44-51.

14. O'Doherty J, Henricson J, Anderson C, Leahy MJ, Nilsson GE, Sjoberg F. Sub-epidermal imaging using polarized light spectroscopy for assessment of skin microcirculation. *Skin Res Technol*. 2007;13:472-484.

15. McNamara PM, O'Doherty J, O'Connell ML, et al. Tissue viability (TiVi) imaging: temporal effects of local occlusion studies in the volar forearm. *J Biophotonics*. 2010;3:66-74.

16. Henricson J, Nilsson A, Tesselaar E, Nilsson G, Sjoberg F. Tissue viability imaging: microvascular response to vasoactive drugs induced by iontophoresis. *Microvasc Res*. 2009;78:199-205.

17. Nilsson GE, Zhai H, Chan HP, Farahmand S, Maibach HI. Cutaneous bioengineering instrumentation standardization: the Tissue Viability Imager. *Skin Res Technol*. 2009;15:6-13.

18. Dellon AL, Keller KM. Computer-assisted quantitative sensorimotor testing in patients with carpal and cubital tunnel syndromes. *Ann Plast Surg*. 1997;38:493.

19. Jensen MP, Gammaitoni AR, Olaleye DO, Oleka N, Nalamachu SR, Galer BS. The Pain Quality Assessment Scale: Assessment of Pain Quality in Carpal Tunnel Syndrome. *Journal of Pain*. 2006;7:823-832.

20. Victor TW, Jensen MP, Gammaitoni AR, Gould EM, White RE, Galer BS. The dimensions of pain quality: factor analysis of the Pain Quality Assessment Scale. *Clin J Pain*. 2008;24:550-555.

21. Waterman C, Victor TW, Jensen MP, Gould EM, Gammaitoni AR, Galer BS. The Assessment of Pain Quality: An Item Response Theory Analysis. *Journal of Pain*. 2010;11:273-279.

22. Strauch B, Lang A, Ferder M, Keyes-Ford M, Freeman K, Newstein D. The ten test. *Plast Reconstr Surg*. 1997;99:1074-1078.

23. Yamagishi A, Morita T, Miyashita M, Kimura F. Symptom prevalence and longitudinal follow-up in cancer outpatients receiving chemotherapy. *J Pain Symptom Manage*. 2009;37:823-830.

24. Levine DW, Simmons BP, Koris M, et al. A self-administered questionnaire for the assessment of severity of symptoms and functional status in carpal tunnel syndrome. *JOURNAL OF BONE AND JOINT SURGERY-AMERICAN VOLUME-*. 1993;75:1585-1585.

25. Greenslade JR, Mehta RL, Belward P, Warwick DJ. Dash and boston questionnaire assessment of carpal tunnel syndrome outcome: What is the responsiveness of an outcome questionnaire? *J Hand Surg*. 2004;29 B:159-164.

26. Katz JN, Gelberman RH, Wright EA, Lew RA, Liang MH. Responsiveness of self-reported and objective measures of disease severity in carpal tunnel syndrome. *Med Care*. 1994;32:1127-1133.

27. Chatterjee JS, Price PE. Comparative responsiveness of the Michigan Hand Outcomes Questionnaire and the Carpal Tunnel Questionnaire after carpal tunnel release. *J Hand Surg Am*. 2009;34:273-280.

28. Brant R. Inference for Means: Comparing Two Independent Samples Available at: http://stat.ubc.ca/~rollin/stats/ssize/n2.html. Accessed 10/30, 2012.

29. Goldsmith CH, Boers M, Bombardier C, Tugwell P. Criteria for clinically important changes in outcomes: Development, scoring and evaluation of rheumatoid arthritis patient and trial profiles. *J Rheumatol*. 1993;20:561-565.

30. Stern LD. *A Visual Approach to SPSS for Windows.* 2nd ed. Pearson; 2010.

31. Micceri T. The unicorn, the normal curve, and other improbable creatures. *Psychol Bull*. 1989;105:156.

32. Gardner RC. *Psychological Statistics using SPSS for Windows.* Prentice Hall Upper Saddle River, NJ; 2001.

33. Geisser S, Greenhouse SW. An Extension of Box's Results on the Use of the F Distribution in Multivariate Analysis. *The Annals of Mathematical Statistics*. 1958;29:885-891.

34. Povlsen B. High incidence of absent nerve conduction in older patients with bilateral carpal tunnel syndrome. *Ann R Coll Surg Engl*. 2010;92:403-405.

35. Blumenthal S, Herskovitz S, Verghese J. Carpal tunnel syndrome in older adults. *Muscle and Nerve*. 2006;34:78-83.

36. Bodofsky EB, Campellone JV, Wu KD, Greenberg WM. Age and the severity of carpal tunnel syndrome. *Electromyogr Clin Neurophysiol*. 2004;44:195-199.

37. Kouyoumdjian JA, Zanetta DMT, Morita MPA. Evaluation of age, body mass index, and wrist index as risk factors for carpal tunnel syndrome severity. *Muscle and Nerve*. 2002;25:93-97.

38. Kouyoumdjian JA. Carpal tunnel syndrome. Age, nerve conduction severity and duration of symptomatology. *Arq Neuropsiquiatr*. 1999;57:382-386.

39. Smith AG, Singleton JR. Diabetic neuropathy. *CONTINUUM Lifelong Learn Neurol*. 2012;18:60-84.

40. Rempel D, Keir PJ, Smutz WP, Hargens A. Effects of static fingertip loading on carpal tunnel pressure. *Journal of Orthopaedic Research*. 2005;15:422-426.

41. Gelberman RH, Szabo RM, Williamson RV, Dimick MP. Sensibility testing in peripheral-nerve compression syndromes. An experimental study in humans. *The Journal of bone and joint surgery.American volume*. 1983;65:632.

42. Carvalho VF, Ferreira MC, Vieira SAT, Ueda T. Cutaneous sensibility threshold in the feet of diabetic patients with pressure specified sensory device: an assessment of the neuropathy. *Revista da Associação Médica Brasileira*. 2009;55:29-34.

43. Tassler P, Dellon A. Correlation of measurements of pressure perception using the pressure-specified sensory device with electrodiagnostic testing. *Journal of occupational and environmental medicine*. 1995;37:862.

44. Lin MI, Liang HW, Lin KH, Hwang YH. Electromyographical assessment on muscular fatigue--an elaboration upon repetitive typing activity. *J Electromyogr Kinesiol*. 2004;14:661-669.

45. Galea LA, Mercieca A, Sciberras C, Gatt R, Schembri M. Evaluation of sympathetic vasomotor fibres in carpal tunnel syndrome using continuous wave Doppler ultrasonography. *J Hand Surg Br*. 2006;31:306-310.

46. Yayama T, Kobayashi S, Awara K, et al. Intraneural blood flow analysis during an intraoperative Phalen's test in carpal tunnel syndrome. *J Orthop Res*. 2010;28:1022-1025.

47. Zakaria D. Rates of carpal tunnel syndrome, epicondylitis, and rotator cuff claims in Ontario workers during 1997. *Chronic Dis Can*. 2004;25:32-39.

48. Gold JE, Cherniack M, Buchholz B. Infrared thermography for examination of skin temperature in the dorsal hand of office workers. *Eur J Appl Physiol*. 2004;93:245-251.

49. Berolo S, Wells RP, Amick 3,Benjamin C. Musculoskeletal symptoms among mobile hand-held device users and their relationship to device use: A preliminary study in a Canadian university population. *Appl Ergon*. 2011;42:371-378.

4 Overview of this Thesis

The overall theme in this thesis was to explore the properties and applications for sensory tools among patients with CTS. We wanted to explore how certain tools responded to orthotic intervention and after common hand activities. The specific focus of this thesis was to evaluate the psychometric properties (clinical important difference, construct validity, and responsiveness) of sensory threshold tools after orthotic treatment in CTS and to determine the effects of cell phone texting on blood flow and sensation in CTS. The details of the findings of this thesis are:

In the first study, we tested two sensory tools (one for vibration threshold and one for touch threshold). We determined the clinically important difference of the tool for measuring touch threshold and the outcome measure for rating symptom severity. We found that the tool for measuring vibration threshold demonstrated greater construct validity to measures of hand function and was more responsive compared to touch threshold.

In the second study, we determined the feasibility of conducting a large scale study in a hospital setting and the adverse effects of cell phone texting in CTS in comparison with healthy controls.

4.1 What is Already Known on This Topic

Sensory testing is a common method of verifying a diagnosis for neuropathy and for the evaluation of neuropathy. The CID of the SSS has been determined for after surgery, [1] and steroid injection. [2] Sensory threshold tools have demonstrated substantial change between preoperative measures and after surgery. [3] Sensory tools have also been found to be reliable. [4-6] However, limited research has been done examining the construct validity of sensory tools to functional measures, and the responsiveness of sensory tools.

Texting on a cell phone has been shown to increase muscle activity in the musculature of the hand in patients with upper extremity injury. [7] However, limited research has examined the short term and long term effect of cell phone texting in patients with CTS.

4.2 What This Thesis Adds to Our Knowledge Base

The first study found the CID to discriminate patients who responded to orthotic intervention for the PSSD and the SSS. The CID for the PSSD and the SSS were $0.15 g/mm^2$ and 0.50 respectively. The Vibrometer is a better overall representation of functional measures for the hand and is more responsive after orthotic intervention.

The second study determined that the recruitment of patient subjects was feasible to expand into a larger study to compare the effects of cell phone texting in patients with CTS with age-gender matched controls. Our study had a recruitment rate of 73%. In order to complete a full study, we would need to have 182 participants (or 92 participants per group) to complete a full study [based on an 80% power (α= 0.05, β= 0.20), and in order to detect a 20% difference between-groups.]

4.3 Implications

Sensory evaluation is a determining component in a peripheral nerve entrapment, especially in CTS. This thesis has provided evidence based research for two sensory tools during the rehabilitation process to guide clinical decisions on interpreting sensory measures. In addition, this thesis provides preliminary findings on the impact of specific activities on patient symptoms during the recovery period. This thesis helps provide insight for clinicians to answer the question, "How can I tell if the sensory ability and symptoms in my patients are improving or worsening from a specific intervention or activity?"

4.4 Limitations

This thesis did have some limitations on the whole. We were unable to establish a cut point for the Vibrometer for discriminating patients after orthotic intervention. All subjects who were tested with the Vibrometer had achieved an important improvement on the SSS. We also had inconclusive findings on the impact of texting on superficial blood cell concentration, sensory threshold and symptoms because of small sample size of n=15 in pilot study. We were unable to make conclusive statements about the impact of texting, since it was under powered.

4.5 Future Research Directions and Recommendations

- Recommendations for future psychometric studies:
- Future studies should focus on examining the clinically important change on commonly used tools in clinics.
- Clinical tools should have their psychometric properties validated to provide important information for clinicians, including reliability, validity, and the ability of a tool to measure change. [8] The property of construct validity, responsiveness, and clinically important change help to inform a clinicians' decision when treating patients with CTS.
- Future studies should also examine the decision making process of how clinicians use findings from sensory tools to inform their practice for treating CTS.

4.6 Recommendations and Future Research Directions for Pilot Studies:

- A full study should be completed with 182 participants to evaluate the long term effects of texting in patients with CTS and in healthy controls.
- Exclusion criteria for recruiting participants should be more specific to clearly identify eligible patients for the future full study.

- Different cell phone models should be tested to capture variability in texting performances

4.7 References

1. Kim JK, Jeon SH. Minimal clinically important differences in the Carpal Tunnel Questionnaire after carpal tunnel release. *J Hand Surg Eur Vol*. 2012.

2. Ozyurekoglu T, McCabe SJ, Goldsmith LJ, LaJoie AS. The minimal clinically important difference of the Carpal Tunnel Syndrome Symptom Severity Scale. *J Hand Surg Am*. 2006;31:733-8; discussion 739-40.

3. Macdermid JC, Richards RS, Roth JH, Ross DC, King GJ. Endoscopic versus open carpal tunnel release: a randomized trial. *J Hand Surg Am*. 2003;28:475-480.

4. Hubbard MC, MacDermid JC, Kramer JF, Birmingham TB. Quantitative vibration threshold testing in carpal tunnel syndrome: analysis strategies for optimizing reliability. *J Hand Ther*. 2004;17:24-30.

5. Dellon AL, Keller KM. Computer-assisted quantitative sensorimotor testing in patients with carpal and cubital tunnel syndromes. *Ann Plast Surg*. 1997;38:493.

6. Novak CB, Mackinnon SE, Williams JI, Kelly L. Establishment of reliability in the evaluation of hand sensibility. *Plast Reconstr Surg*. 1993;92:311-322.

7. Gustafsson E, Johnson PW, Hagberg M. Thumb postures and physical loads during mobile phone use - A comparison of young adults with and without musculoskeletal symptoms. *Journal of Electromyography and Kinesiology*. 2010;20:127-135.

8. Finch E, Dina. Brooks, Stratford PW. Physical rehabilitation outcome measures. . 2002.

Appendix A 2 – Screen Tool for Chapter 3

Screening Tool for CTS Study

Name: _____

Date: _____

This form will be completed by the potential participant to screen participants for the study by verbal response to each question the investigator will read to him or her. The investigator will fill in the form by putting an "x" in the boxes indicating Yes or No. If the participant is uncertain, he or she will be asked to answer to the best of their ability.

Question	**Yes**	**No**
1. Are you confirmed by a health provider from St. Joseph's hospital to have Carpal Tunnel Syndrome?		
2. Are you between the ages of 18-65 years old		
3. Have you received any treatment offered by any hospital for the symptoms for carpal tunnel syndrome?		
4. Have you had a recent injury to your neck, shoulder, elbow, wrist, or hand within the past year – muscle, bone, nerve injury, osteoarthritis (as of January 2011)		
5. Do you have a heart condition?		
6. Are you a diabetic		
7. Are you pregnant?		
8. Do you have cancer or a tumour?		
9. Do you have any vascular problems in your hands or arms?		

*If YES to 1 and NO to 3-9, then put into as PATIENT

*If No to 1, 3-9, then put into as CONTROL

*If yes to one of questions 3-9 regardless, then exclude from study

If eligible as patient:

Thank you for your time. You are eligible for this study.

If not eligible as patient:

Thank you for your time. You are not eligible for this study. Is it okay though to keep your name on our database so that we can contact you for other studies?

If eligible as control:

Thank you for your time. You are eligible for this study.

If not eligible as control:

Thank you for your time. You are not eligible for this study. Is it okay though to keep your name on our database so that we can contact you for other studies?

Appendix A 3 – Numeric Rating Scale for Pain, Fatigue, and Numbness

Subject Code: _____

Stage:_____

Numeric Rating Scale for Pain, Fatigue, and Numbness in the Hand

At this moment:

Please rate the pain in each hand from 0-10. 0 being no pain. 10 being the worst pain experienced. Circle the corresponding number and label it with "R" for right hand or "L" for left hand.

(NONE) 0 1 2 3 4 5 6 7 8 9 10 (WORST)

Please rate the fatigue in your hand from 0-10. 0 being no fatigue in your hand. 10 being "too fatigued to continue." Circle the corresponding number and label it with "R" for right hand or "L" for left hand.

(NONE) 0 1 2 3 4 5 6 7 8 9
10 (WORST)

Please rate the Numbness or Tingling experienced in your hand from 0-10. 0 being no numbness or tingling. 10 being unable to feel anything. Circle the corresponding number and label it with "R" for right hand or "L" for left hand.

(NONE) 0 1 2 3 4 5 6 7 8 9
10 (WORST)

Appendix A 4 – Script

Standardized Script (Dec 27, 2011).

Please respond to each of the questions with the cell phone by texting in your response using only your thumbs. After each response is entered, please enter a period and a space before entering in the next response.

This script will have repeated questions – just continue answering them. If you make an error, please correct the mistake with the delete button as in the practice session.

Once time is up, please send the entire text to [redacted]

1. How did you hear about this study?

2. Where do you plan to go after this study?

3. Where is your favourite place for vacation?

4. How many times have you been there?

5. What would you recommend others to see if they went to visit?

6. When is the next time you would like to visit that place?

7. If you were given a billion dollars, what would you do with it?

8. If you could give a billion dollars to anyone, who would that be?

9. What is your favourite hobby?

10. Would you do it for a living?

11. If yes, why would you do it for a living? If no, why not?

12. What does TTYL mean?

13. What does LOL mean?

14. What does TGIF mean?

15. What does FYI mean?

16. What does XOXO mean?

17. What does BRB mean?

18. Do you find this winter very cold?

19. Are you a tea or coffee drinker?

20. Have you had tea or coffee today?

21. How did you hear about this study?

22. Where do you plan to go after this study?

23. Where is your favourite place for vacation?

24. How many times have you been there?

25. What would you recommend others to see if they went to visit?

26. When is the next time you would like to visit that place?

27. If you were given a billion dollars, what would you do with it?

28. If you could give a billion dollars to anyone, who would that be?

29. What is your favourite hobby?

30. Would you do it for a living?

31. If yes, why would you do it for a living? If no, why not?

32. What does TTYL mean?

33. What does LOL mean?

34. What does TGIF mean?

35. What does FYI mean?

36. What does XOXO mean?

37. What does BRB mean?

38. Do you find this winter very cold?

39. Are you a tea or coffee drinker?

40. Have you had tea or coffee today?

41. How did you hear about this study?

42. Where do you plan to go after this study?

43. Where is your favourite place for vacation?

44. How many times have you been there?

45. What would you recommend others to see if they went to visit?

46. When is the next time you would like to visit that place?

47. If you were given a billion dollars, what would you do with it?

48. If you could give a billion dollars to anyone, who would that be?

49. What is your favourite hobby?

50. Would you do it for a living?

51. If yes, why would you do it for a living? If no, why not?

52. What does TTYL mean?

53. What does LOL mean?

54. What does TGIF mean?

55. What does FYI mean?

56. What does XOXO mean?

57. What does BRB mean?

58. Do you find this winter very cold?

59. Are you a tea or coffee drinker?

60. Have you had tea or coffee today?

Appendix A 5 - Symptom Severity Scale

Symptom Severity Scale

The following questions refer to your symptoms for a typical 24-hr period over the past 2 weeks. For each question, please circle one answer.

How severe is the hand or wrist pain that you have at night?
1. I do not have wrist pain at night.
2. Mild pain
3. Moderate pain
4. Severe pain
5. Very severe pain

How often did hand or wrist pain wake you through the night in the past two weeks?
1. Never
2. Once
3. Two or three times
4. Four or five times
5. More than five times

Do you typically have pain in your hand or wrist during the day time?
1. I never have pain during the day.
2. I have mild pain during the day.
3. I have moderate pain during the day.
4. I have severe pain during the day.
5. I have very severe pain during the day.

How often do you have hand or wrist pain during the daytime?
1. Never
2. Once or twice a day.
3. Three to five times a day.
4. More than five times a day.
5. The pain is constant.

How long, on average, does an episode of pain last during the daytime?
1. I never get pain during the day.
2. Less than 10 minutes.
3. 10 to 60 minutes.
4. Greater than 60 minutes.
5. The pain is constant throughout the day.

Do you have numbness (loss of sensation) in your hand?
1. No
2. I have mild numbness
3. I have moderate numbness.
4. I have severe numbness.
5. I have very severe numbness.

Do you have weakness in your hand or wrist?
1. No weakness
2. Mild weakness
3. Moderate weakness
4. Severe weakness
5. Very severe weakness

Do you have tingling sensations in your hand?
1. No tingling
2. Mild tingling
3. Moderate tingling
4. Severe tingling
5. Very severe tingling

How severe is the numbness (loss of sensation) or tingling at night?
1. I have no numbness or tingling at night.
2. Mild
3. Moderate
4. Severe
5. Very severe

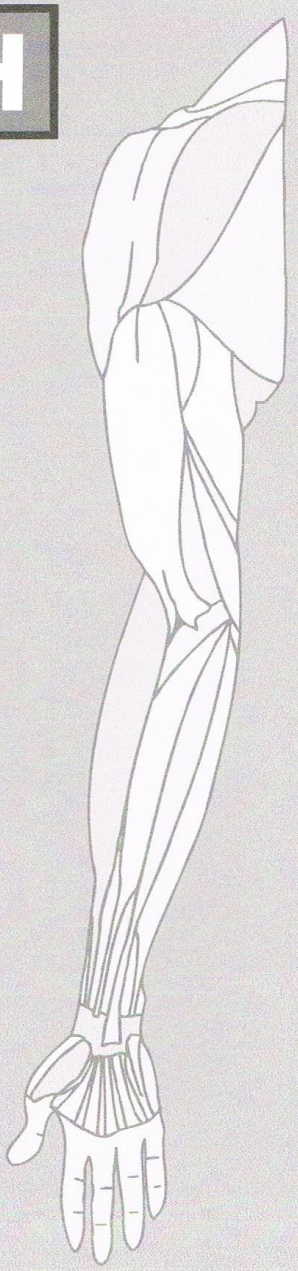
How often did numbness or tingling wake you up during a typical night during the past 2 weeks?
1. Never
2. Once
3. Two or three times
4. Four or five times
5. More than five times

Do you have difficulty with the grasping and use of small objects, such as keys or pens?
1. No difficulty
2. Mild difficulty
3. Moderate difficulty
4. Severe difficulty
5. Very severe difficulty

Appendix A 6: DASH questionnaire

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE DASH



INSTRUCTIONS

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

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

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

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

DISABILITIES OF THE ARM, SHOULDER AND HAND

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

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

DISABILITIES OF THE ARM, SHOULDER AND HAND

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

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

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

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

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

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

Scoring DASH function/symptoms: Add up circled responses (items 1-30); subtract 30; divide by 1.20 = DASH score. If there are responses missing, see detailed instructions.

DISABILITIES OF THE ARM, SHOULDER AND HAND

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

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

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

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

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

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

WORK MODULE (OPTIONAL)

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

Please indicate what your job/work is: _____

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

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

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

INSTITUTE FOR WORK & HEALTH
INSTITUT DE RECHERCHE SUR LE TRAVAIL ET LA SANTÉ

AAOS COMSS

Appendix A 7 Ethics Approval Forms

Research Western

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
Review Number: 17933E
Review Level: Delegated
Approved Local Adult Participants: 73
Approved Local Minor Participants: 0
Protocol Title: The Validation of Sensory Threshold Tools and Self-reported Measures of Function in Patients with Carpal Tunnel Syndrome
Department & Institution: Surgery, University of Western Ontario
Sponsor:
Ethics Approval Date: May 09, 2011 **Expiry Date:** August 31, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
UWO Protocol		

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

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

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

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

[redacted]

Ethics Officer to Contact for Further Information

Janice Sutherland (jsutherl@uwo.ca)	**Grace Kelly (grace.kelly@uwo.ca)**

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

LAWSON HEALTH RESEARCH INSTITUTE

FINAL APPROVAL NOTICE

RESEARCH OFFICE REVIEW NO.: R-11-216

PROJECT TITLE: The validation of sensory threshold tools and self-reported measures of function in patients with carpal tunnel syndrome.

PRINCIPAL INVESTIGATOR: Dr. Joy MacDermid

DATE OF REVIEW BY CRIC: June 2, 2011

Health Sciences REB#: 17933E

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

Was Approved

PLEASE INFORM THE APPROPRIATE NURSING UNITS, LABORATORIES, ETC. BEFORE STARTING THIS PROTOCOL. THE RESEARCH OFFICE NUMBER MUST

BE USED WHEN COMMUNICATING WITH THESE AREAS.

Dr. David Hill

V.P. Research

Lawson Health Research Institute

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

cc: Administration

Research Western

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
Review Number: 18224E
Review Level: Delegated
Approved Local Adult Participants: 60
Approved Local Minor Participants: 0
Protocol Title: Determining the Effects of Thumb Typing with Mobile Phones on Measures of Hand Function in Pateints with Carpal Tunnel Syndrome (CTS)
Department & Institution: Surgery, University of Western Ontario
Sponsor:
Ethics Approval Date: July 21, 2011 **Expiry Date:** May 31, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
UWO Protocol		
Letter of Information & Consent		2009/03/16
Advertisement		

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

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

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

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

[redacted]

Ethics Officer to Contact for Further Information

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

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

LAWSON HEALTH RESEARCH INSTITUTE

FINAL APPROVAL NOTICE

RESEARCH OFFICE REVIEW NO.: R-11-350

PROJECT TITLE: Determining the Effects of Thumb Typing with Mobile Phones on Measures of Hand Function in Patients with Carpal Tunnel Syndrome (CTS)

PRINCIPAL INVESTIGATOR: Dr. Joy MacDermid

DATE OF REVIEW BY CRIC: July 28, 2011

Health Sciences REB#: 18224E

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

Was Approved

PLEASE INFORM THE APPROPRIATE NURSING UNITS, LABORATORIES, ETC. BEFORE STARTING THIS PROTOCOL. THE RESEARCH OFFICE NUMBER MUST

BE USED WHEN COMMUNICATING WITH THESE AREAS.

Dr. David Hill

V.P. Research

Lawson Health Research Institute

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

cc: Administration

Research Western

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
File Number:100838
Review Level: Delegated
Approved Local Adult Participants:60
Approved Local Minor Participants:0
Protocol Title: Determining the Effects of Thumb Typing with Mobile Phones on Measures of Hand Function in Pateints with Carpal Tunnel Syndrome (CTS) - 18224E
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,Western University
Sponsor:
Ethics Approval Date: May 29, 2012 **Expiry Date:**September 30, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Revised Study End Date	The study end date has been extended to September 30, 2012 to account for slow recruitment.	

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

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

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

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services [redacted]

Ethics Officer to Contact for Further Information

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

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

Curriculum Vitae 1

Curriculum Vitae

Name:	Derek KM. Cheung
Post-secondary Education and Degrees:	McMaster University Hamilton, Ontario, Canada 2006-2010 BSc Kinesiology
Honours and Awards:	CIHR Travel Grant March 2011
Related Work Experience	Teaching Assistant for Anatomy HS2300 and Kin 2222 Western University 2010-2012 Exam Proctor King's University College 2012 Summer Undergraduate Student Researcher University of Toronto June to August 2009 and 2010

Publications

Derek K. Cheung, Joy C. MacDermid, Dave Walton, Ruby Grewal. The Validity of Sensory Threshold Measures and Functional Measures in Patients with Carpal Tunnel Syndrome. Journal of Hand Therapy, Volume 24, Issue 4, October–December 2011, Pages 380-381. (2011 American Society of Hand Therapy Conference Proceedings)