The Usefulness of a Carpal Tunnel Compression Assessment Tool: Evidence of Reliability and Validity in Assessing Carpal Tunnel Syndrome

by

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In partial fulfilment of the requirements

For the degree of Master of Science in Kinesiology

SCHOOL OF KINESIOLOGY

LAKEHEAD UNIVERSITY

THUNDER BAY, ONTARIO

November 2014

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ABSTRACT

Carpal Tunnel Syndrome (CTS) is a medical condition (neuropathy) that affects many individuals throughout their daily lives. The condition is caused by the compression of the median nerve in the carpal tunnel space, with repeated flexion and extension of the wrist increasing the risk of developing CTS. At present, there is a lack of CTS assessment tools that are easy, accurate, and less expensive to implement than traditional methods to help medical professionals, workers and employers identify potential causes of CTS within the workplace. The purpose of this study was to provide evidence for the validation of a simple and easy to implement carpal tunnel compression assessment tool (CTCAT) to more accurately assess CTS. The CTCAT is a portable testing device that can easily be used by medical professionals to assist with reducing diagnostic wait times and/or costs associated with CTS. As the CTCAT is a new instrument, much of the work in this study involved prototype development. A sample of 19 participants was used for this study (10 with CTS, nine controls). Participants with CTS must have been clinically diagnosed. All participants were over 18 years of age. Physical testing was completed with the CTCAT based on the Carpal Compression Test protocol (Durkan, 1991). Construct-related evidence of validity was provided by relating the CTCAT to the Boston Carpal Tunnel Questionnaire and a 10 point Likert pain scale. The findings were analyzed by using correlation techniques (i.e., intraclass and Pearson's correlations) and measures of internal consistency (i.e., Cronbach's alpha). The outcome of this study revealed that the CTCAT produced reliable and valid measures when assessing participants with CTS based on response time to symptom onset on two testing dates. This study builds on the research of Durkan (1991) for the use of participant response time measures to CTS symptom onset as an avenue to diagnose individuals with and without CTS.

Keywords: carpal tunnel syndrome, carpal compression test, assessment tool, validity

ACKNOWLEDGEMENTS

I would like to acknowledge the support of my thesis committee to the completion of my Master's thesis. Dr. Carlos Zerpa: thank you for being so supportive and helpful with all of the road blocks that we ran in to with this study. Thank you for helping me with some aspects of the research that I might not have fully understood if I tried to understand them on my own. Without your endless support, I would be nowhere near completion of the study. Dr. Ian Newhouse: thank you for providing the guidance I needed in certain situations and being so helpful with the study. Dr. Paolo Sanzo: thank you for helping me with parts of the study that I was having difficulty with. Your patience and understanding is greatly appreciated. I would also like to acknowledge the commitment of Mr. Dan Vasiliu to the development and modification of the carpal tunnel compression assessment tool. Without your creative ideas and artistic vision, testing with the device would not have been as successful as it was. Lastly, I would like to thank the participants who took part in this study. Thank you for volunteering your time (and wrists) to this study. Your help was greatly appreciated.

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CHAPTER ONE- INTRODUCTION

Overview

Carpal Tunnel Syndrome (CTS) is a median entrapment neuropathy that produces symptoms varying from numbness or tingling to burning in the median nerve distribution, being the volar and first three and a half digits. It is now well known that focal compression of the median nerve at the carpal tunnel leads to the symptoms of CTS caused by injury to both the sensory and motor nerves (Wang, 2013). Females, more than males, are affected to a greater extent by the neuropathy mainly due to anatomical differences (Love, 2003). As the condition worsens, the motor supply of the median nerve is affected, which can lead to general clumsiness with the hands when picking objects up and knowing how hard the hand is being squeezed. When the motor control of the hand is affected, CTS is in the advanced stages of the disease (Love, 2003).

Carpal tunnel syndrome affects mainly middle aged working individuals, and the occurrence of CTS is high for individuals working both sedentary (i.e., desk) and active jobs (i.e., manual labour) (Silverstein, Fine, & Armstrong, 1987). Carpal tunnel syndrome is most commonly associated with rheumatoid arthritis, diabetes, hypothyroidism, estrogen replacement therapy (Solomon, Katz, Bohn, Mogun, & Avorn, 1999), oophorectomy (Pascual, Giner, Arostegui, Conill, Ruiz, & Pico, 1991), and pregnancy (Stolp-Smith, Pascoe, & Ogburn, 1998). Carpal tunnel syndrome symptoms can also be caused by heavy manual work, vibrations, and awkward positions of the wrist (Roquelaure et al., 1997; Siverstein et al., 1987; Van Rijn et al., 2009). Over time, CTS may become more prominent in some work environments than others; such as clerical work, construction, welding, and other physically demanding positions. The

disorder can have a debilitating effect on individuals if proper safety precautions are not taken into consideration to avoid strenuous repetitive movements, vibrations, and awkward wrist positions.

One way to increase the diagnostic efficacy for CTS claims is through electrodiagnostic testing, such as electromyography and nerve conduction studies (Atroshi et al., 2003). This assessment method is costly to the healthcare system in Canada, costing $400 per test; and is usually associated with long wait times for the patient to see the proper medical professional (Fowler, Maltenfort, & Ilyas, 2013).

Currently, there are many CTS self-report questionnaires and few clinical tests that are quick and easy to implement to get an idea of both subjective and objective reports of a CTS condition. Some of these questionnaires, however, do not deal directly with the hand and wrist, which can then lead to improper CTS assessments and diagnoses (Jahedi & Mendez, 2012). In addition, CTS self-report questionnaires contain a certain degree of biased information due to the subjective nature of the assessment tools.

Based on these concerns, there is a need to develop self-report questionnaires and assessment tools with high degree of reliability and validity measures that are easy to use and administer in CTS diagnostics to minimize measurement error, healthcare cost and time.

Purpose

With these concerns in mind, the purpose of this study was to develop a prototype for a carpal tunnel compression assessment tool (CTCAT) and then provide evidence of reliability and validity measures for the use of the CTCAT in assessing CTS when compared to the Boston

Carpal Tunnel Questionnaire (BCTQ) and a 10 point self-report Likert pain scale. Three research questions were developed to address the purpose of the study:

1. How reliable are the measures obtained from the BCTQ with the current data?
2. Can a 10 point self-report Likert pain scale question be used to assess CTS when compared to the BCTQ?
3. To what extent is the CTCAT able to assess CTS when compared to the BCTQ and 10 point self-report Likert pain scale?

To address the research questions, the Carpal Compression Test (CCT) protocol (Durkan, 1991) was administered at two different testing sessions held two days apart, where a test of normality and a variety of statistical correlation techniques were conducted to analyze the data. Question one was answered by conducting Cronbach's alpha correlations to analyze each testing session to examine the internal consistency of the BCTQ measures with the current data. An intraclass correlation analysis was also conducted to examine the consistency of participants' responses across replications of the BCTQ.

To answer research question two, a test of normality and intraclass correlations were conducted to examine the consistency of participants' responses when using the 10 point Likert pain scale across different administrations of the CCT. A second intraclass correlation analysis was conducted to provide evidence of validity for the use of the 10 point Likert pain scale as validity criteria to assess participants with CTS when compared to the BCTQ part one pain scores. Evidence of face validity was also provided through the use of qualitative and quantitative measures. The development of the 10 point Likert pain scale was necessary because the BCTQ did not measure participant pain during the administration of the test, but rather the

pain felt within the last 24 hours before administering the CCT. More specifically, the 10 point Likert pain scale measured participant perceived level of pain before and after the administration of the CCT, which allowed for the computation of the amount of pain felt by the participant during the administration of the test. This computation was accomplished by subtracting the pre-test pain measures from the post-test pain measures.

Lastly, to address research question three, Pearson's correlations were used to provide convergent and discriminant evidence of validity for the use of the CTCAT response time measures as an avenue to assess CTS when compared to the 10 point Likert pain scale and BCTQ.

Significance

Treatment for CTS is costly to the healthcare system, with estimated workers compensation claims costing roughly $11, 993 Canadian dollars per claim (Li, Liu, Miyazaki, & Warren, 1999), totaling over $33 million Canadian dollars per year in 2001 (Watts, Osei-Tutu, & Lalonde, 2003). Given the high incidence of CTS and the associated cost in lost productivity and treatment, research that may aid in the accurate assessment of CTS is needed. More specifically there is a need to assess the reliability and validity of a proprietary tool (CTCAT) to assist with improving assessment and diagnostic measures within the healthcare system.

The use of both self-report questionnaires and objective measures are important in the assessment and diagnosis of CTS. There are currently many questionnaires in use to assess and diagnose CTS, each focusing on different areas of the upper extremity, and asking a variety of questions. It is therefore important to use a specific questionnaire when diagnosing a medical condition affecting a particular area of the body. This study serves to build on the

implementation of the BCTQ by Levine et al. (1993) as a self-report assessment tool for CTS. The BCTQ was used to subjectively assess the participants' current level of CTS pain and discomfort, while the results will be statistically analyzed to ensure the results provided on multiple testing dates is both valid and reliable.

As the BCTQ assesses both the pain and difficulty with an individual's CTS symptoms up to 24 hours before assessment, but does not give an estimate of pain experienced from pre- to post-test to be used as validity criteria for the CTCAT, there was a need to incorporate a 10-point Likert scale item to measure the amount of pain experienced by each participant during the carpal compression test.

From the theoretical perspective, this study aims to build on the existing research work by Durkan (1991) for the use of participant response time measures to CTS symptom onset as an avenue to diagnose individuals with and without CTS. The CTCAT is a portable device that could easily be used by many medical professionals in a variety of medical clinics to assess and diagnose patients with CTS. The objective testing measures that do exist are costly, and frequently require patients to wait for quite some time to be assessed in the clinical setting either for a general appointment or electrodiagnosis appointment. With long wait times for a patient to been seen by the proper medical professional comes secondary issues, such as increased morbidity and time off work or out of normal activity. As Reuben and Siu (1990) stated, direct (objective measures) provide an unbiased measure that may provide more accurate and reliable information than self-reports (subjective measures).

In summary, this study builds on the research of both Durkan (1991) and Levine et al. (1993), while furthering the development of a subjective pain measure to be used when

completing CTS physical tests such as the CCT. This study also aims to provide evidence of reliability and validity for an innovative objective testing measure to be used to assess and diagnose CTS in the clinical setting.

CHAPTER TWO- LITERATURE REVIEW

This chapter summarizes and highlights the literature available surrounding CTS and its impact on the upper extremity and society as a whole. It expands on the different methods and techniques used in diagnosing the disorder, and treatment methods currently used for CTS. Lastly, this chapter also aims to review the literature dealing with the reliability and validity of assessment tools and the differences between self-report questionnaires and direct measures.

Use of the Upper Extremity

As bipedal mammals, humans rely heavily on the upper extremities (shoulder, upper and lower arm, wrist and hand) for daily functional activities as simple as picking up a coin to those as complex as putting on a pair of shoes and tying them up. To perform these tasks, humans use two main forms of movement skills: fine motor and gross motor movements (Haywood & Getchell, 2005). Fine motor skills involve the use of the smaller muscle groups and body parts, such as the wrist, hands, and fingers while gross motor skills involve the use of the larger, more powerful muscles and appendages of the body such as the core, legs and arms.

Anatomy of the wrist. As depicted in Figure 1, the wrist is composed of eight carpal bones, and a band of fibrous tissue called the carpal cartilage or the flexor retinaculum (Love, 2003), forming the floor and the roof of the carpal tunnel. The carpal tunnel is a confined small space that has many moving bones with nerves, blood vessels, ligaments, and tendons passing through it. The carpal tunnel serves as a pulley aiding the function of the flexor tendons (Netscher et al., 1997). It is no wonder that this congested area is prone to injury and repetitive wear and tear that leads to the development of symptoms. The carpal tunnel measures a total of five millimeters long by ten millimeters wide, housing the median nerve and nine long flexor

tendons (flexor digitorum profundus- four tendons, flexor digitorum superficialis- four tendons, flexor policis longus- one tendon, and the median nerve) (Wang, 2013).

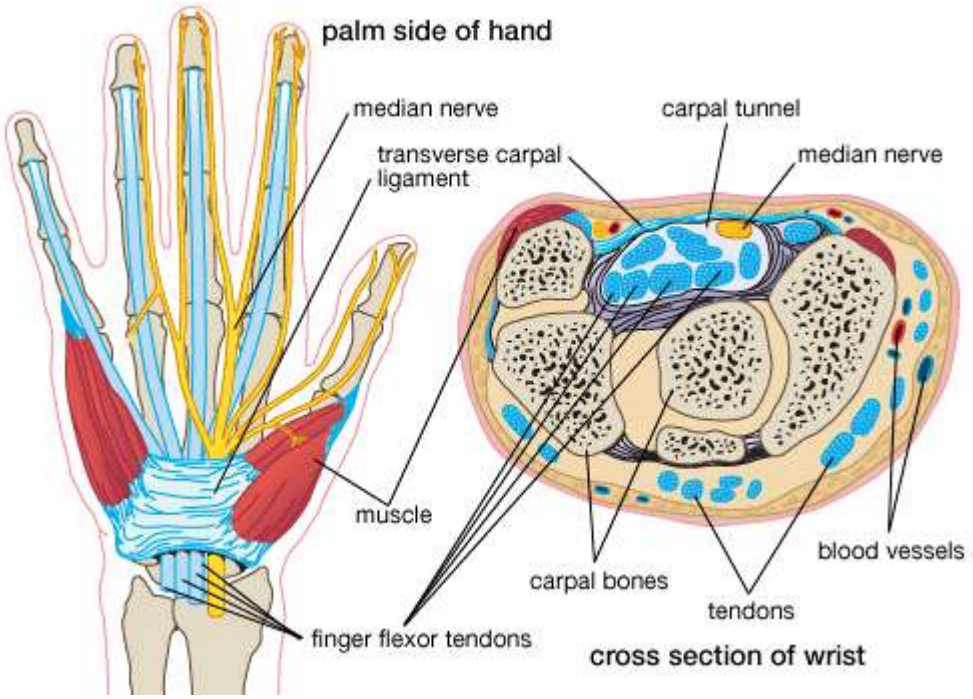

Figure 1. The carpal tunnel space and associated anatomical structures. This figure illustrates the complexity of the carpal tunnel space. Retrieved from clearpathchiropractic.com

The median nerve is derived from the lateral and medial cords of the brachial plexus and C6 to T1 nerve roots, which then follow a path close to the elbow by the brachial artery (Wang, 2013). The nerve supplies sensory and motor fibres to the thumb, index, middle finger and half of the ring finger of the hand. At the level of the carpal tunnel, the median nerve is composed of 94% sensory fibers and only 6% motor fibers (Kostopolos, 2004). With such a large percentage of the nerve supply being sensory, many individuals suffer from sensory deficits such as tingling, burning, aching, and general pain in the affected fingers (Atroshi et al., 1999). As CTS is a peripheral nerve lesion, sensory nerve conditions generally progress from numbness and tingling to a hot, burning sensation which is brought on by repetitive motion (Love, 2003).

A loss in the sensory nerve supply due to compression of the median nerve leads to CTS, where patients may complain of being clumsy and dropping items when using the affected hand (Love, 2003). Proprioception in the hand is affected by CTS and, as a result, individuals who work with their hands lifting heavy objects or tools on a daily basis (e.g., mechanics, welders) will grip their tools or items in their hands harder than they need to as they cannot tell how hard they are gripping (Love, 2003). As the disease progresses, the motor supply of the nerve is affected, where patients may report general weakness between the thumb and the fingers. Love (2003) states that as the motor supply of the median nerve is affected, grip strength decreases further, as does the pinch strength between the tip of the thumb and the fingers. When motor control of the hand is affected, the patient can be classified as being in an advanced stage of the disease (Love, 2003).

Although women are generally affected more than men after the age of 40, the incidence rate between the two sexes is nearly equal before the age of 40 years (Love, 2003). Females are more affected with CTS than males at a staggering rate of four to one after the age of 40, which may be mainly due to the smaller wrist size of females (Love, 2003). The carpal tunnel space of females is smaller than that of males but has the same number/size of tendons and nerves passing through it, leading to an increased chance for aggravation to occur (Love, 2003). After the age of 40, with hormonal changes in a woman's body, fluid retention and general swelling can lead to an increased incidence of CTS in women (Simon & Zieve, 2013). In the past, women filled the majority of clerical positions such as secretaries, clerks, accountants, and bank tellers. These mainly hand-wrist dominant careers were a strong contributor to the development of CTS in the female population (Love, 2003).

Overuse of the wrist. Thurston (2000) proposed that all individuals are predisposed to suffering CTS in their lifetime. CTS may develop when predisposition worsens because of lifestyle, health, and career influences. Most commonly, CTS is classified as an overuse injury, which may be caused by poorly designed job tasks, work stations, and practices (Carragee & Hentz, 1988; Weirich & Gelberman, 1993). Generally speaking, the more repetitive and strenuous a job or functional task is on the wrists, the more likely the individual is to suffer from CTS in the future.

Not only is CTS brought on by work-related activities and repetitive motions, but it can also be brought on by a number of sport-specific movements. Sports such as cycling, football, golf, hockey, lacrosse, rock climbing, weightlifting, wheelchair sports, and wrestling may lead to an increased risk for CTS (McKeon, 2008). It is apparent that individuals need to be cautious with their movements both at work and during their recreational time, constantly monitoring wrist position if discomfort arises.

Distinctly, CTS arises from compression of the median nerve as it passes through the carpal tunnel (Love, 2003). As the carpal tunnel is a very confined area to begin with, it does not take much soft tissue swelling or fluid build up to cause a great deal of discomfort and pain to those individuals affected with CTS. Tissue damage in the carpal tunnel area that leads to CTS can be brought on by repetitive, forceful movements with the wrist held in a fixed position for extended periods of time (Dobyns, 1991). It does not matter if the wrist is held in neutral, flexed, or extended. As long as the wrist is held in a fixed position continuously, the risk of CTS is higher. Other specific causes of overuse damage in the carpal tunnel area stem from repetitive or prolonged tool use that causes the hand and wrist to vibrate (Dobyns, 1991). The types of tools that may aggravate the median nerve include jack-hammers, hammer drills, concrete saws, and

impact wrenches. If tools are used on a regular basis and not ergonomically designed, there is a greater risk for the development of CTS. Finally, damage to the structures in the carpal tunnel area can result from excessive data entry, mouse, computer keyboard and cash register use (Feuerstein, 1997).

Although CTS is mainly an overuse injury where the onset of symptoms cannot be attributed to a single event, in some cases, it may be brought on by repetitive use combined with episodes of tissue damage to the carpal tunnel caused by injuries sustained during a fall onto an outstretched hand (Dobyns, 1991). CTS can be either unilateral where it affects only one wrist, or bilateral affecting both wrists. It is well documented that if the condition is unilateral, it often appears in the dominant wrist; while if the condition is bilateral, the symptom severity is greatest in the dominant wrist (Love, 2003).

Manktelow, Binhammer, Tomat, Bril, and Szalai (2004) found that 50% of the reported CTS cases in the province of Ontario in 1996 (n=964) originated from fabrication or assembly line workers. Clerical workers accounted for 16% of the diagnosed population, with up to 75% of all cases reported having bilateral involvement. Manktelow et al. (2004) also reported that in some cases, patients experienced symptoms for as long as three years before receiving treatment, with as much as 46% of patients reporting ongoing symptoms even after receiving treatment. With so many cases reported, and with such a high rate of recurrence, there is an increasing need for better diagnostic tools and methods.

Effect of Carpal Tunnel Syndrome on Society

Healthcare. According to Fnais, Gomes, Mahoney, Alissa, and Mamdani (2014), there are approximately 10 procedures per 10,000 population carpal tunnel release surgeries performed

annually in Ontario. The performance of this many surgeries for one specific disease stresses the healthcare system, and reduces the amount of available surgery time that could be used to treat more severe diseases. Not only is the total number of surgeries carried out by the surgeons costly, but the expenses of postoperative care and rehabilitation also tax the healthcare system.

Work force. The reported incidence of work-related musculoskeletal disorders, including CTS, has remained stationary since 1992, in contrast to other work-related injuries and illnesses that reached a peak in 1992 and have been on a steady decline since then (Falkiner, 2002). Falkiner (2002) points out that in 1999, CTS claims made up 1.6% of workplace injuries requiring time off work. With the number of reported CTS claims staying stable and not decreasing like other workplace injuries for so long, there is an increasing demand on all employers to keep updating their workplaces. Workplace updates could include work station renovations and tool replacement to make job tasks more ergonomically friendly for their employees. If the total number of reported cases is not being reduced, there is still an issue with workplace practices, activities, and tools.

CTS also puts stress on members of the workforce by increasing the total number of sick days taken per year. On average, the total number of days taken off for a medical condition is highest for those suffering from CTS (27 days) as compared to fractures (20 days) and amputations (18 days) (Falkiner, 2002). Lost time injuries cost employers significantly in the form of lost productivity in their workforce and delays in progress on certain projects and tasks. As time taken off work also results in workers filing compensation claims, employers are penalized and financial resources are stretched thin very quickly.

Individual life. Living with a medical condition or disease (e.g., CTS) stresses both an individual's psychological and financial stability due to the cost of special medications and physical rehabilitation time. The overall cost of living with a long-term disability can add up very quickly, even in a society such as Canada where the medical system is supported very heavily by provincial funding. The stresses are more pronounced in countries without subsidized healthcare. For example, in the United States between the years of 1996-1997, a carpal tunnel claim cost an average of $13,263, while a claim in British Columbia in 1997 cost $11, 993 (Li, Liu, Miyazaki, & Warren, 1999). This was only surpassed by the cost of motor vehicle accidents, other traumatic injuries, and bone fracture, crush, and dislocation injuries (Falkiner, 2002).

Diagnostic Techniques

As CTS is becoming a prevalent condition, more websites, educational pamphlets, and information flyers are being produced and released discussing the condition, treatment, and prevention. The availability of information about CTS has led to more self-diagnoses being made by the general public before they receive an assessment from a medical professional. As the disease is more common in some workplaces, some employees self-diagnose themselves before being medically examined, frequently through the use of information on the internet (Falkiner, 2002).

The most common tests used in the diagnosis of CTS include the CCT, Phalen's Test and Tinel's Test, all of which attempt to reproduce the patient's symptoms in order to confirm the diagnosis. All three tests are provocative in nature, and they may give false negative findings if the patient has excessive median nerve dysfunction, or the disease is in the later stages (Falkiner, 2002).

The issue that arises with diagnosis of CTS is that there is not one specific test that is used. Medical professionals all have their own preferred method for testing and diagnosing CTS, which creates issues when other professionals are involved in the care of the patient. How does the CTS diagnosis by one professional compare to the diagnosis of another? Can a professional say that the chosen testing methodology for diagnosing CTS compares to the diagnostic technique that another professional uses? As Falkiner (2002) states, there is no standardized diagnostic technique for CTS. None of the physical tests, questionnaires, or electrodiagnostic techniques is, by itself, a "gold standard" for diagnosing CTS.

Treatment Methods for Carpal Tunnel Syndrome

Many treatment methods exist for CTS and include: manual therapy techniques (soft tissue mobilization, stretching, augmented soft tissue mobilization, neurodynamic technique), topical pain relief creams, splints and braces, electrotherapeutic modalities (ultrasound, transcutaneous electrical nerve stimulation), steroid injections, and surgical release methods (Jackson, 2012). While treatment methods have pros and cons, medical professionals have their personal preferences with regards to treatment methods; some professionals prefer to treat patients manually, and others prefer to treat using electrotherapeutic modalities.

Optimally, the least invasive treatment methods should be utilized and exhausted first. As Love (2003) stated, the most essential care is through the early detection of early symptoms, but before a patient seeks surgery as a treatment option, he/she should seek advice from a professional specializing in upper quadrant, wrist, and hand dysfunction. Surgery has specific applications; for example, the aim of decompression surgery may be to increase the volume of the carpal tunnel space in order to relieve pressure on the median nerve (Love, 2003). Although

decompression surgery is a fairly quick and simple technique, Love (2003) points out that there are many complications that can arise such as hemorrhage, damage to the ulnar nerve, swelling, infection, weakness of finger flexion, and post-operative chronic pain and numbness

Validity of an Assessment Tool

In order to implement less expensive CTS treatment methods, health professionals and employers must use CTS assessment tool measures that are simple to use, but with high degree of validated evidence. One commonly accepted definition of validity used to provide evidence for the validation of assessment tool measures is "the degree to which evidence and theory support the interpretation of test scores entailed by proposed uses of tests" (*Standards*, 1999, p. 9). Kane (2006) also commented on the meaning of the relationship between validation and validity:

> "validation" and to a lesser extent the term "validity" tend to have two distinct but closely related usages in discussions of measurement. In the first usage, "validation" involves the development of evidence to support the proposed interpretations and uses; in this usage, "to validate an interpretation or use" is to show that it is justified. In the second usage, "validation" is associated with an evaluation of the extent to which the proposed interpretations and uses are plausible and appropriate. In this sense, "to validate an interpretation or use" is to evaluate its overall plausibility. The first usage implies an advocacy role, in the building of a case for the validity of a proposed interpretation. The second usage implies a more-or-less objective appraisal of the evidence, pro and con. (p. 17)

To simplify this explanation, validity refers to the accuracy of the interpretation of scores from any test, which is the most critical aspect of any measure.

Evidence for validation of an assessment tool. In a number of ways, researchers have developed validity arguments to address the inferences made based on test-score interpretations when using an assessment tool (Kane, 2006). Validity arguments may entail providing evidence to support the test score interpretations and their relevance to the proposed use. These validity arguments may include construct-related evidence, content-related evidence, and concurrent-related evidence.

Construct-related evidence. *Standards* (1985) defines construct-related evidence of validity as a category that focuses primarily on the test score as a measure of the characteristic of interest (p. 9). For example, endurance is a frequently used construct to measure athletes' performance. Construct-related evidence of validity for the interpretations of test scores when measuring a construct can be obtained from a variety of methods. These methods may entail inter-correlations among items that can be used to support the assertion that a test measures primarily a single construct. The relationship to other variables is also another method that can be used to address the degree to which the construct being measured consistently relates to external variables (*Standards*, 1985). That is, when administering a test to measure pain, the researcher or practitioner may be interested in examining if pain increases or manifests in relation to time. This relationship may lead to a convergence of indicators that can be used to provide evidence for the validity of test score interpretations from the assessment tool.

Content-related evidence. *Standards* (1985) states that content-related evidence of validity is

> the degree to which the sample of items, tasks, or questions on a test are representative of some defined universe or domain of content. The methods often rely on expert judgments

to assess the relationship between parts of the test and the defined universe, but certain logical and empirical procedures can also be used. (p. 10)

For example, when developing an assessment tool to measure a specific construct (e.g., pain), the major facets of the construct to be measured can be identified and an expert in the area (e.g., physiotherapist, doctor) can be asked to assess the degree of pain manifested by a subject to each of those facets on the test.

Face-related evidence. Holden (2010) defines face validity as "the appropriateness, sensibility, or relevance of the test and its items as they appear to the persons answering the test" (p. 637). For example, a doctor could have a patient complete a set of wrist exercises. After the patient had completed the exercises, the doctor would then ask the patient if they had any difficulty with certain exercises.

Concurrent-related evidence. *Standards* (1985) states that concurrent-related evidence of validity is "the degree to which the criterion information obtained from a sample of items, tasks, or questions on a test relates to the same criterion information obtained from a standard when both measures are obtained simultaneously" (p. 10). For example, a researcher can correlate the measures obtained from a wrist pressure device created to assess pain with a standard compression test designed to measure pain by applying pressure to the wrist. If both measures correlate closely, then the measures obtained from the wrist pressure device have concurrent-related evidence of validity when assessing pain.

Reliability of an Assessment Tool

While validity is concerned with providing evidence for validation based on the inferences made from the assessment results of the tool or device, reliability is concerned solely

with how test scores are expected to vary when repeatedly using the assessment tool (Haertel, 2006). The proportion of variance across replications of the measures obtained from the assessment tool is usually examined using reliability coefficients (Kane, 2006). That is, evidence of reliability can be provided by examining the internal consistency of the items on the assessment tool in relation to a latent variable or construct (e.g., pain). The strength of the relationship among the test-items can then be used as an indicator of how much variance is accounted for by the relationship of the items when measuring a latent variable or construct (Bonett, 2003). When measuring a construct using an assessment tool, implementing a pre- and post-test design can also test its reliability. The strength of the relationship between the pre and post-test measures can be used as an indicator of the variance present when repeating the measure (Bonett, 2003). Ideally, reliability and validity are established through the completion of any research study. Kane (2006) stated that the inferences made from test scores cannot be claimed as evidence of validity if the test scores are not proven to be reliable.

Differences Between Self-Report and Direct Measures

When providing evidence for the validation of test score interpretations, a researcher may use self-report questionnaires (subjective measures) or direct measures (objective measures). The self-report measures may include information related to "the primary complaint, mechanism of injury, characteristics of the symptoms, and related medical history" (Anderson, Hall, & Martin, 2005, p. 96). Self-report information is mainly obtained by using a questionnaire that the individual fills out independently, addressing topics such as physical pain and difficulties with activities of daily living (ADLs). Direct measures, on the other hand, incorporate "measurable documentation relative to the affected individual's condition" (Anderson et al., 2005, p. 96).

These measures may include assessment techniques examining functional abilities, range of motion, nerve conduction, physical strength, and sensation of the affected individual.

Advantages and disadvantages of self-report questionnaires. Self-report questionnaires, more commonly known as subjective measures or outcome measures, have strengths and weaknesses. An advantage of self-report measures is that they "can effectively capture changes in both the explicit and the implicit components of the variable being measured, and, therefore, they can be better suited for the study of broadly defined concepts than objective measures" (Jahedi & Mendez, 2012, p. 3). Furthermore, self-report measures can provide a better method of examining latent constructs such as the patient's attitude or satisfaction with a medical assessment or treatment. Lastly, they are easy to use clinically, with a diverse variety of instruments that are patient/injury specific and validated.

The disadvantages of self-report measures vary. For example, Jahedi and Mendez (2012) reported two clear disadvantages. First, interpreting self-report measures can be more difficult than interpreting direct measures because they are expressed in ordinal scales. For example, individual understandings of the same question will vary based on interpretation. That is, if the responses to a self-report item are based on an ordinal scale (e.g., fair, good, very good) and two individuals answer the same question but one answers "fair" while another individual answers "good", how can a researcher be sure that these two individuals are accurately answering the proposed question? Another disadvantage of self-report measures is that the questionnaire responses supply a subjective source of bias which can be either intentional or unconscious in nature (Vogt, Selvin, Widdowson, & Hulley, 1977). As self-report measures are most commonly questionnaires that are filled out individually by the patient, the patient can easily state that his/her current health or medical condition is better than it truly is. When assessing CTS for

example, it is easy for an individual to misread or improperly answer questions on a questionnaire. As questionnaires rely on individual response, an individual may choose to answer questions dishonestly to take advantage of the healthcare system, subsequently increasing the number of malingerers (Pransky, Feuerstein, Himmelstein, Katz, & Vickers-Lahti, 1997). The American Psychiatric Association (2000) defines malingering as the intentional reproduction of false or largely exaggerated complaints with the aim of receiving an incentive. This reward could include time off work, an insurance settlement, or drugs to treat a medical condition. Pransky et al. (1997) point out that through assessing diagnostic techniques, malingerers cannot be accurately identified through the use of subjective measures. The total number of malingerers is not known, however it is estimated that true symptom fraud occurs in less than 5% of all clinical CTS cases (Millender & Conlon, 1996). In order to reduce the number of malingerers within the healthcare system, there is a need to develop non-invasive objective testing protocols into one testing battery to increase the validity of CTS assessment and diagnosis.

Advantages and disadvantages of direct measures. Direct measures, also known as objective measures, are "a basic measurement that can be based upon a standard unit preserved in some permanent location" (Michels, 1983, p. 210). Simply put, a direct measure can be represented by weight, height, or length of an object, for example. Direct measures provide an objective means of measuring the important physical and functional abilities during medical assessments and diagnoses to minimize the chance of inaccurate diagnosis and other errors that may occur with subjective measures.With respect to CTS, a direct measure can involve nerve conduction testing of the median nerve, or grip strength testing of an affected wrist. With respect to a cardiac patient, a direct measure would, for example, use a heart rate monitor to gauge an individual's heart rate during a test. One advantage of direct measures is that they can provide an

unbiased or objective measure (Reuben & Siu, 1990). In a medical situation, for example, an individual may report that their CTS symptoms have progressively become worse over time.

Another advantage of direct measures is that "this method may provide more accurate and reliable information than self report or proxy report" (Reuben & Siu, 1990, p. 1105). Unlike subjective measures, direct measures eliminate individual error. For example, an individual suffering from CTS may rate his/her overall physical symptoms on a questionnaire as being worse than these symptoms actually are. Objective measurement (e.g., nerve conduction tests) on the same individual, however, may indicate that the symptoms are not as severe as reported on the questionnaire. As objective scores are typically considered more representative measures of a condition than subjective scores, the treating medical professional may opt to use objective measures as an avenue to get a more accurate idea of the individual's true condition and abilities.

While direct measures have many advantages, these measures also have disadvantages. For example, Reuben and Siu (1990) reported that a disadvantage of direct measures is cost. Since they require more staff time and effort, clinical time must be booked with a professional. In addition, direct measures can be costly in terms of the labour and consultation to the individual receiving the testing as they may have to book time off work to have the testing completed. Lost time in the workplace costs not only the employee, but also the employer. Furthermore, Hadler (1990) and Mackinnon (2002) found that in CTS cases that are labeled as "cumulative trauma disorders," the symptoms may not always be substantiated by the use of direct measures, as the CTS symptoms frequently persist even when negative findings on well-established assessment methods are found.

There is a need to produce a testing battery that will assist in the better diagnosis of CTS as there are currently many subjective questionnaires and objective testing measures. The issue is

that there is no true correlation seen between any two testing protocols. For example, Pransky et al. (1997) reported that many of the current questionnaires used to assist with diagnosing CTS are generalized to the upper limb, and do not focus directly on the wrist.

Assessing Carpal Tunnel Syndrome via Self-Report Questionnaires

According to Sambandam et al. (2008), there are six main self-report questionnaires used in the assessment and diagnosis of CTS. These questionnaires include the Boston Carpal Tunnel Questionnaire (BCTQ), Michigan Hand Outcome Questionnaire (MHQ), Disability of Arm Shoulder and Hand (DASH), Patient Evaluation Measure (PEM), Historical-Objective Scale (Hi-Ob Scale), and the Upper Extremity Functional Scale (UEFS).

Boston carpal tunnel questionnaire. The BCTQ, created by Levine et al. (1993), is the most commonly used outcome measure in the assessment of patients with CTS (Sambandam et al., 2008). The focus of the questionnaire is on two scales, the symptom severity scale (SSS, 11 items) and functional status scale (FSS, eight items).

The scales were found to be highly reproducible, showing intraclass reliability of r= .91 for the SSS and an even higher r= .93 for the FSS. Cronbach's alpha was found to be .89 for the SSS and .91 for the FSS (Sambandam et al., 2008).

Michigan hand outcome questionnaire. The MHQ was developed by Chung, Pillsbury, Walters and Hayward in 1998 to assist with assessing various hand disorders. The test questionnaire items were grouped into six specific areas, including overall hand function, ADLs, pain, work performance, aesthetics, and patient satisfaction with hand function (Chung, Pillsbury, Walters, & Hayward, 1998). Unlike other questionnaires, the MHQ focuses on both unilateral and bilateral CTS, with four of the six areas relating to both the right and left hand; this allows for comparison of an affected wrist to an unaffected wrist (control) when possible.

Researchers reported that the test-retest reliability for the MHQ ranged from .81 on the aesthetics scale to .97 on the ADL scale. Test-retest reliability was tested by having participants fill out the initial questionnaire in a clinical setting and completing the same questionnaire one week later to reduce recall rate. Cronbach's alpha, which tests internal consistency, was shown to be between .86 for the pain scale and .97 for the ADLs scale (Chung et al., 1998). During pilot studies, factor analysis was used to reduce the MHQ to six main factors: overall hand function, ADLs, pain, work performance, aesthetics, and patient satisfaction with hand function. A total of 37 testing questionnaires are listed under the six main factors stated above (Sambandam et al., 2008) and content validity was evaluated by hand surgeons, therapists, and patients with hand disabilities (Chung et al., 1998). Construct validity was established by comparing the items in the MHQ to an already validated similar questionnaire, the SF-12. The SF-12 is a general questionnaire that is used to assess a variety of upper limb conditions, focusing on difficulty in completing tasks and general physical and mental health (Ware, Kosinski, & Keller, 1996).

Disability of arm, shoulder, and hand. The DASH is a general questionnaire, which was created in a joint effort by the American Academy of Orthopaedic Surgeons, the Council of Musculoskeletal Societies, and the Institute for Work and Health (Beaton et al., 2001, Sambandam et al., 2008). It assists with diagnosis and assessment of upper extremity issues from the shoulder to the hand. Although the DASH is the most widely used subjective measure for upper extremity disorders, this general questionnaire has not been extensively studied for its transferability to be used in assessing CTS specifically.

The researchers established criterion validity for the questionnaire through demonstrating a strong correlation between the DASH and the PEM. Other than this original validity testing,

there has been no research done to provide further evidence of validity of the questionnaire in assessing and diagnosing CTS (Sambandam et al., 2008).

Patient evaluation measure. The PEM is a self-administered measure of a patient's physical health. The PEM has three subscales dealing with treatment (five items), feeling and using the hand (10 items), and overall assessment quality (three items). The questionnaire is vague and can be easily misunderstood by either the patient answering the questions or the treating medical professional interpreting the results.

Overall reliability of the PEM was found to be .83, with inter-item consistency of .88 and internal consistency of .94 (Sambandam et al., 2008). Although initial testing results were positive, the first validity testing was not carried out for almost five years after the questionnaire was put into practice. The testing that was completed showed high correlation between grip strength testing and overall perceived level of distress items within the PEM questionnaire (Sambandam et al., 2008).

Historical-objective. Created in 2002 by Giannini and colleagues, the Hi-Ob Scale is based on the clinical history and physical examination findings of physicians (Sambandam et al., 2008). Although it was tested directly on individuals suffering from CTS, it has many disadvantages. Some disadvantages of the questionnaire are that it has never been validated by external sources, commonly missed or misunderstood questions have not been identified, time to completion has not been established, and cross-cultural validation is lacking (Sambandam et al., 2008).

In the original research testing, the questionnaire was validated using 168 hands that were affected by CTS. Evidence of validity was provided by showing a high correlation between the Hi-Ob questionnaire score and the symptom/functional subscales of the more popular BCTQ, as

well as neuro-physiological measures (pain) (Sambandam et al., 2008). As the two questionnaires test roughly the same aspects of CTS, the functional and symptomatic subscales of the Hi-Ob were validated against the already validated BCTQ function and symptom subscales. Researchers tested the reproducibility of the questionnaire reporting a Cohen coefficient of .69, and good overall responsiveness with the testing.

Upper extremity functional scale. The UEFS was created by physicians and occupational therapists testing patients with upper extremity disorders (Sambandam et al., 2008). Developed in 1997 by Pransky, Feuerstein, Himmelstein, Katz, and Vickers-Lahti, this non-specific questionnaire of the upper extremity focuses on assessing the outcome of work-related upper extremity disorders. The questionnaire is not specific, and can be used on any part of the upper extremity from the shoulder region to the fingers. A serious drawback to this questionnaire is that it only takes into account functional disabilities of the patient and ignores symptom severity and objective scores of physical, mental, or social health (Sambandam et al., 2008). To score the questionnaire, a 10 item Likert scale is used, with a score of one representing no problem with a specific activity, and 10 representing not being able to perform the activity at all. Although this questionnaire was designed to assess functional disabilities of the upper extremity, it is also found to have an internal consistency range varying from an alpha score of .83 to .93 for patients with CTS (Sambandam et al., 2008).

Construct related evidence of validity for the UEFS was established by demonstrating a high degree of correlation between the UEFS score and a Likert scale measure of subjective pain, physical measures, and psychological measures.

Assessing Carpal Tunnel Syndrome via Direct Measures

Carpal compression test. Durkan developed the CCT in 1991. The test consists of applying a steady pressure of 150mm Hg directly over the carpal tunnel space with the pads of

the thumb tips in order to compress the median nerve. This pressure is held steady for a maximum of 30 seconds, and the testing ceases when the participant's CTS symptoms (pain and/or numbness) are aggravated or worsened. Durkan (1991) applied pressure to the median nerve in two ways: 1) with the assistance of a hollow ball attached to a blood pressure gauge to show the researcher how much pressure they were applying to the carpal tunnel space and; 2) with just the thumb pads over the carpal tunnel space applying what the researcher believed to be 150mm Hg pressure. The problem that arises with the second method is that the individual applying the pressure to the carpal tunnel space has no true knowledge of how much pressure they are applying to the carpal tunnel space.

A total of 31 participants were assessed in this study, with a total of 46 wrists being tested. The CCT was found to be more sensitive and specific than the Tinel's and Phalen's Tests when tested on the participants with CTS, producing positive results in 87% of the hands assessed (69% positive with Phalen's, 56% with Tinel's) (Durkan, 1991).

Electrodiagnostic testing. Electrodiagnosis is an extension of the history and physical examination of CTS, which began in the 1950's (Wang, 2013). There are currently two forms of electrodiagnostic testing being used: electromyography (EMG) and nerve conduction study (NCS). Of the two, NCS is more valuable than EMG testing due to the demyelination involved in CTS (Wang, 2013), with NCS better assessing the demyelination of the nerve tissue in comparison to EMG. Since electrodiagnostic techniques need to be administered under strict conditions to gain the best insight into the patient's condition, variables such as electrode placement, distance measurements, stimulation intensity, and skin temperature must be closely monitored for the most reliable results (Wang, 2013). One method used to assess CTS symptoms electrodiagnostically is through the use of the combined sensory index (CSI). The CSI is an

attempt to maximize the sensitivity of diagnosis without reducing specificity (Wang, 2013). The CSI is calculated through the combination of three sensory latencies, where CSI= ringdiff+thumbdiff+palmdiff (Wang, 2013). When the upper latency limit is set to 0.9s, the test sensitivity is 0.83, while specificity is 0.95 (Wang, 2013).

Although this testing method produces reliable results, the procedure is typically expensive; for example, Fowler, Maltenfort, and Ilyas (2013) reported that the average cost of an electrodiagnostic procedure ranged between $400.30 to $428.30 at general practitioner clinics and specialists' clinics, respectively. With the availability of CTS self-report and direct measures that are either costly or lack evidence of validity, developing assessment tools that are simple and less expensive to administer in CTS diagnostics would assist patients and reduce healthcare costs.

CHAPTER THREE- METHOD

Goals of the Study

The purpose of this study was to develop a prototype for a CTCAT and provide evidence of validity and reliability for the use of the CTCAT in assessing CTS when compared to the BCTQ and a 10 point self-report Likert pain scale.

Prototype Development Procedures

For more information on the CTCAT, see Appendix A: Carpal Tunnel Compression Assessment Tool. The proprietary CTCAT as depicted in Figure 2 and Figure 3 is a portable testing device that is easy to set up and use. The device is a small box that has one opening for the hand of the participant. There is a hinged moving arm that is locked in place with a Velcro strap once the participant's hand is in the proper testing position. The carpal tunnel space is rested on top of a pressure ball that pushes directly into the carpal tunnel space, while the palm rests on a ball rest during the testing session. On the bottom of the device, there is an inflatable bladder that presses on a pressure ball, which pushes on the carpal tunnel region of the wrist. The bladder is inflated by a hand pump, which the researcher controls. To monitor the pressure of the bladder, a small pressure gauge is attached. The pressure ball serves to compress the median nerve in the same fashion as the medical professional would by applying a steady pressure with his/her thumbs to conduct the CCT.

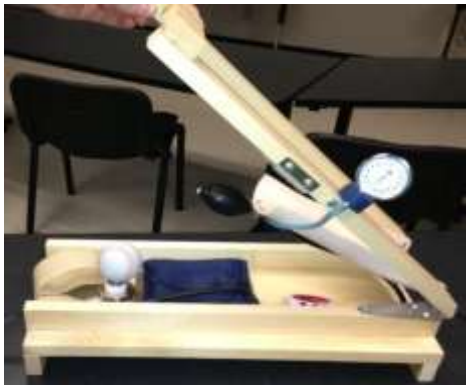

Figure 2. CTCAT device. The device in the open position, with the blue inflation pad, the white hand rest ball, and the black pressure ball.

Figure 3. CTCAT testing position. The carpal tunnel space is placed on top of the black pressure ball with the retainer strap on the back of the wrist. The hand rests on the white ball to maintain wrist angle during testing.

Device development took place over the period of five months, where design ideas were brought forward and prototypes were created. During creation of the device, it was kept in mind that the CTCAT needed to apply pressure steadily and evenly for the allotted testing time. In order to apply pressure to the wrist at the specified pressure, there needed to be a pressure gauge incorporated into the device to allow the testing researcher to monitor the pressure during the testing. This was accomplished through attaching a sphygmomanometer gauge to the device. The device also had to have a quick-release feature to allow pressure to be removed from the participant's wrist the second their CTS symptoms increased. The quick-release function was

then added to the device with the Velcro strap on the end of the moving arm. This would then allow the participant to open the device immediately upon feeling a change in their CTS pain or symptoms. Wood was chosen as the primary construction material for this prototype due to its low cost and ease of use. Future prototypes will be constructed of aluminum and other light weight materials to save on weight and also increase durability of the device. Mr. Dan Vasiliu assisted with device development and construction, putting his engineering knowledge in the area to use. Lastly, clinical guidance was provided by an orthopaedic surgeon and an occupational therapist to use the CCT (Durkan, 1991) as the physical testing protocol for the study.

As was found in the pilot study, the original pressure ball spread the required pressure over too large of an area when the device was inflated, which then required modifications to be made to the device. The first pressure ball that was used was an inflation bulb from a sphygmomanometer, which is soft rubber. As the pressure placed on the ball increased, the pressure point applied to the wrist got larger, which spread the load over a larger area. This pressure area did not mimic the pressure area of the average thumb very well (roughly one inch squared). The sphygmomanometer bulb was then replaced with a smaller, harder ball, and this ball held its shape better when the pressure load was placed on it, mimicking the area of the thumbs much closer than the previous ball. The flaw was noted after the first round of testing was completed and there were no positive results being produced with the CTCAT. The ethics package was then sent to Health Canada for the proprietary device to be reviewed and approved for use. Upon review, Health Canada granted approval for the device to be used as a Class 1 medical device for research purposes. After developing a prototype that appeared to satisfy the design requirements of providing a portable instrument that allows an objective measurement of

pressure that mimics a clinician's thumb pressure, the next step was to address issues of validity and reliability which led to the following research questions.

Research Questions

The following research questions guided the study:

1. How reliable are the measures obtained from the BCTQ with the current data?
2. Can a 10 point self-report Likert pain scale question be used to assess CTS when compared to the BCTQ?
3. To what extent is the CTCAT able to assess CTS when compared to the BCTQ and 10 point self-report Likert pain scale?

In order to address the purpose of the study and answer these research questions, evidence of reliability and validity of the BCTQ, CTCAT and the 10 point self-report Likert pain scale were provided by using quantitative and qualitative methods. The data included self-report measures of pain and direct measures of response time based on participants' tolerance to withstand pain due to carpal tunnel compression.

Participants

Recruitment. Carpal tunnel syndrome participants were recruited for this study through convenience sampling by using posters (see Appendix D: Recruitment Poster), asking individuals to participate, and contacting medical clinics within the city of Thunder Bay from November 2013 to February 2014. This process was conducted over three months. All potential participants must have been over the age of 18 at the time of testing to be included. In the case of medical clinics, recruitment packages were submitted multiple times to 10 large clinics (e.g., physiotherapy, chiropractic, medical doctor) in Thunder Bay to ensure the most representative

sample size possible. Before distributing the recruitment packages to the medical clinics, however, the practicing professionals were asked about their willingness to help recruit participants for the study. If the professional expressed that he/she was currently treating patients with CTS and willing to assist with recruiting participants, recruitment packages were left at the clinic to be distributed to the potential participants. Ten participants with CTS were recruited to this study through the use of these recruitment procedures. Carpal tunnel syndrome participants who had decompression surgery were less difficult to recruit as these participants were being treated by medical professionals and clinics for post-surgery rehabilitation. Out of the 10 participants with CTS, six had decompression surgery, and four did not have decompression surgery. All of the participants with CTS had the condition bilaterally.

Nine control participants were recruited directly by the researchers. Classmates, family and friends were asked to partake in the study. These participants were then asked to refer another individual to the study. Potential control participants were included if they had no wrist pain or discomfort, and were excluded if they had sought medical attention for a hand or wrist condition in the past.

There was an attempt made to both gender match and age match participants in the control group to the CTS group. The age of participants included in this study ranged from 20 to 67 years old. The CTS group included six female participants and four male participants, while the control group was composed of six female participants and three male participants. The average age of the CTS group was 46 years old, while the average age of the control group was 34 years old.

Exclusion. Potential participants for the CTS testing group were excluded if his/her CTS symptoms and pain were not clinically diagnosed by a medical professional as truly being CTS. These individuals were excluded from the study to ensure that the testing was only completed on participants with CTS and not other hand and wrist ailments. Potential participants for the control group were excluded if they reported any hand and/or wrist difficulties such as numbness, soreness, or stiffness in the hand and wrist area.

Testing. Participant testing took place in the School of Kinesiology research laboratory at Lakehead University, Thunder Bay, Ontario. Participant testing sessions took place after work hours to ensure that participants were able to attend his/her testing sessions on the scheduled days. The testing period lasted a total of one month. Participant testing was approved by Lakehead University's Research Ethics Board before testing commenced. Written informed consent was obtained from all participants in the study (see Appendix H: Control Participant Consent Form and Appendix I: Carpal Tunnel Syndrome Participant Consent Form).

Instruments

Boston carpal tunnel questionnaire. (See Appendix B: Boston Carpal Tunnel Questionnaire). This instrument was used to address the first research question of this study. The BCTQ is a two subscale questionnaire, comprised of a symptom severity scale (SSS, pain, discomfort) and a functional status scale (FSS, difficulty with certain daily activities).

The BCTQ questionnaire asks straight forward questions, and pertains directly to the area of interest in this study (the wrist and hand). The BCTQ is easy and quick to fill out, and gives accurate scores as to the difficulty and pain associated with the participants' CTS symptoms. The BCTQ was chosen as part of the subjective testing aspect for the study due to its simplistic

nature and focus specifically on CTS. Few hand and wrist medical questionnaires in existence are as specific as the BCTQ in addressing issues specifically dealing with the hand and wrist.

Ten point self-report Likert scale. (See Appendix G: 10 Point Likert Pain Scale). This instrument was created by the researcher to provide additional information on participant level of pain before and after each testing session. Participants were asked to rate their perceived level of pain when asked the following question: "Perceived level of pain: please rate your pre-/post-test pain and/or discomfort in your wrists". The measures of pain obtained from the 10 point self-report Likert scale were compared to the BCTQ to provide concurrent-related evidence of validity for the 10 point Likert scale as a measure of pain. "Perceived level of pain: please rate your pre-/post-test pain and/or discomfort in your wrists". The pain scale was rated on a scale of one to 10, one meaning no pain or limited pain in the wrist/hand area from CTS symptoms; 10 meaning the worst pain the participant felt in relation to his/her CTS symptoms.

Carpal tunnel compression assessment tool. (See Appendix A: Carpal Tunnel Compression Assessment Tool). This instrument was created by the researchers to mimic the CCT created by Durkan (1991). The device aims to remove the subjective judgment of medical professionals to minimize measurement error that can occur when the CCT is completed manually due to differences in thumb pad size and the medical professionals' kinesthetic feeling of exerted pressure.

Procedures for Assessing Reliability and Validity

Participants were administered two physical testing sessions two days apart, with each testing session containing a pre- and post-test to answer the research questions pertaining to this

study. Both testing sessions that were carried out used the exact same testing procedures as one another, being the BCTQ, the 10 point Likert pain scale, and the CTCAT.

Each participant (control group and CTS group) was asked to complete the consent form upon arriving on their first day of testing. Once the consent form was completed, the participant was then asked to complete the BCTQ in regards to their CTS symptoms/discomfort over the previous 24 hour period. All participants were asked to complete the BCTQ as honestly as possible to avoid skewed testing results. For testing session two, the participants were given the BCTQ to complete upon arriving for testing. Although the BCTQ has strong evidence of reliability and validity as stated by Sambandam et al. (2008), further evidence of reliability are provided with the current data to verify the consistency of the measures obtained from the BCTQ across replications with the current data.The participants (both CTS and non-CTS) were then asked to rate his/her CTS pre-test pain via the 10 point Likert scale before conducting the CTCAT on both testing dates.

The participants were asked to remain seated after completing the required pre-test forms (consent form, BCTQ, 10 point Likert pain scale) and to insert his/her dominant hand into the CTCAT device with the carpal tunnel area being placed directly over the centre of the pressure ball. Once the wrist had been rested on the pressure ball in the proper position by the researcher, the wrist angle was adjusted through the use of an adjustable ball rest. The pressure bladder was then inflated to 150mmHg as per the CCT guidelines created by Durkan (1991). Pressure was maintained at 150mmHg for a maximum of 30 seconds based on testing protocol guidelines stated by Durkan (1991). Participants were reminded that if their CTS symptoms worsened during testing that the testing would be stopped immediately by releasing the Velcro safety strap, which instantly released the pressure applied on the carpal tunnel area.

After completing the CTCAT test, participants were asked again to rate his/her level of pain/discomfort using the 10 point Likert scale as a post-test pain measure. Lastly, before participants left the testing session, a second testing session was booked for two days from their first testing session.

Analysis- Research Question One- How reliable are the measures obtained from the BCTQ with the current data?

Cronbach's alpha inter-item reliability tests for the BCTQ were conducted to verify the internal consistency of the questionnaire items as measures of pain when diagnosing individuals with CTS using the current data. Intraclass correlations were also computed to verify the consistency across replications of the BCTQ with the current data by comparing the BCTQ scores of session one and two. As the non-CTS participants' questionnaire responses showed no variability, the statistical results for this group data set were excluded. Intraclass correlation coefficients were computed by comparing the data of session one and two to provide evidence of consistency across replications when administering the BCTQ.

A test of normality was completed to further support the results provided by the BCTQ. The test of normality ensured that the results fell within the normal distribution curve when assessing scores from both part one and part two of the questionnaire.

Analysis- Research Question Two: Can a 10 point self-report Likert pain scale question be used to assess CTS when compared to the BCTQ? Evidence of reliability is provided by conducting two intraclass correlation analyses to compute correlation coefficients. The first intraclass correlation analysis was conducted by comparing the 10 point Likert scale pre-test pain measures between session one and two. The second intraclass correlation analysis

was conducted by comparing the 10 point Likert scale post-test pain measures between session one and two.

Concurrent-related evidence of validity for the 10 point Likert pain scale was provided by computing an intraclass correlation between the pre-test Likert pain scale scores and the BCTQ part one. Before any statistical analyses were completed, the scores of the BCTQ part one and the 10 point Likert pain scale had to be scaled as the BCTQ part one is scored out of 45, and the 10 point Likert scale is scored out of 10. Once the scores for two instruments were scaled by computing z-scores, the statistical analyses were completed. As there was no noted change in pain for the non-CTS participants, this group was excluded from this part of the statistical analysis.

Construct-related evidence was provided by comparing the 10 point Likert scale pre-test pain measures to the BCTQ part two, which measures difficulty with certain ADLs when affected by CTS using intraclass correlation analysis. As there was no noted change in pain for the non-CTS participants, this group was excluded from this part of the statistical analysis.

Face-related evidence of validity was obtained from qualitative measures by asking the participants the following open ended question: "At any time after the testing session, did your CTS symptoms increase? If so, please describe the symptoms and duration of aggravation" to triangulate the measures. This rationale is also supported on the standards on evidence for validation "based on participants' qualitative responses" (Patton, 2002). To support the qualitative measures, descriptive and inferential statistics analyses were conducted.

A test of normality was completed to further support the results provided by the 10 point Likert pain scale as the scale rates participant pain and discomfort on a scale of one to 10. The

test of normality ensured that the results provided from the pre-test and post-test fell within the normal distribution curve.

Analysis- Research Question Three: To what extent is the CTCAT able to assess CTS when compared to the BCTQ and 10 point self-report Likert pain scale? Evidence of reliability for the CTCAT was established through using the test-retest method. Times measured between sessions one and two were compared to examine the degree to which the time measures produced by the CTCAT were consistent across replications.

To provide convergent-related evidence of validity, the CTCAT time scores were correlated to the pain measured during the test. Pain measured during the test was computed by subtracting the 10 point Likert scale pre-test pain measures from the post-test pain measures.

To provide discriminant-related evidence of validity, the CTCAT time to symptom onset measures were correlated to BCTQ part one and the 10 point Likert scale pre-test data.

CHAPTER FOUR- RESULTS

To provide evidence of reliability and validity of the instrument measures used to validate the measures of the CTCAT, this chapter contains the results that answer the three research questions. Five months of CTCAT design and development work resulted in a prototype that could subsequently be assessed for reliability and validity. Three group data sets were assessed: non-CTS participants, CTS participants and all testing participants, which included non-CTS and CTS participants. The results are provided in terms of descriptive, inferential statistics, correlations, and qualitative measures.

Research Question One- How reliable are the measures obtained from the BCTQ with the current data?

Inter-item reliability tests for the BCTQ. As shown in Table 1, the Cronbach's alpha coefficients for testing session one for part one of the BCTQ ranged from: $r = .925$, $p < 0.001$, $n = 10$ (CTS participants) to $r = .972$, $p < 0.001$, $n = 19$ (all participants). Results for part two of the BCTQ for testing session one varied from: $r = .968$, $p < 0.001$, $n = 10$ (CTS participants) to $r = .978$, $p < 0.001$, $n = 19$ (all participants).

The Cronbach's inter-item reliability coefficients for testing session two, part one of the BCTQ as depicted in Table 2, ranged from: $r = .922$, $p < 0.001$, $n = 10$ (CTS participants) to $r = .974$, $p < 0.001$, $n = 19$ (all participants). Cronbach's alpha inter-item reliability scores for part two of the BCTQ for testing session two varied from: $r = .938$, $p < 0.001$, $n = 10$ (CTS participants) to $r = .963$ $p < 0.001$, $n = 19$ (all participants). Reliability scores for testing session two, in terms of internal consistency of the items, were similar to those of testing session one. This outcome indicated that the measures obtained from the BCTQ during testing session one

and two provided reliable measures in terms of internal consistency of the test items to assess a patient's pain and difficulty with certain ADLs when affected by CTS.

Table 1

Inter-item Reliability for BCTQ Testing Session One

Participants	*r*	*n*
CTS, part 1	.925	10
CTS, part 2	.968	10
All, part 1	.972	19
All, part 2	.978	19

Note: $p < 0.001$

Table 2

Inter-item Reliability for BCTQ Testing Session Two

Participants	*r*	*n*
CTS, part 1	.922	10
CTS, part 2	.938	10
All, part 1	.974	19
All, part 2	.963	19

Note: $p < 0.001$

Test/retest reliability measures of the BCTQ. Table 3 shows the results of these tests. The intraclass correlation scores for the BCTQ part one were as follows: $r = .954$, $p < 0.001$, $n = 10$ (CTS participants) to $r = .985$, $p < 0.001$, $n = 19$ (all participants). Part one of the BCTQ addresses the participants' pain and discomfort in relation to their CTS symptoms over the previous 24 hour period. The outcome of these correlation scores suggested that the BCTQ part

one provided consistent measures of pain across replications of the test when using the current data.

The intraclass correlation scores for the BCTQ part two, which measured difficulty with certain ADLs over the previous 24 hour period were also computed by comparing the data of session one and two. The intraclass correlation coefficients were as follows: $r = .976$, $p < 0.001$, $n = 10$ (CTS participants) to $r = .987$, $p < 0.001$, $n = 19$ (all participants). The outcome of the intraclass correlation coefficients for the CTS participants group indicated that the BCTQ part two provided reliable measures of the participant's difficulty with certain ADLs when administering the test on more than one occasion.

Table 3

Intraclass Reliability for BCTQ

Participants	*r*	*n*
CTS, part 1	.954	10
CTS, part 2	.976	10
All, part 1	.985	19
All, part 2	.987	19

Note: $p < 0.001$

Test of normality for the Boston carpal tunnel questionnaire. A Shapiro-Wilk's test ($p > .05$) (Shapiro & Wilk, 1965; Razali & Wah, 2011) showed that the BCTQ scores were approximately normally distributed for both the symptom severity scale and the functional status scale for testing session one. For the symptom severity scale, skewness was found to be -0.038 (SE = 0.717) while kurtosis was found to be 0.289 (SE = 1.40); a skewness of 0.242 (SE = 0.717) and a kurtosis of 1.251 (SE = 1.40) was found for the functional status scale.

For testing session two, the symptom severity scale skewness was found to be -0.483 (SE = 0.687) while kurtosis was found to be 0.617 (SE = 1.334); a skewness of 0.394 (SE = 0.687) and a kurtosis of -0.951 (SE = 1.334) was found for the functional status scale. The outcome of the Shapiro-Wilk's test confirmed that the data collected from the BCTQ symptom severity scale and the functional status scale fell within the normal distribution curve.

Research Question Two- Can a 10 point self-report Likert pain scale question be used to assess CTS when compared to the BCTQ?

Research question two related to assessing the participants' perceived level of pain at the wrist before and after administering the CCT. This question was used as criteria to provide evidence for the validation of the CTCAT measures. Evidence of reliability and concurrent-related evidence of validity are provided to support research question two.

Evidence of reliability. Table 4 shows the results of this test.

Non-carpal tunnel syndrome participants. As no participants in the non-CTS group reported a change in pain between pre- to post-test pain during session one and two, there was not need to conduct an intraclass correlation analysis for this group.

Carpal tunnel syndrome participants. The reliability scores for the 10 point Likert pain scale pre-testing pain measures between session one and two produced moderate reliability measures; r= .770 (p= .020, n= 10); while the post-testing pain reliability for this group data set was r= .772 (p= .019, n= 10) between session one and two. Significant moderate correlations suggested that the 10 point Likert scale scores showed consistency across replications when assessing the participants' pain both before and after the physical testing.

All participants. The reliability scores for the 10 point Likert pain scale pre-testing pain measures between session one and two produced reliability scores of $r = .867$ ($p < 0.001$, $n = 19$). Post-testing pain reliability measures for this group data set was, $r = .898$ ($p < 0.001$, $n = 19$) between session one and two. Significant correlations suggested that the 10 point Likert scale scores were consistent across replications when assessing the participants' pain before and after the CTCAT physical testing session.

Table 4

Pre-test and Post-test Pain Score Reliability

Participants	*r*	*p*	*n*
CTS, pre	.770	.020	10
CTS, post	.772	.019	10
All, pre	.867	< 0.001	19
All, post	.898	< 0.001	19

Evidence of concurrent validity. Table 5 depicts these results.

Non carpal tunnel syndrome participants. As there was no noted change in pain for the non-CTS participants when using either the BCTQ or 10 point Likert scale, this group was excluded from this part of the statistical analysis. Table 5 depicts these results.

Carpal tunnel syndrome participants. The intraclass correlation result produced for testing session one when comparing the scores of the BCTQ part one to the 10 point Likert scale pre-test pain scores was $r = .885$, $p = .002$, $n = 10$; while the intraclass correlation result for testing session two was $r = .871$, $p = .003$, $n = 10$. Strong significant correlations for the CTS only participant group data set suggested that the BCTQ part one and the 10 point Likert scale pre-test

pain questionnaire measured pain to almost the same degree as one another. Since the BCTQ is considered a standard measure of pain in CTS diagnosis felt before the administration of the CTCAT test, this outcome provided concurrent-related evidence of validity for the use of the 10 point Likert Scale as a measure of pain in CTS diagnosis.

All participants. The correlation scores for testing session one when comparing the BCTQ pain scores to the 10 point Likert pre-test pain measures produced significant results of r= .897 p< 0.001 n= 19. Testing session two also produced significant correlation results of r= .906 p< 0.001 n= 19. Since healthy participants were included in this part of the statistical analysis, it was expected that the correlation scores would be higher than the CTS only group. Significant results from this analysis, however, suggest that the 10 point Likert pain scale pre-test data and the BCTQ part one pain measures are strongly related. This outcome provided concurrent-related evidence of validity.

Table 5

Concurrent Validity for 10 Point Likert Scale Compared to BCTQ

Participants	*r*	*p*	*n*
CTS, session one	.885	.002	10
CTS, session two	.871	.003	10
All, session one	.897	< 0.001	19
All, session two	.906	< 0.001	19

Evidence of construct validity. Table 6 illustrates these results.

Carpal tunnel syndrome participants. Pearson's correlation for the 10 point pre-test pain for testing session one to the BCTQ part two was found to be r= .661, p= .053, n= 9. The pre-test

pain correlation for testing session two was found to be r= .857, p= .002, n= 10. Although testing session one correlation between the two instrument measures was marginally significant, the results suggest that when a participant's pre-testing CTS pain is high, it can be expected that their level of difficulty with ADLs will also be high. Since the two measures (pain and difficulty with ADLs) converge, this outcome provided some construct-related evidence of validity.

All participants. For testing session one, when correlating 10 point Likert scale pre-test pain measures to the BCTQ part two, the Pearson's correlation was found to be r= .801, p< 0.001, n= 18. For testing session two, the Pearson's correlation was r= .911, p< 0.001, n= 19. It was expected that the correlation would increase when non-CTS participants were included. Significant correlation results, however, suggested that the two measures converge. That is, participants' pre-testing pain symptoms can assist in predicting their current difficulty in performing ADLs.

Table 6

Construct-related Validity 10 Point Pre-pain to BCTQ Part 2

Participants	*r*	*p*	*n*
CTS, session one	.661	.053	10
CTS, session two	.857	.002	10
All, session one	.801	< 0.001	18
All, session two	.911	< 0.001	19

Evidence of face validity. Due to the low number of individuals with CTS, qualitative and quantitative measures were completed to assess the degree to which participants felt symptom aggravation after the administration of the CCT to provide further evidence for the use of question two as validity criteria for the CTCAT. Qualitative measures revealed that when

assessing the individual responses to question 2, “at any time after the testing session, did your CTS symptoms increase? If so, please describe the symptoms and duration of aggravation”, some participants experienced their CTS symptoms after leaving the testing. After the administration of the CTCAT, one participant from the CTS group data set reported, “I had latent numbness in my thumb tip and long finger that lasted an hour”. Another participant from the CTS group who did not have decompression surgery also reported, “On my drive home, my symptoms came on within a minute after leaving. They lasted 5 minutes, and then went away”. When these participants were questioned further about the severity of their symptom onset and whether or not the symptoms were worsened the next day, both participants stated that their symptoms lasted between 5-60 minutes. The descriptive, inferential and qualitative analysis results provide some evidence of face validity to use question 2 as a criterion for the validation of the CTCAT measures.

To support the qualitative measures, descriptive and inferential statistics analyses were conducted and depicted in Table 7. For the CTS only participants, the mean pre-test pain score from the 10 point Likert pain scale for testing session one, M= 2.90, SD= 1.663, was lower than the post-test pain score mean, M= 4.10, SD= 2.283. For testing session two, the pre-test pain score mean, M= 3.20, SD= 2.098, was also lower than the post-test pain score mean, M= 4.20 SD= 2.150.

Table 7

Pre-test and Post-test Pain Descriptive Statistics

Participants	M	SD
CTS, session one pre	2.90	1.663
CTS, session one post	4.10	2.283
CTS, session two pre	3.20	2.098
CTS, session two post	4.20	2.150
Non, session one pre	1.0	0.0
Non, session one post	1.11	0.33
Non, session two pre	1.0	0.0
Non, session two post	1.11	0.33

Inferential statistics (t-test) revealed a significant difference in the scores for pre-test pain in comparison to post-test pain for the CTS participants group in regards to testing session one $t(9)= -3.087, p= .013$. For testing session two, the CTS group results computed were also marginally significant $t(9)= -2.236, p= .052$. When the same tests were completed for the non-CTS participant group, testing session one results provided non-significant differences $t(8)= -1.00, p= .347$. Testing session two, t-test results also showed no significant differences $t(8)= -1.00, p= .347$ between pre-test and post-test. The outcome of the statistical analysis supported the qualitative measures, as shown in Table 8. That is, the pain symptoms were aggravated for those individuals with CTS during the administration of the CCT.

Table 8

Comparison of Pre-test Pain to Post-test Pain on 10 Point Scale

CTS Participants	*t score*	*p*
Session one	*t(9)= -3.087*	.013
Session two	*t(9)= -2.236*	.052
Non-CTS Participants		
Session one	*t(8)= -1.00*	.347
Session two	*t(8)= -1.00*	.347

Test of normality for 10 point Likert pain scale. A Shapiro-Wilk's test ($p > .05$) (Shapiro & Wilk, 1965; Razali & Wah, 2011) showed that the 10 point Likert pain scale scores were approximately normally distributed for both the pre-test and post-test pain for testing session one. For the pre-test pain, skewness was found to be 0.337 (SE = 0.687) while kurtosis was found to be -0.447 (SE = 1.334); and a skewness of -0.013 (SE = 0.687) and a kurtosis of -1.473 (SE = 1.334) was found for the post-test pain.

For testing session two, the pre-test pain skewness was found to be 0.665 (SE = 0.687) while kurtosis was found to be -0.471 (SE = 1.334); and, a skewness of -0.406 (SE = 0.687) and a kurtosis of -1.201 (SE = 1.334) was found for the post-test pain. The outcome of this test confirmed that the data collected from the 10 point Likert pain scale fell within the normal distribution curve.

Research Question Three- To what extent is the CTCAT able to assess CTS when compared to the BCTQ and 10 point self-report Likert pain scale?

To address the third research question, evidence of reliability and validity are provided for the CTCAT by using intraclass correlations and Pearson's moment correlations. Construct-

related evidence of validity is provided by correlating time measures of the CTCAT physical test to the change in pain (pre-test pain subtracted from post-test pain) scores for the 10 point Likert pain scale measures for session one and two independently. As the non-CTS group reported no change in pre- to post-test pain, this group was excluded from this part of the statistical validity analysis.

Evidence of reliability for the CTCAT. Table 9 depicts these results.

Non-carpal tunnel syndrome participants. To analyse this part of the question, an intraclass correlation for the measures of time was conducted between session one and two. As there was no noted change in testing time observed between the two testing sessions, this group was excluded from this part of the statistical analysis.

Carpal tunnel syndrome participants. The intraclass correlation for the measures of time between session one and two was $r = .906$, $p < 0.001$, $n = 10$. This high reliability result suggested that it is possible to reproduce the participant time to symptom onset measures across replications when using the CTCAT.

All participants. The intraclass correlation for the measures of time between session one and two when including all participants revealed that for this data set, the correlation value was $r = .932$, $p < 0.001$, $n = 19$. It was expected that the correlation value would increase due to the inclusion of non-CTS participants in the data who did manifest changes in measures of time during the test. High reliability results, however, support the use of the CTCAT across replications when measuring time to CTS symptom onset.

Table 9

CTCAT Reliability

Participants	*r*	*n*
CTS	.906	10
All	.932	19

Note: $p < 0.001$

Construct-related evidence of validity for the CTCAT measures. Convergent-related and discriminant-related evidence of validity are included in Table 10 and provide evidence for the use of the CTCAT time measures as an assessment technique for CTS diagnosis.

Convergent-related evidence of validity. Table 10 shows these results.

Carpal tunnel syndrome participants. Pearson's moment correlation revealed that the measure of pain during the test when using the 10 point Likert pain scale for testing session one significantly and negatively correlated to testing time, $r = -.925$, $p < 0.001$, $n = 10$. For testing session two, however, the Pearson's moment correlation revealed a marginally significant moderate correlation between the 10 point Likert scale measures of pain during the test and time to symptom onset, $r = -.574$, $p = .082$, $n = 10$. Moderate correlation for session two may be related to participants' variability on symptom onset based on their ADLs conducted during the day. This outcome, however, provides some convergent-related evidence of validity when relating the CTCAT measures to the 10 point Likert pain scale. That is, high participant pain during the test (the result produced by subtracting the participant pre-test pain from their post-test pain) is expected to produce a small measure of time to symptom onset.

All participants. When conducting the Pearson's moment correlation analysis for all testing participants, the results for testing session one provided significant correlations between time to symptom onset and pain during the test; $r = -.922$, $p < 0.001$, $n = 19$. For testing session two, the Pearson's correlation was $r = -.651$, $p = .003$, $n = 19$; this was expected to be higher than the CTS data set because it included non-CTS participants who did not manifest changes in pain and time during the test. Since the CTCAT measures of time to symptom onset correlated to the measures of pain during the test when using the 10 point Likert scale pain measures for either CTS participants or all participants, this outcome provided some convergent-related evidence of validity for the possible use of the CTCAT times measures in CTS diagnosis.

Table 10

Convergent Validity for CTCAT

Participants	*r*	*p*	*n*
CTS, session one	-.925	.001	10
CTS, session two	-.574	.082	10
All, session one	-.922	.001	19
All, session two	-.651	.003	19

Discriminant-related evidence of validity for the CTCAT. Table 11 and Table 12 illustrate the results from this analysis.

Carpal tunnel syndrome participants. For testing session one, Pearson's correlation revealed no significant correlation between the BCTQ part one scores and participant testing time, $r = .128$, $p = .724$, $n = 10$. For testing session two, the correlation was also found to not be significant, $r = .017$, $p = .963$, $n = 10$. When comparing the participant testing time to the pre-test data from the 10 point Likert Scale pain measures for testing session one, no significant

correlations were found for testing session one, r= -.097, p= .790, n= 10 and testing session two, r= .337, p= .341.

All participants. Pearson's correlation revealed no significant correlations when comparing the BCTQ part one score to the testing time for session one, r= -.326, p= .173, n= 19 and session two, r= -.440, p= .059, n= 19. Similarly when comparing the CTCAT measures of time during the test to the 10 point Likert scale pre-test pain measures, the results revealed no significant correlations for testing session one, r= -.376, p= .112, n= 19 and testing session two, r= -.105, p= .669, n= 19. This outcome provided discriminant-related evidence of validity due to the BCTQ part one and 10 point Likert scale pre-test pain measures assessing participant level of pain before each testing session, while the CTCAT served to assess pain differences in relation to time to symptom onset produced during the testing session.

Table 11

Discriminant Validity for CTCAT, BCTQ Part One

Participants	*r*	*p*	*n*
CTS, session one	.128	.724	10
CTS, session two	.017	.963	10
All, session one	-.326	.173	19
All, session two	-.440	.059	19

Table 12

Discriminant Validity for CTCAT, 10 Point Scale Pre-test

Participants	*r*	*p*	*n*
CTS, session one	-.097	.790	10
CTS, session two	.337	.341	10
All, session one	-.376	.112	19
All, session two	-.105	.669	19

CHAPTER FIVE- DISCUSSION

The results of the current study are discussed in terms of theoretical and empirical rationales to provide evidence of reliability and validity for the use of the CTCAT measures as a technique to assess CTS. Prototype development will be covered first, followed by the first three sections that contain a discussion of the results for each research question. The remaining four sections contain discussions about limitations of the study, conclusions, recommendations, and future directions.

Prototype Development

Developing a new assessment tool requires much thought and consideration. It also requires a great deal of patience and ingenuity. Throughout the development of the CTCAT, there were many issues that arose both before and during the pilot testing. As the device was created from scratch, with no other design plans to model the device after, it took quite some time to come up with a working prototype that could be used to carry out the CTCAT testing.

The initial design process for the CTCAT took roughly one month of discussion between the researchers to come up with a functional unit. The initial prototype was too simple, and would not have let the pressure be applied steadily for the required testing time. It did not have a quick-release strap or a pressure pad to lock the wrist in place and maintain the pressure for the length of testing. The initial prototype design was thrown out, and a new design was created. The new prototype then had a quick-release strap that also acted as a restraint strap during the testing to allow the pressure to be applied steadily over the testing period. To apply pressure to the wrist space, an inflation pad, pressure gauge, and pressure ball were added to the device. This modification, in combination with the addition of the quick-release strap, allowed pressure to be

applied evenly and steadily for the duration of the testing. Small trial tests were then completed where the wrist of the researcher was inserted into the device for the allotted testing time to ensure that the pressure would stay steady and that the device would not open during testing. After the researchers were satisfied with the new CTCAT prototype, a pilot study was completed to test the function of the device.

After the device design was finalized and a prototype was constructed, pilot testing was then completed. A design flaw was quickly noted once data collection for the pilot was underway, causing issues with how the pressure was being applied to the carpal tunnel space. This flaw was addressed, with proper modifications made to the device, and data collection then carried out. Once the pressure ball flaw was sorted out, testing ran smoothly with no more issues encountered along the way.

Research Question One- How reliable are the measures obtained from the BCTQ with the current data?

Boston carpal tunnel questionnaire inter-item reliability. According to Sambandam et al. (2008), the BCTQ developed by Levine et al. (1993) is the most commonly used outcome measure in the assessment of patients with CTS. Levine et al. (1993) found that the inter-item reliability scores for the two scales (the SSS and FSS) of the BCTQ were highly reproducible generating Cronbach's alpha reliability scores of $r = 0.91$, $n = 38$ for the SSS and r=.93, $n = 38$ for the FSS. Although the inter-item reliability scores from the current study appear to be higher than the scores stated in the literature, the difference may be attributed to sample size. For example, the study by Levine et al. (1993) used a sample size of 38 participants with CTS, while the current study used a sample size of 10 participants with CTS and nine participants without

CTS. Lack of variability from the non-CTS participants may have impacted the inter-item reliability scores and increased the correlation value; thus, the small sample size for participants with CTS in this study might have affected the results. The data gathered from the current study for each administration of the BCTQ, however, supports the literature as the results are similar to those found by Levine et al. (1993); that the BCTQ measures are reproducible and contain a high degree of internal consistency when using these items to assess individuals with CTS.

Boston carpal tunnel questionnaire test/retest reliability. Intraclass correlation scores for part one of the BCTQ, which measured participant level of pain felt in the last 24 hours were assessed by comparing the scores produced between first and second administration of the test. The strength of the relationship between the pre- and post-test measures can be used as an indicator of the variance present when repeating the measure (Bonett, 2003). The scores observed between the first and second administration of the BCTQ test in the current study revealed minimal variance, supporting the literature that suggests the level of pain reported by participants on the BCTQ part one was consistently measured between the two administrations of the test. It is also possible that the pain scores for the CTS only participants vary on a day to day basis, which can lower the intraclass reliability scores produced across replications of the instrument measures. To account for this variability, it may be necessary to administer the test more than twice. Reliability scores for the CTS only group were slightly lower than the "all participants" group, which may be attributed to the inclusion of the non-CTS participants in the intraclass correlation analysis who did not manifest change in pain symptoms across replications of the test.

Intraclass correlation scores for the BCTQ part two, which measured participant level of difficulty with ADLs in the last 24 hours, were also computed using a similar approach as part

one of the BCTQ. High reliability scores suggest that the BCTQ produced consistent results with regards to participants' difficulty with functional ADLs between the first and second administration of the test. This outcome supports the literature, which states that reliability is concerned solely with how test scores are expected to vary when repeatedly using the assessment tool (Haertel, 2006).

As the CTS participants' level of pain may vary on a daily basis, their abilities to perform functional ADLs such as buttoning a shirt or twisting a bottle cap off can also vary. To overcome this variability issue, it may be necessary to increase the number of replications of the test. It is interesting, however, that the intraclass correlation scores produced for part two of the BCTQ are slightly higher than the intraclass correlation scores for the BCTQ part one. This outcome may suggest that the participants' perceived level of pain on testing days may vary slightly more than their perceived level of difficulty with certain daily functional tasks.

The test of normality for the BCTQ confirms that the scores provided on both sections (functional status scale, symptom severity scale) fell within the normal distribution curve. This supports the notion that the data provided by the BCTQ is parametric in nature.

In conclusion, the inter-item and intraclass reliability analyses in the current study provided consistent results for part one and two of the BCTQ. These outcomes support the literature (Bonett, 2003) and indicate that the BCTQ measures produce reliable results to be used as validity criteria for further analysis. Similarly, the strength of the relationship across replications of the measures can be used as an indicator of the variance present when repeating the measure. Since the scores of this questionnaire were shown to be consistently reliable not only within testing sessions, but also between testing sessions, there is a strong evidence to

suggest that the inferences made from the test score interpretations of the BCTQ consistently measure pain and difficulty with certain daily functional activities as found in previous studies (Sambandam et al.,2008).

Research Question Two- Can a 10 point self-report Likert pain scale question be used to assess CTS when compared to the BCTQ?

In order to develop a criterion to measure the amount of pain produced during the CTCAT test for further validation of the CTCAT as a CTS diagnostic tool, it was crucial to provide evidence for the validation of the 10 point Likert pain scale. This approach was necessary because the BCTQ does not provide measures of pain during the administration of the test, but rather measures of pain symptoms and difficulty with ADLs within 24 hours before the administration of the CTCAT. To provide evidence for the validation of the 10 point Likert pain scale, the concept of validity by Messick (1989) was used, which states that "validity is an integrated evaluative judgment of the degree to which empirical evidence and theoretical rationales support the adequacy and appropriateness of inferences and actions based on test scores or other modes of assessment…it is important to note that validity is a matter of degree, not all or none" (p.13). Messick addressed the word integrated, which, in his concept of validity, referred to the summation of many sources of information based on the existing evidences and the interpretation of test scores. In the current study, empirical evidence and theoretical rationales in combination with different sources of information were used to validate the 10 point Likert pain scale measures and included concurrent-related, construct-related, and face-related evidence of validity.

Evidence of reliability of the 10 point Likert pain scale found through testing enables the use of this measure as validity criterion for further analysis. As stated by Kane (2006), the inferences made from test scores interpretations cannot be claimed as evidence of validity if the test scores are not proven to be reliable.

Ten point Likert pain scale reliability. To assess the reliability of the 10 point pain Likert scale, intraclass correlation analyses were conducted that compared the pre-test pain scores for testing session one to the pre-test pain scores for testing session two. Strong to moderate significant intraclass correlation coefficients revealed consistency across replication of the scale. Over the two testing sessions, the Likert pain scale scores for the CTS participants, non-CTS participants and all participants groups were found to be significantly reliable. The outcome supports the reliability literature, which is solely concerned with how test scores are expected to vary when repeatedly using the assessment tool (Haertel, 2006). As expected, the results were highly reliable for the non-CTS participants who did not experience symptoms of pain throughout the test and moderately reliable for the CTS participants who experienced different levels of pain due to their CTS. Some of the variability or inconsistencies for CTS participant across replications of the test can also be attributed to those CTS participants who did not have decompression surgery and potentially had less tolerance to pain.

Ten point Likert pain scale concurrent validity. According to *Standards for Educational and Psychological Testing* (1985), concurrent-related evidence of validity is "the degree to which the criterion information obtained from a sample of items, tasks, or questions on a test relate to the same criterion information obtained from a standard when both measures are obtained simultaneously" (p. 10). For this study, concurrent-related evidence of validity was provided by comparing the 10 point Likert pain scale pre-test pain measures to the BCTQ part

one (symptom severity) measures when the two assessments were administered simultaneously. The similarity between the two instrument measures was assessed by first putting the two instrument pain measures under the same scale and conducting intraclass correlations analyses for both testing sessions.

Strong significant correlation between the two instrument pain measures provided construct-related evidence of validity for the use of the 10 point Likert scale as an instrument to measure pain related to CTS. While the comparison only involved the 10 point Likert scale pre-test measures of pain and not the post-test measures, this approach was necessary because the BCTQ only measured pain discomfort for the last 24 hours and not during the administration of the CCT. Furthermore, comparing the BCTQ pain scores to the 10 point Likert scale post-test measures would not provide concurrent-related evidence of validity as CTS participant pain levels were more likely be increased due to the administration of the compression test causing differences in participant pain tolerance level. Significant correlation results, however, provided evidence for the use of the 10 point Likert pain scale as validity criteria to assess CTS pain for later analyses.

Ten point Likert pain scale construct-related validity. In regard to construct-related evidence of validity, *Standards* (1985) states that the relationship to other variables is also another method that can be used to assess the degree to which the construct being measured (pre-test pain) consistently relates to external variables (difficulty with daily functional tasks). Construct-related evidence of validity can be divided into two categories, convergent and discriminant validity. In the current study, the 10 point Likert pain scale pre-test scores were compared to the BCTQ part two, which measured participant difficulty with performing ADLs in the last 24 hours before the administration of the CTCAT test. Since the difficulty with ADLs

was expected to correlate with the 10- point Likert scale pre-test pain measures, the outcome provides some convergent-related evidence of validity for the use of the 10 point Likert scale as a measure of CTS pain. That is, as the participant's CTS pain increases, so does his or her difficulty with performing ADLs. In conclusion, the outcome of this analysis strengthened the concurrent-related evidence of validity found in the previous analysis for the use of the 10 point Likert scale as validity criteria to assess CTS measures of pain.

Ten point Likert pain scale face validity. As the 10 point Likert scale is a newly developed assessment scale to be used as validity criteria to measure the participant pain during the administration of the CTCAT test, providing evidence of face validity was necessary to strengthen the overall validity of the 10 point Likert scale pain measures under theoretical and empirical rationales stated by Kane (2006) and Messick (1989). Evidence of face validity for the 10 point Likert scale pain measures was provided by using qualitative and quantitative measures to assess the degree to which the 10 point Likert scale measured participant pain during the administration of the CTCAT physical testing. These outcomes were also supported by qualitative data, as two participants reported that they had CTS symptoms brought on after the testing session was completed. More specifically, one participant reported that the symptoms lasted one hour after the physical testing, while the other participant reported a five minute flare up after the test. The test of normality completed for the 10 point Likert pain scale confirms that the scores provided for both the pre- and post-test pain scores fell within the normal distribution curve. This supported the notion that the data provided by the 10 point Likert pain scale was parametric in nature.

These results support the literature on the use of self-report pain measures as an avenue to measure and diagnose CTS (Jahedi & Mendez, 2012). The results also provide evidence for the

validation and use of the 10-point Likert scale as a measure of pain, based on the integration and summation of many source of information, which are grounded on empirical and theoretical rationales developed by Messick (1989) and Kane (2006).

Research Question Three- To what extent is the CTCAT able to assess CTS when compared to the BCTQ and 10 point self-report Likert pain scale?

While self-report questionnaires measures such as the 10 point Likert scale and the BCTQ have the advantage that they can be easily implemented to capture participant information (e.g., pain measures) (Jahedi & Mendez, 2012), the responses may contain a subjective source of bias that can affect the variance of the intended construct being measured (Vogt, Selvin, Widdowson, & Hulley, 1977). One avenue to minimize the degree of subjectivity as a source of noise embedded within participant responses when using self-report measures (e.g., pain measures) is to include direct measures (Michels, 1983; Reuben & Siu, 1990). Including direct measures in the assessment in conjunction with subjective measures creates a test battery of measures that minimize threats to the validity of the data (Reuben & Siu, 1990). Based on this rationale, in the current study, a CTCAT was designed to minimize the subjectivity imparted by a medical professional when administering the CCT. The CTCAT was also designed to provide another source of evidence in CTS diagnostic when administering the CCT (Durkan, 1991). By using response time measures during the administration of the CCT in conjunction with self-report measures of pain, it may be possible to more accurately assess individuals with CTS. This approach was implemented based on the concept of validity, described by Kane (2006) and Messick (1989) and the research work of Love (2003).

To use the CTCAT as an additional source of evidence for CTS diagnostics when capturing participant information, it was crucial to provide evidence of reliability and validity of the CTCAT response time measures. As Love (2003) stated, when there was a loss in sensory nerve supply due to compression of the median nerve in the carpal tunnel space, symptoms such as tingling, numbness, or clumsiness with the affected hand may be reported depending on the severity of the participants' CTS symptoms on the testing date. That is, participants may require more time under compression to increase their CTS symptoms and stop the physical testing.

Carpal tunnel compression assessment tool reliability. Based on Love's (2003) rationale, the reliability for the CTCAT response time measures was assessed by comparing the administration of the CCT for testing sessions one and two using an intraclass correlation. Highly significant reliability results in terms of intraclass correlation time scores suggest that over the two testing sessions, the amount of time that passed before the participants needed to end the physical testing was roughly the same. This outcome provided evidence of reliability for the use of the CTCAT response time measures across replications of the CCT. These results also support Love's (2003) statement that in order to trigger participant CTS symptoms, compression of the median nerve must take place over time.

Construct validity for the carpal tunnel compression assessment tool. Construct-related evidence of validity allowed for the use of the CTCAT response time measures as a CTS diagnostic tool to be administered in conjunction with self-report measures of pain as a CCT clinical testing battery. That is, the degree to which the self-report pain measures based on empirical and theoretical rationales supported the inference made from the CTCAT response time measures in diagnosing CTS (Cronbach & Meehl, 1955). This outcome was accomplished by providing convergent and discriminant-related evidence of validity.

Convergent-related evidence of validity. Campbell and Fiske (1959) stated that convergent validity is the degree to which two constructs that are believed to be related, are in fact, related. In the current study, convergent-related validity was provided by correlating the response time measures to the amount of pain felt by the participant during the administration of the CCT. Higher negative correlations for the all participants group may be due to the inclusion of non-CTS participant in the data set, who did not reveal any pain symptoms during the administration of the test as expected. Regardless, these outcomes provide some convergent-related evidence of validity for the use of response time measures as an assessment technique for CTS. Moderate significant correlation scores for testing session two, however, may be due to the participants' variability in daily pain symptoms as indicated by Love (2003). Furthermore, negative correlations between response time measures and self-report measures during the administration of the CCT indicated that as the participant amount of pain felt during the administration of the CCT increased, the response time to CTS symptom onset decreased, an outcome that supports the literature (Kane, 2006; Campbell & Fiske, 1959; Love, 2003).

Discriminant-related evidence of validity. In order to claim that the CTCAT response time measures had strong evidence of construct-related validity to assess CTS when administering the CCT, it was necessary to provide discriminant-related evidence of validity, the degree to which measures that are believed to be unrelated are, in fact, truly unrelated (Kane, 2006; Campbell & Fiske, 1959). The current study hypothesized that the response time to symptom onset during the administration of the CCT would not correlate to measures of pain before the administration of the CCT. This hypothesis was formulated based on Love's (2003) theoretical rationale, that in order to trigger a participant's CTS symptoms, compression of the median nerve must take place over time.

Non-significant correlation results with the pain measures before the administration of the test indicated that the CTCAT response time measures depended only on triggering participant's CTS symptoms by compressing the median nerve over time. This outcome supports Love's rationale and this study's hypothesis. It also provided discriminant-related evidence of validity as defined in the literature (Kane, 2006; Campbell & Fiske, 1959) for the use of the CTCAT response time as a valid measure to access CTS when combined with self-report measures of pain.

In summary, the results of this study revealed that the CTCAT has construct-related evidence of validity and it seems to provide an avenue for health professionals to use simple measures of response time in combination with a 10 point Likert pain scale to assess and diagnose individuals with CTS. The result of this study also supports the notion that the CTCAT does, in fact, elicit CTS symptoms in participants who have not had CTS release surgery.

Limitations

The primary limitation on this study was the small sample size of participants with CTS. Initially, this study aimed to include 20-30 participants with CTS to the testing group, but recruitment for this testing cohort proved to be harder than originally thought. Although fairly large medical clinics were approached within the city, some professionals were either not interested in helping to recruit participants, or were not currently treating any patients in their clinics with CTS. The CTS sample size could have been expanded by attempting to recruit more participants through contacting and approaching a larger number of medical centers within the city of Thunder Bay. Although there was a fairly even number of male and female participants, and a diverse age range in the sample used, a larger cohort of participants with CTS would have

strengthened the correlation analyses used when providing evidence of reliability and validity of the instrument measures.

A secondary limitation to this study was age matching. Although an attempt was made to match both gender and age as closely as possible, the age matching was not as close as it could have been. The average age of the CTS group was 46 years, while the average age of the control group was 34 years. Ideally, age matching could have been closer to create a more representative study sample. Age matching could have been monitored more closely during the data collection stage in order to balance the two testing cohorts.

Strengths

The primary strength to this study is the creation of the CTCAT. This study is the first of its kind to attempt to build an objective measuring instrument for assessing CTS to potentially be used in the clinical setting. Introducing a device like this to the healthcare system would greatly reduce wait times for CTS assessment and diagnosis, thereby increasing the effectiveness of clinical time spent on assessing and diagnosing the condition. Through development and testing of the CTCAT in this study, the results support the use of the device in potentially assessing and diagnosing CTS clinically.

Future Research

Future research in this area that included a larger sample size of participants with CTS would strengthen evidence of the reliability and validity of the CTCAT response time measures. With more participants comes a better statistical standpoint for future research, which could make it possible to create standards to assess the severity of the participants' symptoms to a higher degree when using response time measures. Ultimately, using a system that accurately

determines whether or not the individual has mild, moderate, or severe CTS symptoms will help medical professionals use the appropriate modalities to better understand a patient's true range of symptom severity encountered on a daily basis, and to treat the symptoms.

Furthermore, future research should match participant age and gender more closely to increase validity measures of the CTCAT when being used to assess CTS. The CTS testing group should also not include participants with CTS who have had decompression surgery. Including participants with CTS who have had decompression surgery into the CTS testing group can skew results as these participants could potentially present as a healthy participant if their decompression surgery was successful.

Another addition to future research would be to compare the measures of the traditional carpal compression test to the CTCAT to examine the degree to which the two testing measures differ from one another. Sensitivity and specificity could then be calculated for the CTCAT.

It would be beneficial to ensure that CTS participants that are included in the study are accurately and reliably diagnosed with CTS through the use of a standardized regimen, such as a standard clinical exam and EMG/NCS testing wherever possible. Screening potential participants for future research in this way would limit the number of participants included in the CTS group who may have other hand and wrist complications other than CTS. Future research should focus on assessing time to numbness instead of time to pain, as pain can be a late finding when assessing CTS. Numbness is more generally the first symptom of CTS that an individual encounters.

Another suggestion for future research is to examine the accuracy of the CTCAT in assessing and diagnosing CTS by including a number of other objective testing measures, such

as functional MRI, NCS, or EMG. Using functional MRI may provide an avenue to determine a more accurate response time to symptom onset by examining how the pain onset affects certain areas of the brain. Comparing the CTCAT to both NCS and EMG studies would also allow the researcher to gauge the degree of sensitivity and specificity of the device when assessing CTS in the clinical setting. This approach may provide stronger evidence of validity for the use of the CTCAT as a CTS diagnostic tool if it can be correlated to standardized objective testing protocols.

An additional suggestion for future research will be to assess CTS individuals based on their chosen career path. If research participants were divided into career classes, such as desk jobs or manual labour jobs, the CTCAT testing may be able to also assess whether one type of job versus another produces more severe cases of CTS. This approach may be beneficial for employers and medical professionals to help people with appropriate ergonomics set ups and treatment modalities.

Lastly, future research could look at adapting the CTCAT to be a more compact, portable tool. As the device prototype used for this study was the first model designed, it is larger than it could and should be. Future research could incorporate a more compact version of the CTCAT, potentially including automatic features as well. If the device was made to be more compact, it could then be more portable and easily transported.

Implications

The current study has implications for researchers, patients, and health professionals. The research findings from this study indicate that the BCTQ serves as a measure of pain for CTS based on ADLs and discomfort, but does not relate to pain due to nerve compression. This

study's outcome, however, supports the use of self-report questionnaires in diagnosing and assessing CTS because it provides evidence of reliability and validity for the use of a simple 10 point Likert pain scale specifically to assess CTS pain instead of pain at the upper extremities.

The outcome of this study also revealed that using the CTCAT to elicit participant CTS symptoms and pain supports the research of Durkan (1991) and the findings put forth by Love (2003). As found through the current research, in order to cause a change in participants' pain and symptoms, the median nerve had to be compressed for a period of time; in this case, no longer than 30 seconds. The use of the CTCAT also builds on the research of Durkan (1991) as the testing revealed that a steady, direct pressure roughly the size of the thumb pads held over the median nerve is required to reproduce a participant's CTS pain and symptoms. When used on CTS participants who have not had decompression surgery, the CTCAT elicited symptoms in all testing participants on both testing occasions.

The potential use of the device in the clinical setting does not completely support Reuben and Siu (1990), who stated that objective assessment measures may require more staff time and effort, resulting in higher operating costs. As the CTCAT physical testing can be carried out by one person, and is non-invasive, it could therefore reduce diagnostic and assessment wait times and costs associated with diagnosis and assessment of CTS.

From the practical perspective, the outcome of this study provides an avenue for health professionals and patients to assess CTS symptoms with a simple technique composed of a 10 point Likert scale pain questionnaire and a CTCAT with moderate to strong evidence of reliability and validity measures. As the device gives reliable results without being technologically complex, medical professionals could easily use it to assess and diagnose CTS in a clinic setting. Introducing a simple to use assessment tool to the healthcare system would

greatly reduce the wait periods associated with more complex objective testing measures such as NCS and EMG, improving the speed with which accurate CTS diagnoses can be made.

In summary, this study provided evidence of reliability and validity measures for the use of the CTCAT as a potential clinical assessment tool for CTS. The results also support the use of a simple and easy-to-administer 10 point Likert pain scale to assess CTS during the administration of the CCT. These outcomes provide support for healthcare professionals and employer for the use of simple and inexpensive measures, as a potential clinical testing battery to assess individuals at risk for CTS or who have CTS.

Conclusion

This study examined the potential usefulness of the CTCAT for clinical settings to assess CTS when compared to the BCTQ and the 10 point Likert pain scale. The study was conducted because it is evident that a combination of subjective questionnaires and simply administered objective testing measures better diagnose CTS in the general population. As stated in the literature, the irritation of the median nerve at the carpal tunnel space produces CTS symptoms such as tingling, burning, general discomfort, and aching in the affected fingers (Atroshi et al., 1999), which are problematic symptoms for individuals to perform their ADLs and work tasks. It was found that the CTCAT could then potentially be used to assess and diagnose CTS within the clinical setting due to the success rate observed when assessing those with CTS who have not had release surgery.

This study found that the CTCAT measures, when combined with the 10 point Likert pain scale into a testing battery, produced strong evidence of validity; that is, the CTCAT response time measures to symptom onset were highly correlated to participant pain produced by

the compression of the median nerve when implementing the CCT. This outcome supports and builds on the work of Levine et al. (1993) and Durkan (1991) as it combined a more objective measure (the CTCAT response time) with self-report measures of pain (BCTQ, 10 point Likert pain scale).

Finally, the CTCAT provides an avenue to minimize measurement error associated with the traditional administration of the CCT, which requires a health professional to carry out the test manually. As the device is controlled by an inflation pad and pressure gauge, the health professional guess work associated with how much pressure to place over the median nerve is completely removed. Based on this approach and outcome of the data, it can be stated that the CTCAT provides reliable and valid measures of the participants' response time to symptom onset when administering the modified CCT. In conclusion, the CTCAT, when combined with a subjective pain measure, is able to assess individual CTS symptoms to give patients more accurate and consistent estimates on their current CTS symptom condition.

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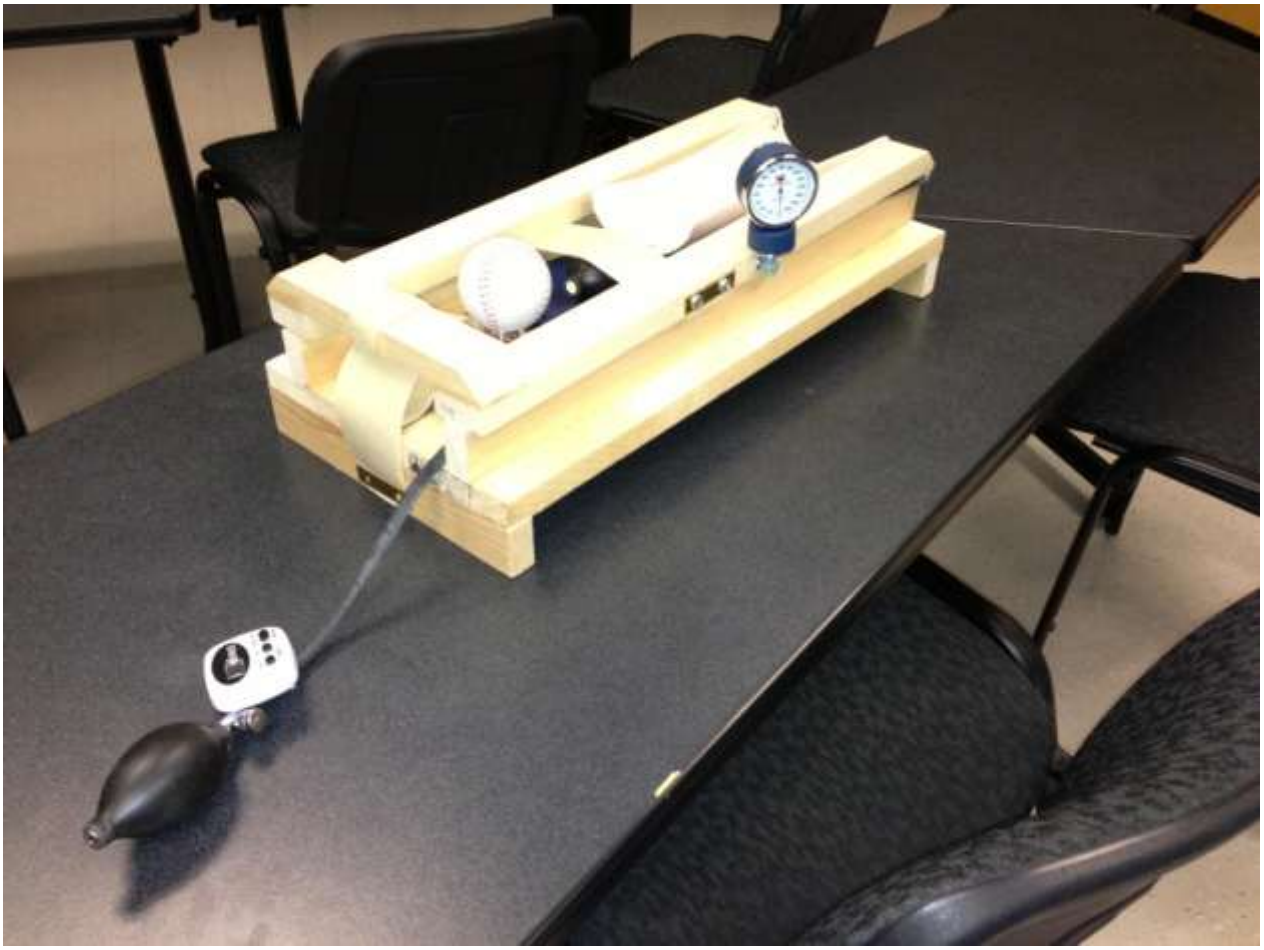
APPENDICES

Appendix A: Carpal Tunnel Compression Assessment Tool

Carpal Tunnel Compression Assessment Tool



The testing instrument is a portable testing device that is easy to set up and use. The device is a small box that has one opening for the hand of the participant. There is a hinged moving arm that is locked in place with a Velcro strap once the participant's hand is in the proper testing position. Once the wrist has been rested on the sphygmomanometer bulb in the proper position, the wrist angle is adjusted through the use of an adjustable ball rest. On the bottom of the device, there is an inflatable bladder that presses on a sphygmomanometer bulb, which pushes on the median nerve area of the hand. The bladder is inflated by a hand pump, which the researcher controls. To monitor the pressure of the bladder, a small pressure gauge is attached. The sphygmomanometer bulb serves to compress the median nerve in the same fashion that the Carpal Compression Test does. If the participant feels uncomfortable at any time, the device can be opened immediately to free the hand by pulling the Velcro strap open.

Appendix B: Boston Carpal Tunnel Questionnaire

Boston Carpal Tunnd Questionnaire

ANNEX 1

SELF-EVALUATIONPROTOCOL–BOSTONPROTOCOL

Name:.....
RGHSP:.....Hand:( ) Right ( ) Left
Evaluation Date:...../...../__ Surgery Date: ...../...../.....

THE FOLLOWING QUESTIONS REFER TO YOUR SYMPTOMS WITHIN A TYPICAL PERIOD OF 24 HOURS, DURING THE LAST TWO WEEKS.
(Oloose one answer in each question)

1) How strong is the pain on your hand or wnst at night?
1- I feel no pain on hand or wrist at night.
2-Irttle pain
3- modefate pain
4- intense pain
5- severe pain

2) How many t mes did your hand or wrist pain wake you upm a typical night for the last two weeks?
t- never
2-once
3- twice or three times
4- four to five times
5- more than frve times

3) Do you usually feet hand or wrist pain during the da'(?
1- I never feet pain dur ng the day
2- I feel little pain during the day
3- I feel moderate pain during the day
4- I feel intense pain during the day
5- I feel severe pain dur ng the day

4) How often do you feet hand or wrist pain during the da'(?
1- never
2- once or twice a day
3- three to five lim!!$ a day
4- more than live times a day
5- constant pain

5) In average, how long do daylime pain episodes last?
1- I never feet pain during the day
2- less than 10 minutes
3- from 10 to 60 minutes
4- more than 60 minutes
5- I feel constant pain during the day

6) Do you feel your hand dormant (lost sensitiveness)?
1-no
2- 1 feel little dormancy
3- I feel moderate dormancy
4- I feel intense dormancy
5- I feel severe dormancy

n Do you feet weakness on your hand or wriSI?
1-no weakness
2- litUe weakness
3- moderate weakness
4intense weakness
5- severe weakness

8) Do you feel a bnghng sensation on your hand?
1- no tinging sensation
2- little tin g ing sensation
3- moderate tingling sensati on
4- 1ntense tingling sensabon
5 severe t ngling sensation

9) How strong is dormancy (lost sensitivity) or tingling sensation at night?
1- I never feel dormancy o r ting ng sensation at night
2-little
3 -moderate
4- intense
5- severe

10) How often did dormancy or tinging sensation wake you up during a typical night for the last twO weeks?
1- never
2- once
3- twice to three times
4• four to frve times
5- more than five times

11) How difficult do you feel in taking and using small objects. such as keys or pens?
1- not diffiCUlt
2- a litUe difficult
3- moderately d fficult
4- very difficult
5 severely difficult

IN A TYPICAL DAY FOR THE LAST TWO WEEKS, HAVE YOUR HAND OR WRIST SYMPTOMS BROUGHT ANY DIFFICULTY IN PERFORMING THE ACTIVITIES LISTED BELOW?

Please. circle the number that best describes your ab ity to perform the activity.

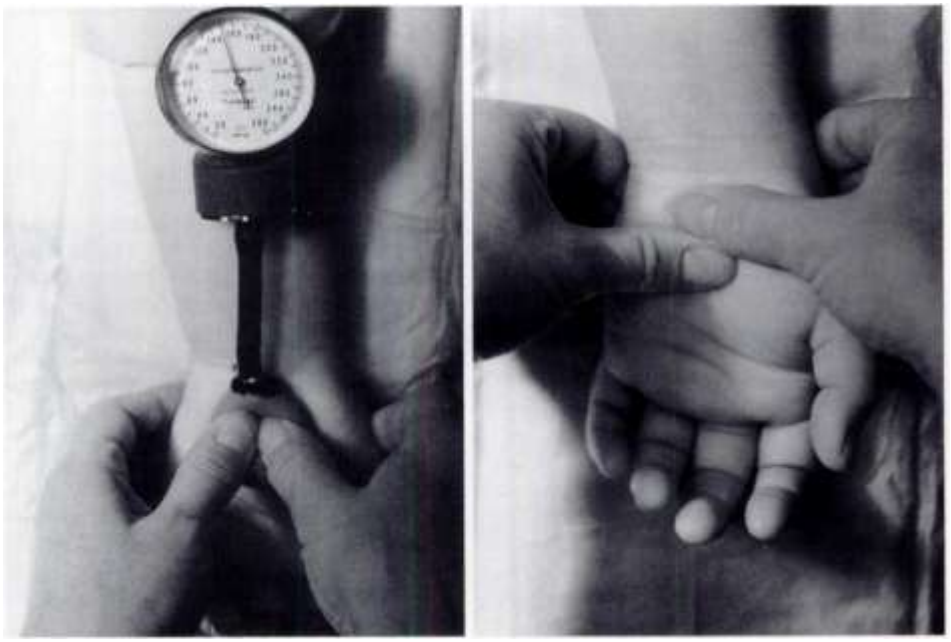
ACTIVITY	DEGREE OF DIFFICULTY				
Writing		2	3	4	5
Buttoning dothes	1	2	3	4	5
Holding a book whae reading	1	2	3	4	5
Holding the telephone hang	1	2	3	4	5
Housekeeping		2	3	4	5
Opening a glass vial cap		2	3	4	5
Carrying market bags	1	2	3	4	5
Bathing and dressing	1	2	3	4	5

No difficulty 1
Little difficulty 2
Moderate difficulty 3
Intense difficulty 4
Cannot perform the activity at all due to hands and wrists symptoms 5

Investigator's opinion: .....

Appendix C: Carpal Compression Test

Carpal Compression Test



The Carpal Compression Test was invented and tested in 1991 by J. A. Durkan. The test is a physical test that focuses on compression of the median nerve with the thumbs. A pressure of 150mmHg is applied to the carpal tunnel space for a maximum of 30 seconds, in attempt to reproduce the patient's CTS symptoms. If the patient's symptoms come on before the 30 seconds has passed, the physical testing is ceased. Original testing used a sphygmomanometer inflation bulb attached to a blood pressure cuff pressure gauge (left picture). This method was used to ensure a constant pressure of 150mmHg was used. However, current Carpal Compression Testing is completed through use of the testing professional's two thumbs (right picture). Testing completed this way leads to large individual difference in perception of pressure and the size of an individual's thumb pad.

Appendix D: Recruitment Poster

Attention Clinic Patients

Do you have Carpal Tunnel Syndrome?

Would you like to take part in a quick study in regards to your condition?

If you would like to take part in this quick study, please consult your health care provider to get more information about this study

Appendix E: Participant Recruitment Form

Carpal Tunnel Study Recruitment Form

Name:

Phone Number:

Email:

Signature:

Date:

Appendix F: Healthcare Professional Cover Letter

Lakehead
UNIVERSITY

School of Kinesiology

Tel: (807) 343-8544
Fax: (807) 343-8944

Dear Healthcare Provider:

My name is Devin Jackson, and I am a Master of Science in Kinesiology student at Lakehead University. My research study is entitled "Providing Evidence for the Validation of a Carpal Tunnel Compression Assessment Tool." At this time, I would appreciate your willingness to assist me in recruiting individuals that you see fit for this study, or that you believe would like to participate in this study. I am conducting this research study under the supervision of Dr. Ian Newhouse (supervisor) from the Department of Kinesiology. This study has two purposes: a) to provide evidence for the validation of a Carpal Tunnel Compression Assessment Tool (CTCAT) in assessing Carpal Tunnel Syndrome (CTS) when combined with the Boston Carpal Tunnel Questionnaire (BCTQ), b) to gain an understanding of the potential change in blood oxygen saturation/heart rate at the moment of symptom onset during testing with the CTCAT through the use of a finger-tip oximeter.

The participant will be required to attend two testing sessions that will require roughly 30 minutes per session. Once the participant has signed the consent form and completed the BCTQ and a perceived rating of pain/discomfort, the physical testing will be completed. The physical test includes completing the CTCAT testing, where the participant's affected wrist is inserted into the CTCAT, and the device is inflated to 150mmHg which places pressure over the carpal tunnel space (similar to the Carpal Compression Test) for a maximum of 30 seconds. If the participant's CTS symptoms come on before 30 seconds has elapsed, testing will cease immediately. After the physical testing is completed, a post-testing session will be booked for three days from the initial testing date. I will be responsible for conducting all physical testing.

Due to the nature of the study, some risk is incorporated. Risk of participating in this study includes the onset of the participant's CTS symptoms during physical testing. The risk of experiencing discomfort during the testing is likely, and every attempt will be made to reduce risk during the testing.

If you feel that a patient that you are currently treating with unilateral **OR** bilateral CTS who either has or has not had decompression surgery may be interested in participating or learning more about the study, kindly take a minute to talk with him or her during an appointment in regards to the study. If an individual is potentially interested in this study, please supply him or her with the attached recruitment form and have him or her leave the completed form with your front desk staff in the envelope supplied. Hopefully, you will find time in your busy schedule to assist me with this study. Thank you for your time and participation.

SEE REVERSE

955 Oliver Road Thunder Bay Ontario Canada P7B 5E1 www.lakeheadu.ca

If you have any questions, please feel free to contact me by telephone at (807) 629-8824 (cell), (807) 473-9788 (home), by fax (807) 343-8944, or email dtjackso@lakeheadu.ca. You may also contact my supervisor, Dr. Ian Newhouse, at (807) 343-8074. This research study has been approved by the Lakehead University Research Ethics Board. If you have any questions related to the ethics of the research and would like to talk to someone other than the researchers, please contact Sue Wright at the Research Ethics Board at (807) 343-8283 or research@lakeheadu.ca.

PLEASE DISCUSS THE STUDY WITH POTENTIAL PARTICIPANTS BY FEBRUARY 7TH. I WILL PICK UP ANY COMPLETED FORMS FROM YOUR RECEPTIONIST AT THIS TIME.

Yours truly,

Devin Jackson
dtjackso@lakeheadu.ca

Dr. Ian Newhouse
inewhous@lakeheadu.ca

Appendix G: 10 Point Likert Pain Scale

Perceived Level of Pain/Discomfort

Please rate your pre-test pain and/or discomfort in your wrists

1 2 3 4 5 6 7 8 9 10

No/limited pain Worst pain ever

Please rate your post-test pain and/or discomfort in your wrists

1 2 3 4 5 6 7 8 9 10

No/limited pain Worst pain ever

Appendix H: Control Participant Consent Form

Lakehead
UNIVERSITY

School of Kinesiology

Tel: (807) 343-8544
Fax: (807) 343-8944

CONSENT TO PARTICIPATE IN "PROVIDING EVIDENCE FOR THE VALIDATION OF A CARPAL TUNNEL COMPRESSION ASSESSMENT TOOL" STUDY

I have read the information presented in the information letter about a study being conducted by Devin Jackson under the supervision of Dr. Ian Newhouse of the School of Kinesiology at Lakehead University, entitled "Providing Evidence for the Validation of a Carpal Tunnel Compression Assessment Tool". This project has been reviewed by, and received ethics clearance through, the Research Ethics Board of Lakehead University.

I understand there is potential minimal risk involved in this study. I understand that I am being asked to take part in physical testing that incorporates the use of a Carpal Tunnel Compression Assessment Tool and the Boston Carpal Tunnel Questionnaire. I understand that through this testing, general discomfort and/or numbness in the wrist and hand region may arise. I am aware that I am a volunteer, that I may withdraw from the study at any time by advising the researchers of this decision, and that I may choose to not answer any questions. I understand that all information that I provide will be confidential and the results will be stored in a locked filing cabinet at Lakehead University for a minimum time period of five (5) years with Dr. Ian Newhouse. I understand that if the research is published publicly, I will remain anonymous. I understand that the research findings are available to me upon request through email.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.

_____
Print Name

_____
Signature of Participant

_____
Dated

_____
I would like a copy of research findings
(provide email address)

955 Oliver Road Thunder Bay Ontario Canada P7B 5E1 www.lakeheadu.ca

Appendix I: Carpal Tunnel Syndrome Participant Consent Form

Lakehead
UNIVERSITY

School of Kinesiology

Tel: (807) 343-8544
Fax: (807) 343-8944

CONSENT TO PARTICIPATE IN "PROVIDING EVIDENCE FOR THE VALIDATION OF A CARPAL TUNNEL COMPRESSION ASSESSMENT TOOL" STUDY

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I understand there is potential minimal risk involved in this study. I understand that I am being asked to take part in physical testing that incorporates the use of a Carpal Tunnel Compression Assessment Tool and the Boston Carpal Tunnel Questionnaire. I understand that through this testing, my Carpal Tunnel Syndrome symptoms may be reproduced. I am aware that I am a volunteer, that I may withdraw from the study at any time by advising the researchers of this decision, and that I may choose to not answer any questions. I understand that all information that I provide will be confidential and the results will be stored in a locked filing cabinet at Lakehead University for a minimum time period of five (5) years in Dr. Ian Newhouse's office. I understand that if the research is published publicly, I will remain anonymous I understand that the research findings are available to me upon request through email.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.

_____
Print Name

_____
Signature of Participant

_____
Dated

_____
I would like a copy of research findings
(provide email/mailing address)

955 Oliver Road Thunder Bay Ontario Canada P7B 5E1 www.lakeheadu.ca