

Official title: Non-surgical Intervention for Carpal Tunnel Syndrome

NCT number: 03360344

Statistical analysis plan is included.

IRB Approval Date: October 2, 2017

1. PROTOCOL INFORMATION

Title: Non-surgical Intervention for Carpal Tunnel Syndrome

Funding Source: School of Allied Health Professions

Version Date of Protocol: October 2, 2017

Phase of Study: November 2017 – November 2018

2. PRINCIPAL INVESTIGATOR INFORMATION

PI: Heather Javaherian-Dysinger, OTD, OTR/L, Loma Linda University School of Allied Health Professions

Name & Address of Research Institution:

Loma Linda University

School of Allied Health Professions

Nichol Hall, A901

Loma Linda, CA 92350

Phone: 909-558-5828 (ext 47325)

Fax: 909-558-0239

Email: hjavaherian@llu.edu

3. STUDY PERSONNEL

Donnamarie Krause, MS, OTR/L, PhD Candidate

Noha Daher, DrPH, Committee Member

Shawn Roll, PhD, Committee Member

Nicholas Cvjetkovic, OTS, ATC, BS, Student research assistant

Michael Bradley Galloway, OTS, BS, Student research assistant

Diane Ganev, OTS, BA, Student research assistant

Kristin Kolack, OTS, BS, Student research assistant

4. STUDY INFORMATION

The location of the research will take place on scheduled dates at the Loma Linda University School of Allied Health Professions campus, 11139 Anderson Street, Loma Linda, California and Stanbridge University campus on 2041 Business Center Drive in Irvine, California.

Expected start date is December 1, 2017 and expected end date of research is December 1, 2018. The research consists of a mixed method design and includes a single blind randomized control trial with a repeated measure design. A qualitative element includes semi-structured interviews of participants.

5. INCLUSION/EXCLUSION CRITERIA

INCLUSION

- Adults > 18 years of age
- Fluent in English
- Report signs and symptoms of carpal tunnel syndrome
- Pain, numbness, and tingling of the forearm, wrist, or hand, which worsen at night
- Demonstrate positive Phalen's Test or Tinel's Test of the affected extremity

EXCLUSION

- Currently receiving treatment for carpal tunnel syndrome
- History of surgical carpal tunnel release
- Pregnant
- Diabetes not controlled by medication
- Radiculopathy ie: cervical radiculopathy, diabetic radiculopathy
- Thoracic outlet syndrome
- Allergy to adhesives or compromised skin integrity
- Past history of traumatic event, surgery, or congenital impairment of the forearm, wrist, or hand

6. SUBJECT RECRUITMENT & SCREENING

Based on a power analysis, 64 participants are needed with an expected attrition rate of 20% increasing the total number of participants to 78, with 26 in each of three groups.

Participants will be fluent in English, males and females age 18 years and older. The study will include participants from any race or ethnicity that meet eligibility criteria and demonstrate a positive Phalen's Test or positive Tinel's Test. The study population includes individuals who have symptoms of or have received a diagnosis of carpal tunnel syndrome, or experience forearm wrist hand pain and currently not receiving treatment. If participant has symptoms in both extremities, the researcher will use each extremity as a separate unit and apply corresponding intervention to both extremities.

Participants will be recruited using snowballing and judgmental sampling via word-of-mouth, flyers, emails, and social media with a \$5.00 gift card provided per visit for each of the five visits for the study. Flyers will be distributed throughout the Southern California area due to proximity but participants may come from any region if satisfying inclusion criteria and time commitment. Flyers will be placed in, but not limited to, common public places such as pet grooming places, community postings, manufacturing facilities, clinics, hair stylists, dental hygienists, sonographers, office buildings, and more. The principal investigator or appropriate personnel for Loma Linda University, and by the student researcher or appropriate personnel for the Stanbridge University access will acquire email addresses of potential participants. Specific social media outlets will include posting on but not limited to, Facebook, Instagram, and Twitter, with a website that will be accessed at: carpaltunnelstudy.wordpress.com for information. The contact information of the principal

investigator and student researcher will be available on the flyer with an invitation to contact researchers with any questions about the study.

7. INFORMED CONSENT PROCESS

A student researcher will facilitate the informed consent process with the eligible participants once participants have agreed to take part in the study. The informed consent process will take place in a designated private room at Loma Linda University School of Allied Health Professions and in a private classroom at Stanbridge University with time allotted for questions from the participant. HIPPA compliance forms will be included in the informed consent process and a copy of the participants' Bill of Rights. All research records will be secured by placing them in a locked cabinet in a locked office of the principal investigator and/or student researcher.

8. STUDY DESIGN

a. Background or rational for this study

Carpal tunnel syndrome, a common neuropathy of the median nerve may be caused from an increased pressure of the carpal tunnel, prolonged exposure to hand-arm vibrations, a combination of repetitive hand use or hand force, and in recent years has expanded to include the use of computers and similar devices (Ali, Battecha, & Mansour, 2013). It is believed chronic repetitive use of the fingers and wrist may generate a shearing between the carpal tunnel, the median nerve, and the flexor tendons.

Carpal tunnel syndrome is the most frequent type of injury and makes up 41% of all identified upper extremity musculoskeletal disorders (Roll, 2016; United States Department of Labor, 2015). Annually \$15 – 18 billion dollars are spent in costs related to upper extremity musculoskeletal disorder and carpal tunnel syndrome (United States Department of Labor, 2015). Commonly related to repetitive work exposures, prevalence increases with age and is three to one more prevalent in females. The targeted population of carpal tunnel syndrome is highly associated with overuse of the upper extremities (Thomsen, Gerr, & Atroshi, 2008).

Individuals who work in highly repetitive work environments have a significant chance of being diagnosed with carpal tunnel syndrome. Jobs in manufacturing, the service industry, and nursing are identified among this population. However, evidence now includes office workers as Coggon et al. (2013) found individuals who use computers for four hours a day also experience a high incidence of carpal tunnel syndrome. Goldfarb (2016) furthered the Coggon et al. (2013) study with findings that those who use computers and work 12-hour days over an eight-year span are primarily the at-risk population, putting students at the highest risk.

According to the Occupational Therapy Practice Framework, it is within Occupational Therapy's domain to intervene in musculoskeletal disorders as it impairs body function. Established treatment strategies for carpal tunnel syndrome include surgical interventions and non-surgical interventions; however, in a systematic review, Roll & Hardison (2017) found no standardized protocol exists for management and treatment of carpal tunnel syndrome. Both surgical and non-surgical interventions have been found to have similar results and governmental regulation, along with decreased reimbursement are putting demands on early worksite intervention (Lysaght et al., 2010). The most common accepted non-surgical protocol for carpal tunnel syndrome include lumbrical stretching exercises and a general cock-up splint, with one study reporting symptom relief up to 24-weeks (Baker et al., 2012; Manente et al., 2012). None of the accepted protocols take into consideration new evidence that suggests the wrist positioned in neutral and fingers supported in extension, provides the best outcomes for individuals with carpal tunnel syndrome (Bulut et al., 2015), and leaves the issue of splint compliance unaddressed. Clearly, a new intervention for carpal tunnel syndrome is needed.

Kinesio Tape is transitioning from the sports arena into rehabilitation as a modality for pain, increased activation of the lymphatic system, as an endogenic analgesic, and to correct musculoskeletal alignment (Kase et al. 1998). Fourteen peer-reviewed studies had been conducted for lower extremity pain and function, with few studies of Kinesio Tape on the upper extremities. Common application protocol for carpal tunnel syndrome is on the flexor side of the wrist and hands. The Kase accepted method of application to the flexor surface of the wrist has face validity only. To the best of our knowledge there are no studies that exist on the dorsal application of Kinesio Tape to facilitate wrist neutral and finger extension.

The primary purpose of this randomized controlled trial graduate student research study is to explore the effect of dorsal application of Kinesio Tape on occupational performance as measured by pain, strength, and function of individuals with carpal tunnel syndrome forearm wrist hand pain as compared to the usual and accepted most common non-surgical intervention of lumbrical stretching exercises and general cockup splint. The secondary purpose is to explore changes in occupational performance through semi-structured interviews in order to understand if Kinesio Tape contributed to results and if so, how. In order to help us understand how the participants perceived the interventions, the third purpose is to explore concepts of adherence to interventions with carpal tunnel syndrome.

b. Objectives

1. Determine if the dorsal application of Kinesio Tape applied to the wrist extensors for individuals with carpal tunnel syndrome and forearm wrist hand pain makes a difference in occupational performance as measured by pain, strength, and function.
2. Explore the perspectives of participants to understand if Kinesio Tape contributed to changes in occupational performance, and if so, how.

3. Explore concepts of adherence to interventions with carpal tunnel syndrome.

c. Procedures involved (Research Interventions)

The following procedures will be used for this multi-method study design that consists of a randomized control trial and descriptive qualitative study, upon IRB approval:

1. Recruit via snowballing, word-of-mouth, flyers, emails, and social media (See Appendix A)
2. Respond to study interest via Phone Script to answer questions regarding the study (See Appendix B) and set up a meeting time to review consent and initiate study procedures.
3. Review Informed Consent, HIPPA documents, and Patient's Bill of Rights and obtain consent from those interested in participating in study.
4. Screen participants for inclusion criteria by administering the Phalen's Test or Tinel's Test (Appendix C).
5. Administer Demographic questionnaire (Appendix D).
6. Administer baseline Week One Visit One Boston Carpal Tunnel Questionnaire, Numeric Pain Rating Scale, Visual Analogue Scale (Appendices E – F - G). If participant has symptoms in both extremities, the researcher will use each extremity as a separate unit and apply corresponding intervention to both extremities.
7. Collect Week One Visit One Baseline Grip and Pinch measurements (Appendix H).
8. Randomly assign participants using a random number generator, to one of three groups:
Intervention group, control group, or usual protocol group. A script will be used to control for bias and ensure consistency between groups.

Intervention group:

The student researcher and/or student research assistants who have been trained in Kinesio Tape and application procedures will apply the baseline dorsal application of Kinesio Tape according to determined protocol. The Kinesio Tape will be measured along the participant's lateral epicondyle to metacarpophalanges, the Kinesio Tape then bifurcated. Anchor Kinesio Tape on the dorsal side at the musculotendinous juncture to digits 1 and 5, just past the carpalmetacarpophalangeal joint of digit 1 and metacarpophalange of joint 5, wrist in flexion to stretch the skin, paper off tension (10%). Kinesio Tape application to digits 1 and 5 with carpalmetacarpophalangeal and metacarpophalange flexion during application. Two space correction pieces

applied to both the extensor and flexor surface at 75% stretch, then radially deviate, smooth edges, ulnarly deviate, smooth edges, repeat.

A handout with Kinesio Tape Removal Instructions will be provided (Appendix I). A symptom journal will be provided with instructions to complete daily (Appendix J). A script will be used with participants (Appendix K).

Control group:

The student researcher and/or student research assistants will apply the Sham application of Kinesio Tape, a four-inch strip of Kinesio Tape to the participants' shoulder (scapular spine). A handout with Kinesio Tape Removal Instructions will be provided (Appendix I). A symptom journal will be provided with instructions to complete daily (Appendix J). A script will be used with participants (Appendix K).

Usual protocol group:

The student researcher and/or student research assistants will provide a general wrist cock up splint with instructions to wear nightly and record compliance in a Splint and Exercise journal (Appendix L). Wrist Lumbrical exercises will be demonstrated by the student researcher or student research assistants and a handout with instructions provided (Appendix M). A symptom journal will be provided with instructions to complete daily (Appendix J). A script will be used with participants (Appendix K).

9. Week One Visit Two a student researcher and/or student research assistants will remove Kinesio Tape, check splints, and collect symptom journals and the Usual protocol group Splint-wearing and Exercise journal. Participants will complete Boston Carpal Tunnel Questionnaire, Numeric Pain Rating Scale, Visual Analogue Scale. Grip and Pinch measurements will be recorded.

Student researcher and/or student research assistants will re-apply Kinesio Tape and check splint and exercises resumed with the Usual protocol group.

Total exposure to application and removal of Kinesio Tape is four times as participants return every third day of Weeks One and Two.

10. Week Two Visit Three a student researcher and/or student research assistants will remove Kinesio Tape, check splints, and collect symptom journals and the Usual protocol group Splint-wearing and Exercise journal. Participants will complete Boston Carpal Tunnel Questionnaire, Numeric Pain Rating Scale, Visual Analogue Scale. Grip and Pinch measurements will be recorded.

Student researcher and/or student research assistants will re-apply Kinesio Tape and check splint and exercises resumed with the Usual protocol group.

11. Week Two Visit Four a student researcher and/or student research assistants will remove Kinesio Tape, check splints, and collect symptom journals and the Usual

protocol group Splint-wearing and Exercise journal. Participants will complete Boston Carpal Tunnel Questionnaire, Numeric Pain Rating Scale, Visual Analogue Scale. Grip and Pinch measurements will be recorded.

Student researcher and/or student research assistants will re-apply Kinesio Tape and check splint and exercises resumed with the Accepted protocol group.

12. Week Three Visit Five a student researcher and/or student research assistants will remove Kinesio Tape, check splints, and collect symptom journals and the Usual protocol group Splint-wearing and Exercise journal. Participants will complete Boston Carpal Tunnel Questionnaire, Numeric Pain Rating Scale, Visual Analogue Scale. Grip and Pinch measurements will be recorded.
13. Up to 26 participants from the Intervention group will be invited to participate in a 30-minute semi-structured audio-recorded interview with student researcher (Appendix N).
14. Email Reminder Script regarding study date (Appendix O)
15. See Timeline (Appendix P)

d. Concise review of literature that supports the rationale, objectives, and methodology of the proposed study.

An upper extremity musculoskeletal disorder affect working populations worldwide with evidence indicating 20% - 30% experience symptoms, and is considered the second most common cause of worldwide disability (Luckhaupt et al., 2013; Murray et al., 2012; 2013). In the United States alone, upper extremity musculoskeletal disorders are the second most common diagnosis, just behind low back injury for missed days of work, and accounted for 34% of all work-related injuries in 2015, according to the U.S. Bureau of Labor Statistics (2015), but less than 2% of the national Institute for Health budget is allocated to musculoskeletal disorders (Weinstein, 2016). Occupational performance is the process of assisting clients in becoming actively engaged in their life activities while developing healthy behaviors and minimizing costs (Baum & Law, 1997). An upper extremity musculoskeletal disorder impairs an individual's ability to work, complete daily self-care tasks of both gross and fine motor (United States Bureau of Labor Statistics, 2015).

The most common musculoskeletal disorder of the upper extremity is Carpal Tunnel Syndrome and is 41% all off upper extremity repetitive movement disorders (Roll, 2016). Occupational therapists historically have had a role in treating upper extremity musculoskeletal disorder conditions and holistically address the link between reductions in impairment to functional tasks (Roll, 2017). According to Roll (2017) studies of the upper extremity have evaluated orthosis and modalities to increase body structure and occupation as specific interventions for upper extremity musculoskeletal disorder of carpal tunnel syndrome; however, there is a lack of homogeneity within publications. Musculoskeletal disorders and carpal tunnel syndrome are often treated by occupational therapists but in

separate departments (Roll, 2017), which cause problems for researchers and injured individuals alike. Traditionally Occupational Health Occupational Therapists provide interventions to individuals injured at work, often pre-surgically while Hand Occupational Therapists report treating individuals with carpal tunnel syndrome post-surgically. These distinctions carry over into publications and research, though interventions and outcomes are the same.

Diagnosis of carpal tunnel syndrome is confirmed through electromyography; however, medical personnel including Occupational Therapists assess carpal tunnel syndrome based on signs and symptoms and through an orthopedic special test known as the Wrist Flexion Test or the Phalen's Test. Evidence suggests Phalen's Test and Tinel's Test to be valid with high specificity, validity, and reliability. Denham et al. (2015) reported that specificity of the Phalen's Test was 80% with confirmed diagnosis of carpal tunnel syndrome. Other studies indicate that the sensitivity of the Phalen Test and electromyography between 68% and 85% and 73% to 89%. Kotevoglou & Gulbahce-Saglam (2005) found that there was a correlation of ($r = 0.80$, $p < 0.001$) for the Phalen Test using diagnostic ultrasound and Tinel's Test correlation factor of ($r = 0.70$, $p < 0.001$). No standardized protocol for management and treatment of carpal tunnel syndrome exists; however, common established strategies consist of surgical or non-surgical interventions. Surgical interventions are mostly positive but a recent study by Nanavati, Walker-Bone, Stanworth and Williams (2013) found almost one-third reported difficulty completing activities of daily living or experienced a return of symptoms 28 days or more following surgery.

Non-surgical interventions lack established uniform protocol according to a systematic review by Amini (2011), and Oiyun and MacDermid (2011) found an analysis of conservative approaches plateaued in effectiveness after three months. The most common non-surgical intervention is splinting with evidence for either full-time or night depending on protocol and patient compliance with only mediocre effectiveness (Amini, 2011). Recent evidence indicates finger position can influence properties of the median nerve with significant palmar bowing of the flexor retinaculum for finger extension and a flattening of the median nerve during the isometric squeeze grip (Nadar et al. (2013). Bulut et al. (2015) found evidence that the wrist positioned in neutral and metacarpophalanges supported, provides the best outcomes, but is yet to be seen in clinical practice. One non-surgical intervention transitioning from Sport Medicine into Rehabilitation is Kinesio Tape.

Kinesio Tape is applied to the epidermis of the skin and by compression released on the nociceptors (pain receptors) provides input through the subcutaneous tissue layer to the body's proprioceptive system according to Kase, Hashimoto and Okane (1998). This hypodermic input influences pain, edema, and is able to provide musculoskeletal correction based on application (Kase et al, 1998). Application ranges from injury management to muscle facilitation and include neurologic impairment interventions as well. Brateanu (2009) elaborated on Kinesio Tape's ability to be worn for several days, three to five, without reapplication and evidence of common applications for patellar pain syndrome, low back pain, and shoulder instability. Few studies exist on upper extremity use of Kinesio Tape on forearm, wrist, hand pain and function, such as with carpal tunnel syndrome. The Kase accepted method of Kinesio Tape application is on the flexor surface for musculoskeletal

disorder of carpal tunnel syndrome symptoms but has face validity only. Kocjan (2016) in a randomized control trial of Kinesio Tape on the flexor side for carpal tunnel syndrome using a non-Kase method of application concluded no statistical significant results. To the best of our knowledge no literature exists on the dorsal application of Kinesio tape for positioning the wrist in neutral, with the finger supported. The process of exploring the effects of Kinesio Tape on musculoskeletal disorders includes understanding participant's issues of compliance as it relates to pain and non-surgical interventions.

9. DATA COLLECTION

Data collection procedures on the affected extremity include psychometric assessments of pain, using the Numeric Pain Rating Scale and Visual Analogue Scale. Occupational performance will be measured using the Boston Carpal Tunnel Questionnaire completed by the participants and grip and pinch from each participant will recorded by the student research assistants.

At the final visit, the student researcher and/or student research assistants will conduct a 30-minute 6-item semi-structured interview exploring the intervention group participant's perception of wearing Kinesio tape and its impact on the participant's occupational performance.

Study intervention will be held at the beginning of the week and the end of the week during various times of day to account for sign and symptoms related to occupation and activities of daily living. The researchers know which intervention is being studied; however, the participants will not know which intervention is being studied to increase accuracy of findings. The benefit of blinding participants in this graduate student randomized controlled trial to the objective of the study is to determine if there is indeed a benefit of the intervention of dorsal application of Kinesio Tape versus the usual protocol or current care of splint and lumbrical exercises for carpal tunnel syndrome forearm wrist hand pain. There Kinesio Tape application on the shoulder is to determine if there is an intervention effect is evidence to suggest even that application site could be beneficial. All participants will be emailed the results of the study.

Participants will complete a demographic questionnaire at baseline, which will include age, gender, ethnicity, current occupation and duration in that position. The demographic information will be used during data analysis to determine the influence of these variables on study outcomes. Participants will complete the Numeric Pain Rating Scale and Visual Analogue Scale to allow a subjective measure of participants experiencing mild to moderate carpal tunnel syndrome forearm wrist hand pain, which will be completed at baseline, weeks one, two, and three. These assessment tools are self-report measures using ordinal data with superior sensitivity, test retest reliability ($r = 0.96$ and 0.95) as well as construct validity ($r = 0.86$) (Hawker, Mian, Kendzerska, & French, 2011; Hjerstad et al., 2011). The student researcher and/or student research assistants at baseline will record functional grip at weeks one, two, and three using a calibrated Jamar Dynamometer and standardized protocol and position. The dynamometer is the only available tool to objectively measure functional grip

strength necessary to complete occupations of work, activities of daily living, household, and work tasks and demonstrates high test-retest reliability ($r > 0.80$), inter-rater reliability ($r = 0.98$) and concurrent validity (Roberts et al., 2011). Pinch strength will be collected by the student researcher or student research assistants at baseline, weeks one, two, and three using a calibrated pinch meter with standardized protocol and position as it is a commonly available tool to objectively measure functional pinch strength necessary for fine motor control, hand use for occupations and tasks of daily living skills. The pinch meter demonstrates high inter-rater reliability ($r = 0.97$) and test re-test reliability ($r = 0.80$) (Mathiowetz et al., 1985).

Participants will also complete an 11-question standardized Boston Carpal Tunnel Questionnaire a commonly accepted subjective measure of function and severity as it relates to carpal tunnel syndrome and efficacy related to functional activities using an ordinal scale. The Symptom Severity Scale demonstrates high test-retest reliability ($r = 0.91$), with internal consistency of 0.80 – 0.90, and the Functional Status Scale also demonstrates high test-retest reliability ($r = 0.93$) with internal consistency of 0.88 – 0.93 (Carvalho Leite, Jerosch-Herold, & Song, 2006).

See attached appendices D - O: Boston Carpal Tunnel Questionnaire, Demographic Questionnaire, Numeric Pain Rating Scale Questionnaire, Visual Analogue Scale, Splint and Exercise Compliance Log, Symptom Log, Kinesio Tape Removal Instructions, Interview Guide, Scripts.

10. LABELING & STORAGE OF DATA & SPECIMENS

Informed consents, HIPPA documents, and research records of functional grip and pinch measurements, occupational performance scales, and interviews will be stored in a locked cabinet in a locked office of the Principal Investigator. Any electronic research records of functional grip and pinch measurements, occupational performance scales, interviews and other research information will be stored on a secured and password protected computer. Data will be secured in a locked cabinet for a period of three years and then destroyed.

11. DATA ANALYSIS

The research analysis plan will include a repeated measures multi-factorial analysis of variance to analyze continuous data for the functional grip and pinch measurements, with an analysis of covariance to rule out any confounding variables between groups. For Objective 1 of the randomized controlled trial of the study continuous data will be analyzed with change score analysis from baseline to end of study. To compare groups post-hoc Bonferroni will be used. Non-parametric statistics using the Friedman's Test will be used with the Numeric Pain Rating Scale, Visual Analogue Scale, and Boston Carpal Tunnel Questionnaire.

For Objective 2, qualitative data will be analyzed for thematic coding. Transcripts will be individually read and coded for emerging themes by the research team and then analyzed as a group to increase rigor. For Objective 3 to explore concepts of adherence to interventions with carpal tunnel syndrome, triangulation will be used with data obtained through interviews and with journals using a deductive approach to explore Kinesio Tape on performance. Data will be analyzed until redundancy is achieved.

12. RISK AND INJURY

Participants may experience discomfort or skin irritation from wearing the tape, splint or completing the exercises. Participants may also experience fear and/or anxiety, and/or hyperventilation before during, or after application of Kinesio Tape, and/or splint, and/or exercises. Under these circumstances the Kinesio Tape will be removed from the participant's forearm wrist hand and provide first aid and seek medical care as needed. To minimize the potential of risks to participants the student researcher and student research assistants will ask if any known allergies to adhesives. Participants with a history or current allergy to adhesives will be excluded from the study. Risks may also include a participant may feel uncomfortable answering questions during interviewing. Loss of confidentiality may occur if two participants know each other. In order to protect confidentiality a number will be assigned to each participant. The master list and Informed Consent will be kept separate in the Principal Investigator's office.

13. BENEFIT (S)

The benefit of this study may help determine the validity of a non-surgical cost effective intervention that can be applied at the work site and allow for increased participation in occupations of daily living for carpal tunnel syndrome forearm wrist hand pain. Results of the study could provide insights to practitioners and researchers working with carpal tunnel syndrome forearm wrist hand pain and the influence of Kinesio Tape on occupational performance. Improving the understanding of terminology and inherent factors in current accepted protocols for carpal tunnel syndrome may be an additional benefit.

14. COMPENSATION

Participants will receive a \$5.00 gift card per visit for each of the five visits for the study.

15. CONFIDENTIALITY

Numbers will be used to identify participants and a coding sheet known only to the researcher will be kept in a locked office. All identifying information will be removed. Any published document resulting from this study will not disclose participant identity without written permission. All data will be secured in a locked cabinet in a locked office.

16. LITERATURE REVIEW

Musculoskeletal disorders are consistently considered sprains, strains, tears resulting from over exertion of the muscles during an activity and result in an injury to muscles, joints, ligaments, tendons, cartilage, or nerve (Lysaght, Donnelly, & Luong, 2010; United States Bureau of Labor, 2015). Upper extremity musculoskeletal injuries account for the second most common musculoskeletal disorder according to the United States Department of Labor (2015) with carpal tunnel syndrome the most frequently identified (41%) of all upper extremity repetitive movement disorders (Roll, 2016; United States Department of labor, 2015).

Carpal tunnel syndrome is a common neuropathy of the median nerve of the wrist with progressive intermittent signs and symptoms leading to impaired function and even muscle atrophy with nocturnal pain and paresthesia, decreased tactile sensation, and numbness in the first three fingers, as well as pain in the upper extremity, weakness of the hand and wrist (Ozgen et al., 2011). Carpal tunnel syndrome increases with age and three to one females to males experience symptoms with co-morbidities of diabetes and even pregnancy can be found to be contributing factors (Ozgen et al., 2011). Ali and colleagues (2013) concluded carpal tunnel syndrome may be caused from an increased pressure of the carpal tunnel, prolonged exposure to hand-arm vibrations, a combination of repetitive hand use and the use of hand force, and in recent years has expanded to include the use of computers and similar devices. It is believed that chronic repetitive use of the fingers and wrist may generate a shearing between the carpal tunnel, the median nerve, and the flexor tendons, which results in a restricted hyperplasia and fibrosis of the tenosynovitis of the flexor tendons and the median nerve in the tunnel (Ali et al., 2013).

Walker and colleagues (2000) identified individuals who work in highly repetitive environments have a significant chance of being diagnosed with carpal tunnel syndrome, for example individuals in manufacturing, service industry personnel such as hairdressers, massage therapists, gardeners, pet groomers, chefs, construction workers, and nurses are identified among this population. However, office workers are now included as Coggon and colleagues (2013) found workers who use the PC for 4-hours a day experience a high incidence of this disabling upper extremity musculoskeletal disorder of carpal tunnel syndrome. Goldfarb in (2016) furthered Coggon and colleagues (2013) study with findings that those who use computers and work 12 hour days over an 8-year span are primarily the at-risk population and could now include students. Common interventions for this disorder lack protocol, homogeneity, and consistency of results. Passive interventions are a patient's first choice, and at times a physician's but evidence based practice governmental regulation, as well as cost containment needs are pushing for increased and early worksite interventions, according to Lysaght and colleagues (2010). Accepted protocols include combining intervention modalities such as splinting and lumbrical exercises, with varied mediocre effectiveness and high issues surrounding patient compliance (Amini, 2011). In a systematic review Roll and Hardison (2016) found splinting type and position remain unstandardized.

One study using a combination of lumbrical stretching exercises and a general cock-up splint provided symptom relief up to 24 weeks, longer than any combination of conservative intervention (Baker et al., 2012; Manente et al., 2012). New evidence by Nadar et al. (2013)

found finger position can influence properties of the median nerve and Bulut et al. (2015) found the wrist positioned in neutral and metacarpophalanges supported provides the best outcomes. Kase et al. (1998) identified four principles of Kinesio Tape, that it supports muscles by improving muscle contraction, increases flow of body fluids, activates the endogenous analgesic system resulting in decreased pain, and corrects joint alignment based on application. Fourteen peer review studies between 2004 – 2014 provide evidence of KT for lower extremity pain and edema. Few and poor studies exist on upper extremity use of KT, such as with carpal tunnel syndrome and the Kase accepted method of Kinesio Tape application for carpal tunnel syndrome is on the flexor surface (palm of the hand and wrist) but has face validity only. However, if Kinesio Tape is to support or facilitate muscles based on application, as well as provide musculoskeletal re-positioning, and influence sub-acute pain, then using Kinesio Tape on the flexor surface would seemingly only increase compression on the median nerve by pulling the wrist and fingers into flexion/grip position. The application of Kinesio Tape on the extensor surface may reposition the wrist into neutral and open the carpal tunnel while supporting the metacarpophalanges. Thus, the purpose of this study is to determine if the dorsal application of Kinesio Tape applied to the wrist extensors for individuals with carpal tunnel syndrome, makes a difference in occupational performance of pain, strength, and function and to explore the perspectives of participants to understand if Kinesio Tape contributed to changes in occupational performance and compliance and if so, how.

References

- Ali, R.R., Battecha, K.H., Mansour, W.T. (2013). Influence of kinesio tape in treating carpal tunnel syndrome. *Journal of Medical Science and Clinical Research*, 1(1), 1-9.
- American Occupational Therapy Association. (2014). Occupational therapy practice framework: Domain and process (3rd ed.). *American Journal of Occupational Therapy*, 68(Suppl. 1), S1–S48. <http://dx.doi.org/10.5014/ajot.2014.682006>
- Amini, D. (2011). Occupational therapy interventions for work-related injuries and conditions of the forearm, wrist, and hand: A systematic review. *American Journal of Occupational Therapy*, 65, 29-36. <http://dx.doi.org/10.5014/ajot.2011.09186>
- Baker, N., Moehling, K., Rubinstein, E., Wollstein, R., Gustafson, N., & Baratz, M. (2012). The comparative effectiveness of combined lumbrical muscle splints and stretches on symptoms and function in carpal tunnel syndrome. *Archives of Physical Medicine and Rehabilitation*, 93(1), 1 – 10. <https://dx.doi.org/10.1016/j.apmr.2011.08.013>
- Baum, C. & Law, M. (1997). Occupational therapy practice: Focusing on occupational performance. *American Journal of Occupational Therapy*, 51(4), 277 – 289.
- Bulut, G., Caglar, N., Aytakin, E., Ozgonenel, L., Tutun, S., Demir, S. (2015). Comparison of static wrist splint with static wrist and metacarpophalangeal splint in carpal tunnel syndrome, *Journal of Back & Musculoskeletal Rehabilitation*, 28(4), 761 – 767. <https://dx.doi.org/10.3233/BMR-140580>

- Carvalho Leite, J., Jerosch-Herold, C., & Song, F. (2006). A systematic review of the psychometric properties of the Boston Carpal Tunnel Questionnaire. *BioMed Central Musculoskeletal Disorders*, 7(78). <http://dx.doi.org/10.1186/1471-2474-7-78>
- Coggon, D., Ntani, G., Palmer, K. T., Felli, V. E., Harari, R., Barrero, L. H., ... & Bonzini, M. (2013). Disabling musculoskeletal pain in working populations: Is it the job, the person, or the culture? *Pain*, 154(6), 856-863. doi:10.1016/j.pain.2013.02.008
- Denham, S., Lee, J., Wilhite, M., McGrady, T., Booth, B. (2015). Agreement between the upper limb tension test and the phalen test in the diagnosis of carpal tunnel syndrome. *Orthopaedic Physical Therapy Practice*, 27(1), 20-24
- Giannini, F., Cioni, R., Mondelli, M., Paua, R., Gregori, B., Amico, P., Padua, L. (2002). A new clinical scale of carpal tunnel syndrome: Validation of the measurement and clinical-neurophysiological assessment. *Clinical Neurophysiology*, 113, 71 – 77.
- Goldfarb, C. A. (2016). The clinical practice guideline on carpal tunnel syndrome and workers' compensation. *The Journal of Hand Surgery*, 41(6), 723-725. doi:10.1016/j.jhsa.2016.04.003
- Kase, K. (2003). *Illustrated kinesio taping* (4th ed.). Albuquerque, NM: Ken'i Kai Information.
- Kase, K., Hashimoto, T., & Okane, T. (1998). *Kinesio perfect taping manual: Amazing taping therapy to eliminate pain and muscle disorders*. Albuquerque, NM: Kinesio Taping Association.
- Kotevoglou, N. Gulbahce-Saglam, S. (2005). Ultrasound imaging in the diagnosis of carpal tunnel syndrome and its relevance to clinical evaluation. *Joint Bone Spine*, 72(2), 142 – 145. <http://dx.doi.org/10.1016/j.jbspin.2004.03.012>
- Lysaght, R., Donnelly, C., & Luong, D. (2010). Best practices in the rehabilitation of acute musculoskeletal disorders in workers with injuries: An integrative review and analysis of evolving trends. *Work*, 35, 319 – 333.
- Luckhaupt, S., Dahlhamer, J., Ward, B., Sweeney, M., Sestito, J., & Calvert, G. (2013). Prevalence and work-relatedness of carpal tunnel syndrome in the working population, United States, 2010 National Health Interview Survey. *American Journal of Industrial Medicine*, 56(6), 615 – 624. <http://dx.doi.org/10.1002/ajim.22048>
- Nadar, M. S., Dashti, M. H., & Cherian, J. (2013). Finger position alters the median nerve properties within the carpal tunnel: a pre-post MRI comparison study. *Plos One*, 8(11), e79273. <http://dx.doi.org/10.1371/journal.pone.0079273>
- Nanavati, N., Walker-Bone, K., Stanworth, H., & Williams, C. (2013). Outcomes of open carpal tunnel decompression. *New Zealand Medical Journal*, 126(1369), 60 – 67.

Qiyun, S., & MacDermid, J. (2011). Is surgical intervention more effective than non-surgical treatment for carpal tunnel syndrome?: A systematic review. *Journal of Orthopaedic Surgery & Research*, 6(1), 17 – 25.

Ozgen, M., Gungen, G., Sarsan, A., Ardic, F., Caliskan, S., Sabir, N., . . . Baydemir, C. (2011). Determination of the position on which the median nerve compression is at the lowest in carpal tunnel syndrome and clinical effectiveness of custom splint application. *Rheumatology International*, 31(8), 1031-1036. <http://dx.doi.org/10.1007/s00296-010-1414-5>

Putnam, J. J. (1880). A series of cases of paraesthesia, mainly of the hand, of periodic occurrence, and possibly of vaso-motor origin. *Archives of Medicine (New York)*, 4, 147-162.

Roll, S. (2017). Current evidence and opportunities for expanding the role of Occupational Therapy for adults with musculoskeletal conditions. *American Journal of Occupational Therapy*, 71, 7101170010 <http://dx.doi.org/10.5014/ajot.2017.71102>.

Roll, S. (2016). *Carpal tunnel syndrome: Improving intervention effectiveness*. Retrieved from www.CE-Express.com

Roll, S., & Hardison, M. (2017). Effectiveness of occupational therapy interventions for adults with musculoskeletal conditions of the forearm, wrist, and hand: A systematic review, *American Journal of Occupational Therapy*, 71, <http://dx.doi.org/10.5014/ajot.2017.023234>

United States Bureau of Labor Statistics. (2015). *Nonfatal occupational injuries and illnesses requiring days away from work, 2014 (USDL 15-2205)* [News release]. Retrieved from <http://www.bls.gov/news.release/pdf/osh2.pdf>

United States Department of Labor. (2015a). *Nonfatal occupational injuries and illnesses requiring days away from work, 2015*. Retrieved from <http://www.bls.gov>

United States Department of Labor. (2015b). OSHA. Retrieved from <http://www.osha.gov>

Walker, W. C., Metzler, M., Cifu, D. X., & Swartz, Z. (2000). Neutral wrist splinting in carpal tunnel syndrome: A comparison of night-only versus full-time wear instructions. *Archives of Physical Medicine and Rehabilitation*, 81(4), 424-429. <http://dx.doi.org/10.1053/mr.2000.3856>

Weinstein, S.L. (2016). The burden of musculoskeletal conditions. *Journal of Bone and Joint Surgery*, 98, 1331. <https://dx.doi.org/10.2106/jbjs.16.00595>