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Carpal tunnel syndrome (CTS) is symptoms like paresthesias and weakness caused by compression of the median nerve. It affects up to 10% of the adult population in the U.S. with medical costs exceeding $2 billion annually. The goal of this study is to evaluate the benefits of Osteopathic Manipulative Treatment (OMT) on the symptom severity and daily functioning of subjects with CTS. The OMT group was compared to a ultrasound placebo group. Outcome measures include symptom severity, functional status scores, and strength measures. Subjects receive six treatments with measures taken at three points in the study. Thirty-two subjects were used in the study analysis. The OMT group had significantly improved symptom severity and functional status scores over time. These scores were not significantly different from the changes in the ultrasound group. While outcome measures show trends toward improvement with OMT, they are not significantly different from placebo.

EFFECTS OF OSTEOPATHIC MANIPULATIVE TREATMENT ON SYMPTOM SEVERITY AND FUNCTIONAL STATUS IN CARPAL TUNNEL SYNDROME

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EFFECTS OF OSTEOPATHIC MANIPULATIVE TREATMENT ON SYMPTOM SEVERITY AND FUNCTIONAL STATUS IN CARPAL TUNNEL SYNDROME

MASTER'S THESIS

PRESENTED TO THE GRADUATE COUNCIL OF THE UNIVERSITY OF NORTH TEXAS HEALTH SCIENCE CENTER AT FORT WORTH IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF
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TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

INTRODUCTION

Carpal Tunnel Syndrome (CTS) is a collection of symptoms and dysfunction caused by compression of the median nerve within the carpal canal of the wrist. It affects up to 10% of the adult U.S. population and medical costs exceed $2 billion annually.[1] Individuals with CTS experience a range of pain, numbness, decreased strength and restricted movement of the hand and wrist. Every year in the U.S. approximately 500,000 surgeries are performed to relieve this condition. Osteopathic manipulative treatment (OMT) may be an effective, non-surgical alternative to alleviating the symptoms associated with CTS and may increase the patient's day to day ability to function. Limited but promising studies published to date suggest that a more rigorous study design is worthwhile to study the effects of OMT on CTS.

This study is a collaborative effort by two medical students and predoctoral fellows (PDF) in Osteopathic Manipulative Medicine (OMM), who worked together to design the study, conduct the interventions, and collect and analyze the data under the supervision of an OMM specialist and with the assistance of a clinical research coordinator. For the purpose of each master's thesis each student had different hypotheses, outcome measures, and analyzed different aspects of the study. This thesis explores the effects of OMT on symptom severity and functional status of CTS patients. The collaborating thesis explores the effects on biomechanical changes and nerve conduction studies in the same patients.

SPECIFIC AIMS

The overall goal of this research is to evaluate the benefits of OMT in treating persons with CTS. The specific aim is to determine whether OMT can decrease pain and improve strength and mobility for CTS patients.

The specific hypotheses to be tested are:

Hypothesis 1: OMT will decrease pain and other symptoms of CTS patients measured by the Carpal Tunnel Symptom Severity Questionnaire and the visual analog pain scale.

Hypothesis 2: OMT will improve the daily functioning level of subjects with CTS as measured by the Functional Status Questionnaire and grip and pinch strengths.

BACKGROUND AND SIGNIFICANCE

Introduction to Carpal Tunnel Syndrome

The symptoms of median nerve compression were first described in the late 1800s in relation to a distal fracture of the radius. It was not until 1938 that it was given the name "carpal tunnel syndrome", and Phalen popularized the phrase in the 1950s. Today the prevalence of CTS in the general population of the U.S. has been reported as high as 10%.[1] Carpal tunnel syndrome occurs more frequently in women than men and is more common from ages 30 to 60.[2,3] CTS has many possible etiologies including: alterations of fluid balance (pregnancy, renal failure), inflammatory conditions (rheumatoid arthritis, gout), infections, tumors, anatomical abnormalities hemorrhagic disorders, trauma, neuropathic manifestations of systemic disease (diabetes mellitus, alcoholism), and idiopathic.[1]

Carpal tunnel syndrome is defined as a collection of signs and symptoms caused by compression of the median nerve within the carpal canal at the wrist.[2,3] The distribution of the median nerve includes the thumb, index finger, middle finger, and half the ring finger. The classic symptoms of CTS include numbness and tingling in the thumb and first two fingers. Patients often complain of waking up at night with numbness in their hand, as if it "fell asleep". This is due the tendency of the hand to be flexed during sleep, and it often resolves with shaking or wringing of the hands. Paresthesias can occur at

anytime when the hand is held in prolonged flexion or extension: while driving a car, reading a book, or holding a telephone receiver.[2] Pain can also radiate up to the elbow or even the shoulder.

When there is motor involvement, clumsiness is often the complaint.[3] Weakness of the intrinsic muscles of the hand develops leading to hand fatigue and decreased ability to grip objects. As the condition progresses muscle atrophy may be seen, particularly in the thenar eminence. A chiropractic study comparing subjects with CTS to a control group without CTS showed the CTS group to have significantly decreased grip and tip pinch strengths, significantly higher pain scale scores, and slower task performance than the controls.[4]

Michelsen described three stages of CTS: early, intermediate, and advanced. CTS may be differentiated by the presence or absence of thenar muscle strength. The early stage, less than 1 year, does not generally have loss of strength and non-operative treatments are usually used. In later stages, when symptoms become disabling or muscle atrophy is present surgery is the standard recommendation.[1] CTS severity can also be described in terms of nerve conduction studies (Table 1):

Minimal	Abnormal median/ulnar comparative tests only
Mild	Abnormal short segment median sensory or mixed nerve latency with normal median motor distal latency
Moderate	Abnormal median sensory/mixed nerve and median motor latency
Severe	Absence of median sensory/mixed and abnormal median motor latency
Extreme	Absence of median sensory/mixed and motor [5]

Table 1: Severity of Carpal Tunnel Syndrome

In this model Severe and Extreme ratings are more likely to be considered for surgical treatment.

There are many tests available to the clinician to evaluate wrist and hand pain for carpal tunnel syndrome. They include:

Tinel's test - The evaluator percusses over the middle of the line between the base of the thenar and hypothenar eminences for greater than 30 seconds or until paresthesias develop. A positive test is paresthesias or dyesthesias in the median nerve distribution.[6] The sensitivity has been described from 26-79% with the specificity from 40-100%.[7]

Phalen's test – The hands are flexed for 60 seconds. A positive test is paresthesias in the median nerve distribution.[6] This test has a sensitivity from 10-88% and specificity from 47-100%.[7]

Compression test – The evaluator applies gentle, sustained pressure with his/her thumb over the carpal canal. A positive test is paresthesias that disappear within 30 seconds of removal of the pressure. The sensitivity of the test is 87% with a specificity of 90%.[7]

OK Sign test – A piece of paper is placed between the thumb and forefinger. If the patient is not able to hold onto the paper when it is pulled, the test is a positive. The test is also positive if the patient is not able to make the OK sign. This is a non-specific test for median nerve dysfunction.[6]

Patients presenting with CTS-like symptoms should have a full evaluation of the arm and neck including a thorough neurologic exam. Symptoms are more likely in the first three digits of the hand following the sensory distribution of the median nerve. As CTS becomes more severe, the motor nerve is affected, which is evaluated by abductor pollicis brevis strength. Nerve conduction studies are used in conjunction with the clinical signs and symptoms to diagnose CTS.

Nerve Conduction Studies

Although some argue that CTS is primarily a clinical diagnosis, nerve conduction studies have become an integral part of making or confirming the diagnosis. Nerve conduction studies (NCS) stimulate a nerve at one location and measure the electrical response at another, thus measuring the local electrical gradient caused by nerve depolarization.[5] According to a literature review done by the American Academy of Neurology, NCS confirm a CTS diagnosis with sensitivity greater than 85% and specificity of greater than 95%.[8] NCS for CTS include measuring sensory and motor conduction across the wrist with delays shown by absolute criteria or by comparison of median nerve to either ulnar or radial nerve conduction. Median nerve sensory measures show abnormalities first because 94% of median nerve axons at the wrist are sensory. The motor nerve potential abnormalities follow and give insight into the severity of the disorder.[5] For this study, sensory and motor nerve latencies were measured and compared to an absolute standard as well as compared to latencies of the ulnar nerve. Other considerations when performing nerve conduction studies include monitoring and maintenance of hand temperature at or above 32 degrees Celsius and use of normative data from previous studies of a reference population or normative data within the laboratory.[8]

Possible Etiologies of CTS

There are many theories as to what causes carpal tunnel syndrome. Michelsen and Posner described pressure differences in the carpal canal with changes in wrist motion.

In a neutral position, the interstitial pressure is 2.5 mm Hg and it increases to 30 mm Hg with maximum flexion or extension. At levels of 20 mm Hg, epineural blood flow can be reduced with axonal transport being impaired above 30 mm Hg. Increases in pressure can lead to clinical manifestation such as paresthesias. The authors noted that many patients with CTS have average interstitial pressures of 32 mm Hg.[1]

Upton and McComas have also proposed a *double crush theory.* According to this theory a proximal site of compression could cause more distal sites to be susceptible to nerve compression.[9] The sites of nerve compression in series can be additive causing decreased axoplasmic flow and symptoms. Systemic diseases, such as diabetes mellitus, are also considered in the *double crush theory* for their ability to lower nerve compression threshold and make patients more susceptible to CTS. In some cases, NCS have shown proximal slowing of median nerve forearm conduction in addition to slowing at the carpal canal. This should not be considered a second site of compression despite the cause being unknown.[5]

The most common cause of CTS is from an idiopathic or occupational mechanism resulting from repetitive motion of the wrist joint with subsequent inflammatory processes and compression of the median nerve.[2] Other causes include peripheral neuropathies, other nervous system disorders, endocrine disorders, tumors of the wrist and hand, inflammatory conditions, as well as many others.

Osteopathic Manipulative Medicine and CTS

Prevention is an important first step in Osteopathic care for patients at risk for carpal tunnel syndrome. Examples of preventive action include good workplace ergonomics, evaluation tools utilized for repetitious work, reduction of excessive force on wrist, protection from vibratory forces, and even rotation of employee tasks in the factory environment. Poor posture and decreased muscle tone can contribute to CTS and therefore can be addressed as part of a preventive treatment regimen.[3] Conservative treatment of CTS involves osteopathic manipulative treatment (OMT), rigorous home stretching, splinting, and necessary medications. This study focuses on the OMT aspect of full Osteopathic care.

The majority of published works on CTS and OMT are case studies done by Dr. Benjamin Sucher. His early case studies focus on manipulation at the carpal canal itself. Using myofascial release of the transverse carpal ligament and with rigorous home stretching, he shows improvement in symptoms and palpated somatic dysfunction. By opening the carpal canal through these methods, he hoped to reduce pressure on the median nerve.[10] In addition to palpatory findings, Sucher also uses NCS and suggests the use of MRI for documentation of pressure changes within the carpal canal. MRI is a way to measure dimensions and volume of the carpal canal which were correlated with increased pressure within the canal. Sucher revisited the *double crush effect* focusing on CTS and thoracic outlet syndrome. In these cases, Sucher treated both at the wrist and along the shoulder girdle since treating only one site may result in continued symptoms. He suggests that in order to fully treat CTS with OMT, points of restriction along the

nerve pathway should be treated.[11] These studies show the positive effects of OMT while outlining treatments for CTS such as Opponens roll (defined in protocol). However, they do not follow the structure of statistical analysis required by today's push for evidence based medicine.

Ramey used case studies to evaluate the efficacy OMT with MRI, NCS, and pain scales as outcome measures. Ramey treated the thoracic and cervical spine and forearm tenderpoints with no direct manipulation of the transverse carpal ligament. With this treatment, his subjects showed significant improvements in pain ratings, wrist motion, and NCS. Some of the subjects also showed decreased swelling of the median nerve and carpal tunnel on MRI.[12]

By combining the work of both these researchers one could develop a treatment approach that follows the course of the median nerve starting from its origins in the brachial plexus. Possible areas of compression of the neurovascular bundle are the anterior and middle scalenes, the first rib, and the pectoralis minor. In the arm, the median nerve passes deep to the bicipital aponeurosis and between the two heads of pronator teres muscle. Finally, the median nerve passes under the transverse carpal ligament and in close proximity to the carpal bones.[12] Osteopathic teaching emphasizes that OMT must also address the sympathetic innervation to the upper extremity originating from spinal levels T2 through T8. Increased sympathetic activity causes constriction of the larger lymphatic vessels as well as constriction of the arterioles.[13-14] Lymphatic drainage must be optimized with treatment to decrease the fluid volume

within the carpal canal.The increase in interstitial pressure can lead to symptoms of CTS.[1]

Although OMT has often been used in the treatment of CTS, published research to date consists mainly of case studies. Sucher showed, through cadaver studies, the ability of low force over a period of time to elongate the transverse carpal ligament.[15] He also showed positive changes in MRI and NCS with treatment of the wrist and transverse carpal ligament.[10,16-17] Ramey took a different approach and showed improvement in MRI measures to assess fluid content when he treated the forearm, upper thoracic spine, and cervical spine without OMT to the wrist region.[18]

Chiropractic Treatment and CTS

Bonebrake studied strength and pain measure changes between CTS and non-CTS subjects, as well as outcomes in the CTS subjects following chiropractic treatment. In his research, the manipulation is applied to the whole body along with at-home strengthening exercises and nutritional supplementation. The duration of treatment varied with each subject. He found a significant difference in grip strength and pinch strength between CTS subjects and healthy subjects. The CTS subjects also showed significant improvement in both pinch and grip strength following the treatment.[4] He found that this improvement was sustained over a six-month period following treatment.[19]

Surgical Treatment and CTS

Surgery was first proposed to treat CTS as early as 1913.[1] Carpal tunnel surgery involves complete resection of the transverse carpal ligament in an effort to decrease pressure within the carpal canal and on the median nerve. There are many surgical techniques by which this is accomplished. The two main techniques are open incision and endoscopic surgery. In cases where NCS failed to improve within a few months following surgery, incomplete nerve decompression was often found. Grip and pinch strength have been shown to return to their preoperative levels within 3 months, and by 6 months post-operatively the measures were stronger than the preoperative measures.[20] Phalen showed up to 77% of patients returning to normal sensation postoperatively with subjective sensory function showing improvement within 10 days.[20] Using the same CTS Symptom Severity and Functional Status questionnaires to be used in this proposed study, Katz found surgically treated patients improved 1.2 to 1.6 points on the 5 point scale. The subjects were compared to those receiving non-operative care, not including OMT, which showed little change.[21]

Complications of carpal tunnel surgery include incomplete transection of the transverse carpal ligament, damage to structures including median nerve, ulnar nerve, palmar cutaneous branches, digital nerve, tendons, superficial arch, and the ulnar artery.[22] Patients complain of pillar pain, decreased strength, recurrence of symptoms, or diagnosis of another process. Patients with unsatisfactory results have either recurrence of symptoms or new symptom patterns. New diagnoses following surgery included de Quervain's tenosynovitis, lateral epicondylitis, and cervical pathology. These may have

symptoms as bad as CTS. Incomplete relief of symptoms is from the incomplete division of the flexor retinaculum. Scar formation and perineural fibrosis can cause recurrent nerve compression.[20] Although carpal tunnel surgery has been found to help many sufferers of CTS, due to the risks of surgery and the various complications, exploration of non-surgical treatments using the same outcomes measures is important.

Ultrasound in Research

Ultrasound therapy has been studied for its efficacy in treating carpal tunnel syndrome. Some of the OMT and chiropractic studies have used ultrasound as an adjunctive therapy.[4,11] Ultrasound treatment with an intensity range of 0.5-2.0 W/cm^2 induces biophysical effects in tissue. Ebenbichler et al. used an intensity of 1.0 W/cm^2, a frequency of 1MHz, and pulsed mode of 1:4.[23] Ultrasound has also been used as a placebo control in studies evaluating outcomes of physical medicine and osteopathic manipulative medicine. In using ultrasound as a placebo treatment, Deyle et al. set the intensity below the proposed therapeutic range at 0.1 W/ cm^2 with a 10% pulsed mode.[24] Using sub-therapeutic ultrasound as a placebo in this thesis study allows for similar patient contact time with a treatment which may be perceived as beneficial. Ultrasound also eliminates the dilemma of light touch, another popular choice for placebo in OMT research, as a believable sham with a population familiar with OMT.

Tools for Assessment

In 1993, Levine et al. published two self-administered questionnaires, Symptom Severity Scale (SSS) and Functional Status Scale (FSS) (see appendix). These questionnaires are designed to supplement other outcome measures of CTS treatments. A central focus of these questionnaires is on the symptoms and activities of daily living related to the CTS. The SSS and FSS are internally consistent with the cronbach alphas of 0.89 and 0.91 respectively. These instruments are valid because scores change in the expected direction when compared to more objective measures such as grip and pinch strength and sensory testing. The SSS and FSS are responsive to clinical change in subjects' pre and post surgery.[25] The Levine questionnaires have been used to evaluate outcomes in carpal tunnel surgery. Using the same tool in this thesis study maintains a consistent use of outcomes in evaluating treatments of CTS. Katz found that the SSS and FSS detected clinical change better than many more objective measures such as strength and sensory measurements.[21,26] This tool was also found to be a better measure for symptoms associated with CTS than more general questionnaires such as the SF-36 survey.[26,27]

Strength testing has been used to assess severity of carpal tunnel syndrome, and as an outcome measurement in carpal tunnel research. Clumsiness or dropping objects is a complaint among carpal tunnel patients with motor involvement. The thenar eminence may be atrophied in subjects with severe carpal tunnel syndrome. The abductor pollicis brevis is the muscle most often affected and therefore most often evaluated.[7] Muscle strength is evaluated on clinical exam, but more objective measures are used in research.

When Bonebrake evaluated grip strength and pinch strengths in carpal tunnel patients and in a non-CTS control group, he found significant differences in the two groups for grip strength and some of the pinch strengths (different pinch strengths than evaluated in this thesis study).[4] These measures improved for the CTS subjects following treatment with chiropractic manipulation and daily exercises. Grip and pinch strengths have also been used in comparison studies between open and endoscopic carpal tunnel release surgery.[28,29] Most studies use a standard dynamometer, however, research into special instrumentation to better measure the intrinsic muscles of the hand is being done.[30,31]

There are other tools available for sensory testing including Semmes Weinstein monofilament testing and vibrometry. Objective testing is not possible with sensory testing due to the reliance on patient perception. The Semmes Weinstein filament test is considered user friendly and is therefore a preferred method of testing. The test measures pressure sensibility. The calibrated vibrometer can quantify the nerve's adaptation to a vibration stimulus. Innervation density is tested using static or moving two-point discrimination testing. Normal is considered less than 6 mm.[7] It is one limitation of this study that sensation is not measured despite sensory fibers abnormal conduction earlier than motor fibers.

RESEARCH DESIGN AND METHODS

The purpose of this study is to examine whether OMT can improve daily functional status and decrease pain in persons with CTS.

Power Analysis

A power analysis was done in consultation with a biostatistician. For hypotheses 1 and 2, based upon means and standard deviations given in Levine et al.[25], an improvement of 30% in scores was anticipated in both symptom severity score (decrease) and functional status score (decrease). Analysis was done using 3.4 + 1.0 (mean + SD) for symptom severity and 3.0 + 1.1 (mean + SD) for functional status. Using a t-test to detect such a difference at the 0.05 level at 80% power, 17 and 19 subjects per group were needed. Taking into account attrition and the statistical needs for the electrodiagnostic dimension of the study, 25 subjects per group would be needed.

Design and measurements

The protocol goal was for 50 subjects (25 each) assigned in a random fashion to two treatment groups. One group (group A) received OMT to the general areas of the arm, shoulder, neck and back in addition to any current or concurrent standard care as outlined

by the subject's primary care physician. The control group (group B) received a placebo treatment of sub-therapeutic ultrasound to the same areas in addition to any current or concurrent standard care outlined by the subject's primary care physician. The ancillary effects of a placebo were evaluated in this study by a direct comparison between treatment and placebo groups. The research coordinator collecting the outcome measures and the data entry was blinded to the subject's treatment group. Subjects were scheduled to be seen a total of 10 times with 6 treatment sessions.

Hypothesis 1: OMT will decrease pain and improve other symptoms of CTS patients measured by the Carpal Tunnel Symptom Severity Questionnaire and the visual analog pain scale.

Symptoms associated with CTS were measured by the Symptom Severity questionnaire designed by Levine et al. in 1993. The subject rated their symptoms severity over a two week period from 1, no symptoms, to 5, very severe symptoms. The questionnaire was completed by subjects three times during the 10 week study, at visits 3, 6, and 9. The overall symptom severity score was calculated as the mean of all items answered.[25] Pain was measured with the visual analog scale, with pain rated from 1 to 10, ten being the highest, before and after each treatment.

Hypothesis 2: OMT will improve the daily functioning level of subjects with CTS as measured by the Functional Status Questionnaire and grip and pinch strength.

Daily functioning is defined as the ability of the person to manage day-to-day tasks of dressing, caring for oneself, handling items necessary for daily activities, strength, and stamina. The daily functioning of the subjects was measured by the Functional Status Questionnaire developed by Levine et al. in 1993. This tool assesses the activities of daily living specifically related to the use of the hands and therefore carpal tunnel syndrome. This questionnaire is also designed to be given every two weeks and was administered three times during this study (visits 3, 6, and 9). The overall functional status score was calculated as the mean of all items answered.[25] The question regarding handwriting was left unanswered if the subject's non-dominant hand was treated.

Pinch and grip strength were objective measures that mimic actions that a subject would use in daily activities. Grip strength was tested using a Jamar Dynamometer which measures up to 200lbs (91kg). All measures were taken with the elbow flexed to ninety degrees and the wrist in neutral position. The patient was sitting with no support under the arm being tested. Grip strength measures were done at 1.5" (second position) which is the grip distance needed to hold many household items, such as a telephone and tools. [32] Three consecutive measurements were recorded.

The three positions key, tripod, and tip pinch strength measurements also mimic daily activities. Key (palmar or lateral) pinch is appropriately named because it uses the action necessary to hold a car or house key. The tripod (3 jaw or 3 point) pinch evaluates the position necessary to open and close buttons on an article of clothing. Finally, the tip (pulp or ok) pinch is used in many actions like turning the pages in a book. Measurements were taken with the elbow was at ninety degrees and the wrist in neutral

position with no support under the arm being tested. Three consecutive measurements of key pinch, tripod pinch, and tip pinch were recorded.[32] The pinch gauge has a range from 0 to 30lbs (14 kg).

Subject Recruitment

Subjects were recruited by referral from the University of North Texas Health Science Center (UNTHSC) Internal Medicine clinic, Family Medicine clinics, and through campus advertising to staff and students at the. Advertising to the community at large was also done through the local newspaper. Once subjects were recruited for the study, written informed consent for the research protocol was obtained.

Inclusion and Exclusion Criteria

Inclusion criteria for participation in this study was: 1) age 21 to 70; 2) clinical diagnosis of carpal tunnel syndrome; 3) changes in nerve conduction studies consistent with CTS: median nerve sensory peak latency greater than 2.2 ms, a difference between median and ulnar sensory peak latency greater than 0.3 ms, median nerve motor distal latency greater than 4.2 ms, and/or a difference between median and ulnar motor distal latency greater than 1.5 ms.[5] Nerve conduction studies (NCS) used to verify that subjects met the electrodiagnostic inclusion criteria for CTS. Nerve conduction studies were used as inclusion criteria in this study for two reasons, (1) to ensure that there is an increase in the median nerve latency across the carpal canal, making the etiology of compression at

this site more likely, and (2) to facilitate the study of subjects with abnormal NCS when studying the electrodiagnostic dimensions of CTS.

Exclusion Criteria for participation in this study was: 1) severe CTS that has progressed to muscle atrophy; 2) pregnancy; 3) previous wrist surgery; 4) thoracic outlet syndrome; 5) systemic diseases which include, but are not limited to: diabetes mellitus, thyroid disorders, rheumatoid arthritis, Paget's bone disease, gout, myxedema, multiple myeloma, acromegaly, hepatic disease, dialysis patients, and other disease in which peripheral neuropathies are common, and 6) secondary causes for CTS found on MRI including, but not limited to, ganglion cysts, mass, or accessory muscle.

After acceptance into the study protocol, subjects were randomly assigned to one of the two treatment groups and subject demographics were recorded. All clinic visits and treatment sessions took place in the Osteopathic Manipulative Medicine (OMM) clinic. All MRI was done at Monticello Diagnostic Imaging Center which is located two blocks from the OMM clinic. No subjects had MRI contraindications and all subjects were able to participate in all portions of the study. One subject was excluded due to a MRI finding of tenosynovitis. Participants were reimbursed $10 for each visit to the OMM clinic and Monticello Diagnostic Imaging Center.

Protocol

The majority of the assessment and treatment of subjects was done by the two predoctoral fellows (PDF) responsible for the study. However, a small number of subjects were treated by an OMM faculty member instead of the student researchers. The

operator provided both OMT and sub-therapeutic ultrasound. All subjects were directed not to disclose details of their treatment group status to the research coordinator collecting the data. The subjects received OMT or sub-therapeutic ultrasound during the 3rd through 8th visit as outlined in the Experimental Protocol Schedule (Table 3).

Group A (OMT Treatment Group)

Each subject was scheduled for 6 treatments, one per week. Each session lasted approximately 30 minutes. The wrist and forearm treatments were standardized, while more proximal areas were treated according to student or physician preference.

1. Wrist: The wrist and the area of the carpal canal are considered the major site of pathology in CTS, therefore standard treatments to this area were utilized by all operators. Somatic dysfunction in this area may lead to compression of the carpal canal and increased pressure within it, thus affecting the median nerve. Treatments were as follows:
    a. Myofascial release of transverse carpal ligament or Opponens roll – The operator applies outward pressure at the medial and lateral attachments of the carpal ligament while pushing up on the dorsal surface of the carpal bones. The operator's fingers can be interlocked with the pinky finger and thumb of the subject to apply additional stretch.[10]
    b. Squeeze technique – The operators palms are placed on either side of the subject's carpal bones/wrist. While applying pressure through the palms

and distal traction the subject's wrist is articulated through its range of motion.[33]

c. Ligamentous articular strain – The operator takes the subject's wrist to the limit of supination and flexion. While maintaining pressure through the thumb and traction through the fifth metacarpal, the wrist is taken through its range of motion.[34]

2. Forearm: The path of the median nerve continues through the forearm between the two heads of the pronator teres muscle. The interosseous membrane connects the radius and ulna and may lead to dysfunction where the radius interacts with the carpal bones.

   a. Myofascial release of the interosseous membrane – Through monitoring at the elbow and wrist, the tensions in the interosseous membrane are either balanced directly or indirectly, and the operator waits for a release. Direct balance engages the restrictive barrier, while indirect forces balance at *the point of ease* or least resistance.[33,35]

   b. Counterstrain – The treatment of a tenderpoint caused by an inappropriate pain reflex is done by taking the muscle into a position opposite the reflex. Point tenderness is monitored for success of treatment.[35]

3. Shoulder girdle (first rib, supraclavicular fascia, clavicle and pectoralis minor): The brachial plexus passes between the clavicle and the first rib. Restriction in these structures may lead to compressive effect on the brachial plexus. The pectoralis minor muscle crosses anterior to the brachial plexus as well as the

vascular supply and lymphatic drainage to the upper extremity. The lymphatic drainage to the extremities also passes through the supraclavicular fascia, sometimes called Sibson's fascia, on each side of the body. Therefore, dysfunction in these areas can directly affect the median nerve as a part of the *double crush phenomena*, or the dysfunction can affect the efficacy of lymphatic return resulting in edema and stasis of interstitial fluids.[13]

a. Pectoralis minor muscle – The operator uses direct pressure on the muscle in either the seated or supine position.
b. Clavicle – The operator uses indirect method in either the seated or supine position for treatment.
c. First rib – The operator may use any number of techniques including muscle energy, facilitated positional release (FPR) or high velocity low amplitude (HVLA) technique.

OMT Treatment Protocol	
Wrist	Ligamentous Articular Strain Opponens Roll Articulation with Traction (Squeeze Technique)
Interosseous Membrane Forearm Tenderpoints	Myofascial Release Counterstrain
Pectoralis Minor Clavicle First Rib Supraclavicular fascia Thoracic Spine: T1-T8 Cervical Spine	Ligamentous Articular Strain Muscle Energy Facilitated Positional Release Indirect Articulatory High Velocity Low Amplitude Myofascial Release Counterstrain

Table 2: OMT Treatment Protocol

d. Supraclavicular fascia – Direct myofascial release or a combination of supraclavicular and infraclavicular ligamentous articular strain techniques were used.[33,34]

4. Spine: The brachial plexus originates in the cervical spine from C5-C8 and T1. These nerves, in turn, contribute to the median nerve. The thoracic spine provides the sympathetic innervation to the upper extremity. Therefore dysfunction from vertebrae T2-T8 may have an effect on the upper extremity. Increased sympathetic tone may contribute to vasoconstriction and lymphatic constriction within the extremity leading to decreased lymphatic drainage. No specific techniques were required for these regions. The operator was able to choose techniques that worked best for him/herself and for the subject. Technique choices may include HVLA, muscle energy, FPR, myofascial release, indirect technique, articulation, and counterstrain.

Group B (Placebo, Ultrasound Treatment Group)

Placebo groups are an important component in modern clinical research designs. OMT may generate various intentional positive benefits including biomechanical, fluid or neurological outcomes. OMT may also, however, generate a positive clinical response because of ancillary effects from: 1) increased physical contact ("the power of touch"); 2) greater attention and interaction with the treating physician; 3) an expectation of a therapeutic effect. A placebo group is warranted to consider the influence of these possible effects. The subtherapeutic ultrasound treatment provided genuine anticipation

of therapeutic effect, allowed for tactile stimulation over the same anatomical distribution as provided in the OMT treatment group, and provided for similar time and attention as provided in the OMT treatment group.

Sub-therapeutic ultrasound treatments were used over identical regions as addressed in the OMT treatment group for three to five minutes per area. All treatments lasted approximately 30 minutes in an effort to match the time spent with the OMT group. Ultrasound placebo treatments were applied through the subject's clothes, and settings were at the lowest setting, close to zero and below an intensity of 0.1 W/cm^2 and 10% pulsed mode previously used for sub-therapeutic ultrasound.

Protocol Schedule

Table 3 provides a schedule for the protocol to be used in this study. Subjects were seen a total of 10 times with 6 visits being for treatment.

Protocol Schedule								
Session	1	2	3	4-5	6	7-8	9	10
Group A OMT	Consent Demo-graphics NCS	MRI	Strength SFQ OMT	OMT	Strength SFQ NCS OMT	OMT	Strength SFQ NCS	MRI
Group B Placebo	Consent Demo-graphics NCS	MRI	Strength SFQ PST	PST	Strength SFQ NCS PST	PST	Strength SFQ NCS	MRI

Table 3: Study Protocol Schedule
NCS: Nerve Conduction Studies
MRI: Magnetic Resonance Imaging
SFQ: Symptom & Function Questionnaire
PST: Placebo Sub-ultrasound Treatment
OMT: Osteopathic Manipulative Treatment

RESULTS

Introduction

Subjects were ruled into the study based upon a clinical diagnosis of CTS and specific nerve conduction study criteria. Only one person was eliminated following NCS for findings on MRI consistent with tenosynovitis. Thirty-seven subjects began the study, with five failing to complete the study. These five subjects were eliminated from the data analysis, leaving 32 subjects in the analysis. The analysis includes demographic results, relationships between age, BMI, severity if the disease, and outcome measures, and hypothesis testing. A combination of exploratory data analysis and specific statistical tests was performed.

Demographics

The study population was mostly female (72%), right handed (87%), with both hands being affected by carpal tunnel syndrome (84%). During the study the right hand was treated in 56% of subjects and the left hand in 44% of subjects. In over half (68%) of the cases the hand being treated was also the subject's dominant hand.

The OMT group consisted of 14 subjects (5 male and 9 female), while the ultrasound group was 18 subjects (4 male and 14 female). Chi square tests were used to establish that there was no significant difference in gender, dominant hand or hand treated between the OMT and ultrasound groups. The p values using Fisher's exact test were 0.453,

0.565, and 0.721 respectively. In order to test the difference in the groups for dominant hand, one subject, who was ambidextrous, was removed from the calculation.

Age

The average age for the study population was 45.7 years old. The OMT group had a mean age of 42 years, while the ultrasound group's mean age was 48.7 years. The boxplot (appendix, figure 9) shows the OMT group to have a wider range of ages despite the means being close to that of the ultrasound group. The ultrasound group has a tighter range. Analysis using an independent t-test showed that the mean ages of the two groups were not significantly different, $p = 0.146$. The relationship of age to the outcome measures at baseline was also explored through scatterplots and pearson coefficient (appendix, figures 26-31), and no linear relationship was found.

Body Mass Index

Analysis of BMI was also done to explore any relationship with CTS symptoms. The average BMI for the study population was 30.3. The mean BMI for the OMT group was slightly less than that of the ultrasound group, 29.3 and 31.0 respectively. A person is considered overweight when the BMI is between 25 and 29.9 and obese when the BMI is greater than or equal to 30. The study population is at the border between overweight and obese. The two groups were not shown to be significantly different when compared using an independent t-test, $p = 0.523$. Pearson correlation coefficients were used to determine if BMI was associated with outcome measures at baseline. Only a small

positive correlation between BMI and symptom severity scores (pearson coefficient of 0.392, $p = 0.035$) and functional status scores (pearson coefficient of 0.379, $p = 0.043$) was found.

Time Since Diagnosis

The length of time (years since dx) that a subject has had the syndrome could also be relevant to the study outcome. The histogram shows this variable to have a positively skewed distribution curve (appendix, figure 13). The majority of subjects had been diagnosed less than a year. The average time since diagnosis was 3.37 years for the entire study population. The OMT group has a lower average time at 2.71 years compared to 3.87 years for the ultrasound group. Once again there is no significant difference between the two groups when compared by an independent t-test, $p = 0.505$. When looking at the boxplot the percentile ranges are similar, but ultrasound has four subjects above the 75th percentile compared to 2 in the OMT group (appendix, figure 8). It is interesting to note one subject consistently above the 75th percentile in the strength measures also has the shortest time since diagnosis at 0.08 years or 1 month. Pearson correlation and scatterplots do not show a linear relationship between the length of time since diagnosis and the severity of symptoms, decrease in function or strength measures (appendix, figures 20-25).

Nerve Conduction Studies

All subjects were ruled into the study using NCS. Subjects were rated minimal, mild or moderate CTS. The mean initial median motor latencies for the two groups did differ significantly, $p = 0.047$. The OMT group average motor latency was faster than that of the ultrasound group. The median sensory latency measures did not differ significantly. Correlation analysis showed positive correlation between the median motor latency measures and the symptom severity and functional status scores, pearson coefficient of 0.437 and $p = 0.014$ and pearson coefficient of 0.418 and $p = 0.019$ respectively.

Hypothesis Testing

Hypothesis 1: OMT will decrease pain and other symptoms of CTS patients measured by the Carpal Tunnel Symptom Severity Questionnaire and the visual analog pain scale.
Hypothesis 2: OMT will improve the daily functioning level of subjects with CTS as measured by the Functional Status Questionnaire and grip and pinch strengths.

The primary outcome measure for hypothesis one is the symptom severity questionnaire scores and for hypothesis two is functional status questionnaire scores. The scores are created by adding the answers together and dividing by of the total number of questions answered. In subjects where the dominant hand was not the hand treated, the first question of functional status questionnaire which addresses the subject's ability to write was omitted. A lower score on the 1 – 5 scales means the subject has less severe symptoms or less of a decrease in function. The reliability of the questionnaires was tested using the initial data with symptom severity having a cronbach's alpha of 0.797

and functional status having a cronbach's alpha of 0.881. Both initial symptom severity scores and functional status scores were found to have a bimodal distribution (appendix, figures 18-19).

The visual analog pain scale is the secondary outcome measure for hypothesis one and will be discussed later. Secondary outcome measures for hypothesis two include grip strength, key pinch strength, tripod pinch strength, and tip pinch strength. Three trials for each strength measure were done at the beginning, middle, and end of the study, and all were in pounds. There was some debate between using the best trial in each case or the average of the three trials. In testing strengths in healthy individuals, Mathiowetz et al. found the greatest test-retest reliability in using the average of three trials.[32] A paired t-test was done comparing the average and the best of the three trials for the baseline strength measures. There was no significant difference between the average of the trials and the best trial for any of the strength measures. Therefore, the average was used for all subsequent analysis.

Using strength norms from Mathiowetz et al. a comparison of baseline strength measures for this study's subjects to age, gender, and hand matched healthy subjects found in the literature was done. For all strength measures (grip, key pinch, tripod pinch, and tip pinch), the subjects of this study were significantly weaker strengths than the strengths of the healthy subjects. While the final strength measures were closer to the norms, they were still significantly less in all cases. In all strength measures for these subjects the females have significantly lower strength than the males.

Relationships between outcome measures at baseline were explored using scatterplots and pearson correlation coefficients (appendix, figures 32-46). Strong positive correlation was found between all of the strength measures. There was also a negative correlation between functional status scores and the strength measures. Functional status scores and symptom severity scores had a positive correlation. For measures taken at times two and three, all strength measures (grip, key pinch, tripod pinch, and tip pinch) were positively correlated, and strength measures were negatively correlated with functional status scores. Symptom severity scores taken at time three were also negatively correlated to strength measures. As strength measures increased, the symptom severity and functional status scores decreased, therefore when the subjects said they felt and functioned better they were also stronger.

Symptom Severity Scale

An independent sample t-test found no significant difference on baseline symptom severity scores between OMT and ultrasound groups. A boxplot of symptom severity scores show outliers in both OMT and ultrasound for time 3 (appendix, figure 51). A bar graph shows that the mean symptom severity scores for both OMT and ultrasound improved throughout the trial (figure 1). A paired t-test analysis of each group from time 1 to time 3 showed significant change, for OMT ($p = 0.012$) and for ultrasound ($p = 0.010$). ANCOVA analysis was performed using time 3 as the dependent variable and time 1 as the covariate. This showed no significant difference between OMT and ultrasound at time 3 controlling for time 1, $p = 0.301$.

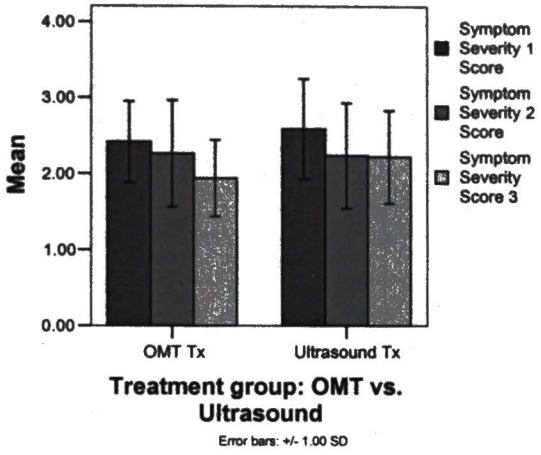


Figure 1: Symptom Severity Scores

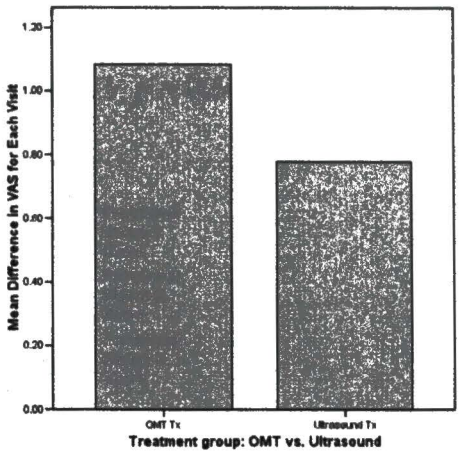


Figure 2: Visual Analog Scale

Visual Analog Scale

Pain was also measured using the Visual Analog Scale (VAS) before and after every treatment. VAS scores decreased in both groups from pre to post treatment over time (appendix, figure 53-54). The average change from pre to post-treatment in the OMT group was 1.083 and 0.778 for the ultrasound group. The means were compared between ultrasound and OMT with an independent sample t-test. While the OMT group had a larger average pain score decrease than the ultrasound group, it was not significantly different ($p = 0.341$) (figure 2).

Functional Status Scale

The baseline functional status scores between OMT and ultrasound were not significantly different ($p = 0.416$). Mean functional status scores changed for both OMT and ultrasound throughout treatment (figure 3). The t-test of the different means from time 1 to time 3 for OMT was significant at $p = 0.019$, but not significant for ultrasound

with $p = 0.092$. The ANCOVA did not show that the change was significant between the OMT and ultrasound groups at time 3 controlling for time 1, $p = 0.663$.

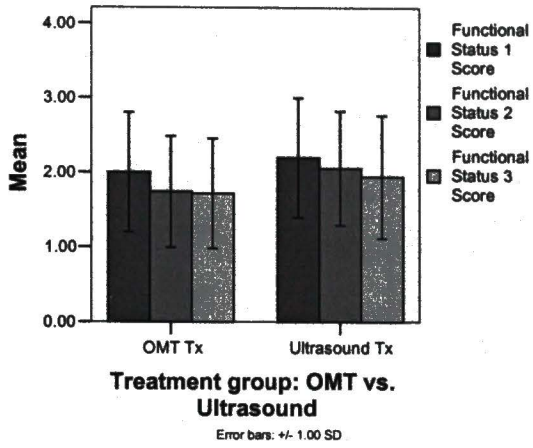


Figure 3: Functional Status Scores

Strength Measures

Strength measures were taken to provide a more objective measure of the subject's functioning. Improvement would be shown by increases in the strength measures, and all strength measures were reported in pounds. The four strength measures did not improve at every interval over time (figures 4-7). However, all strength measures improved from measure 1 to measure 3, except for grip strength in ultrasound group. ANCOVA tests were not significant for any of the strength measures. Grip strength, however, could be clinically important, $p = 0.074$. Independent t-tests were performed for each measure. Grip strengths between OMT and ultrasound were significantly different for times two and three with p values of 0.042 and 0.049 respectively. The means for the OMT group changed significantly from measure one to measure two, and from measure one to measure three with p values of 0.003 and 0.013 respectively. The change from measure two to measure three was not significant ($p = 0.223$). There was no significant change

over each interval for ultrasound. Both pinch and tripod pinch strength changed significantly from time one to three for the ultrasound group, p values of 0.010 and 0.034 respectively, while the OMT did not have significant change. Neither group's tip pinch changed significantly from time one to three.

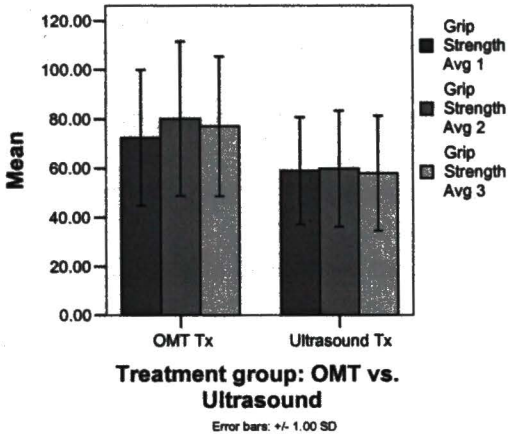


Figure 4: Grip Strength

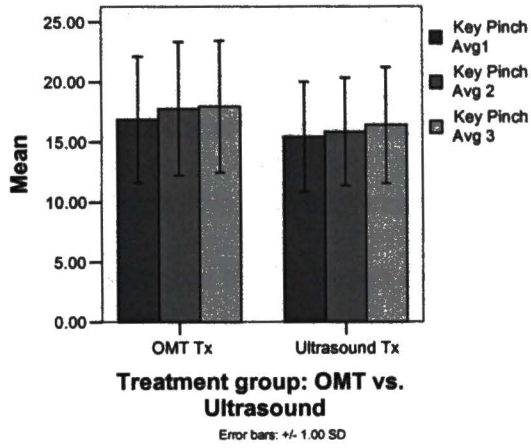


Figure 5: Key Pinch Strength

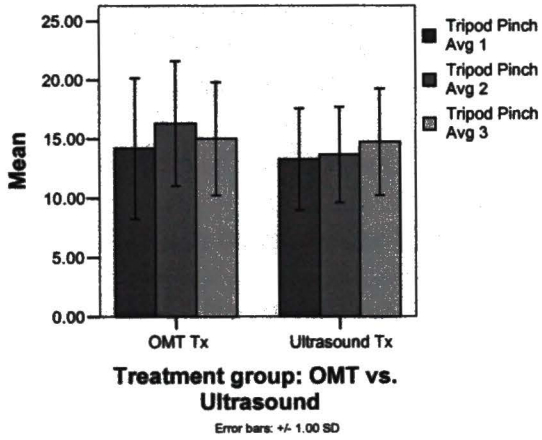


Figure 6: Tripod Pinch Strength

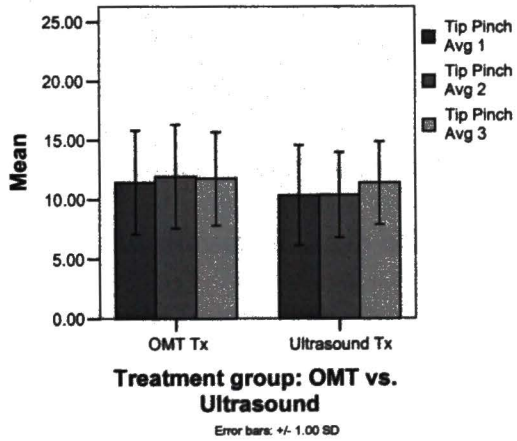


Figure 7: Tip Pinch Strength

DISCUSSION

The goal of this study was to evaluate the benefits of OMT in treating persons with CTS. The placebo control design allowed direct comparison between the treatment group and the sub-therapeutic ultrasound group. Data from thirty-two subjects were analyzed in this study. This is below the number of subjects (42) required by the power analysis. The lack of adequate power decreases the generalizability of the study and to some extent the strength of the statistical analysis tools, and therefore exploratory data analysis was also used to illustrate trends within the data.

The study population was similar to CTS patients described in the literature. This population is mostly female, and the average age of 45 years fits well within the described range of 30-60 years. The two groups were similar to each other in average age, BMI, length of time since diagnosis. However, the ultrasound group had more individuals who had the diagnosis longer than did the OMT group. The groups did not have similar average median nerve latency measures. The ultrasound group had a more severe disease level according to this measure. One might expect the ultrasound group to have less response because of the group make-up.

Hypothesis 1 states that OMT will decrease pain and other symptoms of CTS patients measured by the Carpal Tunnel Symptom Severity Questionnaire and the visual analog pain scale. Although subjects' self reported symptoms decreased significantly

over time, they did so for both OMT and ultrasound. There was no significant difference between the two groups over time. Subjects may have felt better due to natural regression of the disease process or because of the placebo effect. There was a larger change in VAS scores in the OMT group following each treatment session, but the difference between groups was not significant.

Hypothesis 2 states that OMT will improve the daily functioning level of subjects with CTS as measured by the Functional Status Questionnaire and grip and pinch strengths. In the case of functional status scores, the OMT group significantly improved over time while the ultrasound group's scores improved somewhat, but not significantly. Again the difference between the two groups was not significant. For the more objective strength measures, only grip strength showed significant changes for the OMT group and clinically important changes between the two groups.

When looking at the data and analysis more, questions arise for subsequent research. First, a major limitation of the study is numbers. The study is below its desired *N*. Larger numbers would alleviate some of the variations in this small data sample and allow better statistical conclusions to be drawn. A power analysis was done on the two primary outcome measures, symptom severity scores and functional status scores, from this study. Using an effect size calculated from symptom severity score means (d = 0.967), a sample size of 18 subjects per group is necessary to achieve a statistical power of 0.80, using a significance level of 0.05. Using an effect size calculated from functional status means (d = 0.421), a sample size of 90 subjects per group is necessary to

achieve a statistical power of 0.80, using a significance level of 0.05. Therefore, a follow up study would require 180 subjects.

This study used one OMT treatment protocol. In an effort to standardize the study, we limited the number of treatment sessions and created a standard treatment protocol. In an actual patient treatment situation, treatment may vary based on that individual. Given differences in time that individuals had CTS and the severity of their disease process, six treatments over six weeks may not be adequate. Where some subjects may have shown mild improvement during the study more treatments may be necessary for significant change. In practice, OMT is also very individualized, and given the Osteopathic principle describing the interconnectedness of the structure and function of the body, treating only into the thorax may not have been adequate for certain subjects. A somatic dysfunction elsewhere along the spine or pelvis may affect an individual's ability incorporate change from OMT at the areas treated in the study.

An argument could also be made against using medical students in the treatment of subjects. A physician with more clinical experience may provide more effective treatment. Efforts were made to reduce this argument as a limitation by having frequent training sessions with the PDFs and the faculty principle investigator. Although a faculty member provided treatment in this study, he did not treat enough subjects to compare with those treated by the students.

Strength measures, with the exception of grip strength, did not show progressive improvement. A possible explanation for this difference from previous studies may be because those studies prescribed strength exercises in addition to manual treatment. This

trial only addresses OMT. While some improvement was shown with grip strength, the pinch strength measures, which involve more intrinsic hand muscles, did not show significant improvement. Based on the current data one may conclude that OMT alone will not increase hand strength, but a full Osteopathic approach including at home stretching and exercise may be necessary.

Another limitation of this study design was the lack of sensory measures. Sensory changes appear first both clinically and in NCS in CTS patients. When studying subjects who have mild to moderate disease, sensory outcome measures may provide a better tool for evaluating earlier changes.

Overall, this study shows some positive trends in the treatment of CTS with OMT. Graphically the OMT group showed significant improvement over time for symptom severity scores and functional status scores. Subjects related a decrease in pain after treatment with OMT. However, these trends are not shown to be significantly different from changes found in the placebo group. Based on the data from this study, an N of 180 subjects would allow for more statistical power. Additional questions raised in this study may be addressed in subsequent protocols, and larger subject numbers may allow for a more conclusive analysis.

APPENDIX

Symptom Severity Scale

Instructions:
The following questions refer to your symptoms for a typical 24 hour period during the past two weeks. (Circle one answer to each question.)

(1) How severe is the hand or wrist pain that you have at night?
1. I do not have hand or wrist pain at night
2. mild pain
3. moderate pain
4. severe pain
5. very severe pain

(2) How often did hand or wrist pain wake you up during a typical night in the past 2 weeks?
1. never
2. once
3. 2 or 3 times
4. 4 or 5 times
5. more than 5 times

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

(4) How often do you have hand or wrist pain during the daytime?
1. never
2. once or twice a day
3. 3 times a day
4. more than 5 times a day
5. The pain is constant.

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

(6) Do you have numbness (loss of sensation) in your hand?

1. no
2. I have mild numbness
3. I have moderate numbness
4. I have severe numbness
5. I have very severe numbness

(7) Do you have weakness in your hand or wrist?

1. no weakness
2. mild weakness
3. moderate weakness
4. severe weakness
5. very severe weakness

(8) Do you have tingling sensations in your hand?

1. no tingling
2. mild tingling
3. moderate tingling
4. severe tingling
5. very severe tingling

(9) How severe is numbness (loss of sensation) or tingling at night?

1. I have no numbness or tingling at night
2. mild
3. moderate
4. severe
5. very severe

(10) How often did hand numbness or tingling wake you up during a typical night during the past 2 weeks?

1. never
2. once
3. 2 or 3 times
4. 4 or 5 times
5. more than 5 times

(11) Do you have difficulty with grasping and use of small objects such as keys or pens?

1. no difficulty
2. mild difficulty
3. moderate difficulty
4. severe difficulty

5. very severe difficulty

Functional Status Scale

Instructions:
On a typical day during the past week have hand and wrist symptoms caused you to have any difficulty doing the activities listed below?

Activities	No Difficulty	Mild difficulty	Moderate Difficulty	Severe Difficulty	Cannot Do at All
Writing	1	2	3	4	5
buttoning of clothes	1	2	3	4	5
holding a book while reading	1	2	3	4	5
gripping of a telephone handle	1	2	3	4	5
opening of jars	1	2	3	4	5
household chores	1	2	3	4	5
carrying grocery bags	1	2	3	4	5
bathing and dressing	1	2	3	4	5

Responses:
1. no difficulty
2. mild difficulty
3. moderate difficulty
4. severe difficulty

5. cannot do at all due to hand or wrist symptoms

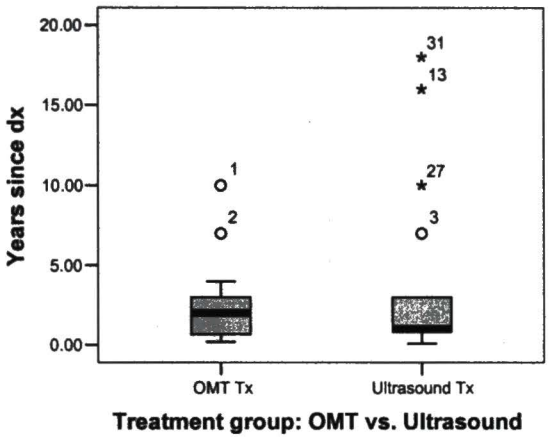


Figure 8: Boxplot Years Since Dx

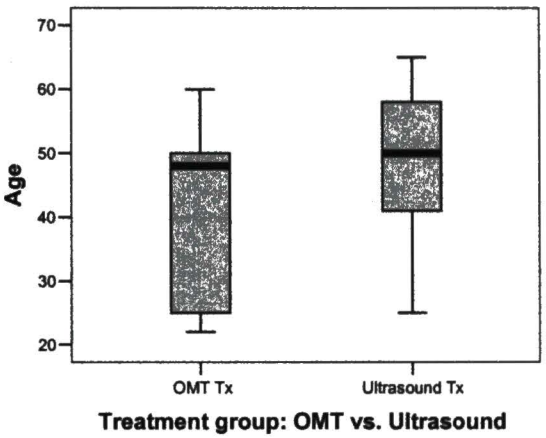


Figure 9: Boxplot Age

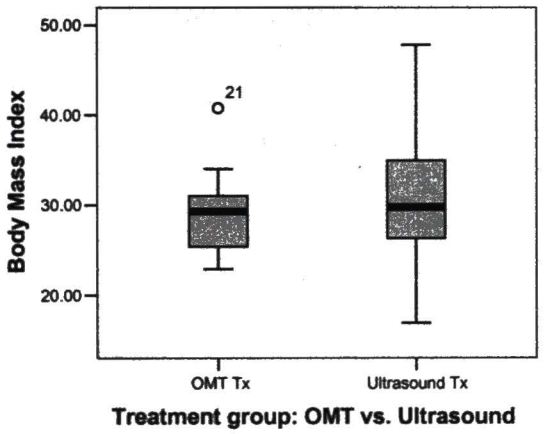


Figure 10: Boxplot BMI

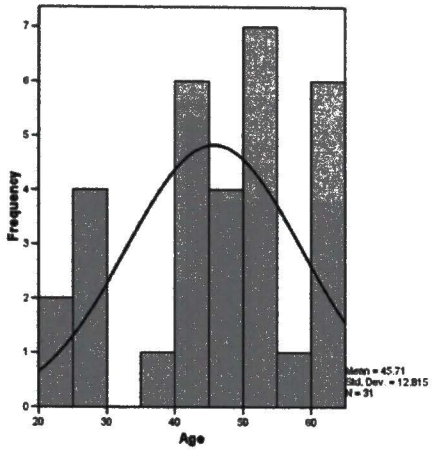


Figure 11: Histogram Age

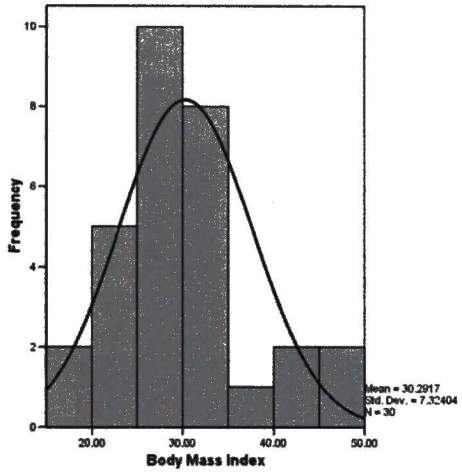


Figure 12: Histogram BMI

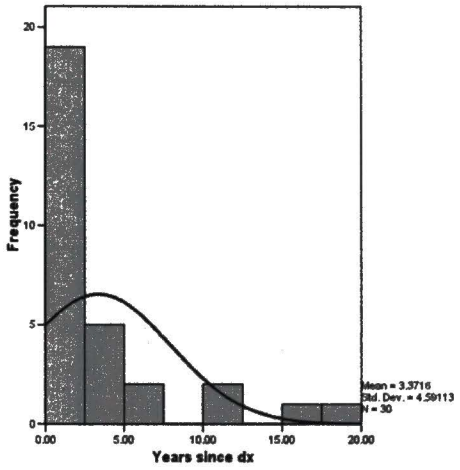


Figure 13: Histogram Years Since Dx

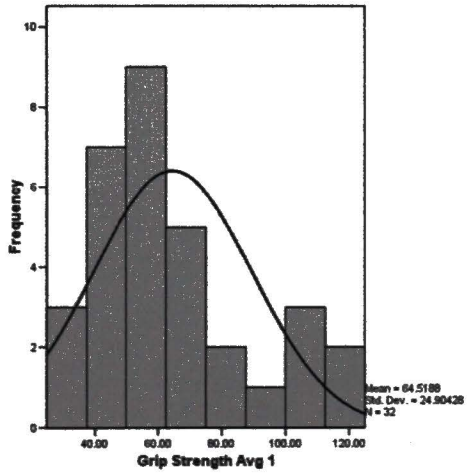


Figure 14: Histogram Grip Strength

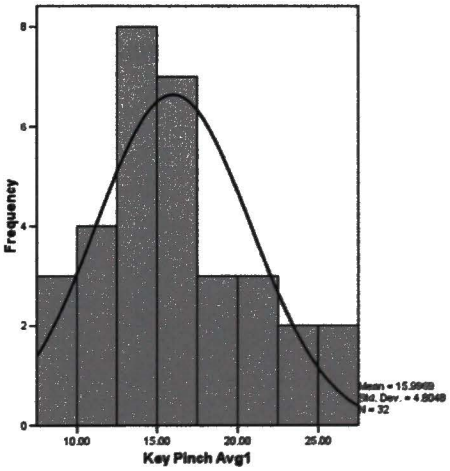


Figure 15: Histogram Key Pinch

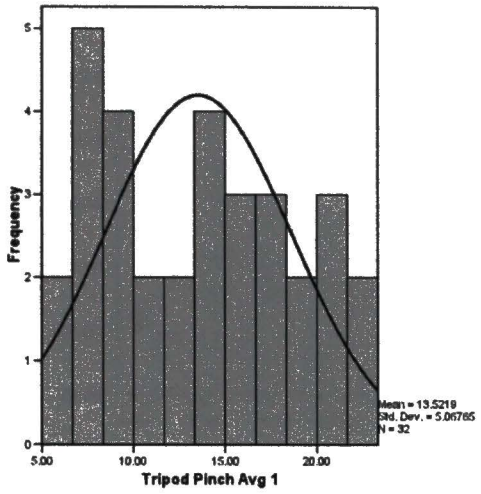


Figure 16: Histogram Tripod Pinch

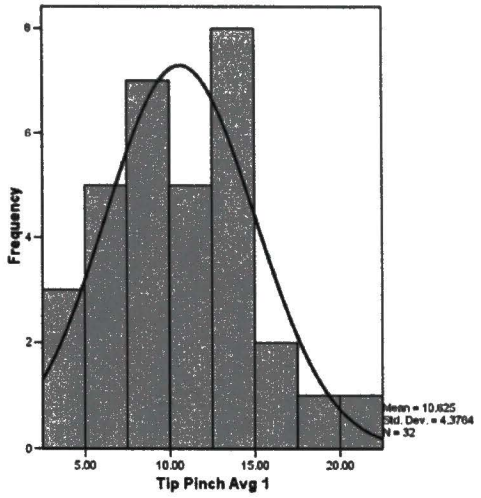


Figure 17: Histogram Tip Pinch

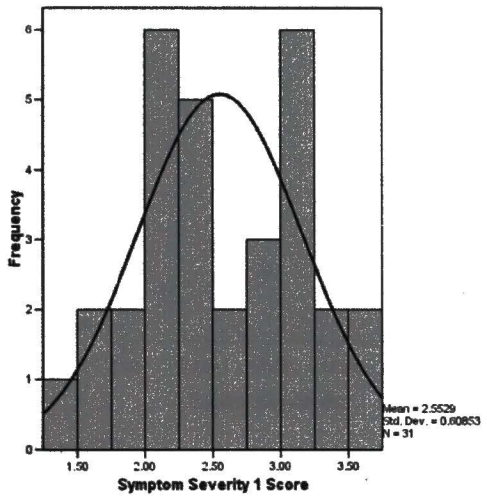


Figure 18: Histogram Symptom Severity

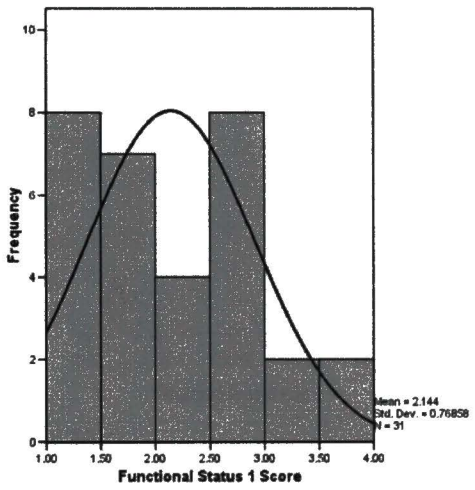


Figure 19: Histogram Functional Status

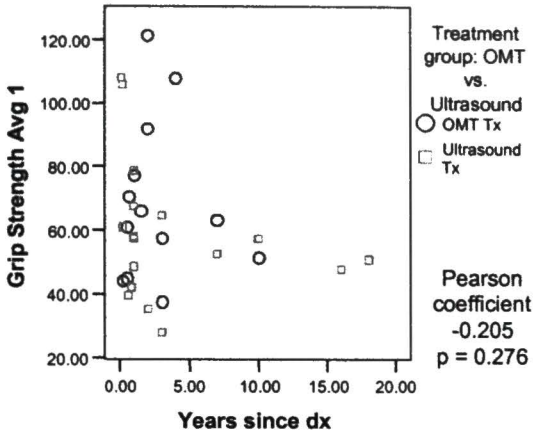
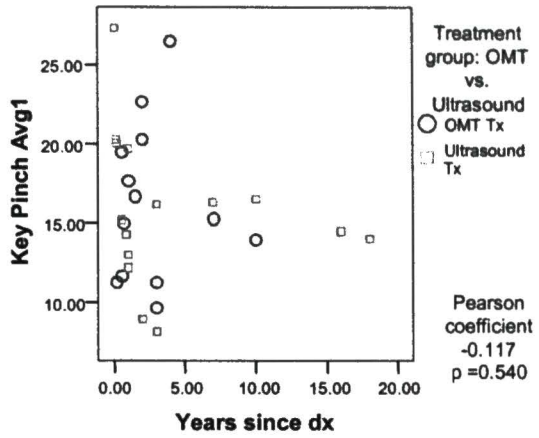


Figure 20



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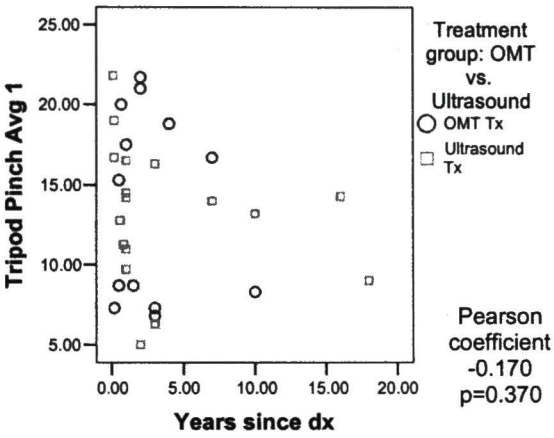

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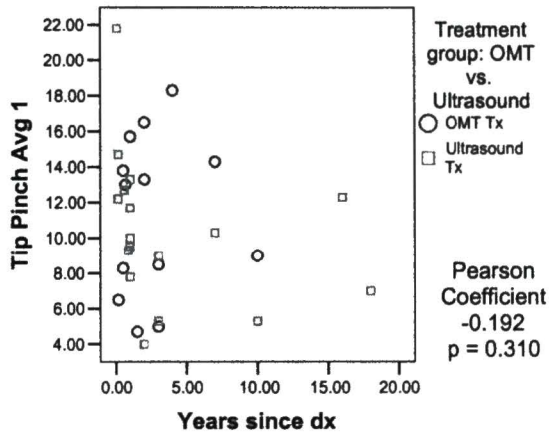


Figure 23

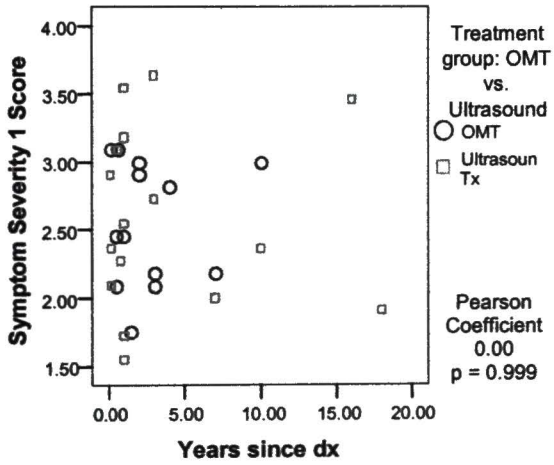


Figure 24

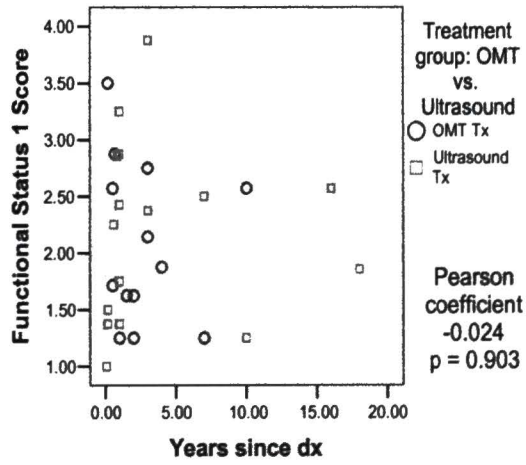
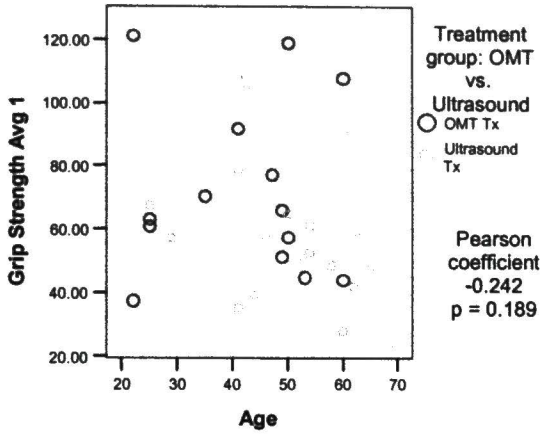


Figure 25



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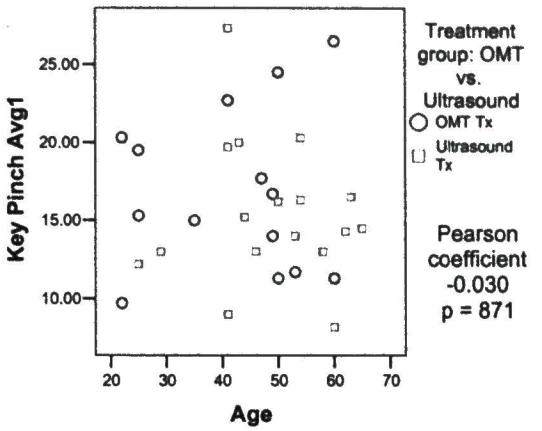

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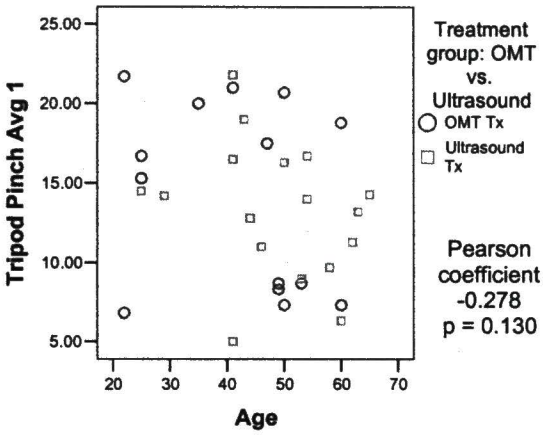

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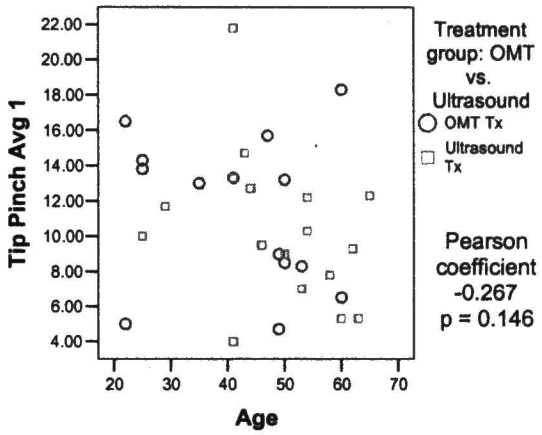

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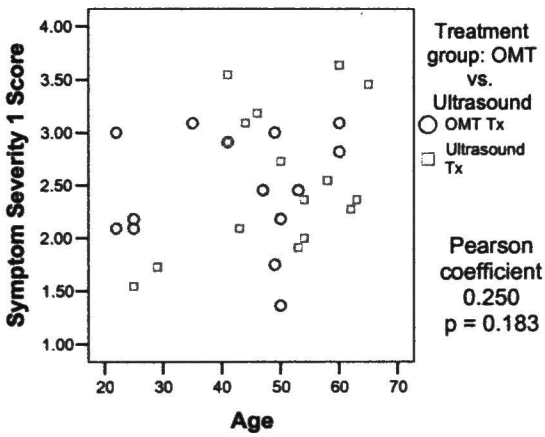

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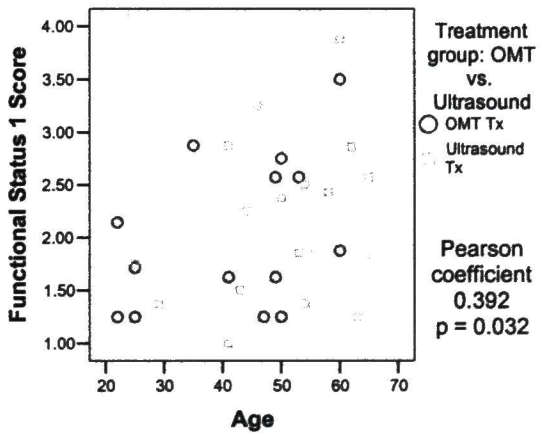

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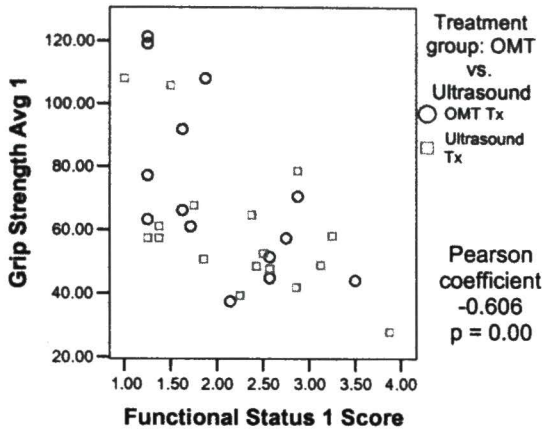

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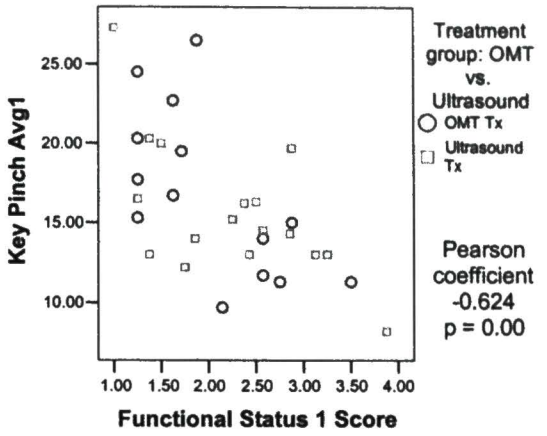

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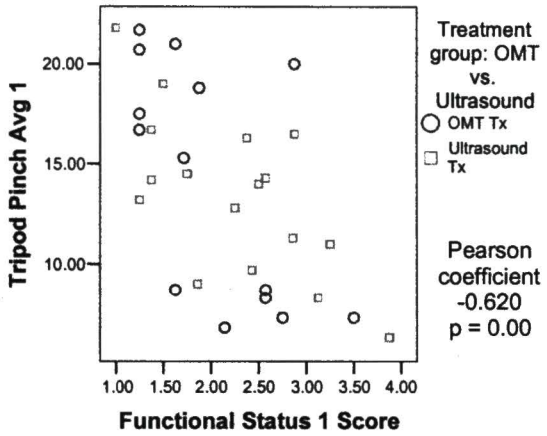

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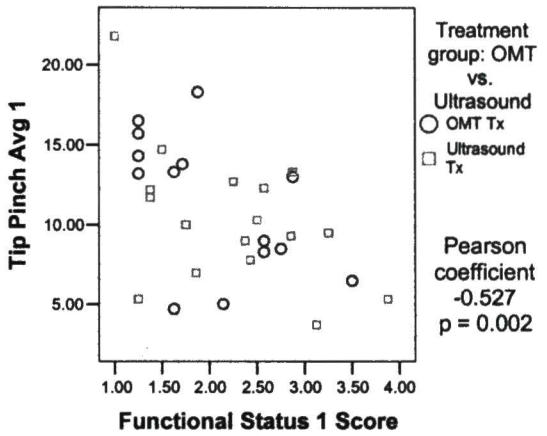

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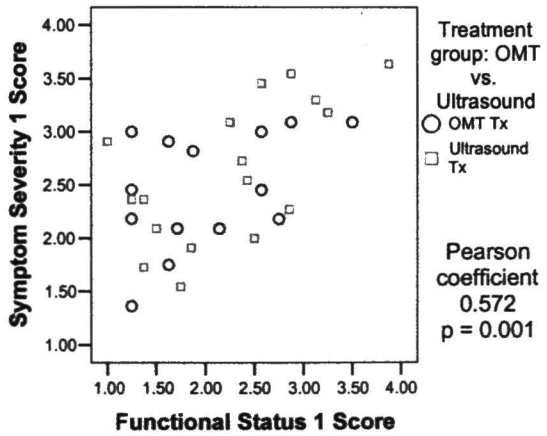

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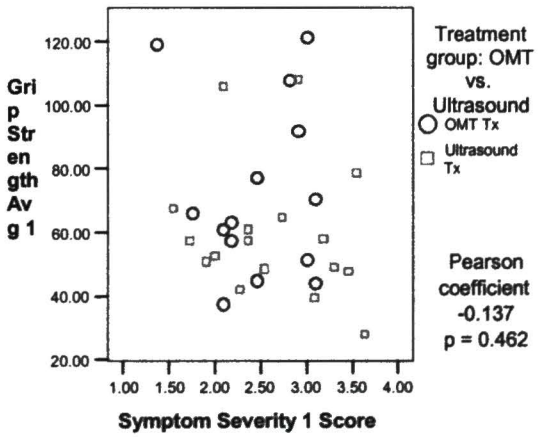

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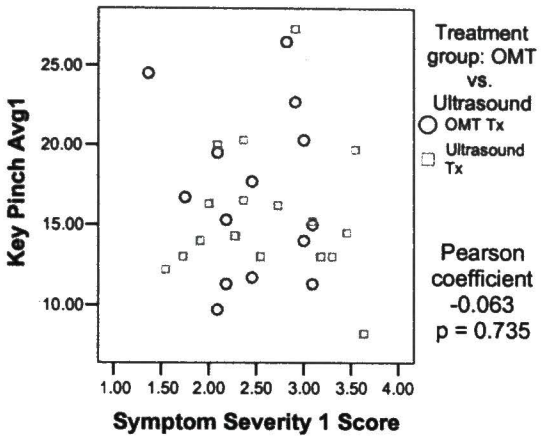

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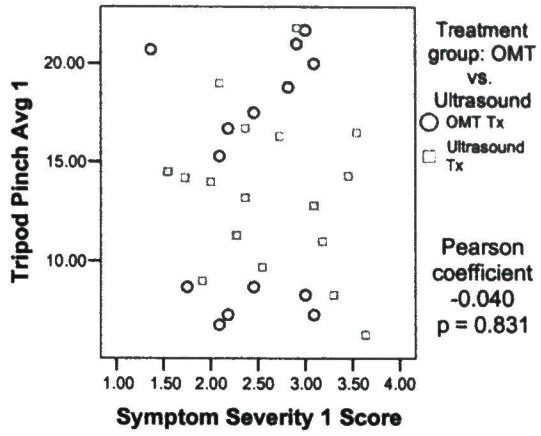

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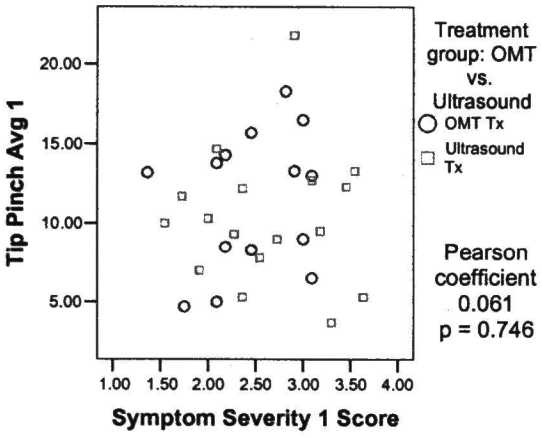

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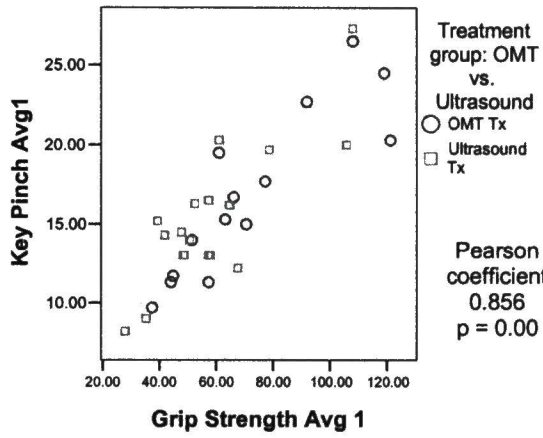

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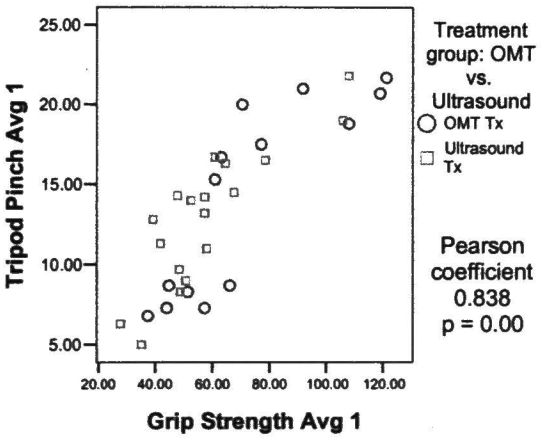

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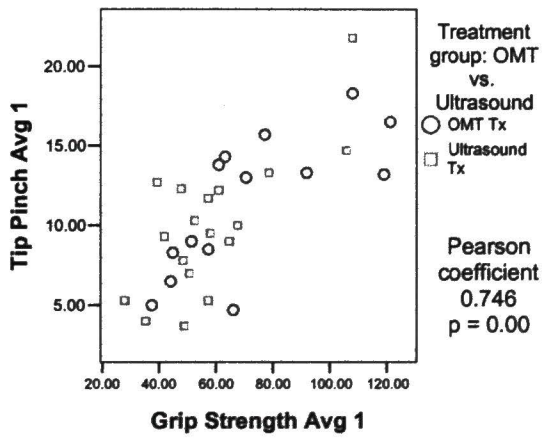

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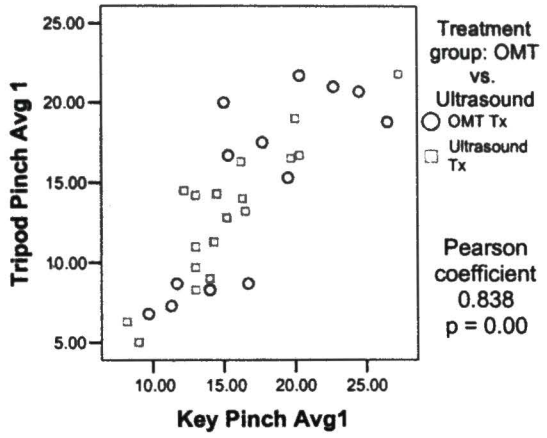

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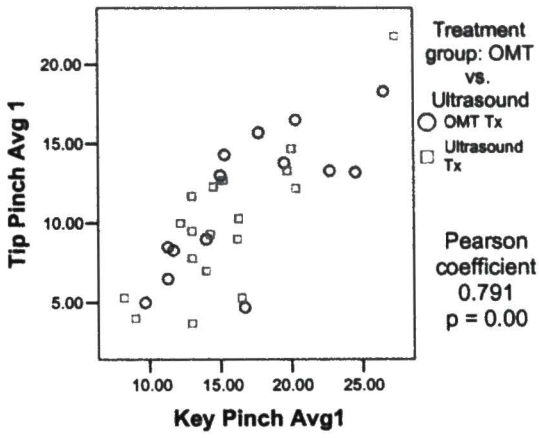

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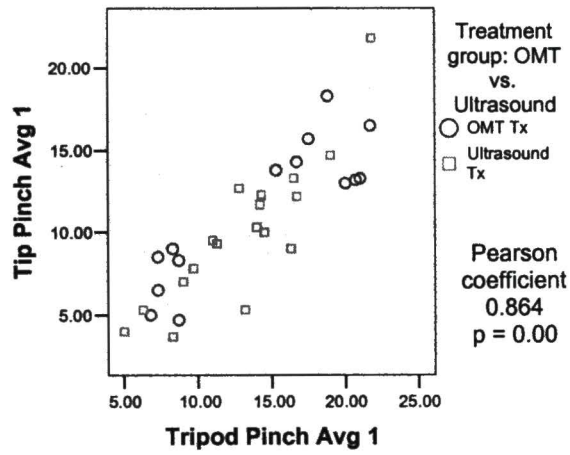

Figure 46

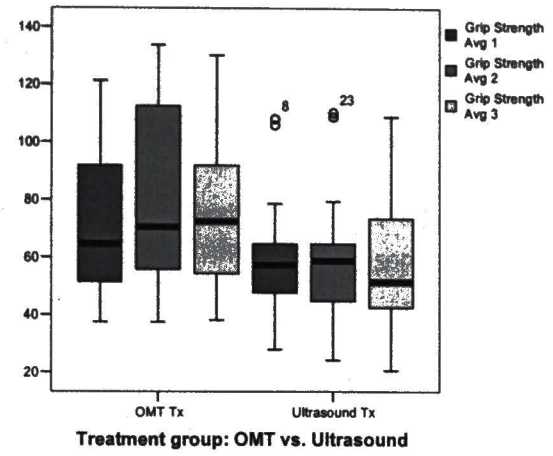

Figure 47: Boxplot Grip Strength

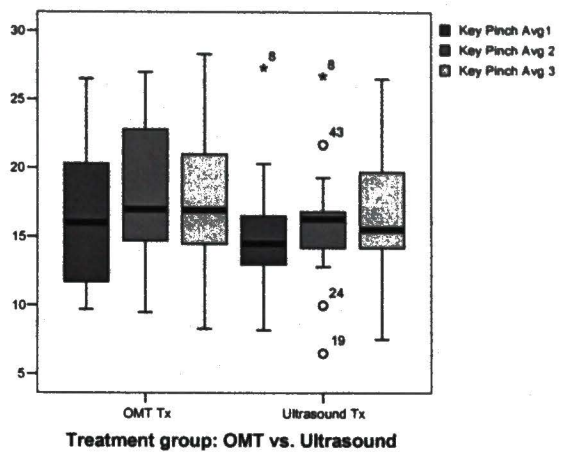

Figure 48: Boxplot Key Pinch

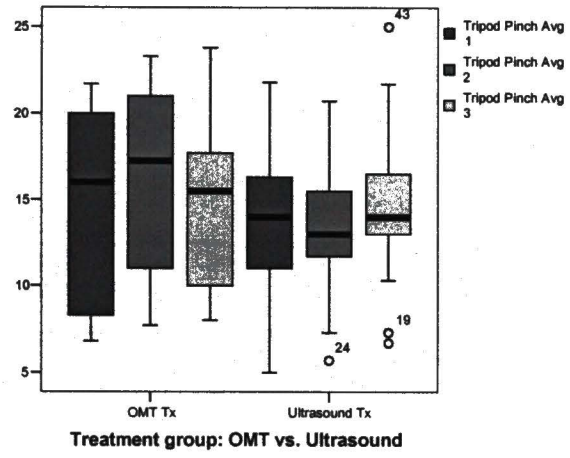

Figure 49: Boxplot Tripod Pinch

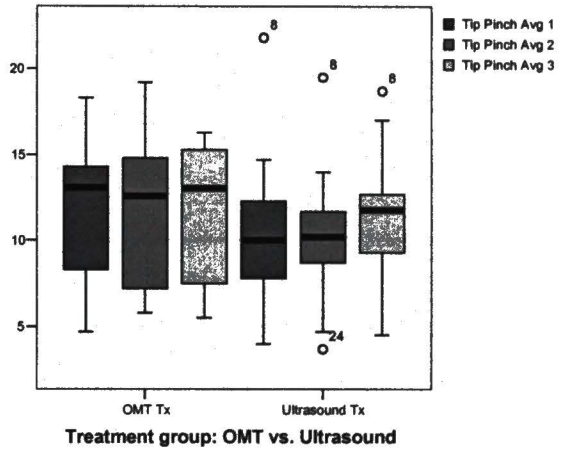

Figure 50: Boxplot Tip Pinch

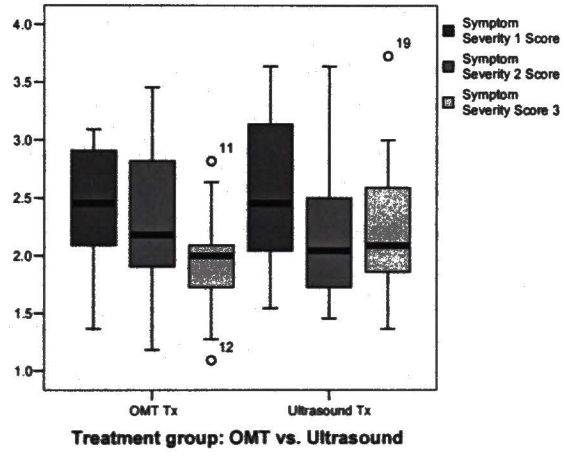

Figure 51: Boxplot Symptom Severity Score

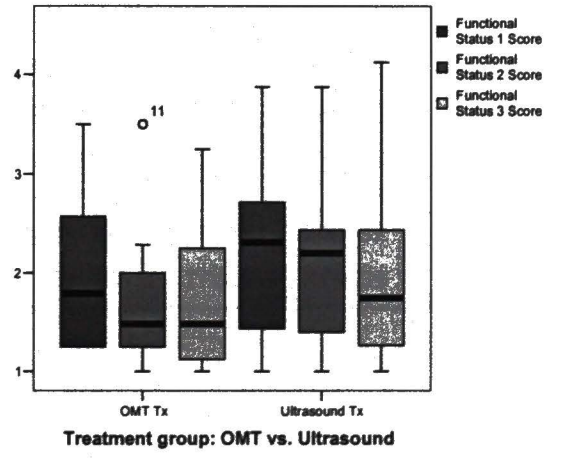

Figure 52: Boxplot Functional Status Score

Treatment group: OMT vs. Ultrasound		Grip Strength Avg 1	Grip Strength Avg 2	Grip Strength Avg 3	Key Pinch Avg1	Key Pinch Avg 2	Key Pinch Avg 3
OMT Tx	Mean	72.3843	80.1521	77.0293	16.8714	17.7786	17.9571
	N	14	14	14	14	14	14
	Std. Deviation	27.64863	31.40452	28.43314	5.25305	5.57455	5.49961
	Std. Error of Mean	7.38941	8.39321	7.59908	1.40394	1.48986	1.46983
Ultrasound Tx	Mean	58.4011	59.7072	57.9465	15.3167	15.7056	16.4059
	N	18	18	17	18	18	17
	Std. Deviation	21.35045	22.99259	23.40682	4.45834	4.39284	4.83638
	Std. Error of Mean	5.03235	5.41940	5.67699	1.05084	1.03540	1.17299
Total	Mean	64.5188	68.6519	66.5645	15.9969	16.6125	17.1065
	N	32	32	31	32	32	31
	Std. Deviation	24.90428	28.45488	27.12415	4.80480	4.97048	5.11833
	Std. Error of Mean	4.40250	5.03016	4.87164	.84938	.87866	.91928

Table 4: Means

Treatment group: OMT vs. Ultrasound		Tripod Pinch Avg 1	Tripod Pinch Avg 2	Tripod Pinch Avg 3	Tip Pinch Avg 1	Tip Pinch Avg 2	Tip Pinch Avg 3
OMT Tx	Mean	14.2000	16.3071	15.0143	11.4357	11.9286	11.7500
	N	14	14	14	14	14	14
	Std. Deviation	5.96902	5.29956	4.79918	4.37925	4.37782	3.93539
	Std. Error of Mean	1.59529	1.41637	1.28263	1.17040	1.17002	1.05178
Ultrasound Tx	Mean	12.9944	13.3611	14.7353	9.9944	10.1000	11.3941
	N	18	18	17	18	18	17
	Std. Deviation	4.34869	4.13836	4.51732	4.39297	3.69578	3.49866
	Std. Error of Mean	1.02500	.97542	1.09561	1.03543	.87110	.84855
Total	Mean	13.5219	14.6500	14.8613	10.6250	10.9000	11.5548
	N	32	32	31	32	32	31
	Std. Deviation	5.06765	4.83469	4.56988	4.37640	4.04682	3.64306
	Std. Error of Mean	.89584	.85466	.82077	.77365	.71538	.65431

Table 5: Means

Treatment group: OMT vs. Ultrasound		Symptom Severity 1 Score	Symptom Severity 2 Score	Symptom Severity Score 3	Functional Status 1 Score	Functional Status 2 Score	Functional Status 3 Score
OMT Tx	Mean	2.4627	2.3831	1.9371	2.0179	1.9205	1.7127
	N	14	14	13	14	11	11
	Std. Deviation	.54367	.81793	.50259	.72725	.93122	.69659
	Std. Error of Mean	.14530	.21860	.13939	.19437	.28077	.21003
Ultrasound Tx	Mean	2.6273	2.3889	2.2834	2.2479	2.2103	2.0095
	N	17	18	17	17	18	17
	Std. Deviation	.66421	.79852	.65388	.80775	.85823	.84960
	Std. Error of Mean	.16110	.18821	.15859	.19591	.20229	.20606
Total	Mean	2.5529	2.3864	2.1333	2.1440	2.1004	1.8929
	N	31	32	30	31	29	28
	Std. Deviation	.60853	.79387	.60901	.76858	.88170	.79325
	Std. Error of Mean	.10930	.14034	.11119	.13804	.16373	.14991

Table 6: Means

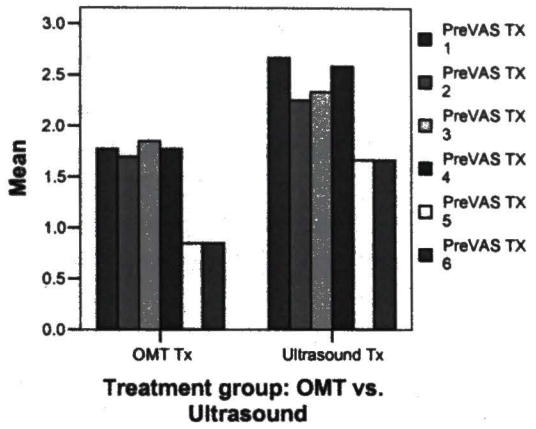

Figure 53: Pre-treatment VAS

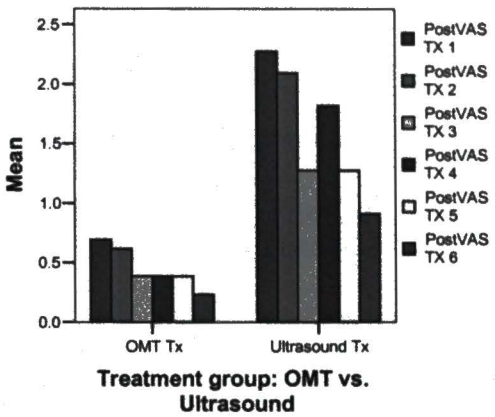

Figure 54: Post-treatment VAS

	N	Minimum	Maximum	Mean	Std. Deviation
PreVAS TX 1	32	.0	8.0	2.500	2.4363
PreVAS TX 2	31	.0	7.0	1.984	1.9599
PreVAS TX 3	32	.0	10.0	2.500	2.7357
PreVAS TX 4	32	.0	10.0	2.359	2.6586
PreVAS TX 5	28	.0	5.0	1.250	1.7559
PreVAS TX 6	29	.0	7.0	1.483	1.8052
PostVAS TX 1	31	.0	9.0	1.742	2.4491
PostVAS TX 2	31	.0	6.0	1.306	1.7208
PostVAS TX 3	32	.0	6.0	1.078	1.7418
PostVAS TX 4	32	.0	8.0	1.188	1.8568
PostVAS TX 5	28	.0	5.0	.786	1.4493
PostVAS TX 6	29	.0	6.0	.690	1.3914
Valid N (listwise)	24				

Table 7: Means VAS

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