A Pilot Study Comparing Two Manual Therapy Interventions for Carpal Tunnel Syndrome

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ABSTRACT

Objective: The purpose of this study was to determine the clinical efficacy of manual therapy interventions for relieving the signs and symptoms of carpal tunnel syndrome (CTS) by comparing 2 forms of manual therapy techniques: Graston Instrument–assisted soft tissue mobilization (GISTM) and soft tissue mobilization administered with the clinician hands.

Methods: The study was a prospective comparative research design in the setting of a research laboratory. Volunteers were recruited with symptoms suggestive of CTS based upon a phone interview and confirmed by electrodiagnostic study findings, symptom characteristics, and physical examination findings during an initial screening visit. Eligible patients with CTS were randomly allocated to receive either GISTM or STM. Interventions were, on average, twice a week for 4 weeks and once a week for 2 additional weeks. Outcome measures included (1) sensory and motor nerve conduction evaluations of the median nerve; (2) subjective pain evaluations of the hand using visual analog scales and Katz hand diagrams; (3) self-reported ratings of symptom severity and functional status; and (4) clinical assessments of sensory and motor functions of the hand via physical examination procedures. Parametric and nonparametric statistics compared treated CTS hand and control hand and between the treatment interventions, across time (baseline, immediate post, and at 3 months' follow-up).

Results: After both manual therapy interventions, there were improvements to nerve conduction latencies, wrist strength, and wrist motion. The improvements detected by our subjective evaluations of the signs and symptoms of CTS and patient satisfaction with the treatment outcomes provided additional evidence for the clinical efficacy of these 2 manual therapies for CTS. The improvements were maintained at 3 months for both treatment interventions. Data from the control hand did not change across measurement time points.

Conclusions: Although the clinical improvements were not different between the 2 manual therapy techniques, which were compared prospectively, the data substantiated the clinical efficacy of conservative treatment options for mild to moderate CTS. (J Manipulative Physiol Ther 2007;30:50-61)

Key Indexing Terms: *Musculoskeletal Manipulations; Carpal Tunnel Syndrome; Clinical Trials*

arpal tunnel syndrome (CTS) is a symptom complex that is associated with localized compression of the median nerve. Sensory and motor deficits

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within the median nerve distribution are secondary to the mechanical compression and local ischemia.[1,2] Of the various surgical techniques, open carpal tunnel release procedures and endoscopic techniques lead to the alleviation of CTS symptoms in the majority of patients, that is, 75% to 99% of the time.[1,3] In addition, complications from open carpal tunnel release procedures and endoscopic techniques occur at similar rates of approximately 1% to 2%.[1,4-8] Although the rate of surgical complications may be deemed quite low, the potential complications represent significant morbidity risks for the patients with CTS.[1,6,9,10] These complications must be viewed with respect to the direct medical costs of surgical interventions as well as the socioeconomic costs in terms of workers' compensation costs, lost or reduced wages for the patient during the rehabilitative process that may last several days to weeks, and potentially long-term disability costs.[1,9,11,12]

Despite the positive clinical outcomes of surgical interventions, the American Academy of Neurology and 40% of neurologists in the Netherlands recommend con-

servative management of CTS before surgical intervention.[13,14] Empirical evidence also indicates that many patients with CTS have self-limiting symptoms and respond to nonoperative conservative treatments—including rest, modification of physical behaviors, splinting, nerve gliding exercises, manual therapy techniques, and anti-inflammatory medications.[1,15] To date, though, there is limited prospective research comparing the efficacy of different surgical techniques and/or comparing surgical techniques to nonoperative conservative treatments.[5,15-19] The few randomized clinical trials comparing surgical interventions to either splinting or other conservative medical management indicate that symptom severity and functional status improve more with surgery than nonoperative therapy.[20,21] However, there were noteworthy complications of the surgery to include scar tenderness, wound infection and hematoma, severe pillar pain, reflex sympathetic dystrophy, and skin irritation.[20] In addition, of patients with failed primary surgical interventions, up to 12% may require a secondary surgical procedure.[22,23] Persistent symptoms after a secondary surgical procedure ranged from 25% to 95%.[24]

The conservative management of CTS with manual therapy is an often overlooked treatment approach, despite anecdotal clinical evidence from physiotherapists and preliminary research evidence from the chiropractic and osteopathic literature.[25] From a mechanistic viewpoint, manual therapy techniques designed to release tissue adhesions and increase the range of motion (ROM) of the wrist may alleviate the mechanical compression of the median nerve without the need for surgical interventions. Increased joint motion may improve blood flow within the vasa nervorum, thereby alleviating local ischemic effects on the median nerve. The limited research on manual therapy techniques, to include soft tissue mobilization (STM), carpal bone mobilization, or median nerve mobilization, indicated a tendency toward clinical improvements of the signs and symptoms of CTS.[25] As such, the conservative management of CTS lends itself to systematic research on various manual therapy techniques that are within the scope of practice of chiropractors.

The Graston Technique is an innovative, patented form of instrument-assisted soft tissue mobilization (GISTM) that may enhance the ability of clinicians to effectively break down scar tissue and fascial restrictions. Preliminary data suggested that GISTM treatments may effectively alleviate the clinical symptoms of various cumulative trauma disorders.[26-29] In the case of CTS, GISTM may be used to provide a precise method of manipulating the myofascia of the forearm, wrist, and palm of the hand, without applying pressure directly over the pathway of the median nerve. GISTM may provide an advantage to frictional massage and myofascial release techniques, administered with the clinician's hands, because the Graston Technique instruments are designed to detect soft tissue adhesions by increasing tactile diagnostic feedback to both the clinician and patient.[30] Besides increasing tactile feedback to the clinician during the treatment of musculoskeletal pain disorders, the various sizes and shapes of the 6 instruments may allow clinicians to more precisely treat the different contours of myofascial restrictions than would be possible with their hands.[30] Graston Technique instruments may also provide an ergonomic advantage to clinicians, by reducing the imposed stress of treatments on their hands.[30]

In summary, clinical efficacy of manual therapy for mild to moderate CTS is lacking sufficient evidence. The purpose of the study was to determine the clinical efficacy of manual therapy interventions for relieving the signs and symptoms of CTS. GISTM was relatively compared to manual STM administered with the clinician hands using a prospective comparative research design. The research was a pilot study or a feasibility trial, because if either modality failed to have a reasonable impact on the signs and symptoms of CTS, then the application of these manual therapy techniques may not be particularly useful to pursue in larger clinical studies given the limitations of time and costs. As a pilot study, the comparison of the innovative technique of GISTM to the "active" control of manual STM seemed most appropriate, because of the proposed advantages of the Graston Technique instruments relative to clinician's hands. In addition, we used a convenience sampling technique to recruit patients, who were actively seeking relief of signs and symptoms of CTS that were not resolving with time (cf Discussion).

METHODS

Study Population

The New York Chiropractic College ethics committee approved all measurement and clinical procedures for this study. Advertisements in local newspapers were used to recruit patients with clinically suspected CTS. A phone interview was used as an initial screening instrument for eligibility to participate in the study. The phone interview addressed the following exclusion criteria: (1) older than 50 years of age; (2) previous treatment interventions with surgery and/or steroid injections; (3) a history of wrist trauma; (4) a history suggesting underlying causes of CTS (eg, diabetes mellitus, thyroid disease, pregnancy); (5) a history of other musculoskeletal medical conditions (eg, osteo or rheumatoid arthritis, reflex sympathetic dysfunction, fibromyalgia); and (6) no pending lawsuits or insurance claims. In addition, the phone interview addressed clinical signs of CTS related to pain and paresthesia within the median nerve distribution and functional abilities to perform daily activities that are typically affected by CTS.

If the patients were eligible according to their answers on the phone interview, then they were scheduled for a clinical examination at the research laboratory to verify their eligibility for enrollment into the study. Before their

appointment, all patients were mailed an informed consent form. At the beginning of the session for the clinical examination, the principal investigator provided a verbal description of all measurement and clinical procedures. Thereafter, all participating patients provided written informed consent before their clinical examination.

The inclusion criteria were based upon the initial electrodiagnosis study. The electrodiagnosis studies revealed deficits of sensory and motor nerve conduction that were consistent with the recommendations by the American Association of Electrodiagnosis, the American Academy of Neurology, and the American Academy of Physical Medicine and Rehabilitation for diagnosing mild to moderate CTS.[31,32] Specifically, the findings from the electrodiagnosis study of the median nerve that were needed to confirm the diagnosis of CTS included (1) median nerve distal sensory latency of the index finger (>3.60 milliseconds) and/or (2) median nerve distal motor latency (DML; >4.20 milliseconds). If there was an electrophysiologic confirmation of the CTS diagnosis, then clinical signs and symptoms of CTS diagnosis were addressed.

The patients needed to present with pain and paresthesia within the median nerve distribution. Ratings of the Katz hand diagrams needed to indicate categorization of CTS symptoms into "classic" or "probable."[3,33] The patients needed to present with an initial self-reported degree of pain rating of 33 mm or greater on the visual analog scale (VAS) pain scale that ranged from 0 mm (no pain) to 100 mm (worst pain possible) for the overall hand-wrist region. Other inclusion criteria based upon physical examination included the presence of at least 2 of 8 of the following clinical findings: sleep disturbances from hand symptoms (nocturnal paresthesias), a mean symptom-severity score of at least 3 of 5, a mean functional-status score of at least 3 of 5, positive results on Tinel's sign, positive results on Phalen's sign, strength deficits, sensory deficits of touch, and limited ROM.[3,34,35]

The exclusion criteria based upon the clinical examination were as follows. Electrodiagnostic findings and physical examination findings that were inconsistent with the diagnosis of CTS. History by clinician that revealed that the patient actually met one of the exclusion criteria addressed in the initial phone interview screening process.

Sample Size Justification

The research design incorporated a control or untreated wrist and an "active" control (STM) to determine the clinical efficacy of GISTM for CTS. A primary outcome measure was not identified as CTS involves a multidimensional array of clinical signs, symptoms, and functional impairments. With the use of the procedures described by Cohen,[36] sample size demands for the main and interaction effects in the proposed factorial design were
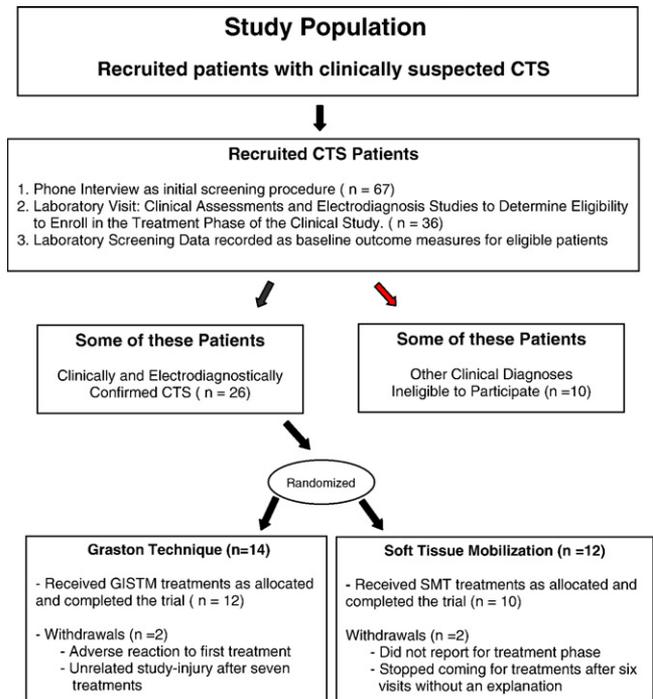

Fig 1. *Progress of patients with CTS through the prospective comparative research design.*

calculated. For all calculations, the level of significance was .05 and power was 0.80. In the absence of preliminary data, sample size demands were calculated for small, medium, and large effect sizes based upon the criteria set forth by Cohen.[36] Based upon calculations of sample size demands for a large effect size, 10 subjects per group were deemed necessary to detect significant differences between treatment interventions. A large effect size between treatment outcomes with GISTM as compared to STM was assumed to establish the need for costly randomized controlled trials on the clinical efficacy of manual therapy interventions for CTS. A sample size of 10 patients per group was consistent with previous literature on manual therapy interventions for CTS.[25]

Treatment Allocation and Blinding

Eligible patients were randomly allocated to receive either GISTM or STM (Fig 1). If bilateral symptoms were present, the wrist with more severe symptoms according to the patient was treated. A random sequence of 30 treatment interventions was generated by using random number tables by an administrative assistant. A study sample of 30 patients was deemed necessary as an anticipated attrition rate of approximately one third of the recruited patients was assumed to account for the fact that manual therapy interventions were lacking sufficient evidence, such that patients would drop-out, if the intervention was ineffective. After meeting the eligibility requirements for the study, the

patients were consecutively enrolled into the treatment phase. The allocation was according to random sequence of 30 treatment interventions. The treating clinician, administrative assistant, and program coordinator were the only members of the research team with knowledge of the treatment allocation. Patients were also encouraged not to reveal any information about their treatment interventions to the clinicians performing the clinical examination immediately posttreatments and at 3 months' posttreatment.

Treatment

One clinician administered both treatment interventions. The clinician had 16 years of experience in manual STM techniques with the necessary training in GISTM. The clinician was deemed by peer review to be able to deliver both treatment interventions with similar clinical expertise. The manual STM technique was designed to mimic the Graston Technique.

The Graston Technique Protocol included a brief warm-up exercise, Graston Technique treatment of the forearm-wrist-hand areas, followed by stretching, strengthening, and ice.[27] The brief warm-up exercise consisted of 12 minutes of either riding a stationary bicycle or walking on a treadmill at a comfortable pace. The Graston Technique treatment involved the use of an innovative, patented form of instrument-assisted STM that enabled the clinician to effectively break down scar tissue and fascial restrictions of forearm-wrist-hand areas. The clinician treated the patients, allocated to STM, with the same basic protocol as prescribed for the patients allocated to GISTM. However, the treatment intervention involved the use of manual STM of forearm-wrist-hand areas with the clinician's hands to break down scar tissue and fascial restrictions. During the manual STM treatment, patients rested their relaxed forearm-wrist-hand on the treatment table and the clinician applied deep pressure by fingers to scar tissue and taut muscle bands and stretched connective tissue and myofascial restrictions using both hands to replicate the treatment intervention delivered with the Graston Technique instruments.

For both treatment interventions, the patients were scheduled to receive 2 treatments per week for the first 4 weeks and then receive 1 treatment per week for the next 2 weeks. At home, exercises involving stretching and strengthening of the closed-kinetic chain of the upper extremity supplemented both treatment interventions. All patients were instructed to refrain from using wrist splints and anti-inflammatory medications during the course of their 6-week treatment protocols. As such, the only difference between the 2 treatment protocols was the use of the Graston Technique Instruments. During the 3 month follow-up period, the patients were phoned monthly by the administrative assistant to maintain contact and inquire about any changes in CTS symptoms or other health

changes from the end of the treatment phase. The treating clinician was available to consult with the patients during the 3-month follow-up period if changes in CTS symptoms or other health changes occurred.

Outcome Assessment

Subjective evaluations of CTS symptoms, functional wrist-hand status, and pain intensity using self-reported VAS ratings, self-administrated hand diagrams, and self-administrated questionnaires are well-accepted outcome measures to document the relief of symptoms and functional loss in CTS after various treatment interventions.[3,33,34,37] An accurate diagnosis of CTS depends upon a combination of electrodiagnostic study findings, symptom characteristics, and physical examination findings.[37] As described below, the outcome assessment included multiple outcome measures to address the multidimensional array of clinical signs and symptoms of CTS and to determine the sensitivity of different outcome measures to detect clinical change given the limited research on the clinical efficacy of manual therapy techniques for CTS.

The outcome measurements were (1) sensory and motor nerve conduction evaluations of the median nerve, (2) a subjective test battery which included self-reported pain and paresthesia evaluations of the hand and self-reported ratings of symptom severity and functional status, and (3) assessments of sensory and motor functions of the hand via physical examination procedures. The time points for the outcome measurements were (1) before treatment as part of the screening procedures; (2) within 1 week of the last clinical treatment session, that is, after 6 weeks of treatments; and (3) at 3 months after the last clinical treatment session. Immediate post and at 3 months, the patients rated on a 5-point scale their satisfaction with their treatment intervention.

Electrodiagnosis studies were conducted according to the recommendations by the American Association of Electrodiagnosis, the American Academy of Neurology, and the American Academy of Physical Medicine and Rehabilitation.[31,32] The patients completed the self-administered Katz hand diagrams to report the specific locations of their CTS symptoms and to characterize them as pain, numbness, tingling, or decreased sensation.[33] The diagrams were rated as classic, probable, or unlikely patterns of CTS according to the classification scheme.[33] The patients self-rated their degree of pain using a VAS that ranged from 0 mm (no pain) to 100 mm (worst pain possible) for both the left and right wrist-hand areas. The degree ratings reflected the overall intensity of pain for the wrist-hand areas during the previous week. The patients also completed these 2 instruments at each treatment session to monitor the progress of the treatment interventions.

The patients completed the self-administered symptom-severity scale and functional-status scale.[34] The symptom-severity scale consisted of 11 questions with multiple

choice responses, scored from 1 point (mildest) to 5 points (most severe). The questions addressed the 6 clinical areas of CTS symptoms: pain, paresthesia, numbness, weakness, nocturnal symptoms, and overall functional status. The overall symptom-severity score was the mean of the ratings on the 11 items. The functional-status scale consisted of daily activities that are performed by most individuals and are commonly affected by CTS. The patients rated their ability to perform the activity on a scale that ranged from 1 point (no difficulty with the activity) to 5 points (cannot perform the activity at all). The overall score for the functional-status scale was the mean of the ratings on the 8 daily activities.

The assessment procedures within the physical examination included ROM, grip and pinch strength, sensory function, and clinical tests. Range of motions for flexion and extension of each wrist were measured using an inclinometer (Fabrication Enterprises, Inc, White Plains, NY). Isometric pinch strength (key and opposition pinch) and isometric grip strength were measured for each hand using the JAMAR Pinch Gauge and the JAMAR Hand Dynamometer, respectively (Sammons Preston, Chicago, Ill). All measurements were repeated 3 times to ensure their reliability. The outcome scores were the mean values of the 3 measurements for each assessment procedure and each wrist.

Two-point discrimination and pressure sensitivities of the first 3 digits of each hand were used to assess sensory function. With the use of calipers whose 2 points were set 4 mm apart, the patients were asked to identify the number of points touching the distal palmar pads of the first 3 digits. The outcome score for each digit of each hand was expressed as normal if 2 points were detected and abnormal if 1 point was detected.[3] According to the instructions provided by Semmes-Weinstein Monofilament Testing Set, the threshold sensibility of each hand was tested by applying Semmes-Weinstein monofilaments (SWMs) to the distal palmar pads of the first 3 digits. The recorded score was the lightest pressure that was perceived by each digit of each hand. The outcome score was the mean of the pressure sensitivities of the first 3 digits.

The clinical signs of CTS were a positive Tinel's sign and/or a positive Phalen's test. A positive Tinel's sign was indicated by paresthesias in the distribution of the thumb, index, and middle fingers, that is, median nerve distribution.[3,35] A positive Phalen's test was indicated by paresthesias in the distribution of the median nerve that occurred during a 60-second test.[3] For each wrist and each clinical test, the outcome scores were recorded as either positive or negative.

Statistical Analyses

SPSS (SPSS, Chicago, Ill) was used for all statistical analyses. A treatment intervention × wrist × time mixed

Table 1. *Patient characteristics*

Intervention	n (female/male)	Age (y)	Weight (kg)	Height (cm)
GISTM	12 (10/2)	39.8 ± 8.75	86.2 ± 20.82	165.7 ± 7.97
STM	10 (9/1)	43.4 ± 5.32	74.3 ± 19.08	160.8 ± 4.33

Values are shown as mean $\pm$ SD.

analysis of variance model was used to reveal the clinical effectiveness of manual therapies on the following outcome measures: distal and sensory motor latencies, self-reported pain ratings on the VAS, mean scores on the symptom-severity scale and functional-status scale (included only factors of treatment intervention × time), ROMs for wrist flexion and wrist extension, isometric strength measurements (grip, $pinch_{opposition}$, and $pinch_{key}$), and the mean of the pressure sensitivities of the first 3 digits. Although there were multiple outcome measures, univariate analyses at the .05 level of significance were deemed appropriate as CTS involves a multidimensional array of clinical signs and symptoms.

Multiple χ^2 analyses were used to reveal the clinical effects of the treatment interventions on the frequency distributions of the following outcome measures: classification schemes based upon the Katz hand diagrams, normal and abnormal 2-point discrimination of first 3 digits, positive and negative Tinel's signs, and positive and negative Phalen's tests. The contingency tables for the multiple χ^2 analyses included (1) outcome measure by wrist at each time point and (2) outcome measure compared between consecutive pair-wise time points for each wrist. The construction of the contingency tables included all patients, GISTM-treated patients only, and STM-treated patients only. The level of significance for each χ^2 procedure was .05 without correction for multiple tests.

Results

Study Population

During a period of 15 months, we phone interviewed 67 patients. Thirty-one of these patients did not qualify based upon our phone interview. Another 10 patients reported to the laboratory for clinical evaluations, but did not meet the inclusion criteria. Twenty-six patients with CTS were enrolled into the research study and were randomly allocated to either GISTM (n = 14) or STM (n = 12). Four of these patients dropped out of the research study. One patient dropped out of the study because of profound bruising and swelling of the treated forearm-wrist-hand after the first GISTM treatment. A second patient dropped out of the study because of an unrelated study injury which prevented the continuation of GISTM treatments. The patient received 7 GISTM treatments before sustaining the unrelated study injury with only

Table 2. *Nerve conduction latencies*

	All patients		GISTM patients		STM patients	
	CTS	Control	CTS	Control	CTS	Control
DML (ms)						
Baseline	4.87 ± 1.199 (4.37-5.37)	4.25 ± 0.870 (3.89-4.61)	4.92 ± 1.065 (4.32-5.52)	4.25 ± 0.893 (3.74-4.76)	4.81 ± 1.193 (4.07-5.55)	4.25 ± 0.889 (3.70-4.80)
Immediate post	4.58 ± 0.984 (4.17-4.99)	4.22 ± 0.990 (3.81-4.63)	4.58 ± 0.664 (4.20-4.96)	4.11 ± 0.899 (3.60-4.62)	4.58 ± 1.312 (3.77-5.39)	4.34 ± 1.123 (3.64-5.04)
3 mo	4.65 ± 1.069 (4.20-5.10)	4.25 ± 1.040 (3.82-4.68)	4.73 ± 0.931 (4.20-5.26)	4.19 ± 0.851 (3.71-4.67)	4.56 ± 1.261 (3.78-5.34)	4.34 ± 1.267 (3.56-5.13)
DSL (ms)						
Baseline	3.90 ± 0.644 (3.63-4.17)	3.51 ± 0.693 (3.22-3.80)	3.99 ± 0.636 (3.63-4.35)	3.63 ± 0.760 (3.20-4.06)	3.80 ± 0.672 (3.38-4.22)	3.37 ± 0.612 (2.99-3.75)
Immediate post	3.65 ± 0.550 (3.42-3.88)	3.44 ± 0.81 (3.10-3.78)	3.82 ± 0.571 (3.50-4.14)	3.61 ± 0.896 (3.10-4.12)	3.43 ± 0.455 (3.15-3.71)	3.23 ± 0.688 (2.80-3.66)
3 mo	3.55 ± 0.410 (3.38-3.72)	3.40 ± 0.63 (3.14-3.66)	3.65 ± 0.448 (3.40-3.90)	3.55 ± 0.657 (3.18-3.92)	3.43 ± 0.351 (3.21-3.65)	3.22 ± 0.587 (2.86-3.58)

Values are shown as mean ± SD (95% confidence interval [CI]).

The goal of the treatment intervention is to restore nerve conduction latencies to within normal limits. In our study, DML was 4.87 ± 1.199 milliseconds and DSL was 3.90 ± 0.644 milliseconds at baseline for the CTS wrist. Our clinical meaningful difference would be 0.67 and 0.30 milliseconds for DML and DSL, respectively, to return to upper limits of normal (4.20 milliseconds for DML and 3.60 milliseconds for DSL, as reported in Methods).

minimal improvements of CTS symptoms as self-reported by the patient. A third patient stopped coming for STM treatments after 6 visits without an explanation. A fourth patient, allocated to STM, did not report for the treatment phase after qualifying for the research study. Thus, 22 patients successfully completed the study protocol (Table 1).

Allocated Treatment

All 22 patients received 10 treatment protocols, either GISTM or STM. Nine of 12 patients allocated to GISTM and 8 of 10 patients allocated to STM were treated, on average, twice a week for 4 weeks and once a week for 2 additional weeks. For these patients, there were occasional scheduling conflicts that extended the treatment duration to 7 to 8 weeks. Two of 12 patients allocated to GISTM and 1 of 10 patients allocated to STM were treated, on average, once a week for a duration of 10 weeks. The 2 remaining patients, 1 from each treatment allocation, missed 2 weeks of treatments, after their fourth visit, owing to an acute medical condition unrelated to the study. All 22 patients adhered to their home exercise program. During the follow-up period of 3 months, none of the patients required adjunct care for their symptoms of CTS.

Study Dates

The recruitment process began in September 2003. The enrollment of subjects began in November 2003 with the last subject being enrolled in November 2004. All treatments were completed in January 2005. The follow-up assessments at 3 months were completed in April 2005.

Distal Motor and Sensory Latencies

Measurements of DML and distal motor sensory latency (DSL) were reliable. Across the testing time points, intraclass reliability coefficients for the control wrist were 0.92 and 0.93 for DML and DSL, respectively. Distal motor latency at baseline was significantly different between the control wrist (4.25 ± 0.870 milliseconds) and the CTS wrist (4.87 ± 1.199 milliseconds; t_{21} = 3.99; P < .05). Similarly, DSL at baseline was significantly different between the control wrist (3.51 ± 0.693 milliseconds) and the CTS wrist (3.90 ± 0.644 milliseconds; t_{21} = 2.85; P < .05).

Posttreatment changes in DML and DSL of the CTS wrist were independent of the type of treatment intervention. There was a slight improvement of 0.29 milliseconds in DML immediately posttreatments, which approached significance (Table 2; $F_{2,40;\ wrist\ \times\ time}$ = 2.47; P < .10). The treatment effects on improvements to DML accounted for 11% of measurement variance ($\partial\eta2$ = 0.110). From immediate post- to 3 months post-treatments, DML slightly increased toward baseline values from 4.58 ± 0.984 to 4.65 ± 1.069 milliseconds. These decreases in DML for the CTS wrist were not clinically meaningful as the upper limit of normal for DML is 4.20 milliseconds. The slight improvement of 0.25 milliseconds in DSL immediately posttreatments reflected the inherent variability of repeated measures as there were also comparable decreases in DSL of the control wrist (Table 2; $F_{2,40;\ wrist\ \times\ time}$ = 1.99; P > .10).

Subjective Test Battery

At baseline, $\chi2$ analyses revealed that classification schemes based upon the Katz hand diagrams were distinctly different between the CTS wrist and control wrist
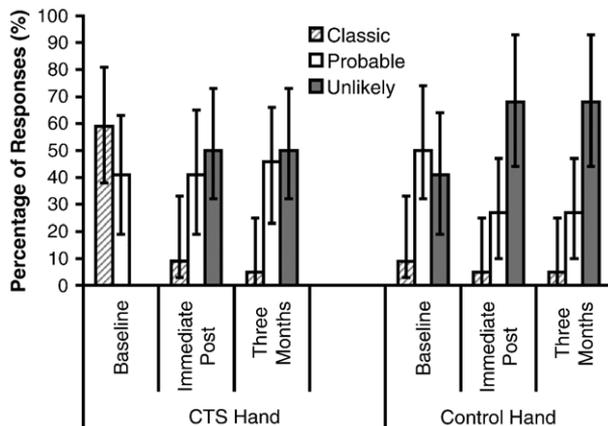
Fig 2. *Katz hand diagram: percentages of classification schemes of self-reported pain and paresthesia affecting the CTS and control upper extremities at each testing time point. Classification schemes are classic pattern, probable pattern, and unlikely pattern of symptoms associated with CTS. Note the changes for the treated CTS hand, immediate post and at 3 months, as evident by the decrease in percentages of the classic pattern (filled black bars) and the increase in percentages of the unlikely pattern (filled gray bars) without concomitant changes of the response distributions (percentages) for the untreated control hand. The categorical changes for the Katz hand diagram represent meaningful clinical differences as they correspond to symptom resolution. The error bars are the 95% CIs for proportions.*

($\chi2 = 17.27$, $df = 2$, $P < .05$). Regardless of the type of treatment intervention, there were significant changes in the classification schemes of the CTS wrists from baseline to immediate post-treatments, which were maintained at 3 months post-treatments ($\chi2 = 48.96$, $df = 2$, $P < .05$). Classification schemes changed from 60% of patients reporting classic patterns of CTS at baseline to 50% of patients reporting unlikely patterns of CTS at immediate and 3 months post-treatments. Classification schemes of the control wrists did not change throughout the study. Figure 2 summarizes the data from the Katz hand diagrams.

There was some inherent variability in the self-reported pain ratings on the VAS for the control wrist. Across the testing time points, the intraclass reliability coefficient of pain ratings for the control wrist was only 0.14. However, this inherent variability represented small measurement variations accompanying a statistical "floor effect," which biased the calculation of the intraclass reliability coefficient. Pain ratings at baseline were significantly different between the control wrist (23.5 ± 21.78 mm) and the CTS wrist (61.1 ± 22.52 mm; $t_{21} = 6.83$; $P < .05$).

Immediately after both treatment interventions, there were decreases in pain ratings for the CTS wrist, without concomitant changes for the control wrist (Table 3; $F_{2,40; wrist \times time} = 12.78$; $P < .05$). The treatment effects on improvements of pain ratings for the CTS wrist accounted for 39% of measurement variance ($\partial\eta2 = 0.390$). There

were baseline differences in pain ratings of the control wrists between patients assigned to GISTM and STM treatments. However, these differences were not deemed clinically meaningful as pain ratings for the control wrist represented a statistical "floor effect," that is, less than one third of self-reported measurement scale. At 3 months post-treatments, there was a slight increase in pain ratings for the CTS wrist in patients treated with STM, whereas improvements of pain ratings for the CTS wrist in patients treated with GISTM were maintained. Statistical evidence for significant clinical differences between the treatment interventions at 3 months was provided by the treatment × time ($F_{2,40} = 5.64$; $P < .05$) and treatment × wrist ($F_{1,20} = 7.61$; $P < .05$) interaction effects.

Immediately posttreatments, there were significant improvements in the ability of patients to perform daily activities that are typically affected by CTS (functional-status scale: Table 4; $F_{2,40; time} = 14.85$; $P < .05$). These improvements in functional abilities were maintained at 3 months. The treatment effects on improvements of functional abilities accounted for 43% of measurement variance ($\partial\eta2 = 0.426$). However, the clinical effect size, which is the mean difference between the pair-wise time points divided by the standard deviation of this difference, was 1.4 times larger immediately after GISTM treatments (1.11) as compared to STM treatments (0.79). Furthermore, criteria for interpreting clinical effect sizes indicate that effect sizes of more than 0.5 are considered moderate and those of more than 0.8 are considered large.[34] Thus, the classifications of effect sizes represent clinically meaningful differences between the treatment interventions. However, caution in the interpretation of these clinical effect sizes is warranted as they do not correspond to a 1-category change on the 5-point rating scale (Table 4).

Immediately posttreatments, there was a reduction in the severity of symptoms, which represented 6 clinical areas of CTS (symptom-severity scale: Table 4; $F_{2,40; time} = 34.16$; $P < .05$). The treatment effects on reductions of symptom severity accounted for 63% of measurement variance ($\partial\eta^2 = 0.631$). At 3 months post-treatments, there was a slight increase in the severity of symptoms in patients treated with STM, whereas alleviations of symptoms in patients treated with GISTM were maintained. Statistical evidence for meaningful clinical differences between the treatment interventions at 3 months was provided by clinical effect sizes and a treatment × time interaction term that approached significance ($F_{2,40} = 2.67$; $P < .10$). The clinical effect sizes for GISTM treatments were similar immediately post (1.80) and at 3 months (1.79), whereas clinical effect sizes for STM treatments were 1.42 and 0.94 immediately post and at 3 months, respectively. At 3 months, alleviation of CTS symptoms after GISTM treatments represented almost a 2-fold clinical difference as compared to STM treatments (1.79 vs 0.94).

Table 3. *Ratings of perceived pain, range of motion, and strength*

	All patients		GISTM patients		STM patients	
	CTS	Control	CTS	Control	CTS	Control
VAS (mm)						
Baseline	61.1 ± 22.52 (51.7-70.5)	23.5 ± 21.78 (14.4-32.6)	61.5 ± 26.56 (46.5-76.5)	32.1 ± 24.09 (18.5-45.7)	60.5 ± 17.90 (49.4-71.6)	13.20 ± 13.50 (4.8-21.6)
Immediate post	12.4 ± 15.98 (5.7-19.1)	5.5 ± 8.27 (2.0-9.0)	9.8 ± 12.54 (2.7-16.9)	5.6 ± 8.93 (0.5-10.7)	15.4 ± 19.62 (3.2-27.6)	5.4 ± 7.89 (0.5-10.3)
3 mo	20.3 ± 24.01 (10.3-30.3)	12.9 ± 23.84 (2.9-22.9)	9.2 ± 11.04 (3.0-15.4)	11.7 ± 22.15 (0-24.2)	33.7 ± 28.84 (15.8-51.6)	14.4 ± 26.88 (0-31.1)
Extension ROM (°)						
Baseline	37.4 ± 11.31 (32.7-42.1)	46.9 ± 10.33 (42.6-51.2)	38.1 ± 9.98 (32.5-43.7)	45.4 ± 10.70 (39.3-51.5)	36.4 ± 13.23 (28.2-44.6)	48.6 ± 10.16 (42.3 -54.9)
Immediate post	44.6 ± 12.72 (39.3-49.9)	47.7 ± 9.92 (43.6-51.8)	45.4 ± 0.69 (39.4-51.4)	45.7 ± 11.28 (39.3-52.1)	43.7 ± 15.36 (34.2-53.2)	50.0 ± 7.93 (45.1-54.9)
3 mo	44.8 ± 10.48 (40.4-49.2)	47.0 ± 9.95 (42.8-51.2)	43.9 ± 0.79 (37.8-50.0)	47.1 ± 11.18 (40.8-53.4)	45.8 ± 10.57 (39.2-52.4)	47.0 ± 8.84 (41.5-52.5)
Flexion ROM (°)						
Baseline	46.0 ± 8.44 (42.5-49.5	50.7 ± 9.55 (46.7-54.7)	44.8 ± 8.91 (39.8-49.8)	50.3 ± 10.62 (44.3-56.3)	47.5 ± 8.05 (42.5-52.5)	51.2 ± 8.64 (45.8-56.6)
Immediate post	52.7 ± 7.76 (49.5-55.9)	52.5 ± 8.22 (49.1-55.9)	52.0 ± 7.59 (47.7-56.3)	51.5 ± 9.02 (46.4-56.6)	53.6 ± 8.28 (48.5-58.7)	53.5 ± 7.47 (48.9-58.1)
3 mo	49.6 ± 10.02 (45.4-53.8)	50.8 ± 8.46 (47.3-54.3)	49.9 ± 8.44 (45.1-54.7)	50.9 ± 9.29 (45.6-56.2)	49.3 ± 12.12 (41.8-56.8)	50.8 ± 7.85 (45.9-55.9)
Grip strength (kg)						
Baseline	21.7 ± 7.94 (18.4-25.0)	24.2 ± 7.94 (20.9-27.5)	20.2 ± 8.79 (15.2-25.2)	24.4 ± 9.27 (19.2-29.6)	23.5 ± 6.78 (19.3-27.7)	24.0 ± 6.47 (20.0-28.0)
Immediate post	25.6 ± 8.31 (22.1-29.1)	25.0 ± 7.55 (21.8-28.2)	25.7 ± 10.56 (19.7-31.7)	24.6 ± 9.56 (19.2-30.1)	25.4 ± 5.01 (22.3-28.5)	25.6 ± 4.53 (22.8-28.4)
3 mo	25.1 ± 6.93 (22.2-28.0)	25.2 ± 7.39 (22.1-28.3)	25.4 ± 7.67 (21.1-29.7)	25.4 ± 8.67 (20.5-30.3)	24.9 ± 6.32 (21.0-28.8)	25.1 ± 5.95 (21.4-28.8)
Pinch strength opposition (kg)						
Baseline	4.8 ± 1.42 (4.2-5.4)	5.7 ± 1.62 (5.0-6.4)	4.6 ± 1.49 (3.8-5.4)	5.6 ± 1.93 (4.5-6.7)	5.1 ± 1.38 (4.2-6.0)	5.9 ± 1.24 (5.1-6.7)
Immediate post	5.6 ± 1.44 (5.0-6.2)	5.9 ± 1.65 (5.2-6.6)	5.8 ± 1.60 (4.9-6.7)	5.8 ± 1.92 (4.7-6.9)	5.4 ± 1.28 (4.6-6.2)	6.0 ± 1.37 (5.1-6.8)
3 mo	5.6 ± 1.36 (5.0-6.2)	6.0 ± 1.32 (5.4-6.6)	5.8 ± 1.42 (5.0-6.6)	6.2 ± 1.57 (5.3-7.1)	5.4 ± 1.31 (4.6-6.2)	5.9 ± 1.01 (5.3-6.5)
Pinch strength key (kg)						
Baseline	5.0 ± 1.61 (4.3-5.7)	5.7 ± 1.13 (5.2-6.2)	4.9 ± 1.58 (4.0-5.8)	5.6 ± 1.30 (4.9-6.3)	5.1 ± 1.71 (4.0-6.2)	5.8 ± 0.92 (5.2-6.4)
Immediate post	6.4 ± 1.74 (5.7-7.1)	6.2 ± 1.25 (5.7-6.7)	6.2 ± 1.36 (5.4-7.0)	6.0 ± 1.17 (5.3-6.7)	6.7 ± 2.15 (5.4-8.0)	6.4 ± 1.37 (5.6-7.2)
3 mo	6.3 ± 1.22 (5.8-6.8)	6.6 ± 1.10 (6.1-7.1)	6.6 ± 0.90 (6.1-7.1)	6.6 ± 1.20 (5.9-7.3)	6.0 ± 1.51 (5.1-6.9)	6.6 ± 1.03 (6.0-7.2)

Values are shown as mean ± SD (95% CI).

The goals of the treatment interventions are functional improvements in the CTS wrist to match the control wrist. For the VAS, ratings on a 100-mm scale of 33 mm or less (<1/3 of scale) are also indicators of meaningful clinical improvements.

Range of Motion

Measurements of ROMs for wrist flexion (ROM$_{flexion}$) and wrist extension (ROM$_{extension}$) were reliable. Across the testing time points, intraclass reliability coefficients for the control wrist were 0.92 and 0.93 for ROM$_{flexion}$ and ROM$_{extension}$, respectively. ROM$_{flexion}$ at baseline was significantly smaller by 9% for the CTS wrist (46.0° ± 8.44°) than for the control wrist (50.7° ± 9.55°; t_{21} = 2.58; P < .05). ROM$_{extension}$ at baseline was significantly smaller by 20% for the CTS wrist (37.4° ± 11.31°) than for the

control wrist (46.9° ± 10.33°; t_{21} = 3.47; P < .05). Post-treatment improvements of ROM$_{flexion}$ and ROM$_{extension}$ for the CTS wrist were independent of the type of treatment intervention (Table 3). Immediately post and at 3 months, ROM$_{flexion}$ ($F_{2,40; \text{ wrist } \times \text{ time}}$ = 3.63; P < .05) and ROM$_{extension}$ ($F_{2,40; \text{ wrist } \times \text{ time}}$ = 3.91; P < .05) were similar between the control wrist and CTS wrist. The treatment effects on improvements of ROMs for the CTS wrist accounted for approximately 15% of measurement variance ($\partial\eta_{flexion}^2$ = 0.154; $\partial\eta_{extension}^2$ = 0.163).

Table 4. *Ratings of functional status and symptom severity on 5-point categorical scales*

	All patients	GISTM patients	STM patients
Functional scale			
Baseline	2.2 ± 0.88 (1.8-2.6)	2.1 ± 0.93 (1.6-2.6)	2.4 ± 0.85 (1.9-2.9)
Immediate post	1.7 ± 0.66 (1.4-2.0)	1.6 ± 0.65 (1.2-2.0)	1.7 ± 0.70 (1.3-2.1)
3 mo	1.6 ± 0.69 (1.3-1.9)	1.6 ± 0.72 (1.2-2.0)	1.7 ± 0.68 (1.3-2.1)
Symptom severity scale			
Baseline	2.9 ± 0.68 (2.6-3.2)	3.0 ± 0.73 (2.6-3.4)	2.7 ± 0.64 (2.3-3.1)
Immediate post	1.9 ± 0.59 (1.7-2.1)	1.8 ± 0.74 (1.4-2.2)	1.9 ± 0.39 (1.7-2.1)
3 mo	2.0 ± 0.61 (1.7-2.3)	1.8 ± 0.61 (1.5-2.1)	2.2 ± 0.59 (1.8-2.6)

Values are shown as mean ± SD (95% CI).

The goal of the treatment intervention is symptom resolution. Ratings of 1 on the 5-point scales for symptom severity and functional status are indicators of symptom resolution. A 1-category change (rounding to the nearest whole digit) for functional-status and symptom-severity scales may also be considered as clinically meaningful differences. The treatment interventions induced a 1-category change of the mean rating for symptom severity (3 to 2), but not for functional status as the mean values at all time points round to a rating of 2.

Isometric Strength

Measurements of grip strength and pinch strength$_{opposition}$ were reliable. Across the testing time points, intraclass reliability coefficients for the control wrist were 0.95 and 0.84 for grip strength and pinch strength$_{opposition}$, respectively. The reliability of measuring pinch strength$_{key}$ (0.62) was less than adequate using the criterion of 0.70 or more for intraclass reliability coefficients. At baseline, grip strength (21.7 ± 7.94 kg vs 24.2 ± 7.94 kg; t_{21} = 2.61, $P < .05$), pinch strength$_{opposition}$ (4.8 ± 1.42 kg vs 5.7 ± 1.62 kg; t_{21} = 3.89, $P < 0.05$), and pinch strength$_{key}$ (5.0 ± 1.61 kg vs 5.7 ± 1.13 kg; t_{21} = 2.90, $P < .05$) were significantly less in the CTS wrist than in the control wrist.

Post-treatment increases in isometric strength measurements of the CTS wrist were independent of the type of treatment intervention (Table 3). The treatment interventions increased grip strength by 18% ($F_{2,40; wrist \times time}$ = 5.93; $P < .05$), which accounted for 23% of measurement variance ($\partial \eta^2$ = 0.229). Although the treatment interventions increased pinch strength$_{opposition}$ and pinch strength$_{key}$ by 17% and 28%, respectively, the wrist × time interaction terms only approached significance ($F_{2,40; opposition}$ = 2.78; $P < .10$; $F_{2,40; key}$ = 3.01; $P < .10$). Immediately post and at 3 months, grip and pinch strengths were similar between the control wrist and CTS wrist (Table 3).

Clinical Tests and Sensory Function

The frequency distributions of positive Phalen's tests, Tinel's signs, and abnormal 2-point discrimination

Table 5. *Patient satisfaction with treatment interventions*

Time	Intervention	Neutral	Satisfied	Very satisfied
Immediate	GISTM	0	25	75
	STM	10	50	40
3 mo	GISTM	0	58	42
	STM	20	40	40

Percentage of patients associated with each satisfaction rating. There were no ratings of either very dissatisfied or dissatisfied.

responses were similar between the CTS wrist and the control wrist at all testing time points ($P > .05$). Pressure sensitivities of the first 3 digits on SWM testing were significantly different between the CTS hand and the control hand ($F_{1,20; hand}$ = 10.60; $P < .05$). However, treatment interventions did not improve pressure sensitivity on SWM testing ($P > .05$). In agreement with the literature, the clinical signs and quantitative tests of sensory function did not show adequate sensitivity and specificity to be useful as diagnostic criteria and/or main outcome measures for CTS.[2,3]

Patient Satisfaction

There were no statistical differences between satisfaction ratings of patients assigned to each of the treatment interventions. Immediately post and at 3 months, patients assigned to the GISTM treatments were either satisfied or very satisfied with the alleviation of CTS symptoms. Immediately post, 1 patient was neutral toward the effectiveness of STM treatments in alleviating CTS symptoms with a second patient rating STM treatments as neutral at 3 months. Table 5 summarizes the ratings of patient satisfaction.

Adverse Effects

Although many patients reported adverse effects of soreness and bruising, most of these were relatively mild of short duration. However, 1 patient withdrew from participation because of profound bruising and swelling of the treated forearm-wrist-hand after the first GISTM treatment. The patient was treated medically for the swelling. However, these acute effects resolved within a week without any long-term adverse effects.

Success of Blinding

The clinicians responsible for data collection did not report any knowledge of the treatment received. The patients did not inadvertently mention their treatment intervention to these clinicians.

DISCUSSION

Manual therapies for CTS were effective at improving objective measures of impairments and patient-centered

measures of symptom severity and functional abilities. Improvements to nerve conduction latencies, wrist strength, and wrist motion were objective indices of the clinical efficacy of manual therapies for CTS. Severity of symptoms and functional impairments are the major reasons that patients seek treatment. Similarly, relief of symptoms and restoration of functional abilities contribute substantially to patient satisfaction with treatment interventions. The improvements detected by our subjective test battery, that is, patient-centered outcomes and patient satisfaction with the treatment outcomes, provided additional evidence for the clinical efficacy of manual therapies for CTS. Although the clinical improvements were not different between the 2 manual therapy techniques, which were compared prospectively, the data substantiated the clinical efficacy of conservative treatment options for mild to moderate CTS.

Clinically meaningful differences for the treatment of CTS are resolution of symptom characteristics (subjective test battery) and return to within normal limits (normative data or contralateral wrist data) of nerve function (DSL and DML) and wrist-hand performance (ROM, grip and pinch strengths). The current research design lacked the sufficient numbers of subjects to detect statistical significance of clinically meaningful differences between treatment interventions. However, our objective indices of clinical improvements after treatment interventions for CTS were consistent with the literature.[20,38,39] In further agreement with this literature, significant differences between treatment interventions on improving objective measures of CTS impairments would be clinically unimportant regardless of sample size. Moreover, our power calculations at the onset of the project assumed a large effect size between treatment outcomes with GISTM as compared to STM to establish the need for costly randomized controlled trials on the clinical efficacy of manual therapy interventions for CTS.

Before this study, there was limited research to address the clinical efficacy of manual therapy for CTS.[25] This study provided statistical evidence that manual therapy increased ROM and grip strength in wrists affected by CTS to within normal limits, that is, no differences between control and CTS wrists, post-intervention. These clinical improvements of wrist function support the theory that manual therapy may increase myofascial mobility of the wrist, thereby increasing blood flow within the vasa nervorum, which, in turn, alleviates local ischemic effects on the median nerve. Clinicians may choose to use the innovative technique of GISTM to complement their STM techniques to provide a precise method of manipulating the myofascia of the forearm, wrist, and palm of the hand in the treatment of CTS.

The abnormal electrodiagnosis studies of sensory and motor nerve conduction latencies of the median nerve do not generally improve with the use of nonsurgical interventions.[38-40] Although retrospective studies reported post-surgical improvements in abnormal motor and sensory latencies of the median nerve, patients who were treated surgically generally have slower latency values than non-surgically treated patients and their values rarely return to normal after surgery.[40,41] Recently, a randomized controlled trial indicated that there were greater improvements in distal sensory latency, but not DML, for surgery as compared to splinting.[20] Thus, our slight improvement in DML after our manual therapies without concomitant effects on distal sensory latency is consistent with previous literature reports. However, the effects of various treatment interventions on abnormal electrodiagnosis latencies accompanying the diagnosis of CTS await further clarification from prospective research studies.

The majority of evidence, to date, does not substantiate the use of objective indices of signs and symptoms of CTS to distinguish clinical efficacy of treatment interventions. However, future research designs still need to include objective indices as inclusion criteria and secondary outcome measures. An accurate diagnosis of CTS depends upon a combination of electrodiagnostic study findings, symptom characteristics, and physical examination findings.[37] The contributions of objective indices as secondary outcome measures are necessary to show that treatment interventions improve nerve function and wrist-hand performance in patients with CTS.

Reliable and valid patient-centered measures may be more appropriate primary outcome measures to distinguish clinical efficacy for CTS, although clinically meaningful differences among treatment options are small.[15-19] Our patient-centered measures documented that clinically meaningful differences between treatment options for CTS were small. Our post hoc power analysis indicated that at least 81 patients with CTS per manual therapy technique would be necessary to detect clinically meaningful differences that would also be statistically significant. However, the current data substantiated that our patient-centered measures were most sensitive to changes to the signs and symptoms of CTS. The contributions of treatment interventions to improvements of our subjective test battery accounted for approximately 40% to 60% of the measurement variance, whereas our objective indices of improvements only accounted for approximately 10% to 20% of the measurement variance.

Despite the limitation of our sample size, the current research substantiated that the administration of low-cost, patient-centered measures can contribute to more rigorous outcomes research. Specifically, the standardized scales used in our subjective-test battery may now be extended from an academic research environment to community-based practice settings to compare the effectiveness of operative and nonoperative interventions for CTS.[33,34] To date, there is limited prospective research comparing the efficacy of different surgical techniques and/or comparing surgical techniques to nonoperative conservative treatments.[18,20,21,42] Similarly, prospective comparisons of the efficacy of different nonoperative conservative treatments are lacking.[25,38,39,43,44] Although patients receiving workers'

compensation may limit the generalizability of the instruments in the subjective test battery, this hypothesis may be tested within a community-based practice setting.[34] Consequently, the data from this study provided sufficient evidence for the clinical efficacy of manual therapies for mild to moderate CTS, which may now be relatively compared to each other and to surgical interventions in community-based practice settings to distinguish clinical efficacy.

The lack of a control group may be deemed as another potential limitation of this research. However, there is enough evidence in the literature to substantiate that no significant reductions in subjective and electrophysiologic measures occur in control groups.[25,38,39,44] The reliability of our data from the control wrist indicated that measurement variance was not contributing to the clinical improvements of signs and symptoms of CTS. In addition, severity of symptoms and functional impairments are the major reasons that patients seek treatment. During the initial screening process, the patients indicated that natural history was not providing relief of the signs and symptoms of CTS and they reported functional impairments of daily activities that are typically affected by CTS.

Future research to enhance the evidence-base of chiropractic health care should relatively compare manual therapies such as joint manipulation, STM techniques, and/or GISTM using a randomized control trial with the main outcome measure being a VAS, the symptom-severity scale, and/or the Katz hand diagram. The measurements of nerve conduction latencies, ROM, and strength as secondary outcome measures are necessary to show that treatment interventions improve nerve function and wrist-hand performance in patients with CTS. Randomized control trials comparing effective manual therapies to surgical interventions would be the next research step with an emphasis extending beyond clinical outcomes to include cost-effectiveness and reduction of adverse events.

CONCLUSION

The current study addressed the clinical efficacy of manual therapy techniques for CTS, which was lacking sufficient evidence. The data from this prospective comparative research design documented the clinical efficacy of manual therapy for mild to moderate CTS. The recommendation for future research is to conduct randomized controlled trials using patient-centered measures as the primary outcome measures to relatively compare operative and/or nonoperative interventions for CTS to distinguish clinical efficacy.

Practical Applications
- Manual therapy interventions improve signs and symptoms of CTS.

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