Final Performance Report

Quantitative Assessment of Carpal Tunnel Syndrome

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LIST OF ABBREVIATIONS

BMI	Body mass index (body mass in kilograms divided by height in meters squared)
Cm	Centimeter
CTS	Carpal tunnel syndrome
Digit 2	Vibration threshold of the index finger measured prior to wrist flexion.
Digit 5	Vibration threshold of the small finger measured prior to wrist flexion.
Diff 2-5	The difference in vibration threshold between the index finger and the small finger measured prior to wrist flexion (Diff 2-5 = Digit 2 - Digit 5)
Digit 2_F	Vibration threshold of the index finger measured after 10 minutes of wrist flexion.
Digit 5_F	Vibration threshold of the small finger measured after 10 minutes of wrist flexion.
Diff 2_F-5_F	The difference in vibration threshold between the index finger and the small finger measured after 10 minutes of wrist flexion (Diff 2_F-5_F = Digit 2_F - Digit 5_F)
Delta Diff	The difference between Diff 2_F-5_F and Diff 2-5 (Delta Diff = Diff 2_F-5_F - Diff 2-5)
Gp	Group
EMG	Electromyography
Kg	Kilogram
Hz	Hertz
Msec	Millisecond
m/s	Meters per second
NS	Not significant
p	Probability
SD	Standard deviation

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SIGNIFICANT FINDINGS

1. Statistically significant group differences in almost all vibrotactile threshold outcomes were observed between subjects with carpal tunnel syndrome and those without carpal tunnel syndrome.

2. The sensitivity of vibrometry performed after ten minutes of wrist flexion was approximately two times that obtained before wrist flexion for detection of electrophysiologically confirmed carpal tunnel syndrome. For example, at specificities of 70 percent and 80 percent, the sensitivities of the vibrometry outcome Diff 2_F-5_F (an outcome obtained after wrist flexion) were 61 percent and 57 percent whereas the sensitivities of the vibrometry outcome Diff 2-5 (an outcome analogous to Diff 2_F-5_F obtained before wrist flexion) were 35 percent and 28 percent.

3. Vibrotactile threshold outcome measures derived from differences between the index and small finger provided better distinction between subjects with electrophysiologically confirmed carpal tunnel syndrome and those with normal electrodiagnostic study results, regardless of symptom status, than did measures based on the index finger alone. This was especially true following the ten minute wrist flexion period.

4. Non-quantitative clinical tests used frequently for detection of carpal tunnel syndrome (e.g., Phalen's and Tinel's signs) were observed to have excellent specificity when used among asymptomatic comparison subjects (95-100%) and poorer specificity (57-93%) when used in a more appropriate comparison group, i.e., subjects with hand pain but without electrophysiologic evidence of carpal tunnel syndrome. Sensitivity was modest among those with electrophysiologically confirmed carpal tunnel syndrome and did not exceed 50% for any clinical test.

5. Study subjects, even those with proven carpal tunnel syndrome, were extremely reluctant to undergo repeat nerve conduction testing due to the mildly aversive nature of the stimulation.

6. When performed twice over a seven month interval, the upper 95th percentile value for an increase in the vibrotactile threshold outcomes Diff 2_F-5_F and Delta Diff were 0.78 log microns and 1.41 log microns for the dominant hand and 0.81 log microns and 1.28 log microns for the non-dominant hand. These values allow classification of the change in an individual's threshold values as normal or abnormal when measured over a several month period.

USEFULNESS OF FINDINGS

1. Use in epidemiologic studies

The results of this study allow rational application of vibrometry in studies of carpal tunnel syndrome. The difference in vibrotactile threshold between the index and the small finger after a ten minute period of wrist flexion (Diff 2_F-5_F) is recommended as the outcome measure of choice when making group comparisons. Relatively large and statistically significant group differences between subjects with carpal tunnel syndrome and those without carpal tunnel syndrome were observed for this vibrotactile threshold outcome.

2 Use in screening and surveillance

None of the outcome measures used in this study had sensitivity and specificity of sufficient magnitude to recommend them for use as a screening tool for identification of individuals with carpal tunnel syndrome. However, when used among subjects most likely to require actual clinical evaluation, i.e., subjects with hand symptoms, several vibrotactile threshold outcomes provided better sensitivity and specificity than did other nonaversive tests in common use, such as two point discrimination, Phalen's sign and Tinel's sign.

3. Use in longitudinal studies

On the basis of subject acceptance, nerve conduction evaluation is not useful in studies requiring repeated measurement of nerve function. Vibrometry is an appropriate choice for use in studies requiring repeated measurement of nerve function.

ABSTRACT

A cross-sectional and longitudinal study was performed to assess the utility of vibrotactile threshold measurement for detection of carpal tunnel syndrome (CTS) among adult subjects. Of special interest was the possible improvement in sensitivity, without loss of specificity, that might follow a ten minute period of wrist flexion. Subjects with symptoms of hand discomfort were recruited from among patients referred to the Emory Clinic Electromyography Laboratory. Asymptomatic subjects were recruited from among office and technical staff at the Emory University School of Public Health. In addition to electrophysiologic evaluation, all subjects were offered a brief clinical examination and vibrotactile threshold measurement of the index and small fingers, bilaterally, before and following a ten minute period of wrist flexion. A total of 144 subjects were recruited; 57 hands had symptoms and electrophysiologic test results compatible with CTS (Group 1), 58 hands had symptoms compatible with carpal tunnel syndrome and normal electrophysiologic test results (Group 2), and 123 hands had no symptoms and normal electrophysiologic test results (Group 3). Analyses were performed separately for dominant and non-dominant hands and results were pooled when appropriate. Outcomes of interest were the vibrotactile thresholds obtained from the index and small fingers before and following ten minutes of maximum voluntary wrist flexion and variables calculated from them. Significant differences in mean vibrotactile threshold were observed between the three hand condition groups for most of the outcomes included in the study. The sensitivity of vibrometry performed after ten minutes of wrist flexion was approximately two times that obtained before wrist flexion for detection of electrophysiologically confirmed CTS. At specificities of 70 and 80 percent, the sensitivities of the vibrometry outcome Diff 2_F-5_F (an outcome obtained after wrist flexion) were 61 and 57 percent whereas the sensitivities of the vibrometry outcome Diff 2-5 (an outcome analogous to Diff 2_F-5_F but was obtained before wrist flexion) were 35 and 28 percent. Non-quantitative clinical tests used frequently for detection of CTS (e.g., Phalen's and Tinel's signs) were observed to have good specificity when performed on asymptomatic comparison subjects (95 - 100%) and intermediate specificity (57-93%) when performed on more appropriate comparison group, i.e., subjects with hand pain but without electrophysiologic evidence of CTS. Sensitivity was modest among those with electrophysiologically confirmed CTS and did not exceed 50% for any clinical test. The investigators were unable to determine the association between repeated nerve conduction outcomes and either repeated vibrotactile outcomes or repeated symptoms outcomes because only a very small proportion of subjects were willing to undergo repeat electrophysiologic evaluation. Estimates of the upper 95th percentile of the change in two of the vibrotactile threshold outcomes obtained twice over a seven month time period are provided to guide investigators who wish to perform studies requiring repeated measurements.

INTRODUCTION

The carpal tunnel syndrome is characterized by dysesthetic hand symptoms such as pain, tingling, and numbness in the distribution of the median nerve as well as by weakness and atrophy of the thenar muscles. It is universally accepted that carpal tunnel syndrome is the clinical concomitant of compression of the median nerve as it passes through the carpal canal. Median nerve neuritis caused by focal entrapment at the wrist was first described by Marie and Foix in 1913 [Brain, 1947]. It is now considered the most common entrapment neuropathy [Dawson et al.,1983]. The lifetime risk of developing symptoms compatible with carpal tunnel syndrome has been estimated to be as high as 10% [Spinner et al., 1989]. In addition, disorders associated with repeated trauma, of which carpal tunnel syndrome is often considered prototypic, have become the most commonly reported category of occupational illness [BLS, 1992].

Anatomy and Pathogenesis

The carpal canal is bounded dorsally by eight carpal bones and ventrally by the transverse carpal ligament. The median nerve and nine flexor tendons of the hand pass through the canal. Because neither the carpal bones nor the transverse carpal ligament are distensible, any space-occupying lesion in the canal can lead to compression of the median nerve and cause carpal tunnel syndrome. Many causes for carpal tunnel syndrome have been described. They include both systemic and local processes such as rheumatoid arthritis, diabetes and other endocrine disorders, flexor tendonitis, trauma, pregnancy, and repetitive hand and wrist movements, typically occurring in the workplace [Kelsey, 1982; Sandzen, 1981; Carragee and Hentz, 1988].

Diagnosis

The diagnosis of carpal tunnel syndrome is usually based on clinical and electrophysiologic findings [Phalen, 1966; Dawson et al., 1983; Kimura, 1989]. Characteristic symptoms include pain, numbness, burning, tingling and loss of sensation in the distribution of the median nerve. Physical signs are typically reported to include diminished or absent cutaneous sensibility to vibration and light touch in the distribution of the median nerve. Two-point discrimination may be abnormal. Thenar muscle weakness and atrophy as well as Phalen's sign (reproduction of hand symptoms after one minute of wrist flexion) or Tinel's sign (electric shock sensation radiating into the hand upon tapping the wrist over the carpal canal) are also classically described findings in carpal tunnel syndrome. Electrodiagnostic studies are now commonly employed in the evaluation of carpal tunnel syndrome. Typical findings include prolongation of the distal motor latencies of the median nerve, slowing of median sensory nerve conduction

velocity across the wrist, and denervation of the abductor pollicis brevis muscle [Stevens, 1987; Kimura, 1989].

No one clinical sign, symptom or test value is diagnostic of the carpal tunnel syndrome. False positive and false negative results have been described for diagnoses of carpal tunnel syndrome that rely solely on symptoms and physical findings as well as for both the Phalen's and Tinel's maneuvers, when compared to diagnoses that incorporate electrodiagnostic studies [Szabo et al., 1984; Gellman et al. 1986]. The sensitivity of electrodiagnostic studies for the detection of carpal tunnel syndrome have also been challenged as some patients with classic symptoms and negative electrodiagnostic studies have responded well to surgical release of the transverse carpal ligament [Grundberg, 1983]. In addition, some apparently asymptomatic individuals meet electrodiagnostic criteria for carpal tunnel syndrome. Most authorities agree, however, that a combination of characteristic symptoms and electrodiagnostic findings is the most valid method of diagnosing carpal tunnel syndrome [Spinner et al, 1989; Dawson et al, 1983; Sandzen, 1981].

Among tests for the detection of abnormal cutaneous sensation used commonly in patients with carpal tunnel syndrome, altered vibration sensibility to a tuning fork has been shown to have some utility for detecting carpal tunnel syndrome. In this regard it is similar to other simple tests such as touch pressure aesthesiometry with Semmes-Weinstein monofilaments, evaluation of light touch with a soft brush, or measurement of static and dynamic two-point discrimination. As non-quantitative or semi-quantitative measures, however, these techniques are not sufficiently sensitive or specific to be utilized as diagnostic tests [Spindler and Dellon, 1982]. In addition, they do not produce a continuous outcome and therefore are difficult to adjust for age, height, and other potential confounders.

Occupational Factors and Carpal Tunnel Syndrome

When carpal tunnel syndrome occurs secondary to occupational ergonomic factors, it is one of a group of conditions known collectively as *disorders associated with repeated trauma*, *cumulative trauma disorders* or *repetitive motion injuries* [Carragee and Hentz, 1988; Armstrong and Chaffin, 1979; Armstrong, 1983]. Other disorders considered related to "cumulative trauma" include tendonitis, De Quervain's disease, trigger finger, ulnar entrapment at the elbow, and medial and lateral epicondylitis.

Studies relating occupational ergonomic factors to these disorders have typically relied upon clinical methods to differentiate carpal tunnel syndrome from other cumulative trauma disorders

[Silverstein et al, 1987; Punnett et al., 1985, Margolis and Kraus, 1987]. Specifically, a symptom-oriented definition of carpal tunnel syndrome has been utilized almost exclusively, and misclassification of disease was possible. Cross-sectional studies of carpal tunnel syndrome in industry have rarely utilized electrodiagnostic evaluation, usually because of the cost, sophistication, and time requirements of this method. In the largest published cross-sectional epidemiologic study of occupational carpal tunnel syndrome available, Silverstein et al. state: "Time and resource constraints precluded use of more elaborate diagnostic tools such as nerve conduction velocity studies." [1987, pp. 347].

Electrodiagnostic studies, in addition to being costly and time consuming, are noxious. Many participants in cross-sectional or longitudinal studies of occupational carpal tunnel syndrome would have few or no symptoms, and may therefore not be motivated to undergo painful tests. A painless diagnostic procedure would be more readily accepted by volunteer participants.

Significance

Quantitative, non-invasive, and non-aversive determination of vibrotactile threshold may be an appropriate substitute for painful, time-consuming, and costly electrodiagnostic testing in both epidemiologic studies and clinical practice. In addition, this new method could also be used for long-term evaluation of treatment in patients suffering from carpal tunnel syndrome in whom repeated electrodiagnostic study might be tolerated poorly. It would also be well suited to a program of surveillance of workers whose jobs place them at risk for the development of the carpal tunnel syndrome. Used in this manner, regular testing that would not be acceptable with standard electrodiagnostic techniques, could facilitate medical removal of workers who develop abnormal thresholds prior to the development of clinically overt disease. Finally, the effects of workplace modification designed to reduce the occurrence of carpal tunnel syndrome could be evaluated with this method, facilitating prevention of this common disorder. Many authors have suggested that vibrometry is a useful method for detection of carpal tunnel syndrome, however, few present data to substantiate the claim [Bleeker, 1986; Bove et al. 1986].

In order to evaluate the utility of vibrotactile threshold measurement as a screening tool for detection of carpal tunnel syndrome a cross-sectional and longitudinal study was performed with the following aims:

1. To determine the specificity and sensitivity of vibrotactile threshold testing for the identification of carpal tunnel syndrome using a combination of characteristic signs, symptoms and electrophysiologic findings as the "gold standard" for the diagnosis.

2. To compare the change in vibrotactile threshold measurement among patients after several months of treatment for carpal tunnel syndrome to the change in both reporting of symptoms and electrophysiologic parameters.

3. To determine the magnitude and variability in change of vibrotactile threshold parameters over time by measuring them serially in a group of asymptomatic subjects free of carpal tunnel syndrome.

METHODS

To address Aim 1, a cross-sectional and longitudinal epidemiologic study was performed to estimate the sensitivity and specificity of vibrotactile threshold measurement for the diagnosis of carpal tunnel syndrome. Of special interest were vibrotactile thresholds obtained following a ten minute period of wrist flexion. To address Aim 2, subjects with nerve conduction confirmed carpal tunnel syndrome were invited to undergo repeat measurement approximately six months after initial evaluation to determine which objective measure (vibrotactile threshold or nerve conduction outcomes) corresponded best to changes in symptoms. Finally, to address Aim 3, asymptomatic subjects with normal electrophysiologic test results were studied prospectively to determine the change in the vibrotactile threshold parameters of interest over 7 months.

Subjects

Symptomatic subjects were recruited from among patients referred to the Emory Clinic Electromyography Laboratory, directed by Linton C. Hopkins, MD. Any patient between ages 18 - 70 years with symptoms of pain, weakness, numbness, or tingling that involved either hand were eligible for inclusion in the study. These eligible patients were asked about their willingness to participate. Those eligible patients expressing an interest in participating were given written materials describing the study. The principal investigator was available to answer any questions potential subjects might have.

Asymptomatic subjects were recruited from among office and technical staff at the Emory University School of Public Health. Potential participants were invited to participate by letter from the PI and follow-up phone call by a research assistant.

All subjects provided informed consent approved by the Emory University Human Investigations Committee for participation in the study.

Questionnaire

A standardized questionnaire including demographics (age, gender, height and weight), occupation, symptoms of carpal tunnel syndrome, medication and alcohol use, and conditions known to predispose to carpal tunnel syndrome (i.e., rheumatoid arthritis, hormone use, menopause, diabetes, chronic renal failure, and pregnancy) was administered to all participants by Dr. Gerr.

Physical Assessment

Sensory and motor evaluations, including physical examination to assess sensibility to two-point (spatial) discrimination, light touch and vibration (pallesthesia), and manual evaluation of thenar weakness and atrophy, were performed, bilaterally. An attempt was made to elicit Phalen's and Tinel's signs. All examinations were performed by one investigator (FG) who was blinded to the results of the electrophysiologic tests. Physical examination was performed according to, DeJong [1979] and is briefly described below.

Vibration perception was determined with a standard 128-Hz tuning fork. The fork was struck by the examiner and applied with moderate pressure to the bony prominence of the distal interphalangeal joint of digits 2 (index finger) and 5 (small finger), bilaterally. The subject was instructed to respond verbally when the vibration was no longer perceptible. The result was recorded as normal, abnormal or equivocal.

Two-point discrimination was determined on digits 2 and 5 with a two-point esthesiometer. The patient was stimulated randomly with either one or two points. Initial determinations were made with the point spacing in gross excess of normal (approximately 10 millimeters); the gap was subsequently reduced until the subject was not able to distinguish two separate points. The smallest distance perceived as two separate points was recorded in millimeters.

Phalen's maneuver was performed by requiring the subject to maintain maximal voluntary wrist flexion for a period of 60 seconds. The test was considered positive if the subject experienced reproduction of his or her hand symptoms. Tinel's sign was positive when tapping over the dorsal aspect of the wrist caused pain or paresthesias to radiate into the affected hand.

Thenar motor strength was assessed by instructing the patient to abduct his/her thumb fully while the examiner resisted the motion and pushed the thumb towards the palm [Hoppenfeld, 1976, p. 97]. Thenar motor strength was graded as normal, equivocal, or abnormal. Thenar muscle mass was examined by inspection and palpation. It was graded as normal, equivocal or abnormal.

Vibrotactile threshold testing

The vibrotactile sensitivity instrument used was the Vibratron-II (Physitemp Inc., formerly Sensortek Inc., Clifton, NJ). It vibrates at a fixed frequency of 120 Hz. The vibration amplitude is manually adjustable from the front of the controller unit. The Vibratron is a direct-reading instrument, with the intensity of vibration displayed on the front of the apparatus. The units are a

non-linear function of the microns of displacement of the 1.4-cm diameter vibrating post. The instrument was calibrated using a Kulite (Kulite Corp, Leonia, NJ) GY-125-10 strain gauge accelerometer and calibration parameters were used to convert recorded "vibration units" to microns of displacement for all measurements.

A standard psychophysical procedure, the method of limits, was used to determine vibrotactile thresholds [Gerr and Letz, 1988; Gerr et al., 1990; Gerr et al., 1991]. The procedure requires the subject to place his or her finger on the stimulus delivery post that protrudes from the instrument. The stimulus intensity was increased until the subject reported that it was felt, then decreased until it was no longer felt. This ramping up and down was repeated five times (three "descending" trials and two "ascending" trials). Stable, reliable, and time-efficient thresholds can be obtained with this procedure [Gerr and Letz, 1988]. Vibrotactile thresholds were measured for the index and little fingers before and following ten minutes of maximal voluntary wrist flexion.

Electrophysiologic Testing Protocol

Standard electrophysiologic techniques were used. All motor nerve conduction measures were performed according to a standard protocol. Sensory nerve conduction measures were performed with either antidromic or orthodromic stimulation depending upon the preference of the electromyographer. Orthodromic sensory conduction results were recorded as latency in milliseconds from the stimulation artifact to the peak of the evoked response and antidromic sensory conduction results were recorded as velocity in meters per second along the nerve segment between stimulating and recording electrodes. All electrophysiologic measures were made with a TECA TD-20 electromyograph (TECA Corp., Pleasantville, N.Y.). Because examinations were performed for clinical indications, some variability in the details of the electrophysiologic examination occurred among symptomatic individuals. In general, sensory and motor studies were performed on the median and ulnar nerves of the affected limb in symptomatic subjects. All subjects had, at least, median motor nerve and median sensory nerve evaluation of the symptomatic hand. In asymptomatic comparison subjects the dominant limb was tested.

Standard needle electromyography (EMG) was performed on all symptomatic subjects at the time of initial evaluation. EMG was performed with the muscle at rest and during voluntary contraction. Abnormalities at rest including fibrillation potentials, positive sharp waves or complex repetitive discharges were considered to indicate active denervation. Abnormalities with voluntary effort, including motor unit potentials of increased amplitude or duration or of

polyphasic configuration or recruitment with increased interference patterns, were considered to indicate chronic denervation.

An electrophysiologic study was considered positive (i.e., consistent with carpal tunnel syndrome) if any one of the following results were found:

1. Median nerve distal motor latency greater than 4.4 ms at a distance of approximately 7 cm in a subject with normal ulnar nerve function.

2. Median nerve distal motor latency of 1.8 ms or greater than the ipsilateral ulnar nerve distal motor latency.

3. Median mixed nerve (sensory and motor) palm to wrist latency greater than 2.2 msec.

4. Median sensory nerve conduction velocity from wrist to finger of less than 44 m/s or median sensory nerve latency from finger to wrist of greater than 3.8 msec.

5. Isolated EMG abnormalities (active or chronic) of the abductor pollicis brevis muscle suggestive of denervation.

Data Management

As the data were collected, the questionnaires were checked for completeness. The data were entered and verified using a program with range and validity checks. Data analysis was done on a personal computer using Epi-Info and PC-SAS.

Data Analysis

1. Estimation of Sensitivity and Specificity.

For the purpose of determining the sensitivity and specificity of the vibrotactile threshold measures, one CTS-positive group (Group 1) and two "CTS-negative" groups (Groups 2 and 3) were established. The CTS-positive group (Group 1) consisted of all subjects with hand symptoms and electrophysiologic test results consistent with carpal tunnel syndrome. Group 2 consisted of all subjects with hand symptoms consistent with carpal tunnel syndrome (pain, numbness, or tingling) and normal electrophysiologic tests, and Group 3 consisted of all asymptomatic subjects who had normal electrophysiologic tests.

Vibration thresholds of the index and little fingers were measured before and after 10 minutes of maximum voluntary wrist flexion. Vibration threshold differences between the index and the little finger were calculated for each subject for measurements made both before and after wrist flexion. In addition, the change in the vibrotactile threshold difference between digit 2 and digit 5 from before and after wrist flexion was calculated. All vibrotactile thresholds are presented in units of log microns. A list and description of outcome measures obtained at the time of examination or calculated from those obtained at the time of examination are provided in Table 1. In order to control for potential confounding, general linear models that included age, height, and BMI as covariates of median nerve vibrotactile threshold were used to test for differences in mean threshold scores among the three patient groups. Analyses were performed separately for the dominant and non-dominant hands.

For the outcome variables Diff 2-5, Diff 2_F-5_F, and Delta-Diff, values that correspond to the 70th, 80th, 90th, and 95th percentiles were used to represent test specificities of 70, 80, 90, and 95 percent, respectively, for that particular outcome. The sensitivity that corresponds to each of these specificities was defined as the proportion of subjects in the disease-positive group (Group 1) who had a value that exceeds the value associated with each of the specificities. These outcome variables were chosen because they were found to be independent of age, height, and BMI, and could therefore be used to provide unbiased estimates of sensitivity and specificity without adjustment for these covariates. Results obtained from both disease negative groups (Group 2 and Group 3) were used to estimate sensitivity and specificity. Results obtained from asymptomatic, electrophysiologically normal subjects (Group 3) were considered "best case" estimates and those obtained from symptomatic, electrophysiologically normal subjects (Group 2) were considered "worst case" estimates.

Analyses were also performed to evaluate the utility of a variety of maneuvers used commonly in the clinical assessment of patients with carpal tunnel syndrome (e.g., Phalen's sign and Tinel's sign). The proportion of abnormal results were calculated for each test for each carpal tunnel group. These outcomes are reported as the proportion of abnormal test results in each of the hand condition groups; the proportions represent the sensitivity ("hit rate") among the diseased subjects (Group 1) and one minus the specificity ("false alarm rate") among the two non-carpal tunnel groups (Group 2 and Group 3).

2. Determination of relationship of change in vibrotactile threshold and electrophysiological parameters following treatment to change in symptoms.

The investigator had planned to compare (1) the prediction of change in the severity of symptoms from the change in the electrodiagnostic test scores to (2) the prediction of change in the severity of symptoms from the change in the vibrotactile threshold test scores in patients with carpal tunnel syndrome. As described below, participation in this component of the project was insufficient to allow for meaningful analyses to be performed.

3. Vibrotactile threshold change over time in disease-free subjects

Among Group 3 subjects, the difference in vibrotactile threshold between digits 2 and 5 at rest (Diff 2-5) and following 10 minutes of wrist flexion (Diff 2_F-5_F) were calculated for the two test sessions (initial and 7 month follow-up). In addition, the mean and standard deviation of the change in these differences from the initial visit to the follow-up visit were estimated. An upper bound of normal for the mean difference between each of these parameters for an individual tested on two separate occasions was defined as the group mean change value plus 1.65 standard deviation units.

RESULTS

A total of 144 subjects were recruited. Of those recruited, 119 met criteria for inclusion in one of the three hand condition groups and were included in the analyses. Demographic characteristics of the study subjects are presented for the total study group (N=119) and stratified by hand condition group for the dominant and non-dominant hands in Tables 2a and 2b. For the dominant hand, 30 subjects met the criteria for Group 1, 30 for Group 2, and 59 for Group 3. For the non-dominant hand, 27 subjects met the criteria for Group 1, 28 for Group 2, and 64 for Group 3. A total of 57 hands met criteria for Group 1, 58 hands met criteria for Group 2, and 123 hands met criteria for Group 3. A significant difference was observed between the three hand condition groups for both mean age and mean BMI for the dominant and non-dominant hands. No significant differences were observed between the three groups for height, sex, and percent right handed.

Objective 1.

Mean dominant hand vibrotactile threshold values before and after wrist flexion for all CTS groups are presented in Table 3a. Vibrotactile thresholds for the index finger (Digit 2) and, surprisingly, the small finger (Digit 5), were significantly different across the hand condition groups prior to wrist flexion. Group 2 thresholds for the index and small fingers were intermediate in value between thresholds of Group 1 and Group 3. The differences in vibrotactile threshold between digit 2 and digit 5 before wrist flexion (Diff 2-5), a measure of difference in sensory function between cutaneous sites in the median and ulnar nerve distributions, was not significantly different across the hand condition groups. Among subjects with carpal tunnel syndrome (Group 1), both digit 2 and digit 5 thresholds increased after the ten minute period of wrist flexion, although digit 2 increased somewhat more than digit 5. Among Group 2 subjects, digit 2 thresholds decreased and digit 5 thresholds were essentially unchanged after 10 minutes of wrist flexion. Among Group 3 subjects, digit 2 thresholds were essentially unchanged and digit 5 thresholds were slightly increased after 10 minutes of wrist flexion. The difference in threshold between digits 2 and 5 after 10 minutes of wrist flexion (Diff 2_F-5_F) was significantly greater among Group 1 subjects than among Group 2 or Group 3 subjects. The difference in the change in digit 2 threshold before and after wrist flexion and digit 5 threshold before and after wrist flexion (Delta Diff) was also significantly different across the three hand condition groups with the largest difference observed among Group 1 subjects.

Mean non-dominant hand vibrotactile threshold values before and after wrist flexion for all CTS groups are presented in Table 3b. The overall pattern of results was similar, but not identical, to that obtained for the dominant hand. Significant differences in index finger

threshold (Digit 2) were observed across the three groups with the highest value observed among Group 1 subjects. Smaller, but still significant, differences in small finger vibrotactile threshold were observed across the three groups with the highest value observed among Group 1 subjects. The difference in threshold between digit 2 and digit 5 before wrist flexion (Diff 2-5) was greatest for Group 1 subjects and essentially zero among Group 2 and Group 3 subjects. Unlike the results obtained for the dominant hand, these differences in thresholds obtained before wrist flexion (Diff 2-5) were significant across the hand condition groups. Digit 2 and digit 5 thresholds increased moderately after wrist flexion among Group 1 subjects and slightly among Group 2 subjects. Essentially no change in thresholds of either finger occurred after wrist flexion among Group 3 subjects. After wrist flexion, thresholds were highest for both fingers among Group 1 subjects, lowest among Group 3 subjects, and intermediate among Group 2 subjects. The difference between digit 2 threshold and digit 5 threshold after wrist flexion (Diff 2_F-5_F) was significantly different across the three carpal tunnel groups. The Diff 2_F-5_F was greatest among Group 1 subjects and essentially zero among Group 2 and Group 3 subjects. The results for Delta Diff were essentially the same as those for Diff 2_F-5_F.

Results from analyses to estimate sensitivities over a range of specificities, for the three vibrotactile threshold outcomes found to be independent of potentially important covariates, are presented by dominant hand (Table 4a), non-dominant hand (Table 4b), and dominant and non-dominant hands combined (Table 4c). Sensitivity and specificity results are presented in each table for analyses performed using both Group 2 subjects (Section I of each table) and Group 3 subjects (Section II of each table) in comparison to Group 1 subjects. When using Group 3 subjects to estimate VT values corresponding to various specificities, the best sensitivities among Group 1 subjects were obtained with the Diff 2_F-5_F outcome (i.e., the difference in VT between the index and small finger *after* 10 minutes of wrist flexion). Results from the dominant and non-dominant hands were similar for this outcome. At a specificity of 80%, the sensitivity of this measure was 57% (all hands combined, Table 4c). The sensitivity obtained with the Diff 2-5 outcome (i.e., the difference in VT between the index and small finger *before* wrist flexion) was poor at all specificities for both dominant and non-dominant hands. In general, the sensitivity of this measure was about half that of the Diff 2_F-5_F measure. For example, at a specificity of 80%, the sensitivity of Diff 2-5 was 28% for all hands combined (Table 4c). Sensitivities obtained using the Delta Diff variable were slightly lower than those obtained using the Diff 2_F-5_F variable. Again referring to a specificity of 80%, the sensitivity of this outcome was 46%.

Results obtained from analyses in which Group 2 subjects were used to estimate VT values corresponding to a range of specificities were similar to those obtained with Group 3.

Sensitivities obtained with the Diff 2-5 variable were poor (Table 4c). Sensitivities obtained with both Diff 2_F-5_F and Delta Diff were again similar and approximately twice as high as those obtained with Diff 2-5. For example, at a specificity of 80%, the sensitivities of Diff 2-5, Diff 2_F-5_F, and Delta Diff were 21%, 61%, and 52%. Unlike analyses using Group 3 subjects, the sensitivity of Delta Diff was slightly higher than that of Diff 2_F-5_F at specificities of 90 and 95 percent.

Analyses were performed to allow comparison of the proportion of abnormality of several standard maneuvers used frequently in the clinical evaluation of individuals with carpal tunnel syndrome and are presented in Table 5a for the dominant hand and in Table 5b for the non-dominant hand. In general, Group 1 subjects had the highest frequency of abnormality and Group 3 subjects had the lowest frequency of abnormality. The frequency of abnormality among Group 2 subjects was generally intermediate between Group 1 and Group 3. For example, Phalen's sign was observed among 50 percent of Group 1 subjects (sensitivity of 50%), 43 percent of Group 2 subjects (specificity of 57%), and 4 percent of Group 3 subjects (specificity of 96%). Similar results were observed for most of the other measures with the exception of abnormal vibration perception and abnormal light touch perception, both of which were more common among Group 2 subjects than among Group 1 subjects for both the dominant and non-dominant hands. In general, the specificity among asymptomatic comparison subjects was much better than the specificity among symptomatic subjects with normal electrophysiologic evaluations.

Objective 2.

Only four Group 1 subjects were willing to undergo even limited repeat nerve conduction velocity testing. No statistical analyses were performed due to the small sample size.

Objective 3.

Repeat vibrotactile threshold measurements were performed on Group 3 subjects seven months after the initial measurements were made. The mean change in Diff 2_F-5_F over the seven month interval was -0.20 log microns (SD=0.58) for the dominant hand and 0.02 log microns (SD=0.48) for the non-dominant hand. The upper 95th percentile values for these results were 0.78 and 0.81 log microns. The mean change in Delta Diff over the seven month interval was -0.01 log microns (SD=0.86) for the dominant hand and 0.12 log microns (SD=0.70) for the non-dominant hand. The upper 95th percentile values for these results were 1.41 and 1.28 log microns.

DISCUSSION AND CONCLUSIONS

A cross-sectional and longitudinal study was performed to assess the utility of vibrotactile threshold measurement for detection of carpal tunnel syndrome. Of special interest was the possible improvement in sensitivity without loss of specificity that might follow a ten minute period of wrist flexion. Significant differences were observed in vibrotactile threshold outcomes between subjects with symptoms consistent with carpal tunnel syndrome and electromyographically demonstrated carpal tunnel syndrome and both subjects with symptoms consistent with carpal tunnel syndrome and normal electromyographic results and subjects without symptoms consistent with carpal tunnel syndrome and normal electromyographic results. Sensitivities observed for the vibrotactile threshold outcomes obtained before the ten minute wrist flexion period were poor. Those obtained after the ten minute wrist flexion period were typically two times or more greater than those obtained before flexion but were still modest in actual value.

The investigators were unable to determine the association between repeated nerve conduction outcomes and either repeated vibrotactile outcomes or repeated symptoms outcomes because only a very small proportion of subjects were willing to undergo repeat evaluation. Estimates of "normal variation" in two of the vibrotactile threshold outcomes over a six month time period are provided to guide investigators who wish to perform repeated measurements.

Estimates in the published literature of the sensitivity and specificity of vibrotactile threshold measurement for detection of carpal tunnel syndrome are quite variable. Using multiple frequency vibrotactile threshold measurements without wrist flexion, Lundborg et al. [1986] found an abnormal result in 77 percent of patients considered to have carpal tunnel syndrome on clinical grounds and in 83 percent of patients with electrodiagnostically-proven carpal tunnel syndrome. However, 54 percent of subjects with hand symptoms and normal electrophysiologic test results had an abnormal measure of vibration threshold suggesting that the high sensitivities may have been achieved by selecting criteria for abnormality associated with poor test specificity.

Using methods similar to those of the current study, Borg and Lindblom [1986] found that vibrotactile thresholds of the index and long fingers increased monotonically as a function of time over a 16 minute period among 100 percent of 12 hands with electrophysiologically proven carpal tunnel syndrome. Two of 12 hands with no electrophysiological evidence of carpal tunnel syndrome also showed an increase. In addition, significant differences in mean vibrotactile threshold were observed between the two groups after 5 minutes of wrist flexion. In another

study of quantitative sensory outcomes among subjects with carpal tunnel syndrome [Borg and Lindblom 1988], vibrotactile thresholds obtained from hands categorized as having CTS were greater than than thresholds obtained from the contralateral, asymptomatic hand. Inadequate information was provided to calculate sensitivity and specificity of the outcome.

A study of multifrequency vibrometry results by Jetzer [1991] used only symptoms and clinical examination results to characterize carpal tunnel syndrome. Statistical methods were not adequately described in the study to allow estimation of sensitivity and specificity.

Using the same vibrometer and a different protocol for measuring vibrotactile thresholds as were used in the current study, Grant et al. [1992] found a significant difference in mean threshold among subjects with electrophysiologically proven carpal tunnel when compared to those who were asymptomatic. Results were not presented in a manner that allowed estimation of sensitivity and specificity.

Vibrotactile thresholds were measured using methods similar to those used in the current study (without wrist flexion) as part of a large government study of office workers [LA Times NIOSH, 1993]. No significant differences in mean threshold were found between "cases" and "controls" of work related upper extremity disorder. In addition, no significant association was observed between vibrotactile thresholds and median nerve conduction parameters. Similarly, Merchut et al. [1990], using the Vibratron II device used in the current study, found no significant differences in mean sensory threshold of the index finger or in the difference between the index finger threshold and the small finger threshold between subjects with electrophysiologically proven carpal tunnel syndrome and matched comparison subjects.

The sensitivity and specificity of clinical maneuvers observed in the current study were similar to those observed in other studies. For example, Katz et al. [1990], reported the sensitivity and specificity of Phalen's sign as 75 and 47 percent among symptomatic subjects categorized on the basis of electrodiagnostic evaluation. In the current study the analogous values were 50 and 57 percent for the dominant hand. They reported the sensitivity and specificity of "sensory loss" as 32 and 81 percent respectively. In the current study the analogous values for loss of vibration perception as determined with a tuning fork were 41 and 86 percent. Possible explanations for the discrepancies include differences in examination technique or different criteria for electrodiagnostic confirmation of carpal tunnel syndrome.

The poor participation rate observed among subjects invited to return for repeated nerve conduction velocity measurement has been described in other studies employing a similar design. Investigators performing studies of the neurotoxic effects of lead in both the United States (Baker et al., 1985) and Finland (Seppalainen et al., 1983) in which nerve conduction outcomes were used also reported large losses of subjects during prospective evaluation. These results emphasize the need to develop objective, quantitative outcome measures of neurologic function that do not use aversive stimulation.

One methodological issue that remains problematic in this area of research is the definition of carpal tunnel syndrome. Specifically, some authors suggest that electrophysiologic studies are not sufficiently sensitive for detection of carpal tunnel syndrome. For example, one author has suggested that the false negative rate of electrodiagnostic evaluation for detection of carpal tunnel syndrome was 8 percent [Grundberg, 1983]. If this were true, estimates of sensitivity made on the basis of electrophysiologically negative, symptom positive subjects would be expected to be biased toward lower values. In the current study, little difference in estimates of sensitivity of the vibrotactile threshold outcomes for any given specificity was observed between the symptomatic and asymptomatic comparison groups. It is noteworthy, however, that such differences were observed for the sta1ndard clinical tests used for detection of carpal tunnel syndrome. The specificities for these outcomes varied substantially between electrophysiologically normal subjects with hand symptoms and electrophysiologically normal subjects without hand symptoms. Among those subjects with hand pain, vibrotactile threshold outcomes based on differences between index and small finger thresholds after wrist flexion discriminated between those with and without electrodiagnostically confirmed carpal tunnel syndrome better than the routine clinical tests.

Conclusions and Recommendations for Future Research

The results of this study allow rational application of vibrometry in epidemiologic studies of carpal tunnel syndrome. The difference in vibrotactile threshold between the index and the small finger after a ten minute period of wrist flexion (Diff 2_F-5_F) is recommended as the outcome measure of choice when making group comparisons. Relatively large and significant group differences between subjects with carpal tunnel syndrome and those without carpal tunnel syndrome were observed for this vibrotactile threshold outcome, especially after a 10 minute period of wrist flexion.

None of the outcome measures used in this study had sensitivity and specificity of sufficient magnitude to justify recommendation of their use as screening tools for identification of

individuals with carpal tunnel syndrome. However, when used among subjects most likely to require actual clinical evaluation, i.e., subjects with hand symptoms, several vibrotactile threshold outcomes provided much better sensitivity and specificity than did other non-aversive tests in common use, such as two point discrimination, Phalen's sign and Tinel's sign.

Because of poor subject acceptance, nerve conduction measurements are not useful in studies requiring repeated measures of nerve function. In this application, vibrometry is an appropriate choice for repeated assessment of nerve function.

Future studies of methods that can produce additional improvement in the sensitivity and specificity of vibrotactile threshold measurement are needed. In addition, improvement in the "gold standard" outcome measure is needed to resolve the debate over the diagnosis of carpal tunnel syndrome. Finally, research to estimate the sensitivity and specificity of any test for carpal tunnel syndrome should use symptomatic disease negative subjects in addition to healthy, asymptomatic subjects in order to obtain unbiased results.

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Table 1. Outcome Variables Used in Analyses

Digit 2	Vibration threshold of the index finger measured prior to wrist flexion.
Digit 5	Vibration threshold of the small finger measured prior to wrist flexion.
Diff 2-5	The difference in vibration threshold between the index finger and the small finger measured prior to wrist flexion (Diff 2-5 = Digit 2 - Digit 5)
Digit 2_F	Vibration threshold of the index finger measured after 10 minutes of wrist flexion.
Digit 5_F	Vibration threshold of the small finger measured after 10 minutes of wrist flexion.
Diff 2_F-5_F	The difference in vibration threshold between the index finger and the small finger measured after 10 minutes of wrist flexion (Diff 2_F-5_F = Digit 2_F - Digit 5_F)
Delta Diff	The difference between Diff 2_F-5_F and Diff 2-5 (Delta Diff = Diff 2_F-5_F - Diff 2-5)

Table 2a. Characteristics of the Study Population Stratified by Carpal Tunnel Group - Dominant Hand

Variable	Total	Gp1	Gp2	Gp3	Prob.
N	119	30	30	59	-
Age (yrs)					
Mean	42.6	50.1	43.9	38.2	<0.001
SD	11.6	11.8	12.6	8.7	
Height (cm)					
Mean	168	166	169	169	NS
SD	9.6	7.4	10.3	10.2	
BMI (kg/m^2)					
Mean	25.3	28.5	26.1	23.3	0.003
SD	5.7	5.6	7.1	3.9	
Sex					
% Female	71.6	83.3	60.0	69.5	NS
Hand dominance					
% Rt. handed	88.0	82.1	90.0	89.8	NS

Table 2b. Characteristics of the Study Population Stratified by Carpal Tunnel Group - Non-Dominant Hand

Variable	Total	Gp1	Gp2	Gp3	Prop.
N	119	27	28	64	-
Age (yrs)					
Mean	41.8	49.0	42.1	38.9	<0.001
SD	10.9	11.7	10.9	9.1	
Height (cm)					
Mean	168	167	167	169	NS
SD	9.6	11.7	10.3	9.9	
BMI (cm/kg^2)					
Mean	25.3	27.6	27.0	23.5	0.01
SD	5.4	5.0	7.1	3.9	
Sex					
% Female	72.3	81.5	71.4	68.6	NS
Hand dominance					
% Rt. handed	72.3	81.5	71.4	68.8	NS

Table 3a. Mean Dominant Hand Vibrotactile Threshold Values Before and After Wrist Flexion for All CTS Groups (Threshold in log microns)

Variable	Group1	Group2	Group3	Prob.*
N	30	30	59	-
Digit 2	0.99	0.75	-0.24	0.002
SD	1.09	1.55	0.71	
Digit 5	0.61	0.37	-0.40	0.009
SD	0.88	1.27	0.65	
Diff 2-5	0.39	0.38	0.16	NS
SD	0.91	0.97	0.55	
Digit 2_F	1.36	0.35	-0.24	<0.001
SD	1.31	1.41	0.73	
Digit 5_F	0.70	0.39	-0.25	NS
SD	0.94	1.31	0.73	
Diff 2_F-5_F	0.67	-0.04	0.01	<0.001
SD	1.00	0.70	0.51	
Delta Diff	0.40	-0.42	-0.16	0.005
SD	1.00	1.09	0.58	

* Statistical significance of group differences from general linear models that include age, height, and BMI as covariates.

Table 3b. Mean Non-Dominant Hand Vibrotactile Threshold Values Before and After Wrist Flexion for All CTS Groups (Threshold in log microns)

Variable	Group1	Group2	Group3	Prob.*
N	27	28	64	-
Digit 2	0.78	0.11	-0.48	<0.001
SD	1.26	0.98	0.64	
Digit 5	0.45	0.11	-0.45	0.02
SD	0.86	0.99	0.68	
Diff 2-5	0.32	0.00	-0.02	0.05
SD	1.02	0.44	0.46	
Digit 2_F	1.02	0.21	-0.46	<0.001
SD	1.59	1.05	0.69	
Digit 5_F	0.32	0.17	-0.39	0.05
SD	0.90	1.01	0.70	
Diff 2_F-5_F	0.69	0.03	-0.08	<0.001
SD	1.23	0.45	0.44	
Delta Diff	0.50	0.03	-0.05	0.002
SD	0.86	0.40	0.37	

* Statistical significance of group differences from general linear models that include age, height, and BMI as covariates.

Table 4a. Sensitivity and specificity for selected vibrotactile threshold outcomes - dominant hand.

I. Group 2 versus Group 1 (dominant hand)

	Specificity			
	70	80	90	95
Sensitivity				
Diff 2-5	30.0	16.7	10.0	10.0
Diff 2_F-5_F	62.1	62.1	34.5	31.0
Delta Diff	65.5	62.1	44.8	34.5

II. Group 3 versus Group 1 (dominant hand)

	Specificity			
	70	80	90	95
Sensitivity				
Diff 2-5	30.0	30.0	16.7	10.0
Diff 2_F-5_F	62.1	55.2	34.5	31.0
Delta Diff	58.6	41.4	31.0	20.7

Table 4b. Sensitivity and specificity for selected vibrotactile threshold outcomes - non-dominant hand.

I. Group 2 versus Group 1 (non-dominant hand)

	Specificity			
	70	80	90	95
Sensitivity				
Diff 2-5	33.3	25.9	22.2	14.8
Diff 2_F-5_F	60.0	60.0	40.0	20.0
Delta Diff	44.0	40.0	40.0	36.0

II. Group 3 versus Group 1 (non-dominant hand)

	Specificity			
	70	80	90	95
Sensitivity				
Diff 2-5	40.7	25.9	22.2	18.5
Diff 2_F-5_F	60.0	60.0	56.0	36.0
Delta Diff	60.0	52.0	44.0	40.0

Table 4c. Sensitivity and specificity for selected vibrotactile threshold outcomes - dominant and non-dominant hands combined.

I. Group 2 versus Group 1 (all hands)

	Specificity			
	70	80	90	95
Sensitivity				
Diff 2-5	31.6	21.1	15.8	12.3
Diff 2_F-5_F	61.1	61.1	37.0	25.9
Delta Diff	55.6	51.9	42.6	35.2

II. Group 3 versus Group 1 (all hands)

	Specificity			
	70	80	90	95
Sensitivity				
Diff 2-5	35.1	28.1	19.3	14.0
Diff 2_F-5_F	61.1	57.4	44.4	33.3
Delta Diff	59.2	46.3	37.0	29.6

Table 5a. Proportion of Abnormal Clinical Examination Results for all Carpal Tunnel Groups - Dominant Hand

	Percent of subgroup with abnormality			
Outcome	Gp1	Gp2	Gp3	Prob.
N	30	30	59	-
Phalen's Sign	50.0	43.3	3.5	<0.001
Tinels Sign	13.3	16.7	1.7	0.03
Two point >= 5mm (digit 2)	13.3	20.7	0.0	0.003
Two point >= 5mm (digit 5)	40.0	31.0	3.4	<0.001
Thenar weakness	41.4	10.0	1.7	<0.001
Thenar atrophy	16.7	6.7	0.0	0.007
Abnormal vibration perception (digit 2)	41.4	13.8	5.4	<0.001
Abnormal vibration perception (digit 5)	24.1	13.8	14.3	NS
Abnormal light touch (digit 2)	34.6	6.9	0.0	<0.001
Abnormal light touch (digit 5)	11.5	10.3	0.0	NS

Table 5b. Proportion of Abnormal Clinical Examination Results for all Carpal Tunnel Groups - Non-Dominant Hand

	Percent of subgroup with abnormality			
Outcome	Gp1	Gp2	Gp3	Prob.
N	27	28	64	-
Phalen's Sign	36.0	23.5	3.2	<0.001
Tinels Sign	14.8	21.4	1.6	0.006
Two point >= 5mm (digit 2)	18.5	22.2	1.6	0.003
Two point >= 5mm (digit 5)	14.8	40.7	7.8	0.001
Thenar weakness	30.8	35.7	1.6	<0.001
Thenar atrophy	14.8	14.3	0.0	0.007
Abnormal vibration perception (digit 2)	26.9	20.0	3.3	0.005
Abnormal vibration perception (digit 5)	15.4	24.0	6.6	NS
Abnormal light touch (digit 2)	17.4	16.0	1.7	0.02
Abnormal light touch (digit 5)	0.0	12.0	0.0	0.006

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16. Abstract (Limit: 200 words) In an effort to assess the utility of vibrotactile threshold measurement for detecting carpal tunnel syndrome (CTS) among adult subjects, a cross sectional and longitudinal study was performed using adults with symptoms of hand discomfort. A control group was also selected. Statistically significant group differences were noted in almost all vibrotactile threshold outcomes between subjects with CTS and those without CTS. The sensitivity of vibrometry performed after 10 minutes of wrist flexion was approximately twice that obtained before wrist flexion for detecting electrophysiologically confirmed CTS. Vibrotactile threshold outcome measures derived from differences between the index and small finger provided better distinction between subjects with electrophysiologically confirmed CTS than did measures based on the index finger alone. Nonquantitative clinical tests used frequently for detecting CTS had excellent specificity when used among asymptomatic comparison subjects and poorer specificity when used in a comparison group with hand pain. The authors suggest that these findings allow rational application of vibrometry in studies of CTS.

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