Treating Carpal Tunnel Syndrome with Dynamic Splinting: A Randomized, Controlled Trial

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Abstract
Carpal tunnel syndrome (CTS) affected more than 7 million Americans in 2006, and paresthesias, pain, and weakness are among the common complaints. The purpose of this study was to examine the effect of using dynamic splinting on patients with CTS. Dynamic splinting is a modality that treats CTS using low-load, prolonged duration stretch to reduce contracture, which contributes to median nerve compression. Fifty patients diagnosed with CTS were recruited for this 60-day study (mean age 51 ± 12). There was a significant difference (improvement) in Levine-Katz functional scores (P < .001, T = 4.265) and in the frequency of improved nerve conduction (P < .001, T = 4.282) for experimental patients. Dynamic splinting reduced experimental patients’ symptoms and improved electrodiagnostic parameters.

Key Words: Contracture reduction, Dynasplint, range of motion, wrist pain

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Introduction
Carpal tunnel syndrome (CTS) is the most common peripheral compressive neuropathy in the United States. With a prevalence of 2.7%, it affected more than 7 million Americans in 2006, and it has a suggested lifetime occurrence of 48 million.1–8 The US Centers for Disease Control Occupational Safety Department estimated the expense of $3.5 billion for this pathology,9 which makes CTS the most expensive peripheral neuropathy in the United States.

Carpal tunnel syndrome is defined as compression and/or entrapment of the median nerve as it traverses through the carpal tunnel, which causes impairment of motor and/or sensory nerve conduction. This results in symptoms that include numbness, paresthesias, and pain in the median nerve distribution.10–21 These symptoms occur as a result of compression of the median nerve at the wrist, frequently due to hypertrophy or edema of the flexor synovium. The rigid, unyielding nature of the transverse palmar carpal ligament and the flexor retinaculum contribute to this compression, and differential diagnosis assessments include patient history, physical examination, and electrodiagnostic tests (nerve conduction and electromyography).22–25 Authors of recent publications have agreed that efficacy of nonsurgical treatment of CTS has not been uniformly curative because such therapeutic treatments (ie, hand therapy or ultrasound) have demonstrated limited opportunity to affect the cause of CTS.

Night (static) splints and corticosteroid injections have been shown effective in reducing pain.4,13,21 Injections may produce temporary relief of symptoms but are rarely curative for individuals with high risk for the condition. Current authors propose investigation of new modalities that may treat the cause of CTS,2,4,6,13,21,24 because modification or cessation of the exacerbating action does not uniformly relieve symptoms of CTS (and it may not be feasible to alter each activity). Dynamic splinting (DS) with low-load, prolonged duration stretch to increase the time at end range (of motion) has been used effectively for more than 25 years for contracture reduction.29–34 Recent studies have shown the efficacy of DS in reducing contracture of both orthopedic and neurological origin in the peripheral body joints of the shoulder, elbow, knee, and ankle.31–33
Treating Carpal Tunnel Syndrome with Dynamic Splinting

The purpose of this study was to examine the effect of using DS (Carpal Tunnel Dynasplint Systems, Dynasplint Systems, Inc., Severna Park, Maryland) on patients diagnosed with CTS.

Methods

Fifty patients were recruited and enrolled in this study from referrals and from the National Institutes of Health (NIH) webpage, www.ClinicalTrials.gov, after gaining approval for the NIH listing. Diagnosis was confirmed with physical examination and a nerve conduction test of the median nerve, and patients then were qualified for participation based on the inclusion/exclusion requirements (Table 1). Five patients were prohibited from participation because they were undergoing manual therapy and/or met other exclusion criteria, and no enrolled patient had a previous CTS diagnosis or previous hand surgery. Table 2 lists patient demographics.

Once recruited and selected for participation, patients were given an informed consent form, briefed on the study (as required by the LifeBridge institutional review board), and randomly assigned to either the experimental or control group. Then each patient had two more scheduled meetings with the surgeon and assistant. All patients were given the standard of care, which included nonsteroidal anti-inflammatory drugs (NSAIDs), and this was the only treatment given to the control patients. Upon enrollment, all patients were given the Levine-Katz function questionnaire, which has been validated as a reliable and reproducible outcome to measure severity of symptoms and functional status in CTS.1–5,17,22,26,35 The Levine-Katz survey used in the study measures symptoms in two categories, totaling 100 points. It first measures the timing, intensity, and duration of pain or paresthesia with the question, “How often do you have wrist pain during the daytime?” The answers ranged from “never” (0) to “constant” (5). The survey then questions functional status, such as difficulty in writing, and the answers ranged from “none” (0) to “unable to do” (5).

Duration of the study was 60 days. This short duration was intentionally designed to measure the immediate change in symptoms and nerve conduction. The experimental patients were treated with DS (Figure 1), and this shorter duration was expected to yield high compliance. One qualified consultant custom fit the DS device to each hand’s length, width, and girth. The first week of DS use was an accommodation period for the patient, and patients were encouraged to wear the unit twice daily for 15 minutes each session. Time was then increased by 2–4 minutes each session.

After the patient comfortably wore the DS device for two 30-minute sessions each day for one week, instructions were given to increase the tension of the DS device once every two weeks, based on tolerance. If the new tension setting caused excess joint fatigue or “soreness,” the patient was instructed to reduce the time to 15 minutes, twice daily, and work the time back up to 30 minutes, twice daily. The goal was to wear the DS device for two sessions per day lasting 30 minutes each and to increase the tension twice a month, based on comfort and tolerance. All patients were instructed to communicate about compliance.

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Table 1

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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<tr>
<td>Patients must exhibit one of the following symptoms of CTS: numbness, tingling, or pain in the wrist or hand</td>
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<td>Patients will be ≥ 18 years old and of either gender</td>
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<td>Patients will agree and be able to sign a voluntary consent to participate form</td>
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<td>Nerve conduction study results as follows:</td>
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<tr>
<td>Sensory conduction latency to peak greater than 3.7 ms when measured with ring pick up on the volar surface of the index finger measured 14 cm from stimulation across the wrist at the median nerve</td>
</tr>
<tr>
<td>Motor conduction latency to take off greater than 4.2 ms when measured with disc pick up on the abductor pollicis brevis muscle measured 8 cm from stimulation across the wrist at the median nerve</td>
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Exclusion Criteria

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<th>Exclusion Criteria</th>
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<tbody>
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<td>Patients that have thenar atrophy of the hand</td>
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<td>Patients that are currently undergoing manual hand therapy</td>
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<td>Patients that have been previously diagnosed with cervical radiculopathy</td>
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<td>Patients whose examination shows evidence of a “double crush” syndrome</td>
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<tr>
<td>Pregnancy</td>
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<tr>
<td>Patients with a ganglion cyst of the wrist</td>
</tr>
<tr>
<td>Nerve conduction study results as follows:</td>
</tr>
<tr>
<td>Sensory conduction latency to peak less than 3.7 ms when measured with ring pick up on the volar surface of the index finger measured 14 cm from stimulation across the wrist at the median nerve</td>
</tr>
<tr>
<td>Motor conduction latency to take off less than 4.2 ms when measured with disc pick up on the abductor pollicis brevis muscle measured 8 cm from stimulation across the wrist at the median nerve</td>
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Table 2

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<tr>
<th>Demographics</th>
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<td>N = 50</td>
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<tr>
<td>Experimental</td>
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<tr>
<td>Control</td>
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<tr>
<td>Mean age: 51.2 ± 12.6 years</td>
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<td>Ethnicity: 48 Caucasian, 1 Asian, 1 Indian</td>
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The purpose of this study was to examine the effect of using DS (Carpal Tunnel Dynasplint Systems, Dynasplint Systems, Inc., Severna Park, Maryland) on patients diagnosed with CTS.
weekly and informed that a second test would be taken after 8 weeks. (All patient records were held in confidence under the Helsinki Declaration by the World Medical Association.)

Data analysis was accomplished with a one-way analysis of variance (ANOVA) with post-hoc t tests to measure difference for these patients. The dependent variable was change in the Levine-Katz function scores, and the independent variables were group and nerve conduction. All data analysis was conducted with an alpha value of 0.05. The SPSS program (Chicago, Illinois) was used for statistical calculations of data transcribed from Microsoft Excel files, and an outside biostatistician, Dr. Ramalingam Shanmugam, from Texas State University, San Marcos, Texas, conducted this analysis.

Results
There was a significant difference in Levine-Katz function scores for the experimental patients ($P < .001, T = 4.265$) but not for the control patients ($P > .05, T = 0.5462$). There was a significant difference between the experimental and control final pain scores ($P < .001, T = 4.408, \text{mean } \Delta = -13.56$) and a significant difference in frequency of improved nerve conduction for the experimental patients ($P < .001, T = 4.282$) (Figure 2). However, a direct, linear correlation was not apparent between reduced pain scores and frequency of improved nerve conduction.

Discussion
The duration of this study was 60 days. This short duration was intentionally designed to measure the immediate change in symptoms and nerve conduction. Dynamic splinting has been shown effective in reducing contracture from head to toe, and this study examines the effect of using DS on patients diagnosed with CTS. The statistically significant reduction in symptoms (determined by improved Levine-Katz function scores) and frequency of improved nerve conduction demonstrated the efficacy of DS in treating the common complaints of CTS.

Other methods of treating symptoms of CTS include immobilization braces, hand therapy, and/or eliminating the action that exacerbates the symptoms, but these methods alone will not reduce compression of the median nerve. Patients whose CTS diagnoses may have been the result of inflammation of the tendon sheaths, advancing osteoarthritis, or other conditions also may benefit by the effect of using DS. This is due to

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**Figure 1. Carpal tunnel dynamic splinting.**

**Figure 2. Results.**
the elongation of the transverse ligament and/or flexor retinaculum, thereby creating increased volume or less compression on the median nerve.

The authors hypothesize that the lack of a direct, statistical correlation between reduced pain scores and improved nerve conduction is attributed to the “learning effect” of taking the Levine-Katz function survey twice within two months. The substantial frequency of improved nerve conduction for the experimental patients (both motor and sensory) demonstrates efficacy in this randomized, controlled trial. Limitations of this study include the short duration, a small subject population, and disproportionate number of women to men. Pure randomization was used instead of a matched-pair experimental design.

Conclusion
This study addresses the need for experiments of new modalities that may treat the cause of CTS. 2,4,6,13,24 The benefit of this noninvasive modality for CTS shows promise. Dynamic splinting was effective in reducing symptoms and improving nerve conduction for patients in this short-term study, and a cross-over study with a longitudinal examination should be conducted to measure the lasting effects of this modality.

References


