Final Report

A Pilot Study of the Carpal Rx for Alleviating Symptoms of Carpal Tunnel Syndrome

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Abstract

A total of 32 subjects with Moderate, Severe or Very Severe carpal tunnel syndrome (CTS) or CTS plus tendonitis began assessment using a short form McGill Pain Questionnaire (MPQ). Of these, 20 subjects completed the study and the remainder was lost to follow-up. Each completed subject used a Carpal Therapist device twice daily for one month. MPQ's obtained at baseline were compared to those obtained after the treatment course. Patient experience and satisfaction reports also were gathered at completion. Relative changes were determined in MPQ scores for hand pain using a severity scale of 1-5 (ranging from none, mild, moderate, severe, very severe). The results demonstrated that 18 subjects (90.0%) improved significantly when compared to baseline (by at least 2.1 severity scale points), which represents a 93.2% improvement. Of these patients, 14 improved dramatically when compared to baseline (by at least 3.0 severity scale points), which represents a 97.9% improvement. Another 2 subjects (10.0%) saw no improvement. Additionally, all 18 subjects who saw improvement (90.0%) reported being "Very Satisfied" with their results. This pilot study concludes that the Carpal Therapist device can provide significant symptomatic relief from CTS and tendonitis.

Introduction

The Carpal Therapist is designed to alleviate the symptoms of carpal tunnel syndrome (CTS) and flexor tendonitis of the wrist and forearm. It is a wearable electromechanical device which performs deep tissue massage and myofascial release within the anterior wrist and forearm. It is intended to alter soft tissue dynamics within the carpal tunnel to achieve symptomatic relief from CTS and tendonitis. This pilot study determined the extent to which subjects with moderate or severe CTS and tendonitis obtained symptomatic relief using this technology. This study also was designed to simultaneously field test the electromechanical components in real-world patient situations.

Subjects and Method

A total of 32 subjects entered the study. Twenty subjects completed the course of therapy with the Carpal Therapist while the remainder was lost to follow-up due to non-contact with the investigator. Completed subjects presented with one of two conditions; carpal tunnel syndrome (CTS) alone (N=13) or CTS in addition to tendonitis (N=7). The primary symptom was hand pain in all subjects. The presence or degree of other symptoms such as numbness and tingling were varied among patients and not evaluated in the efficacy analysis except as part of the patient experience and satisfaction reports (below).

Before therapy was begun, each patient was interviewed with regard to their hand pain and other symptoms as well as hand function abilities. A short-form McGill Pain Questionnaire (MPQ) was completed in accordance with each subject's responses to establish their Baseline symptoms. The short-form MPQ primarily focuses on 15 different qualities of hand pain, where these qualities can be quantified and summarized.

Subjects were shipped a Carpal Therapist along with instructions for use. Each subject was personally contacted within 48 hours of receipt of the device to insure they were using it properly. The therapy schedule for each subject was twice daily treatment (morning and evening) for 15 minutes. Each completed subject received treatment for at least 30 days.

Subjects were contacted one week after therapy began to insure proper device usage operation and to assess initial efficacy. Subjects were again contacted 30-31 days after therapy began to determine efficacy, and to assess any other problems or issues that may have arisen. The short-form MPQ was again completed based on each subject's responses. Subjects were also asked to rate their overall impression of their experience with the Carpal Therapist including their level of satisfaction. This rating scale was "Very Satisfied", "Satisfied", "Unsatisfied" or "Very Unsatisfied".

Follow-up was attempted on all subjects at 45 or 60 days post-therapy. Most subjects were lost to follow-up beyond this time.

The MPQ can be summarized as pain severity ranging between "None", "Mild", "Moderated", "Severe" and "Very Severe".

Summary of Completed Subjects

	Condition	
Subjects	CTS	CTS+Tend
Males	N=11	N=6
Mean Age	37	44
Mean Wt (lb)	209	199
Females	N=2	N=1
Mean Age	29	30
Mean Wt	137	131

Results

A total of 32 devices were shipped to subjects. Four devices malfunctioned (stopped working) where each problem was attributed to mechanical failure (a failed set-screw). Two of those subjects did not want a replacement device. Despite personal instruction, two other subjects misapplied the Carpal Therapist and did not want a replacement. The remaining 28 subjects began therapy. Of those, 20 completed the entire course of therapy (17 male; 3 female). The remainder used the device for various periods of time and reported satisfactory results but failed to return contact by the investigator at one month.

Of the completed subjects assessed at one month, 18 demonstrated decreased pain and other sensations by at least 2.1 severity scale points of the MPQ compared to Baseline symptoms. This means that 90.0% of subjects either improved from "Very Severe" to "Mild", or improved from "Severe/Moderate/Mild" to "None", representing a

93.2% improvement. Of the 18 subjects who demonstrated improvement, 14 improved by at least 3.0 severity scale points. This means that subjects improved from levels of "Very Severe" to "Mild" or "Severe" to "None", representing a 97.9% improvement.

Of the completed subjects assessed at one month, another 2 reported no change in pain and other sensations compared to Baseline symptoms. This means 10.0% of subjects showed no improvement.

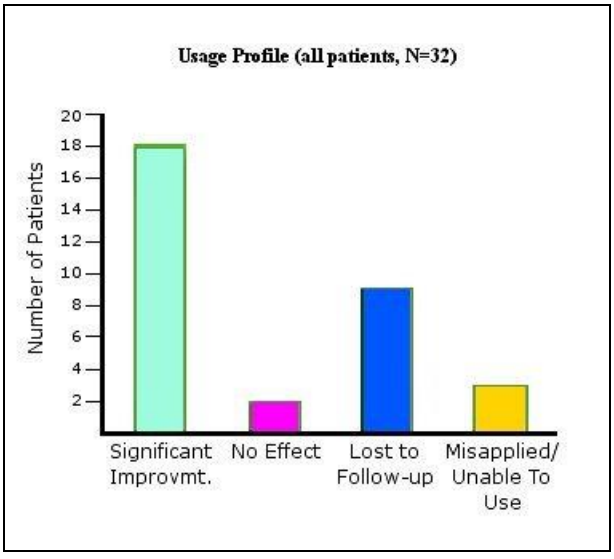
When asked to rate their experience with the Carpal Therapist, all 18 subjects (90.0%) who saw improvement rated their experience as "Very Satisfied". One subject who saw no improvement rated their experience as "Unsatisfied" while the other subject who saw no improvement did not provide satisfaction data.

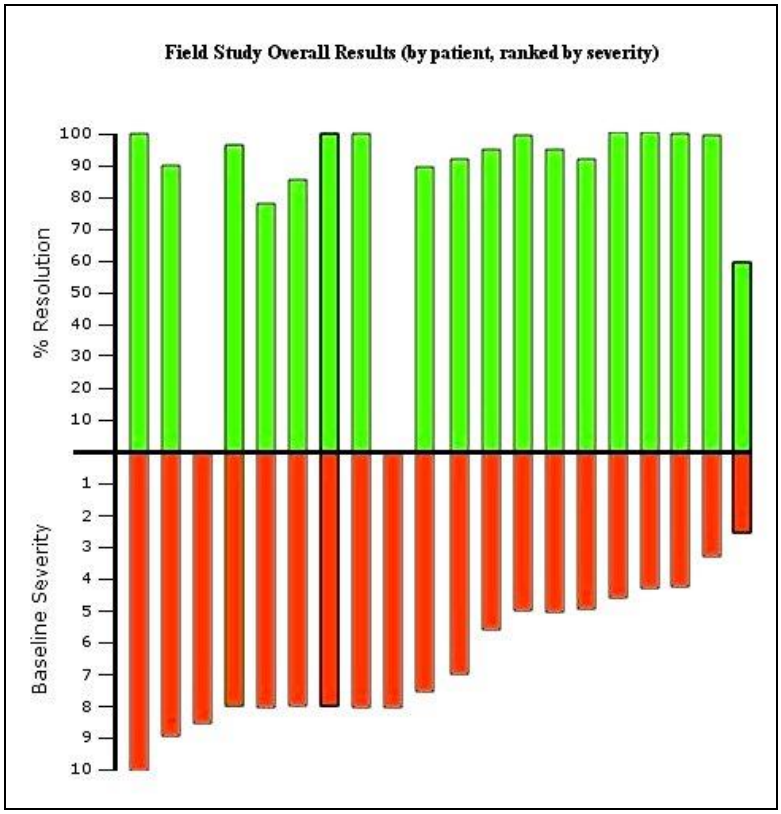
There also were a number of unsolicited testimonials given by the "Very Satisfied" subjects.

The graphs below summarize the results of this study.

Summary of Results for Carpal Therapist Users

Level of Severity	Severity at Baseline	Severity at 1 Month
V. Severe	N=5	N=1
Severe	N=8	N=1
Moderate	N=7	N=2
Mild	0	N=3
None	0	N=13





Discussion and Conclusion

This study concludes that the Carpal Therapist is a simple, non-invasive treatment modality for carpal tunnel syndrome (CTS) and CTS plus tendonitis. It provides dramatic and significant relief from the symptoms of these conditions in a relatively short period of time (one month) with little commitment of time and expense on the part of the sufferer.

The data show that the more severe the baseline pain the more variable the outcome. This might be expected given the more abundant qualities of pain that are characteristic of severe versus moderate CTS.

The significant improvement experienced by most patients is made more interesting in light of the two subjects who saw no improvement. One would expect if they had CTS there would have been "some" decrease in pain. This makes their baseline assessment suspect. In all subjects, the investigator could only verify CTS based on reported symptoms and/or reported personal physician diagnoses. Thus, whether the subjects who saw no improvement actually had CTS or another pain-inducing pathology (arthritis, diabetic neuropathy, etc.) is left to speculation, even though those with such pre-existing pathologies were excluded from study as best as possible.

It is also interesting to note that none of the completed subjects, including those who saw no improvement, wished to return their device for a refund, suggesting each person wished to keep it for continued therapy as needed. This calls the veracity of the patients with no improvement into question. Further, of the 32 subjects who were shipped devices and began therapy, 12 did not return contact by the investigator. Since all subjects were free to return their device without financial or other penalty, yet did not, it suggests that each person wished to keep their device. Presumably, one would only do so if it provided a therapeutic benefit.

It is concluded that the Carpal Therapist is a useful therapeutic instrument in treating moderate to severe CTS in most patients.