Pilot Clinical Study of a Novel Unobtrusive Carpal Tunnel Tissue Manipulation Device in Reducing Symptoms of Carpal Tunnel Syndrome

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INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common peripheral entrapment neuropathy and has been associated with systemic conditions such as rheumatoid arthritis, hypothyroidism, and obesity, as well as occupational tasks involving repetitive manual activities. The most common treatments for CTS have several drawbacks, such as invasiveness (surgery), lack of long-term efficacy (corticosteroid injections), or low compliance (braces).

To overcome these shortcomings, an unobtrusive and non-invasive device was developed to treat CTS by relieving pressure on the median nerve. This carpal tunnel tissue manipulation device (CTMD) is attached to the volar aspect of the wrist and applies a consistent level of tension to the underlying tissue.

Figure 1. Study device (CTMD) vs standard brace for CTS.

A pilot clinical trial was conducted to investigate the feasibility, safety, and efficacy of the CTMD to treat CTS in patients with mild to severe CTS.

METHODS

Clinical Trial Design: Single center, prospective, non-randomized, single subject design

Treatment: CTMD worn 8-10 hours daily for 4 weeks

Primary Outcome Variable: Symptom Severity Scale (SSS) score of the Boston Carpal Tunnel Questionnaire (BCTQ) at 4 weeks vs Baseline.

Inclusion Criteria*:
- Adults ages 21-65
- Mild to severe CTS confirmed via nerve conduction study (NCS) and AANEM criteria (bilateral accepted**)

Exclusion Criteria*:
- No other peripheral neuro-pathies
- No arthritis, thyroid disease, diabetes
- No surgeries, corticosteroid injection, or fractures to the affected wrist(s)

* Abbreviated

** For bilateral subjects, the wrist with higher baseline SSS score was analyzed

RESULT

Improvement in Symptom Severity Scale (SSS)* of the BCTQ

*Symptom Severity Scale (SSS) is on a range of 1 to 5 with 1 being no symptoms and 5 being very severe symptoms.

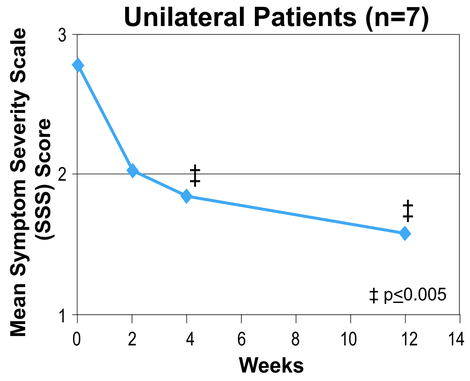

Figure 3. Improvement in Unilateral subjects' SSS scores.

Unilateral subjects' SSS score improved more dramatically than bilateral subjects. Mean SSS score decreased by 0.9 ± 0.5 points (p=0.002) at 4 weeks.

By 12-week follow up, mean SSS score decreased by 1.2 ± 0.5 points compared to baseline (p=0.001).

It was later realized that one unilateral patient had reported wrist arthritis, yet the patient's SSS improved 0.7 pts at 4 weeks up to 0.9 pts by 12 weeks.

Improvement in SSS of the BCTQ

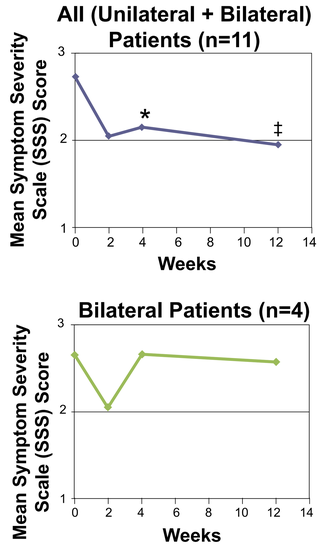

Figure 4a. Mean SSS score at 4 weeks decreased by 0.59 ± 0.68 points vs Baseline (p=0.008). SSS continued to decrease 8 weeks post-treatment, by 0.79 ± 0.74 points (p=0.003).

Figure 4b. Mean SSS for bilateral subjects showed no improvement - primarily weighted by one subject's worsening symptoms.

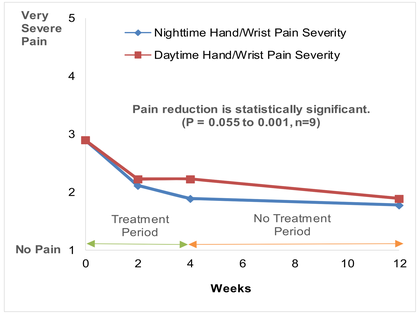

Figure 5. Improvement in Pain Severity

Questions 1 and 3 of the BCTQ-SSS have patients rate their hand or wrist pain severity at night and day time on a scale of 1 (no pain) to 5 (very severe pain).

Table 3. Patient Demographics.

A total of 11 subjects were enrolled. CTS duration was self-reported and based on subject's first diagnosis or first symptoms. CTS severity based on Baseline NCS.

Gender		Age		BMI	
Male	36%	Average	51 ± 11 yrs	Underweight	0%
Female	64%			Healthy	45%
				Overweight	27%
				Obese	27%

Race/Ethnicity		CTS Severity		CTS Duration	
Caucasian	64%	Mild	27%	≤1 yr	36%
African American	18%	Moderate	37%	1-5yrs	9%
Hispanic/Latino	9%	Severe	36%	5-10 yrs	0%
Asian	9%			10-15 yrs	36%
Other	0%			Unknown	18%

DISCUSSION

SSS for combined and unilateral-only patients improved significantly after 4 weeks of wear and when following up 8 weeks post-treatment. This suggests that improvement may be sustained even after the device is no longer worn.

Bilateral patients' average response was dramatically different than unilateral patients', but the sample size was too small to draw meaningful conflusions.

Reduction in pain severity was seen as early as 2 weeks and nighttime pain relief was greater than daytime relief, which is interesting given the device was worn during the day.

High compliance with 4 weeks of daily wear of the device was recorded. In general, subjects reported that the CTMD was very easy to use, very comfortable, and did not restrict range of motion.

CONCLUSION

- **Daily CTMD use for 4 weeks showed significant improvements in CTS symptom severity, with improvement seen as early as 2 weeks and continuing even after treatment stopped.**
- **CTMD use was reported as easy, comfortable, and not restricting range of motion.**
- Future studies are necessary to better understand the reason for improvement, why the effects last after the device is no longer used, and why unilateral patients responded differently than bilateral patients.

ONGOING RESEARCH

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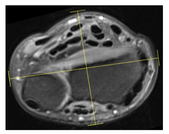

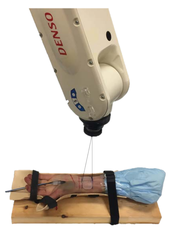

Under an NIH SBIR grant (1R44EB024713-01), further studies are being done to investigate the physiologic and biomechanical changes caused by the device.

- A MRI study is looking at wrist profiles and applied pressures after the device is worn for 10 minutes. The study intends to evaluate fit of the device over a broad range of people, change in median nerve shape and size, and the distribution and magnitude of contact pressures.
- A biomechanical study is ongoing to examine changes in contact pressure on the median nerve in cadaveric hands. The device is attached and then pulled volarly up to 6 mm, and pressure decreases up to 30mmHg have been observed.

Disclosures:
Dr. Jae Son is the inventor of the CTMD and President of PPS. Pauline Luong was employed by PPS and PPS sponsored this study. All authors have ownership interest in an entity established to commercialize the CTMD.

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