(8) Investigation of an Unobtrusive Carpal Tunnel Tissue Manipulation Device for the Treatment of Carpal Tunnel Syndrome: A Pilot Clinical Study

Category: General Rehabilitation

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INTRODUCTION

Carpal Tunnel Syndrome (CTS) involves chronic compression of the median nerve, resulting in numbness, paresthesia, pain, and hand weakness. A novel unobtrusive carpal tunnel tissue manipulation device (CTMD) was developed to relieve pressure on the median nerve without the use of drugs, steroids, or invasive procedures. The device is applied to the volar aspect of the wrist and applies negative pressure to the wrist.

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

Primary Outcome Variable: Change from Baseline in the Symptom Severity Scale (SSS) score of the Boston Carpal Tunnel Questionnaire (BCTQ)*

Table 1. Clinical trial timeline. BCTQ administered at 0, 2, 4, and 12 weeks.

	Treatment Period					Post-Treatment Period							
Wks	0	1	2	3	4	5	6	7	8	9	10	11	12
	CTMD applied 8-10 hrs daily					No CTMD application and no other CTS treatment							
BCTQ	X		X		X								X

Inclusion Criteria (abbreviated):

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

Exclusion Criteria (abbreviated):

- No other peripheral neuropathies
- No arthritis, thyroid disease, diabetes
- No surgeries, corticosteroid injection, or fractures to the affected wrist(s)

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

RESULTS

Improvement in Symptom Severity Scale (SSS)* of the BCTQ
Unilateral Patients (n=7)

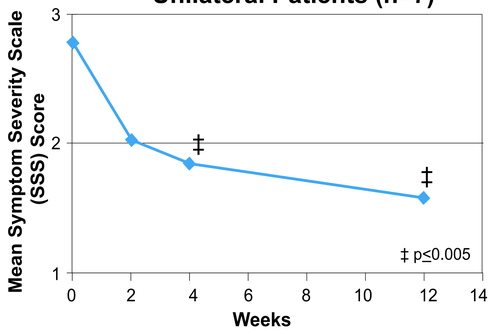


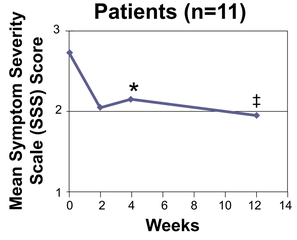
Figure 3. Improvement in Unilateral subjects' SSS scores.

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).

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

All (Unilateral + Bilateral) Patients (n=11)



Bilateral Patients (n=4)

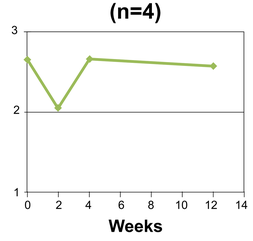


Figure 4a. Mean SSS score at 4 weeks decreased by 0.59 ± 0.68 points vs Baseline (p=0.008). SSS continued to decrease 8 weeks post-treatment, by 0.79 ± 0.74 points (p=0.003).

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

* p<0.05, ‡ p≤0.005

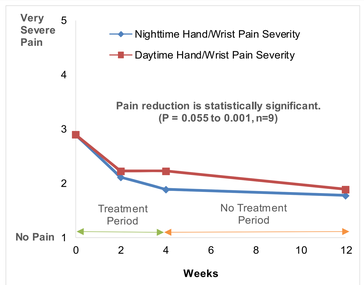


Figure 5. Improvement in Pain Severity

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 2. Change in CTS Severity based on NCS.

Change in NCS-rated CTS Severity	Qty (%)
CTS Resolved	2 (29%)
Improvement	1 (14%)
No change	4 (57%)
Worse	0*

Of the 11 subjects, 7 subjects completed a post-treatment NCS (12-week follow-up).

Change in NCS-related severity is defined as CTS severity rated via NCS at 12-wk compared to Baseline (e.g., moderate to mild).

Nearly half of the subjects with follow-up NCS experienced improvement in CTS severity.

*Though no CTS severity worsened via NCS diagnosis, one bilateral subject reported worse SSS throughout the study.

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		Race/Ethnicity		CTS Severity		CTS Duration	
Male	36%	Average	51 ± 11 yrs	Underweight	0%	Caucasian	64%	Mild	27%	≤1 yr	36%
Female	64%			Healthy	45%	African American	18%	Moderate	37%	1-5yrs	9%
				Overweight	27%	Hispanic/Latino	9%	Severe	36%	5-10 yrs	0%
				Obese	27%	Asian	9%			10-15 yrs	36%
						Other	0%			Unknown	18%

DISCUSSION

Compliance with the CTMD daily for 4 weeks was very high, and subjects reported the device was very comfortable, very easy to wear, and did not restrict range of motion.

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.

While overall SSS improved, most subjects' NCS results remained unchanged. However, 29% of subjects had normal follow-up NCS results, suggesting their CTS had been resolved.

Due to the study design and small sample size, additional investigation with larger sample size and appropriate comparative arms is needed to confirm results and better understand what may cause these findings.

CONCLUSION

- **Daily CTMD use for 4 weeks showed significant improvements in CTS symptom severity.**
- **Symptoms improved as early as 2 weeks and continued to improve even after the treatment period.**
- 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.

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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