PREMUS 2019
10th International Scientific Conference on the Prevention of Work-Related Musculoskeletal Disorders

An Unobtrusive Wrist Orthotic For Carpal Tunnel Syndrome Intervention

Poster 16

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INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common upper peripheral entrapment neuropathy and a common work-related musculoskeletal disorder.

In 2017, work-related CTS led to 30 median days away from work in the USA (a key measure of illness or injury severity).[1] Inability to work costs the employee income and costs the employer in reduces productivity and increased expenses.

A wrist orthotic was developed to treat symptoms of CTS by non-invasively decompressing the median nerve. The CTS wrist orthotic is attached to the volar side of the wrist using hypoallergenic adhesive and worn throughout the day.

A pilot clinical study investigated the safety and efficacy of the CTS wrist orthotic as a treatment for CTS and subsequent biomechanics experiments validated the pressure reduction hypothesis.

Figure 1. CTS wrist orthotic vs standard brace

[1] *https://www.bls.gov/iif/osch0062.pdftvv*

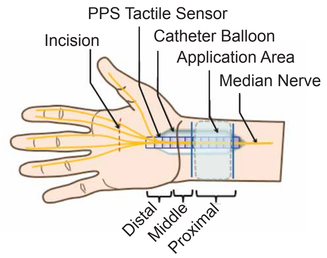
METHODS

Pilot Clinical Study Design:

- Single arm: CTS wrist orthotic, worn 8-10 hours/day
- Treatment Duration: 4 weeks
- Follow-up: 8 weeks post-treatment
- Patients: 11 adults (ages 21-65) with mild to severe CTS, confirmed via NCS
- Outcome Measure: BCTQ SSS (1-5 Likert Scale), assessed fortnightly during treatment and monthly post-treatment

***In Vitro* Pressure Study Design:**

- 10 forearms from underweight, normal and overweight cadavers
- PPS Tactile Pressure Sensors inserted above median nerve within the forearm
- Baseline internal pressure elevated to 100 mmHg - CTS patients have higher carpal tunnel pressures
- Changes in pressure on the median nerve measured in response to cyclic (20x) lifting (d=0-6mm) of the volar wrist tissue by the wrist orthotic, using a programmed robotic arm.



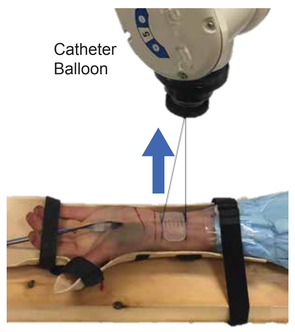
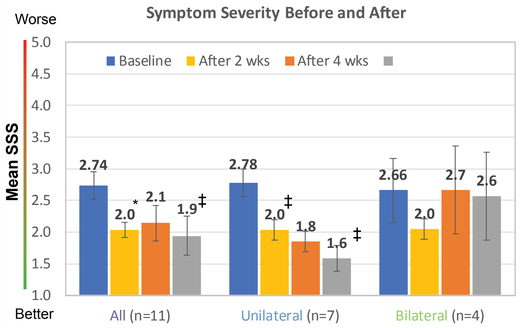


Figure 2. Experimental setup for in vitro simulation and measurement of wrist pressure

RESULTS

Pilot Clinical Study



*error bars=standard error, * p<0.05, ‡ p≤0.005*

Figure 3. Change in SSS of the BCTQ improved by as much as 0.9 points after 4 weeks of daily wear and continued to improve post-treatment, by as much as 1.2 points (p=0.001) compared to baseline.

- Combined patients' SSS improved (i.e. symptom severity score decreased) by an average of 0.59 ± 0.68 points after 4 weeks of daily wear (p=0.008).
- SSS continued to decrease 8 weeks post-treatment, by 0.79 ± 0.74 points (p=0.003).
- Unilateral patients (n=7) SSS improved by an average of 0.9 ± 0.68 points after 4 weeks of daily wear (p=0.002).
- Bilateral patients (n=4) SSS showed no improvement - primarily weighted by one subject's worsening symptoms.

(average ± standard deviation)

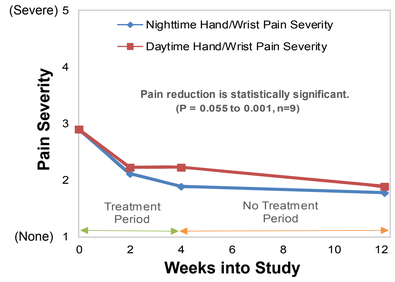


Figure 4. Patients' hand/wrist pain severity at night and day time also decreased from 3 to 2.

- 2 healthcare professionals
- 1 construction
- 1 unemployed
- 1 stay at-home parent
- 3 clerical jobs (notary public, writer)
- 2 academic (student, faculty)
- 1 property manager

Figure 5. Patients came from a broad range of occupations, from labor to clerical jobs.

In Vitro Pressure Study

- Significant reductions in internal wrist pressure were found within the middle and proximal regions of the wrist with increasing volar wrist tissue lifting distance.
- When the volar wrist tissue was lifted 6 mm in repeated trials, distal wrist pressures did significantly decrease, possibly due to tissue stretching.

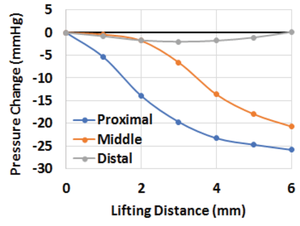


Figure 6. Average pressure change within cadaver wrists as a function of device lifting distance

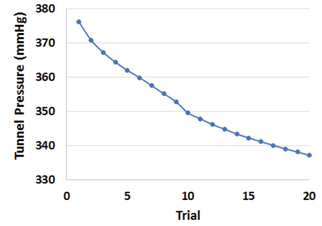


Figure 7. Pressure at the distal (tunnel) region at 6mm lifting over repeated trials

CONCLUSIONS

- Symptom and pain severity may improve as early as 2 weeks into treatment, but study was not statistically powered.
- In vitro cadaver study results suggest symptom reduction seen in patients may be attributed to device lifting the wrist tissue (as little as 3 mm) and reducing pressure within the wrist.
- Although CT pressure was not significantly affected by proximal tissue lifting distance, data suggests repeated use may reduce baseline CT pressure.

DISCUSSIONS & ONGOING WORK

- Wearing the CTS wrist orthotic improved symptom and pain severity, especially for patients with unilateral CTS.
- Bilateral CTS patients may not have responded as well to treatment, due to the inability to compensate with the other, healthier hand.
- A potential placebo effect cannot be ruled out, due to the open design of the study.
- As a follow-up to the pilot study, a larger statistically-powered, randomized, placebo- controlled, multi-center clinical trial exploring 8 weeks of device wear was launched and is over halfway complete.
- Initial efforts to use the device during manufacturing work environments suggest device should be used at night or with tape to additionally secure the device.
- Seeking collaborations with researchers to establish worker health & safety programs using the CTS wrist orthotic as a preventative in hand-intensive tasks.

Acronyms:
BCTQ = Boston Carpal Tunnel Questionnaire
CTS = carpal tunnel syndrome
FSS = Functional Severity Scale
NCS = nerve conduction study
SSS = Symptom Severity Scale
*Symptom Severity Scale (SSS) is on a range of 1 to 5 with 1 being no symptoms and 5 being very severe symptoms.

Disclosures:
PPS: study sponsor.
Dr. Jae Son: CTS wrist orthotic inventor & president of PPS.
Pauline Luong: employed/contracted by PPS.
Son, Luong, Li, King, Dickason, and Diamond have equity in the entity established to commercialize the CTS wrist orthotic.

Research reported in this publication was supported by the National Institute Of Biomedical Imaging And Bioengineering of the National Institutes of Health under Award Number R44EB024713.