

Continuous Low-Level Heat Wrap Therapy Is Effective for Treating Wrist Pain

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ABSTRACT. Michlovitz S, Hun L, Erasala GN, Hengehold DA, Weingand KW. Continuous low-level heat wrap therapy is effective for treating wrist pain. *Arch Phys Med Rehabil* 2004; 85:1409-16.

Objective: To evaluate the efficacy of continuous low-level heat wrap therapy for the treatment of various sources of wrist pain including strain and sprain (SS), tendinosis (T), osteoarthritis (OA), and carpal tunnel syndrome (CTS).

Design: Prospective, randomized, parallel, single-blind (investigator), placebo-controlled, multicenter clinical trial.

Setting: Two community-based research facilities.

Participants: Ninety-three patients (age range, 18–65y) with wrist pain.

Intervention: Subjects with moderate or greater wrist pain were randomized and stratified to 1 of the following treatments: efficacy evaluation (heat wrap, n=39; oral placebo, n=42) or blinding (oral acetaminophen, n=6; unheated wrap, n=6). Data were recorded over 3 days of treatment and 2 days of follow-up.

Main Outcome Measures: The primary comparison was between the heat wrap and the oral placebo group among SS/T/OA subjects for pain relief. Outcome measures included pain relief (0–5 scale), joint stiffness (101-point numeric rating scale), grip strength measured by dynamometry, and perceived pain and disability (Patient Rated Wrist Evaluation [PRWE]); subjects with CTS also completed the Symptom Severity Scale and Functional Status Scale.

Results: Heat wrap therapy showed significant benefits in day 1 to 3 mean pain relief ($P=.045$) and increased day 3 grip strength ($P=.02$) versus oral placebo for the SS/T/OA group. However, joint stiffness and PRWE results were comparable between the 2 treatments. For the CTS group, heat wraps provided greater day 1 to 3/hour 0 to 8 mean pain relief ($P=.001$), day 1 to 3 mean joint stiffness reduction ($P=.004$), increased day 3 grip strength ($P=.003$), reduced PRWE scores ($P=.0015$), reduced symptom severity ($P=.001$), and improved functional status ($P=.04$). In addition, the heat wrap showed significant extended benefits through follow-up (day 5) in the CTS group.

Conclusions: Continuous low-level heat wrap therapy was efficacious for the treatment of common conditions causing wrist pain and impairment.

Key Words: Carpal tunnel syndrome; Heat; Musculoskeletal diseases; Osteoarthritis; Pain; Rehabilitation; Wrist.

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THE WRIST IS A COMMON site of pain and disability resulting from sports-related and occupational injuries. The complexity of wrist injuries and associated patient distress has resulted in wrist pain being termed “the ‘back’ of the upper extremity.”¹ In the 1988 National Health Interview Survey, 1.87 million respondents reported having carpal tunnel syndrome (CTS); 588,000 reported having tendonitis or related syndromes of the hand, and an estimated 2 million had hand-wrist arthritis with 20% reporting a resultant major change in work activities, jobs, or missed work days.²

Wrist pain can occur after a single traumatic incident, repetitive activity, or secondary to arthritis. Repetitive activity is a mechanism of injury for work-related musculoskeletal disorders (WRMSD). Also referred to as cumulative trauma disorder, WRMSDs are associated with significant disability among working-age individuals.³ The burden on society has continued to grow as jobs have changed from being task oriented to time dependent. Increased requirements for speed and efficiency have led to increased muscular tension within the upper extremities, accelerating muscular overload and biomechanical stress on tendons, synovial membranes, joints, and nerves.⁴ The economic impact of these disorders, estimated at more than \$500 million in 1989, has led to requests for sweeping changes in the work environment.⁵ Of these, CTS is among the most frequently claimed WRMSD and one of the most costly injuries of the upper extremity.⁶

Various intervention strategies are used to treat wrist pain when the etiology is not because of fracture or carpal instability. These interventions include the use of pharmacologic agents such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), local steroid injections, immobilization with splints, and in some cases surgical intervention. Despite these interventions, more than 50% of people suffering from upper-extremity WRMSDs continue to have symptoms interfering with work and recreational activities more than 1 year after presentation.^{7,8}

A novel new treatment modality delivering continuous low-level topical heat for at least 8 hours via a wearable wrap has been developed to treat painful conditions of the musculoskeletal system. This heat wrap therapy has been reported to be effective and safe in the treatment of nonspecific low back pain and primary dysmenorrhea.⁹⁻¹² Our study was undertaken to evaluate the therapeutic benefit of continuous low-level heat wrap therapy in the treatment of common painful musculoskeletal disorders of the wrist. The objective of our study was to determine the clinical efficacy of continuous low-level heat wrap therapy as compared with oral placebo treatment in

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subjects with wrist pain because of strains or sprains (SS), tendinosis (T), osteoarthritis (OA), or CTS.

METHODS

This was a prospective, randomized, placebo-controlled, single-blind (investigator), parallel study conducted at 2 community-based clinical research centers. The study was approved by the investigational review board of Research Testing Laboratories, Great Neck, NY. Subjects, ages 18 through 65 (mean \pm standard deviation [SD], $44.8 \pm 10.3y$) were recruited from the clinic database and via print advertising. All 94 subjects provided informed consent.

Participants

Generally healthy subjects with wrist pain, primarily because of strain or sprain, tendinosis, OA, or CTS were recruited for participation. Of the 94 total subjects, 57 had wrist pain associated with a sprain or strain injury, 13 had OA, and 24 with CTS.

Pain had to be of at least moderate or greater intensity using a 6-point categorical scale (0, none; 1, mild; 2, moderate; 3, moderately severe; 4, severe; 5, very severe) at baseline (day 1) on the treatment-targeted wrist.⁹⁻¹² Wrist pain from injury had to have occurred more than 48 hours prior to study enrollment. For those subjects who were classified under the OA group, the diagnosis of OA of the wrist was confirmed based on the available clinical evidence (medical records). The clinical diagnosis of CTS was made based on pain and or paresthesia within the median nerve distribution of the digits¹³ and a positive median nerve compression and wrist flexion test whereby radiating pain or numbness were verified in the lateral 3½ digits.¹⁴ Although the most common symptoms of CTS include paresthesia and pain in the distribution of the median innervated digits, this disorder can also cause pain radiating up the forearm and pain in the volar wrist.¹⁵

Female subjects of child-bearing potential were required to have a negative urine pregnancy test and were required to use an acceptable method of contraception from the last menses and consented to continue this same method for the duration of the study. Subjects were required to abstain from using other forms of sustained heat and ice therapy, magnets, paraffin treatments, hot water bottle, heating pad, massage therapy, joint manipulation treatments, saunas, spa baths, steam rooms, therapeutic hot showers, and holistic or herbal therapies for treatment of pain while participating in this study. Subjects consented to abstain from taking systemic analgesics 24 hours before study treatment initiation (48h for long-acting NSAIDs), other analgesic medication or remedies, or consuming alcoholic beverages approximately 12 hours before taking the first dose of study medication or heat wrap application and throughout the study.

Prospective subjects were excluded from the study if they had any surgery to the most symptomatic wrist in the 6 months before enrollment; had evidence or history of radiculopathy or peripheral neuropathy of the upper extremities, fracture of the involved wrist in the previous 6 months, collagen vascular disease or other systemic diseases causing joint pain, fibromyalgia, diabetes mellitus, peripheral vascular disease, osteoporosis, gastrointestinal (GI) ulcers, GI bleeding or perforation, renal disease, pulmonary edema, cardiomyopathy, liver disease, intrinsic coagulation defects, bleeding diseases or anticoagulant therapy (eg, warfarin); were taking antidepressant or anti-anxiety medications (eg, fluoxetine [Prozac], paroxetine [Paxil], sertraline [Zoloft], lithium); had taken systemic corticosteroid (not including inhaled corticosteroid) medications within 30 days before taking the first dose of study medication



Fig 1. Heat wrap applied to the wrist.

or during the study; had taken systemic muscle relaxant medications, including mild tranquilizers, within 24 hours before taking the first dose of study medication or during the study; had received a corticosteroid injection into the involved wrist in the previous 6 months; or had applied topical capsaicin within 2 weeks before enrollment.

Prospective subjects with any serious medical disease(s) were excluded at the investigator's discretion, as were subjects enrolled in any investigational drug or device trials. People were also excluded if they had skin lesions (eg, rash, bruising, swelling, irritation, laceration, excoriation, ulceration) on the wrist. Additional exclusion criteria were a history of alcohol and/or drug abuse, involvement in a worker's compensation claim, and hypersensitivity to acetaminophen or heat.

Procedure

A total of 94 subjects were recruited for participation and randomized to 1 of 4 treatments in a 6:6:1:1 ratio: heat wrap,^a which heats to 104°F (40°C) within 30 minutes of exposure to air and maintains this temperature continuously for an 8-hour period of wear; oral placebo (2 tablets, 4 times daily); active analgesic (acetaminophen, 500mg/tablet, 2 tablets 4 times daily); or an unheated wrap. The latter 2 groups, included only for blinding purposes, were intentionally small in size (n=6). All treatments were administered for 3 consecutive days; oral treatments were taken approximately 5 hours apart and the wraps were worn for 8 continuous hours after being applied to the wrist with a skin contact adhesive and then wrapped around the wrist and attached back onto itself with a second adhesive tab (fig 1). In case of bilateral wrist pain, the most painful wrist was the target wrist for the heat wrap treatment.

All clinical assessments were standardized between sites. Each clinical testing site had a primary investigator who was blinded to the treatments, as were all of the study staff involved in study conduct. Three visits to the study site were required: visit 1 (day 1) for screening, qualification, and treatment initiation; visit 2 (day 3) to obtain evaluations; and visit 3 (day 5) was to finalize the study.

This study involved 3 consecutive days of treatment. On treatment day 1, pain relief (0–5 verbal rating scale) and joint stiffness (101-point numeric rating scale) were rated at baseline (hour 0), then hourly for hours 1 to 8, and then every 2 hours until 12 hours poststudy treatment initiation. On days 2 and 3, pain relief and joint stiffness were rated at hour 0 and then every 2 hours (hour 2, 4, 6, 8, 10, 12h) after treatment started. Via diary entries, subjects provided additional ratings for these 2 variables approximately 24- and 48-hours after site visit 2 on day 3. Subjects were also required to complete baseline (day 1, hour 0), posttreatment (day 3, hour 8), and follow-up (hour 48 postsite visit 2 on day 3) measurements for grip strength^b assessment¹⁶ and the Patient-Rated Wrist Evaluation¹⁷

Table 1: Demographic and Baseline Characteristics: SS/T/OA Subjects

Statistic	Heatwrap (n=29)	Oral Placebo (n=30)	Oral APAP (n=5)	Unheated Wrap (n=5)	Overall (N=69)
Gender					
Women	47%	47%	100%	40%	50%
Men	53%	53%	0%	60%	50%
Age (y)					
Mean	43.93	43.33	46.60	47.60	44.13
SD	11.19	10.08	6.54	9.56	10.23
Joint stiffness (0–100 scale)					
Mean	53.03	54.87	65.00	58.00	55.03
SD	21.14	21.54	13.69	25.15	20.98
PRWE score					
Mean	57.43	57.76	70.93	58.43	58.64
SD	16.13	19.09	9.97	16.67	17.24
Target wrist pain intensity (0–6 scale) (% of subjects)					
Moderate (2)	60%	60%	60%	60%	60%
Moderate (>2)	40%	40%	40%	40%	40%

Abbreviation: APAP, acetaminophen.

(PRWE). Subjects with CTS also completed a symptom severity scale (SSS) and a functional status scale (FSS).¹⁵ The declared primary study outcome measure was the average pain relief score over the 3-day treatment period. Three secondary efficacy parameters were specified: (1) average 3-day joint stiffness reduction, (2) day 3 change in grip strength assessment, and (3) day 3 reduction in PRWE total wrist score.

The trial hypothesis was that the heat wrap would provide significantly greater day 1 to 3 mean pain relief and secondarily greater day 1 to 3 mean joint stiffness reduction, increased day 3 grip strength, and reduced day 3 PRWE total wrist scores versus oral placebo for both the SS/T/OA and CTS wrist pain groups. Power analyses indicated that a sample size of 26 in each of the heat wrap and oral placebo SS/T/OA groups had at least 80% power to detect a difference in days 1 to 3/hour 0 to 8 pain relief means of .75, assuming that the common SD was 1.02 using 1-tailed testing at the .050 level of significance.

Assessment of safety was made from the evaluation of adverse events voluntarily reported to the study staff and the skin assessments done at screening and after 3 days of treatment on day 5.

Statistical Analysis

Statistical analysis was conducted according to a prespecified analysis plan by using the Statistical Analysis System, version 6.12.^c A set of per protocol or “evaluable” subjects were identified as the primary analysis set before unblinding the data. For all analyses, the study population was divided into SS/T/OA subjects and CTS subjects. Because statistical hypotheses were tested and interpreted marginally for the 2 wrist pain groups, no further adjustment for multiple testing was necessary besides declaring a primary endpoint.¹⁸

Before analysis, derived measures were calculated from the raw efficacy data. For both pain relief and joint stiffness, scores were averaged across consecutive hourly time points during the time of wrap wear to calculate hour 0 to 8 mean scores (analogous to total pain relief over 8h)¹⁹ by treatment day. Grip strength was scored as the mean of 3 consecutive grip strength assessments taken per study visit. Total wrist scores were calculated from PRWE data by averaging the pain and disability and handicap subscale scores.¹⁷ The overall and FSS scores were each calculated as the means of the 11 and 8 individual items' scores, respectively.¹⁵

Hour 0 to 8 mean pain relief scores on study days 1, 2, and 3 were analyzed by using a generalized estimating equation (GEE) model to fit repeated measures data.²⁰ Independent model variables included gender, treatment day, and treatment group. A 1-tailed z test based on empirical standard error (SE) estimates was used to test for statistical evidence of greater overall 3-day pain relief in the heat wrap group compared with the placebo group at the .05 level of significance. Similar GEE methodology was used for the 3-day joint stiffness reduction data, except that baseline joint stiffness was used in place of gender as an explanatory variable (covariate). Analysis of covariance (ANCOVA) models (adjusted for baseline scores) were used to test for treatment differences between the heat wrap and placebo groups for the day 3 change in grip strength assessment and the day 3 PRWE total wrist score reduction by using 1-tailed t tests.

Additionally, 2-way analysis of variance (ANOVA) procedures modeled for gender and treatment group were conducted by time point on pain relief data. ANCOVA procedures, adjusted for baseline scores, were also run by time point on all other efficacy variables including mean SSS and mean FSS scores to detect differences between the heat wrap and oral placebo groups.

Key demographic variables were analyzed by using a series of 2-way ANOVA interaction models in an exploratory manner to determine what, if any, role subgroup variables played with treatment on the study's primary endpoint. These demographic variables included study site, gender, age, race, weight, wrist circumference, tobacco usage, and the incidence that the treatment targeted wrist was on the subject's dominant hand.

RESULTS

A total of 94 subjects were enrolled in the study and randomly assigned to the following treatments: heat wrap (n=40), placebo (n=42), acetaminophen (n=6), and unheated wrap (n=6). Of these, 1 subject was discontinued from the study in the heat wrap group (lost to follow-up). Demographic data break out by diagnosis and treatment groups for subjects that completed the study are provided in tables 1 and 2. The main treatment groups—heat wrap and oral placebo—were comparable with respect to their baseline characteristics. Among the causes of wrist pain, 56 cases (60%) of sprain and strain and tendinosis were because of atraumatic injuries of no defined

Table 2: Demographic and Baseline Characteristics: CTS Subjects

Statistic	Heatwrap (n=10)	Oral Placebo (n=12)	Oral APAP (n=1)	Unheated Wrap (n=1)	Overall (N=24)
Target wrist pain intensity (0–5 scale)					
Moderate (2)	30%	50%	0%	100%	42%
> Moderate	70%	50%	100%	0%	58%
Gender					
Women	90%	75%	100%	100%	83%
Men	10%	25%	0%	0%	17%
Age (y)					
Mean	50.10	45.08	30.00	51.00	46.79
SD	8.82	10.84	NA	NA	10.30
Joint stiffness (0–100 scale)					
Mean	57.50	61.58	65.00	100.00	61.63
SD	30.30	21.76	NA	NA	25.64
PRWE score (0–100)					
Mean	63.38	69.82	41.11	69.89	65.94
SD	21.49	16.07	NA	NA	18.51
SSS (0–5 score)					
Mean	3.21	3.20	2.55	2.18	3.14
SD	0.37	0.78	NA	NA	0.63
FSS (0–5 score)					
Mean	2.84	3.11	2.50	2.63	2.95
SD	0.66	0.98	NA	NA	0.82

Abbreviation: NA, not applicable.

single event, 13 (14%) were because of OA as determined by clinical evidence of medical records, and 24 (26%) were because of signs and symptoms consistent with CTS. In 63 (68%) of the 93 cases, the wrist corresponding to the subject’s dominant hand was evaluated as the target wrist, although 58 (62%) of subjects reported pain of at least mild severity on both wrists at baseline. For all efficacy data, the evaluable per protocol set was used for statistical analysis, as planned.

SS/T/OA Efficacy Results

Pain relief. The primary efficacy analysis indicated that the heat wrap (mean ± SE, 1.68±0.23) provided significantly greater day 1 to 3/hour 0 to 8 mean pain relief than did the placebo (mean ± SE, 1.15±0.21) (*P*=.045) among evaluable SS/T/OA subjects. This represents a 46% increase in the pain relief means for the heat wrap group. Exploratory analyses found that the heat wrap displayed nominally significantly greater pain relief versus placebo at the *P* equal to .05 or greater level of significance for 8 of the 26 time points collected throughout the 5-day study (fig 2).

Joint stiffness reduction. At baseline, SS/T/OA subjects reported a mean joint stiffness score ± SD of 55.03±20.98 out of a maximum score of 100. During treatment, no significant difference in joint stiffness reduction was observed between the heat wrap (mean ± SE, 15.7±4.2) and the placebo (mean ± SE, 9.9±3.0) (*P*=.13) score for the day 1 to 3/hour 0 to 8 means. The heat wrap group showed a nominally significantly (*P*≤.05) greater reduction in joint stiffness versus placebo at 2 of the 26 time points. These differences occurred on day 2 at the first time point postwaking and the first time point after treatment initiation (fig 3).

Change in grip strength. At baseline, SS/T/OA subjects’ grip strength ± SD averaged 19.2±12.8kg of force. Secondary efficacy analyses showed that the heat wrap (mean ± SE, 6.44±1.34kg) was associated with a significantly greater increase in grip strength versus placebo (mean ± SE, 2.48±1.34 kg) (*P*=.021) at the end of the treatment period on day 3. At the day

5 follow-up, additional analyses found that the increase in grip strength for the heat wrap (mean ± SE, 6.14±1.41kg) only trended higher than placebo (mean ± SE, 3.31±1.42kg) (*P*=.08) but failed to reach statistical significance (fig 4).

PRWE reduction. At baseline, SS/T/OA subjects reported a mean PRWE total wrist score ± SD of 58.64±17.24 out of a maximum score of 100. Secondary efficacy analyses found no significant difference in PRWE total wrist reduction scores between the heat wrap (mean ± SE, 13.0±2.3) and placebo (mean ± SE, 12.1±2.2) (*P*=.39) on day 3. Further, no difference was observed between the groups (*P*=.15) on day 5 (fig 5).

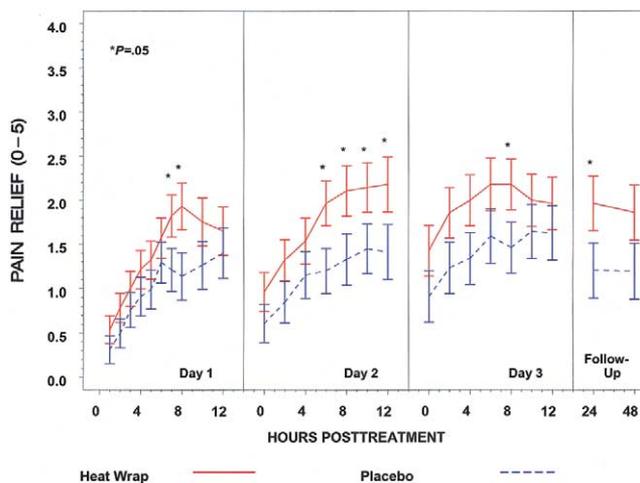


Fig 2. Mean pain relief scores ± SE for the heat wrap group and the oral placebo group over the treatment study period (days 1–3) and follow-up period (days 4–5) for SS/T/OA subjects, with markers to indicate statistically significant differences between groups.

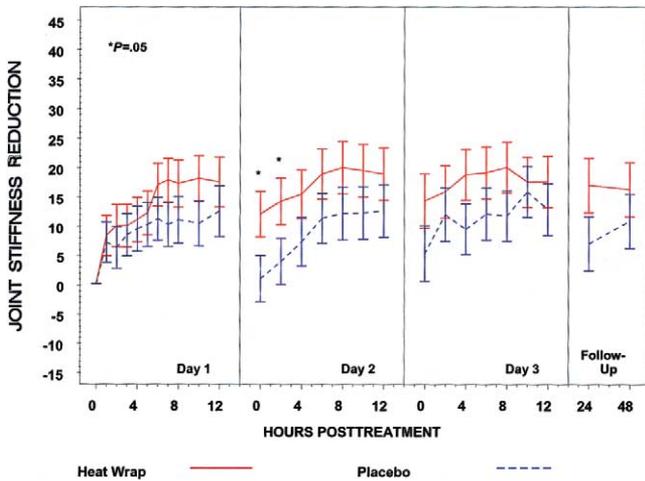


Fig 3. Mean joint stiffness reduction scores \pm SE for the heat wrap group and the oral placebo group over the treatment study period (days 1–3) and follow-up period (days 4–5) for SS/T/OA subjects, with markers to indicate statistically significant differences between groups.

CTS Efficacy Results

Pain relief. Primary efficacy analysis of evaluable CTS subjects indicated that the heat wrap (mean \pm SE, 2.18 \pm 0.34) was associated with significantly greater day 1 to 3/hour 0 to 8 mean pain relief than placebo (mean \pm SE, .95 \pm .25) ($P=.001$). This represented an increase of 129% in pain relief means with the heat wrap. Exploratory analyses found that the heat wrap provided nominally significantly ($P\leq.05$) greater pain relief versus placebo at 20 of the 26 time points collected (fig 6).

Joint stiffness reduction. At baseline, CTS subjects reported a mean joint stiffness score \pm SD of 61.63 \pm 25.64 out of a maximum score of 100. Secondary analysis of CTS subjects indicated that the heat wrap group (mean \pm SE, 21.8 \pm 5.5) provided significantly greater day 1 to 3/hour 0 to 8 reduction in joint stiffness than the placebo group (mean \pm SE, 4.9 \pm 3.1) ($P=.004$). Exploratory analyses found that the heat wrap showed a nominally significantly ($P\leq.05$) greater reduction in joint stiffness versus placebo at 19 of the 26 time points,

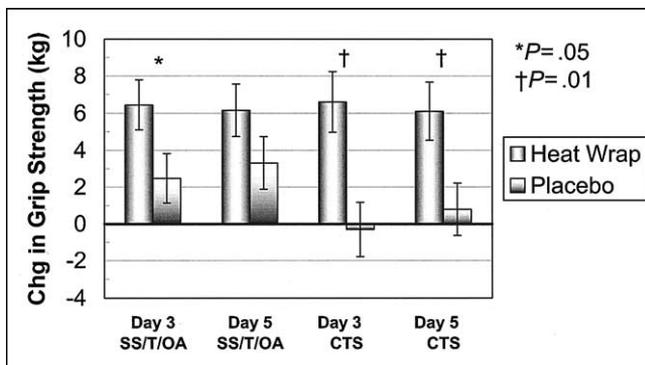


Fig 4. Mean change in grip strength \pm SE for the heat wrap group and the oral placebo group on day 3 and day 5 for SS/T/OA subjects and CTS subjects, with markers to indicate statistically significant differences between groups.

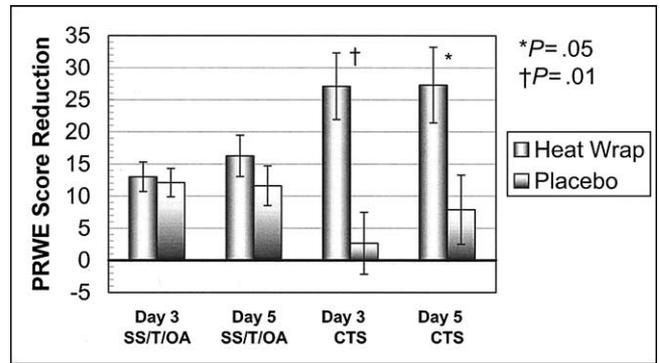


Fig 5. Mean PRWE reduction score \pm SE for the heat wrap group and the oral placebo group on day 3 and day 5 for SS/T/OA subjects and CTS subjects, with markers to indicate statistically significant differences between groups.

beginning with the day 1/hour 8 time point and continuing through the end of the study (fig 7).

Change in grip strength. At baseline, CTS subjects' grip strength averaged \pm SD of 10.7 \pm 10.2kg of force. Secondary analysis determined that the heat wrap group (mean \pm SE, 6.6 \pm 1.6kg) was associated with a significantly greater increase in grip strength versus placebo group (mean \pm SE, -0.3 \pm 1.5kg) ($P=.003$) on day 3, the last day of treatment. Post hoc analysis found that the grip strength for heat wrap group (mean \pm SE, 6.1 \pm 1.6kg) remained significantly greater than placebo group (mean \pm SE, 0.8 \pm 1.4kg) ($P=.012$) on day 5 (fig 4).

PRWE reduction. At baseline, CTS subjects reported a mean PRWE total wrist score \pm SD of 65.94 \pm 18.51 out of a maximum score of 100. The heat wrap (mean \pm SE, 27.1 \pm 5.2) provided a significantly greater reduction in the PRWE total wrist score versus placebo (mean \pm SE, 2.67 \pm 4.81) ($P=.0015$) on day 3. This heat wrap benefit (mean \pm SE, 27.3 \pm 5.9) versus placebo (mean \pm SE, 7.90 \pm 5.39) ($P=.013$) continued through the day 5 follow-up (fig 5).

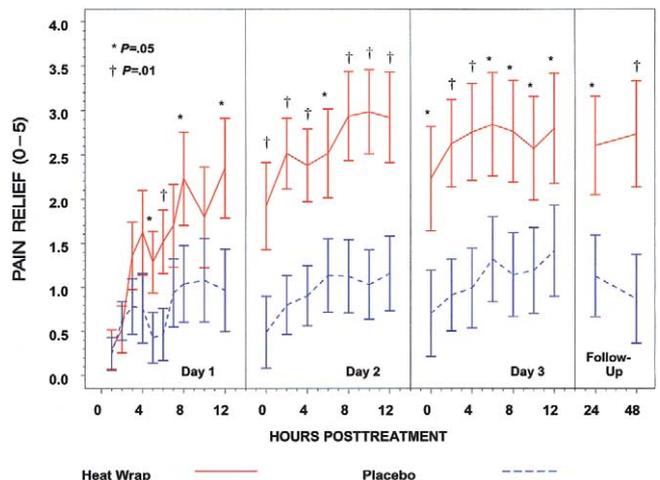


Fig 6. Mean pain relief scores \pm SE for the heat wrap group and the oral placebo group over the treatment study period (days 1–3) and follow-up period (days 4–5) for CTS subjects, with markers to indicate statistically significant differences between groups.

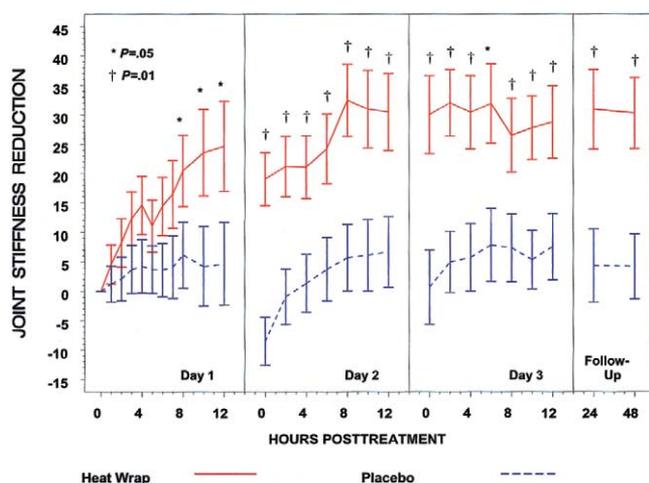


Fig 7. Mean joint stiffness reduction scores \pm SE for the heat wrap group and the oral placebo group over the treatment study period (days 1–3) and follow-up period (days 4–5) for CTS subjects, with markers to indicate statistically significant differences between groups.

Additional CTS Efficacy

SSS reduction. At baseline, CTS subjects reported a mean SSS score \pm SD of 3.14 ± 0.63 out of a maximum score of 5.00. An ANCOVA procedure adjusted for baseline and treatment found the heat wrap (mean \pm SE, $.90 \pm .13$) provided a significantly greater reduction in symptom severity versus placebo (mean \pm SE, $.20 \pm .13$) ($P = .001$) on day 3. This heat wrap benefit (mean \pm SE, $.97 \pm .16$) increased versus placebo on the day 5 follow-up (mean \pm SE, $.14 \pm .14$) ($P \leq .001$).

FSS reduction. At baseline, CTS subjects reported a mean FSS score \pm SD of 2.95 ± 0.82 , out of a maximum score of 5.00. An ANCOVA found the heat wrap (mean \pm SE, $.65 \pm .16$) provided a significantly greater reduction in FSS score versus placebo (mean \pm SE, $.00 \pm .16$) ($P = .006$) on day 3. No statistical difference was observed between the heat wrap (mean \pm SE, $.57 \pm .22$) and placebo (mean \pm SE, $.12 \pm .20$) ($P = .07$) on day 5.

Safety

There were 9 adverse events, mild or moderate in severity, reported by 9 subjects who represented 10% of all study participants. The incidence rate of subjects reporting an adverse event in the test groups was comparable between the heat wrap group ($n = 3$, 7.5%) and the oral placebo ($n = 4$, 9.5%) group. Causality was assessed as doubtful for all but 2 events. A single adverse event in the heat wrap group was assessed as possible (coldness in fingers), and an event in the acetaminophen group was assessed as probable (dyspepsia).

There were no reports of adverse events affecting the skin in any treatment group. All skin quality assessments in the wrap-wearing groups (heated, unheated) were viewed as normal color both at visit 1 (baseline) and the final visit.

DISCUSSION

Work-related musculoskeletal disorders are costly to both employers and employees, contributing to absenteeism, decreased productivity, poor employee morale, and disability.^{21,22} The incidence of these conditions has increased with jobs requiring forceful exertion, repetitiveness, prolonged posturing, increased contact stress, and cold temperatures.²³ These

conditions may also be a significant source of reduced quality of life during performance of activities of daily living, such as bathing, dressing, and grooming, as well as during participation in recreational activities.

CTS is the most common upper-extremity entrapment neuropathy noted in clinical practice. Median nerve compression within the carpal tunnel occurs secondary to factors including vibration, awkward positioning of the wrist and hand, local pressure at the base of the palm, and forceful or repetitive hand motions.^{24,25} Symptoms are produced by intraneural ischemia and not by local nerve compression.^{26,27}

The therapeutic effects of topical heat treatment are mediated via neurologic, vascular, and biopsychosocial mechanisms. Topical heat decreases small nonmyelinated C-fiber activity that inhibits nociceptive signals in the spinal cord and increases proprioception.²⁸⁻³⁰ Heat therapy may also stimulate various regions of the brain. Functional brain imaging has shown nonnoxious warming of the skin activates the thalamus and posterior insula of the brain, supporting noted psychosomatic effects.³¹ The pain-relieving effects of the heat wrap may be indirectly mediated in the brain via skin warming combined with the added physical support to the body region affected with pain. Our overall results of improved pain relief for the group of subjects studied with wrist pain can be explained by a combination of some or all of the various mechanisms of heat-mediated pain relief.

In the CTS study population, continuous low-level heat wrap therapy was shown to provide superior pain relief, grip strength, decreased symptom severity, and improved overall functionality as compared with those subjects treated with oral placebo. The benefits of the heat wrap were more pronounced in subjects with CTS than in the SS/T/OA subjects. Several possible reasons to explain this finding with the heat wrap include the incremental effects on tissue temperature, improved blood flow, and the effect of heat on improving nerve conduction velocity³² (NCV). The demonstrated improvement in grip strength among the CTS subjects in our study lends support to a possible influence of heat on NCV. Improved blood flow through an ischemic region of nerve may also help to explain our results.

Symptoms of CTS are exacerbated by activities that increase carpal tunnel pressure such as flexion and extension of the wrist. Conservative management includes splinting the wrist at night in a position of neutral deviation (eg, not flexed or extended).³³ An argument could be made that the heat wrap could “act as a splint,” and the results we obtained with the heat wrap were because of immobilization of the wrist. However, when the heat wrap is applied, the wrist is able to move freely



Fig 8. Wrist extension while wearing heat wrap.

and comfortably except at extremes of motion (fig 8). Rempel et al³⁴ have shown that wearing a flexible wrist splint does not lessen carpal tunnel pressure.

Injury and inflammation of the tendons and joints of the upper extremity are commonly encountered in work-related injuries. In the SS/T/OA groups, the heat wrap provided significant pain relief and improved grip strength. The effects of topical heat on improving collagen extensibility and blood flow are well known and provide a scientific rationale to explain these results.³⁵ Heat application increases extensibility of the muscles that reduce stiffness and enhance ease of movement.³⁶ Therapeutic heat would be expected to decrease stiffness and enhance removal of inflammatory mediators in the region of tissue injury. Additionally, heating the hands to over 40°C has been shown to reduce metacarpophalangeal joint stiffness, whereas cooling them to 18°C has been shown to increase stiffness proportionately.³⁷

Although significant improvements were noted in the SS/T/OA group, the results for this population were still less dramatic than those noted in the CTS group. Many of these injuries are the result of repeated tendon damage resulting in microtears of the collagen infrastructure and scarring. We hypothesize that the relatively avascular scar tissue may be a limitation to increased blood flow provided by topical heat therapy, explaining the response difference in this group. The small number of subjects in the OA group prevents us from making strong conclusions about the results. Future studies with larger, more homogenous groups will be helpful. Finally, this study used only a single mode of treatment, whereas standard medical practice would include the combination of exercise and, potentially, splinting to the treatment regimen for these common conditions of the wrist. It may be interesting to see in future research whether concomitant use of continuous low-level heat and exercise would provide incremental benefits to control symptoms of pain and improve function in those with wrist pain.

CONCLUSIONS

Continuous low-level heat therapy is a novel strategy in the treatment of musculoskeletal disorders. In this study, increased pain relief, functional gains, and grip strength along with decreased joint stiffness and symptom severity were observed in subjects with CTS treated with the heat wrap as compared with oral placebo. Additionally, subjects with SS/T/OA also had improved pain relief and significant improvements in grip strength as compared with placebo. These results support the benefit of continuous low-level heat wrap therapy in the treatment of common upper-extremity WRMSDs.

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Suppliers

- a. ThermoCare HeatWrap; Procter & Gamble Co, One Procter & Gamble Plz, Cincinnati, OH 45201.
- b. Jamar dynamometer; Sammons Preston, 4 Sammons Court, Bolingbrook, IL 60440-5071.
- c. SAS Institute Inc, 100 SAS Campus Dr, Cary, NC 27513.