

# Continuous Low-Level Heat Wrap Therapy for the Prevention and Early Phase Treatment of Delayed-Onset Muscle Soreness of the Low Back: A Randomized Controlled Trial

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**ABSTRACT.** Mayer JM, Mooney V, Matheson LN, Erasala GN, Verna JL, Udermann BE, Leggett S. Continuous low-level heat wrap therapy for the prevention and early phase treatment of delayed-onset muscle soreness of the low back: a randomized controlled trial. *Arch Phys Med Rehabil* 2006;87:1310-7.

**Objective:** To evaluate the effects of continuous low-level heat wrap therapy for the prevention and early phase treatment (ie, 0–48h postexercise) of delayed-onset muscle soreness (DOMS) of the low back.

**Design:** Two prospective randomized controlled trials.

**Setting:** Outpatient medical facility.

**Participants:** Sixty-seven subjects asymptomatic of back pain and in good general health (mean age,  $23.5 \pm 6.6$ y).

**Interventions:** Participants performed vigorous eccentric exercise to experimentally induce low back DOMS. Participants were assigned to 1 of 2 substudies (prevention and treatment) and randomized to 1 of 2 treatment groups within each substudy: prevention study (heat wrap,  $n=17$ ; control [nontarget muscle stretch],  $n=18$ ) and treatment study (heat wrap,  $n=16$ ; cold pack,  $n=16$ ). Interventions were administered 4 hours before and 4 hours after exercise in the prevention study and between hours 18 to 42 postexercise in the treatment study.

**Main Outcome Measures:** To coincide with the expected occurrence of peak symptoms related to exercise-induced low back DOMS, hour 24 postexercise was considered primary. Pain intensity (prevention) and pain relief (treatment) were primary measures, and self-reported physical function and disability were secondary measures.

**Results:** In the prevention study, at hour 24 postexercise, pain intensity, disability, and deficits in self-reported physical function in subjects with the heat wrap were reduced by 47% ( $P<.001$ ), 52.3% ( $P=.029$ ), and 45% ( $P=.013$ ), respectively, compared with the control group. At hour 24 in the treatment study, postexercise, pain relief with the heat wrap was 138% greater ( $P=.026$ ) than with the cold pack; there were no differences between the groups in changes in self-reported physical function and disability.

**Conclusions:** In this small study, continuous low-level heat wrap therapy was of significant benefit in the prevention and early phase treatment of low back DOMS.

**Key Words:** Exercise; Low back pain; Muscle; Rehabilitation; Thermotherapy.

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**D**ELAYED-ONSET MUSCLE soreness (DOMS) frequently occurs as a result of strenuous physical activity, such as in sports and manual labor, and especially during the first few days or weeks after such activity.<sup>1</sup> Its symptoms typically peak at approximately 24 to 72 hours after exercise and may last for as long as 10 days.<sup>2</sup> Because DOMS results in functional loss and related activity restriction,<sup>3</sup> both its prevention and its treatment are important to recreational and competitive athletes, employees, and to anyone who engages in vigorous exercises and activities of daily living.

Exercise-induced DOMS has been extensively studied in several skeletal muscle groups, but there are few studies on low back DOMS. Early season sports activities and physical work have induced low back DOMS, resulting in painful symptoms and deficits in back strength and range of motion (ROM).<sup>4</sup> Udermann et al<sup>5</sup> demonstrated that low back DOMS can be experimentally induced in a controlled, safe, and predictable manner after eccentric (ie, lengthening of the muscle) back extension exercise on specialized equipment. Without intervention, this exercise protocol has elicited low back DOMS with peak pain intensity of 8 (out of a maximum of 10) at 24 to 30 hours postexercise that dissipates within 5 days.<sup>5</sup> Low back DOMS has also been experimentally induced with other exercise protocols.<sup>6</sup> While pain of muscular origin is plausible in some cases of low back pain (LBP) and experimentally induced low back muscle pain has been studied,<sup>7</sup> the extent and clinical implications of low back DOMS are unknown.

Several modalities and medications have been used to prevent or to treat DOMS, but none has been shown to be clearly superior.<sup>1</sup> A lightweight, disposable, air-activated, commercially available heat wrap<sup>a</sup> has been developed that delivers continuous low-level topical heat to the low back. When the heat wrap is exposed to oxygen, its heat-generating ingredients (iron, charcoal, table salt, water) begin to warm and reach a therapeutic temperature of 40°C within 30 minutes. Each wrap provides approximately 8 hours of controlled heat and is for 1-time use. In contrast to most other thermal modalities, such as hydroculator packs and electric heating pads, the wearer of the heat wrap can remain active while it is in place. A recent Cochrane review<sup>8</sup> on the use of superficial heat or cold therapy for acute LBP found that continuous low-level heat wrap therapy is efficacious in terms of pain relief, muscle soreness, and disability.<sup>8</sup> It is unknown, however, whether continuous low-level heat wrap therapy applied prior to eccentric exercise

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is effective in preventing symptoms and functional limitations related to exercise-induced low back DOMS. It is also unknown whether heat wrap therapy for treatment of DOMS postexercise is efficacious compared with cold pack therapy, which is a form of cryotherapy that is a standard treatment modality for acute musculoskeletal pain.<sup>9-11</sup>

Our purpose in this study was to evaluate the effects of continuous low-level heat wrap therapy for the prevention, and early phase treatment, of symptoms and deficits in self-reported physical function related to exercise-induced low back DOMS. Two prospective randomized trials were conducted—a prevention study that compared a group of subjects who received continuous low-level heat wrap therapy with a control group that engaged in nontarget muscle group stretches, and a treatment study that compared the effects of continuous low-level heat wrap therapy with the effects of cold pack therapy.

## METHODS

### Participants

Potential participants were recruited by newspaper advertisements, flyers, and word of mouth. The study's protocol was approved by the investigators' institutional review board and participants gave their written informed consent prior to enrollment. Inclusion criteria for enrollment were: (1) between the ages of 18 and 45 years, asymptomatic of back pain, in good general health, ambulatory, and untrained in the low back musculature; and (2) women of child-bearing potential with negative urine pregnancy tests who were using an acceptable form of contraception. Subjects were excluded if they had: (1) history of LBP, spinal surgery, kidney problems, high blood pressure, neuromuscular disorders, fibromyalgia, osteoporosis, diabetes mellitus, bleeding disorders, arthritis, malignancy, systemic disease, inflammatory disease, abnormal heat or cold sensitivity, poor circulation, or peripheral vascular disorders; (2) active tuberculosis; (3) skin lesions (eg, rash, bruise, laceration) in the low back region, or a skin condition (eg, poison ivy, urticaria) in other regions that was spreading; (4) psychiatric or psychological disorders; (5) cardiovascular or orthopedic contraindications to resistance exercise; (6) 1 or more "yes"

answers on the Physical Activity Readiness Questionnaire (PAR-Q)<sup>12</sup>; (7) a resting blood pressure outside of 90 to 140 over 60 to 90mmHg; (8) were currently taking muscle relaxant, anti-inflammatory, or analgesic medications, creatine, ephedrine, or pseudoephedrine; (9) had applied topical medication to the low back within 24 hours of enrollment; or (10) were involved in a workers' compensation, disability, or personal injury claim.

All participants were instructed to abstain from the use of analgesic, muscle relaxant, and anti-inflammatory medications, spinal manipulation, physical therapy, massage, herbal and holistic therapies, and other heat and cold therapies during the study. They were told to not participate in activities above their normal activity level, and to perform specific exercises for the low back.

### Procedures

**Screening visit.** An outpatient physical rehabilitation center in San Diego was the site of the screening visit and 4 study visits. At the screening visit, each participant completed a health history questionnaire and the PAR-Q, and were given a physical examination by a physician. Qualified participants reported to the study site on 4 occasions. Table 1 provides a timeline of the study procedures. Figure 1 shows a flow chart depicting enrollment, allocation, follow-up, and analysis. Table 2 lists the subjects' demographic and pre-exercise characteristics. Data were collected between October 5, 2003, and December 17, 2003.

**Study assignment and randomization.** Subjects who qualified for the study were assigned to 1 of 2 substudies: a prevention study or a treatment study. Study assignment was nonrandom and based on the subjects' availability (eg, avoiding potential conflicts with work or school schedules) to complete study visits and assessments at the required times. Within each study, however, participants were stratified by sex and randomized to specific treatment groups (ie, heat wrap or control for the prevention study, and heat wrap or cold pack for the treatment study). Randomization was done by the study coordinator, who used a random number list generated by a statistician. Specific assignments to groups were placed in

**Table 1: Timeline of Procedures Conducted for Each Substudy**

Hour	Visit	Procedure
<b>Prevention study</b>		
-5	Visit 1	Baseline assessment, strength test, randomization
-4	Visit 1	Application of heat wrap (n=17)
-1	Visit 1	Performance of nontarget muscle stretches (controls; n=18)
0 (baseline)	Visit 1	Eccentric low back extension exercise
4		Removal of heat wrap for heat wrap group
24	Visit 2	Midtrial assessment 1
2-46		Completion of home diary evaluations
48	Visit 3	Midtrial assessment 2
72	Visit 4	Final assessment
<b>Treatment study</b>		
-1	Visit 1	Initial assessment, strength test
0	Visit 1	Eccentric low back extension exercise
18 (baseline)	Visit 2	Baseline assessment, randomization, initial application of heat wrap (n=16) or cold pack (n=16)
18-42		Intervention: heat wrap or cold pack per protocol
20-54		Completion of home diary evaluations
42	Visit 3	Midtrial assessment
66	Visit 4	Final assessment

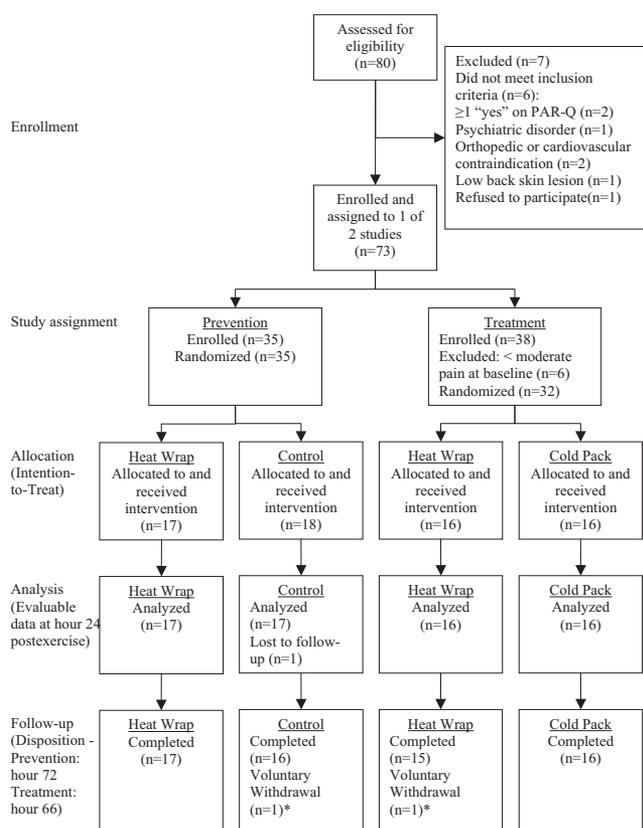


Fig 1. Study assignment, randomization, and disposition. \*Sought outside care for low back muscle soreness.

envelopes that were then sealed and labeled with an enrollment number. The assignments were revealed immediately after baseline measures were taken. Baseline was defined as the measure immediately preceding the onset of intervention. Baseline for the prevention study was hour  $-4$  (ie, 4h before eccentric exercise) on visit 1, while baseline for the treatment study was hour 18 (ie, 18h after eccentric exercise) on visit 2.

**Visit 1: prevention study.** Three days after the screening visit, prevention study participants completed a 6-point verbal rating scale (VRS) of pain intensity<sup>13-16</sup> (0, none; 1, mild; 2, moderate; 3, moderately severe; 4, severe; 5, extreme), the 24-question Roland-Morris Disability Questionnaire (RMDQ),<sup>17</sup> and the Multidimensional Task Ability Profile (MTAP).<sup>18</sup> Next, the participants completed a 7-angle peak isometric lumbar extension strength test on a lumbar dynamometer.<sup>a</sup> The test has been shown to be safe, reliable, and valid.<sup>19</sup> Immediately after the strength test and before the eccentric exercise, participants were randomized to a heat wrap group ( $n=17$ ) or control group ( $n=18$ ), with interventions as follows.

**Visit 1: prevention study—heat wrap group.** Participants applied a wearable heat wrap<sup>b</sup> to the low back region 1 time for 8 hours, beginning at hour  $-4$  on visit 1 (ie, 4 hours before eccentric exercise). The heat wrap is belt-like and is secured to the lower trunk with a self-adhesive-type closure. The area of the wrap's heating element is approximately  $18 \times 25$ cm, which nearly covers the entire lumbar spine. Participants were given standard written instructions concerning placement and wearing of the wrap.

**Visit 1: prevention study—control group.** Participants performed a series of nontarget muscle stretches immediately

before doing the eccentric exercise on visit 1. In an attempt to incorporate a control intervention that was not expected to demonstrate efficacy, stretches included standard flexibility exercises for muscle groups not directly related to the target area of the low back and lower trunk (eg, pectoralis, rear deltoid, gastrocnemius). We attempted to limit a potentially negative bias associated with the control group. Specifically, participants were not made aware in the consent document of the control intent of the stretches, and any potential relative efficacy of the heat wrap (vs control stretches) was not discussed or alluded to when the study's purpose and interventions were described. It is important to note that none of the control group participants recognized the stretches as being a control intervention. For example, no one asked why they performed calf stretches and not low back stretches in a study on the prevention of low back DOMS. Nevertheless, it is not known whether the stretches affected the outcomes. At hour 0, the participants performed eccentric (ie, lowering the weight), dynamic, full ROM resistance lumbar extension exercise on the dynamometer to induce low back DOMS. Participants performed 2 sets of 25 repetitions at a load of 100% peak isometric lumbar extension strength, with a 2-minute rest between sets. The DOMS-inducing exercise protocol has been previously described.<sup>5</sup> At the conclusion of visit 1, participants were given home diaries in which to record pain intensity on the VRS at various time points between hours 2 to 46 postexercise.

**Visits 2, 3, and 4: prevention study.** Prevention study participants returned to the study site at hours 24, 48, and 72 postexercise to complete the same questionnaires they completed on visit 1 (baseline). Participants were discharged from the study after visit 4.

**Visit 1: treatment study.** Three days after the screening visit, participants in the treatment study completed the pain intensity VRS, RMDQ, MTAP, isometric lumbar extension strength test, and DOMS-inducing eccentric exercise as described above.

**Visit 2: treatment study.** The same participants returned to the study site at hour 18 postexercise (baseline) to complete the same questionnaire they completed on visit 1. Thirty-two of the 38 participants (84%) had pain intensity ratings of moderate or greater pain ( $\geq 2$ ) on the VRS and qualified for the remainder of the study. They were then randomized to a heat wrap group ( $n=16$ ) or to a cold pack group ( $n=16$ ), with the following interventions.

**Visit 2: treatment study—heat wrap.** Subjects in this group applied the heat wrap to the low back region in the same manner as described previously, 2 times for 8 hours each, beginning at hours 18 and 32 postexercise.

**Visit 2: treatment study—cold pack.** This group of participants applied a standard gel-filled, reusable cold pack<sup>c</sup> to the

Table 2: Demographic and Pre-Exercise Characteristics of Subjects With Evaluable Data for Primary Efficacy Variable

Variable	Prevention Study		Treatment Study	
	Heat Wrap	Control	Heat Wrap	Cold Pack
n	17 (10F/7M)	17 (9F/8M)	16 (9F/7M)	16 (9F/7M)
Age (y)	22.8 $\pm$ 5.4	21.5 $\pm$ 2.8	25.5 $\pm$ 7.2	24.3 $\pm$ 6.0
Height (cm)	169.6 $\pm$ 12.6	171.2 $\pm$ 10.9	170.5 $\pm$ 10.2	169.9 $\pm$ 11.9
Weight (kg)	62.6 $\pm$ 12.6	66.3 $\pm$ 14.6	67.6 $\pm$ 12.3	69.6 $\pm$ 14.3
Strength* (Nm)	274.3 $\pm$ 96.0	300.6 $\pm$ 112.4	293.7 $\pm$ 121.0	314.3 $\pm$ 113.2

NOTE. Values are mean  $\pm$  standard deviation. Abbreviations: F, female; M, male.

\*Peak isometric lumbar extension torque.

low back for 15 to 20 minutes every 4 hours between hours 18 to 42 postexercise. The area of the cold pack is 27.5×35cm and covers the entire lumbosacral region. Participants were advised to apply the cold pack while lying prone or supine, whichever position was most comfortable and were given written instructions on placement and wear. The application time and frequency for cryotherapy falls within the recommended range of 10 to 20 minutes for application time,<sup>20</sup> between the ranges of 2 to 4 times per day<sup>16</sup> and every 2 hours<sup>21</sup> for frequency. Because there is not a standard guideline for application time and frequency of cryotherapy for acute soft tissue injury, most decisions regarding parameters for clinical ice use are based on what is practical.<sup>10</sup>

After the heat wrap or cold pack was applied, participants were given diaries in which to record pain relief (relative to baseline pain intensity) on a 6-point VRS<sup>13-16</sup> (0, no relief; 1, a little relief; 2, less than half relief; 3, more than half relief; 4, a lot of relief; 5, complete relief) at various time points between hours 20 to 54 postexercise.

**Visits 3 and 4: treatment study.** Participants returned to the study site at hours 42 and 66 postexercise (ie, 24 and 48h postbaseline) to complete the same questionnaires as they completed at baseline, plus a pain relief questionnaire. They also completed a satisfaction with outcome questionnaire<sup>22</sup> and were discharged from the study after visit 4.

## Outcome Measures

**Primary outcome measures.** We designated hour 24 postexercise as the primary endpoint because previous research that used the present study's protocol to elicit low back DOMS found that peak pain intensity and muscle soreness occurs at 24 to 30 hours postexercise.<sup>5</sup> Pain intensity was the primary outcome measure for the prevention study and pain relief was the primary outcome measure for the treatment study. Both were assessed with the VRSs described previously, which have been used in previous studies with the heat wrap for LBP.<sup>13-16</sup>

**Secondary outcome measures.** In both studies, self-reported physical function was assessed with the Rating of Perceived Capacity for spinal function (RPC-spine)<sup>18</sup> derived from the MTAP (0–200 scale, where a higher score equals higher self-reported physical function). The MTAP is a computer-administered questionnaire in which the subject being evaluated ranks his/her ability to perform 111 common physical tasks depicted by drawings and captions on a 6-point scale (1, able; 2, slightly restricted; 3, restricted; 4, very restricted; 5, unable; 6, don't know).<sup>18</sup> Self-reported disability was assessed with the RMDQ.<sup>17</sup> For the prevention study, the incidence of bothersome pain was calculated from the "yes-no" question, "Do you have bothersome pain?" For the treatment study, satisfaction with outcome was assessed by the question, "All things considered, how satisfied are you with the results of your treatment for your low back pain?" Responses were recorded on an 8-point scale (1, extremely satisfied; 2, very satisfied; 3, somewhat satisfied; 4, mixed; 5, somewhat dissatisfied; 6, very dissatisfied; 7, extremely dissatisfied; 8, not sure or no opinion).<sup>22</sup> The binary incidence of positive satisfaction of outcome was calculated for statistical analysis by including the scores of "extremely/very/somewhat satisfied" versus "extremely/very/somewhat dissatisfied" and mixed scores.

## Data Analysis

Based on research utilizing the DOMS model and published research using the primary outcome measures of this study (pain intensity, pain relief),<sup>5,14,15</sup> we anticipated that a sample size of 16 subjects per group was adequate to assess trends at

the .05  $\alpha$  level and a power of .80. Given that our goal was to evaluate the efficacy of preplanned allocated interventions instead of the pragmatic effectiveness of these interventions, all analyses were conducted using per protocol ("evaluable") data rather than intention-to-treat. Reasons for exclusion from the data set included failure to meet the study protocol criteria, voluntary withdrawal, and protocol violations (eg, missed study visits, treatment noncompliance).

The primary comparisons declared in the protocol were hour 24 postexercise pain intensity (prevention study) and pain relief (treatment study). Secondary measures were used to support the primary variable and characterize the treatment effects across the study periods; the *P* values associated with the secondary variables were not adjusted because of the study's small sample size. Pain intensity and RMDQ (prevention study), and pain relief and satisfaction with outcome (treatment study) were analyzed by time point (where applicable) using analysis of variance (ANOVA). For variables with corresponding non-zero baseline values (ie, RPC-spine [both studies] and RMDQ [treatment study]), changes from baseline scores were analyzed by time point using analysis of covariance to compare groups, including baseline scores as the covariate. Incidence variables (for prevention study, bothersome pain; for treatment study, satisfaction with outcome) were analyzed using logistic regression to compare groups. In addition to treatment group, sex was included in the ANOVA and logistic regression models to reduce variability, not to draw inferences. Specificity of effect was assessed with scales embedded in the MTAP that evaluate several functional constructs (eg, lifting, trunk strength, finger dexterity, balance, coordination). Scores from the pertinent construct (ie, RPC-spine) were compared with scores from a construct that should not have been affected by this study's interventions (ie, RPC-finger dexterity) using ANOVA.

Prevention and treatment study data were analyzed separately. Testing between groups was 2-tailed and statistical significance was accepted at  $\alpha$  equal to .05. The effect size and observed power were calculated for the primary outcome measures using between group comparisons. Data are reported as mean  $\pm$  standard error (SE), unless otherwise noted.

## RESULTS

### Prevention Study

**Pain intensity.** Mean pain intensity scores plotted by group and time point are shown in figure 2. At hour 24 postexercise, the mean pain intensity score for heat wrap was 46.8% less than it was for the control group ( $1.4 \pm 0.2$  vs  $2.7 \pm 0.2$ , respectively;  $F = 18.08$ ,  $P < .001$ ). For the pain intensity scores at hour 24 postexercise, the between group effect size was 1.43 and the observed power was .98. At hour 24 postexercise, the incidence of bothersome pain for heat wrap was less than it was for the control group (38.5% vs 100%, respectively;  $\chi^2$  test = 11.56,  $P = .001$ ).

**Self-reported physical function.** Baseline (hour 0) RPC-spine scores for the heat wrap and stretch groups were  $172.7 \pm 4.6$  and  $174.3 \pm 4.4$ , respectively. Adjusted mean change from baseline RPC-spine scores plotted by group and time point are shown in figure 3. At hour 24 postexercise, the adjusted mean change from baseline RPC-spine score for heat wrap was 44.5% less than for the control group ( $-25.4 \pm 5.4$  vs  $-45.7 \pm 5.4$ , respectively;  $F = 6.93$ ,  $P = .013$ ).

**Self-reported disability.** RMDQ scores plotted by group and time point are shown in figure 4. At hour 24 postexercise, the mean RMDQ score for the heat wrap group was 52.3% less than for the controls ( $3.0 \pm 0.8$  vs  $6.3 \pm 1.2$ , respectively;  $F = 5.31$ ,  $P = .029$ ).

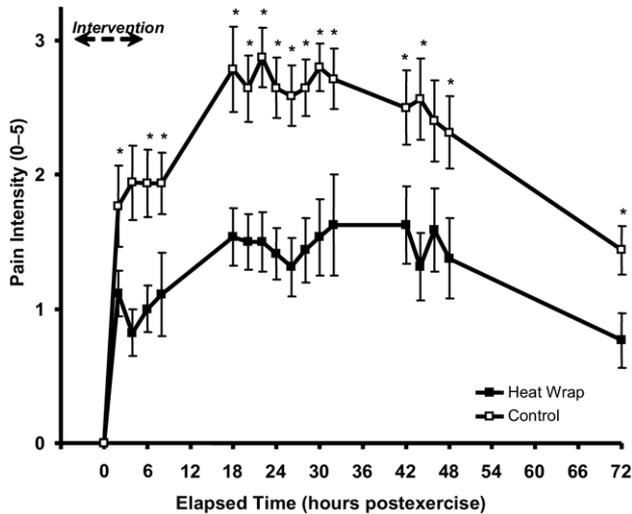


Fig 2. Pain intensity scores plotted by group and time point for the prevention study. NOTE. Values are mean ± SE. \*Control > heat wrap ( $P < .05$ ).

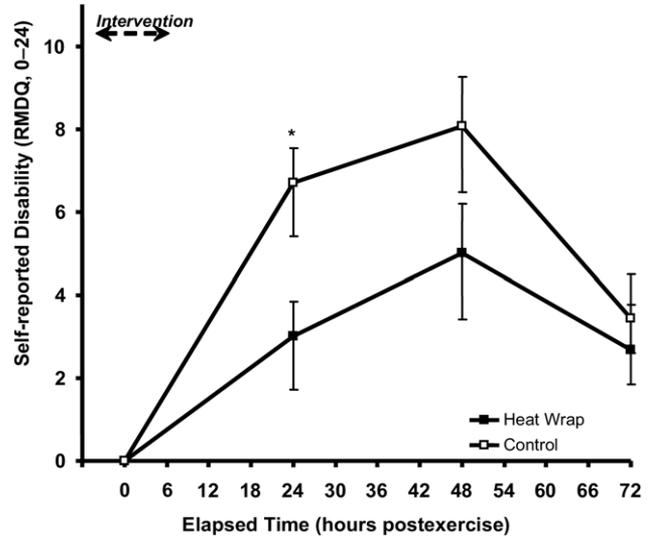


Fig 4. Self-reported disability (RMDQ) scores plotted by group and time point for the prevention study. NOTE. Values are mean ± SE. \*Control > heat wrap ( $P < .05$ ).

Treatment Study

**Pain relief.** Baseline (hour 18) pain intensity scores for the heat wrap and cold pack groups were  $2.6 \pm 0.2$  and  $2.5 \pm 0.1$ , respectively, falling between 2 (moderate) and 3 (moderately severe) on the 6-point VRS. Mean pain relief scores plotted by group and time point are shown in figure 5. At hour 24 postexercise, the mean pain relief score for the heat wrap group was 138% greater than for the cold pack group ( $1.5 \pm 0.4$  vs  $0.6 \pm 0.2$ , respectively;  $F = 5.56$ ,  $P = .026$ ). The mean pain relief score for heat wrap fell between 1 (a little relief) and 2 (less than half relief), while the score for cold pack fell between 0 (no relief) and 1 (a little relief) on the VRS. For the pain relief scores at hour 24 postexercise, the between group effect size was .87 and the observed power was .66.

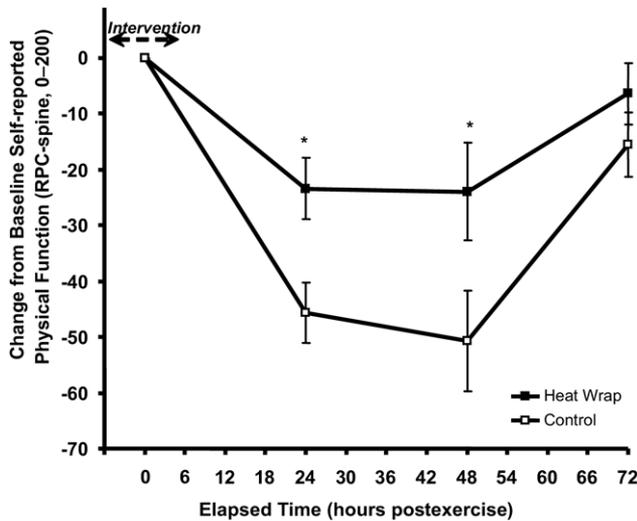


Fig 3. Change from baseline self-reported physical function (RPC-spine) scores plotted by group and time point for the prevention study. Baseline RPC-spine score used as covariate. NOTE. Values are adjusted mean ± SE. \*Heat wrap > control ( $P < .05$ ).

**Self-reported physical function.** Baseline (hour 18) RPC-spine scores for the heat wrap and cold pack groups were  $136.1 \pm 8.2$  and  $127.3 \pm 6.3$ , respectively. Adjusted mean change from baseline RPC-spine scores plotted by group and time point are shown in figure 6. At hours 42 and 66 postexercise, there was no difference in the adjusted mean change from baseline RPC-spine scores between the heat wrap and the cold pack groups (hour 42:  $F = 1.01$ ,  $P = .323$ ; hour 66:  $F = .49$ ,  $P = .491$ ).

**Self-reported disability.** Baseline (hour 18) RMDQ scores for the heat wrap and cold pack groups were  $6.1 \pm 1.6$  and  $6.7 \pm 0.8$ , respectively. Adjusted mean change from baseline RMDQ scores plotted by group and time point are shown in figure 7. At hours 42 and 66 postexercise, there was no difference in the adjusted mean change from baseline RMDQ scores

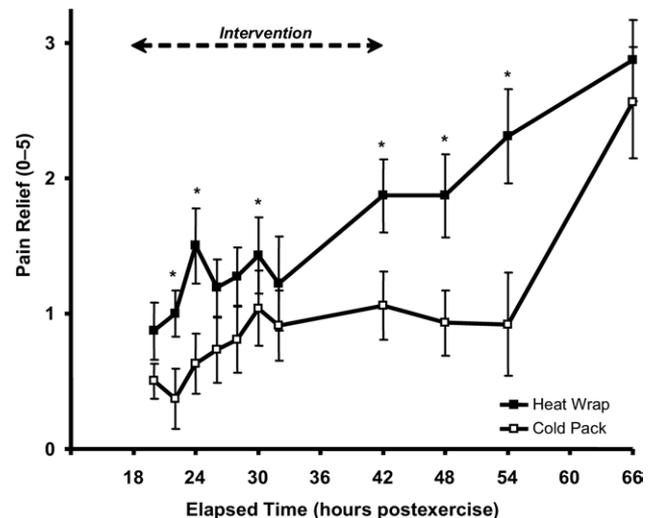


Fig 5. Pain relief scores plotted by group and time point for the treatment study. NOTE. Values are mean ± SE. \*Heat wrap > cold pack ( $P < .05$ ).

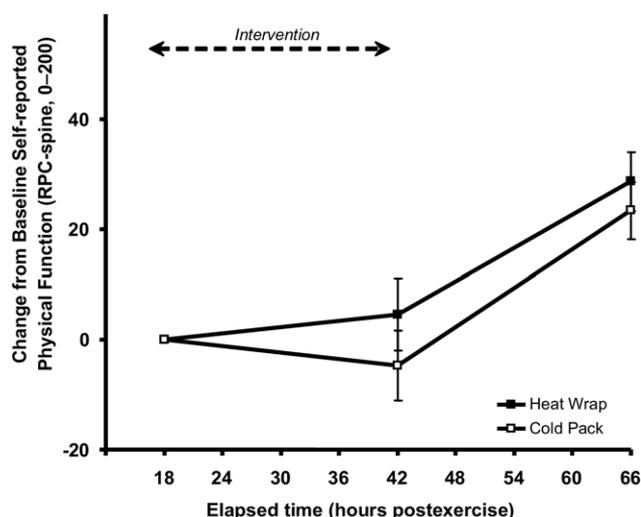


Fig 6. Change from baseline self-reported physical function (RPC-spine) scores plotted by group and time point for the treatment study. Baseline RPC-spine score used as covariate. NOTE. Values are adjusted mean  $\pm$  SE.

between the 2 groups (hour 42:  $F=2.48$ ,  $P=.127$ ; hour 66:  $F=2.64$ ,  $P=.117$ ).

**Satisfaction with outcome.** At the conclusion of the study (ie, hour 66 postexercise), the mean satisfaction with outcome score (excluding "not sure/no opinion" responses) in the heat wrap group was superior to that of the cold pack group ( $3.4 \pm 0.3$  vs  $4.9 \pm 0.5$ , respectively;  $F=5.68$ ,  $P=.025$ ). The incidence of positive satisfaction with outcome with the heat wrap group was greater than for the cold pack group (64.3% vs 26.7%, respectively;  $\chi^2$  test=4.14; odds ratio, 4.95,  $P=.042$ ).

### Specificity of Effect

Our results indicate that the effect of intervention was specific rather than global. In the prevention study, at hour 24 postexercise, for example, the mean decline from baseline score (adjusted to 0–1.00 scale) for RPC-spine was greater than RPC-finger dexterity for heat wrap and controls (heat wrap:  $.13 \pm .03$  vs  $.06 \pm .01$ , respectively; controls:  $.23 \pm .03$  vs  $.05 \pm .02$ , respectively;  $P < .05$ ). Unlike RPC-spine, there was no difference in the RPC-finger dexterity decline from baseline score between the groups ( $P > .05$ ).

### Safety

There were no serious adverse events in this study. One participant in the heat wrap group of the prevention study reported nausea and vomiting after visit 1, which was fully resolved within 24 hours and did not require the subject's withdrawal from the study. Two participants voluntarily withdrew from the study (1 in the control group of the prevention study before visit 2, and 1 in the heat wrap group of the treatment study prior to visit 3) to seek care for low back DOMS induced by the study's eccentric exercise protocol. The conditions fully resolved within 1 week of onset.

Moderate erythema was noted in the lumbar region of 1 participant in the heat wrap group of the treatment study after the second wrap was removed on visit 3. The area of erythema was approximately  $15 \times 20$  cm directly over the wrap site. The condition did not require withdrawal from participation and was fully resolved within 10 days of onset. For comparison, low incidence rates of mild erythema (2.5%) and moderate

erythema (.4%) were reported in 3 previous studies that used the heat wrap to treat acute LBP.<sup>14-16</sup> None of the cases required withdrawal from participation and all were fully resolved without additional treatment.

## DISCUSSION

### Prophylactic Effects of the Heat Wrap

We found in this study that applying continuous low-level heat for an 8-hour period, 4 hours before and 4 hours after strenuous exercise, resulted in a substantial decrease in LBP intensity, lower incidence of bothersome pain, reduction in self-reported disability, and smaller deficits in self-reported physical function compared with controls. Although there are no direct comparisons with the present study on the effect of using low-level heat wrap therapy to prevent low back DOMS, several studies have reported that warm-up of muscle tissue prior to vigorous exercise is ineffective in preventing DOMS symptoms and related functional loss (ie, strength and ROM deficits) in other muscle groups. Evans et al<sup>23</sup> found that passive warm-up (ie, short-wave diathermy) or active warm-up (ie, low-intensity resistance exercise) of the biceps brachii muscle immediately preceding high-load eccentric exercise did not result in fewer clinical signs of muscle damage in a 72-hour follow-up period. Similarly, High et al<sup>24</sup> found that active warm-up of the quadriceps muscles using low intensity exercise did not prevent DOMS. Furthermore, Symons et al<sup>25</sup> noted that warm-up of the elbow flexors using therapeutic ultrasound was not significant in preventing DOMS.

### Therapeutic Effects of the Heat Wrap

The finding in this study that the heat wrap provided superior pain relief at 24 hours postexercise compared with the cold pack treatment of low back DOMS appears to be contrary to the traditional practice of relieving acute muscular pain with cold pack therapy, a form of cryotherapy. Cryotherapy is believed to reduce inflammation and provide pain relief, and therefore is recommended during the first 48 hours postinjury.<sup>11</sup> While cryotherapy is a widely accepted modality for treating acute muscular pain and is recommended for DOMS,<sup>1</sup>

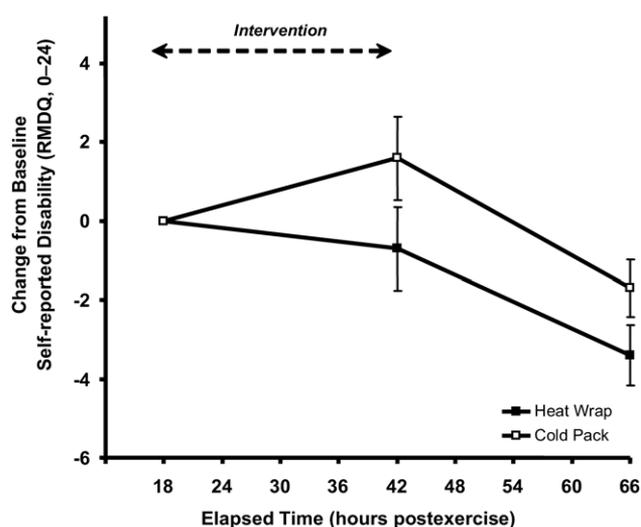


Fig 7. Change from baseline self-reported disability (RMDQ) scores plotted by group and time point for the treatment study. Baseline RMDQ score used as covariate. NOTE. Values are adjusted mean  $\pm$  SE.

evidence from clinical trials raises questions about its efficacy for treating DOMS.<sup>11</sup> For example, cryotherapy has been effective in treating DOMS of the shoulder muscles,<sup>26</sup> but ineffective in treating the elbow flexors.<sup>27</sup> Moreover, a recent Cochrane review<sup>8</sup> concluded that there is insufficient evidence with which to evaluate the effects of cold therapy for LBP. In contrast to cryotherapy, heat therapy is typically reserved for treatment beyond 48 hours postinjury.

### Possible Mechanisms for the Heat Wrap's Effects

There are several possible explanations for the efficacy of heat wraps in preventing and treating low back DOMS that we found in this study, as well as for the apparent discrepancies in previous studies of other heat modalities for DOMS. The most plausible explanation is that it is a combination of factors, including the wrap's thermal effect on muscle tissue, the analgesic properties of topical heat, and the fact that subjects can remain active while wearing the heat wrap.

By elevating the temperature of muscle tissue, connective tissue extensibility is improved and joint ROM is increased.<sup>28</sup> This may increase the resistance of muscle tissue to tearing, improve motor unit recruitment, and allow for smoother muscle contraction.<sup>2</sup> Heat also improves blood flow,<sup>25,29</sup> which may help clear inflammatory mediators from the muscle tissue. Topical heat has also improved the fatigue characteristics of skeletal muscle during exercise,<sup>30</sup> increased proprioception, and inhibited pain signals.<sup>14</sup>

In contrast to most other heat modalities (and the cold pack used in this study), a heat wrap wearer can remain physically active.<sup>14</sup> Maintaining physical activity during the treatment of acute LBP is typically associated with superior outcomes, compared with bedrest and passive modalities.<sup>31</sup> Nuhr et al<sup>32</sup> showed that active heating is superior to passive heating in relieving acute LBP during emergency transport. Research is needed into the mechanisms that produce the heat wrap's therapeutic benefits.

### Clinical Implications

Although low back DOMS is not generalizable to all cases of acute LBP, our findings in this study may have substantial clinical implications. Prevention and treatment modalities for acute low back muscular soreness may be important to employees, athletes, patients with LBP in the early stages of a rehabilitative exercise program, and anyone who engages in unfamiliar and strenuous activities involving the low back muscles. Further research is needed, however, to evaluate the heat wrap's effects on pain and self-reported physical function in several activities that are at risk for low back DOMS.

### Study Limitations

One limitation of this study is that we enrolled a small, homogeneous sample with a wide range of exclusion criteria, which limits the generalizability of its findings. Also, despite random treatment group assignment within each substudy, selection bias was possible because the initial study assignment was nonrandom. Moreover, we did not include a negative control group in the treatment substudy, so it was not possible to directly compare heat wrap and cold pack therapy with natural history. Another limitation of the study is that we cannot rule out a potential bias favoring heat wrap therapy as a possible mechanism to explain the superiority of heat wrap therapy versus control and cold pack therapy. Participants were not blinded to the treatments because the study's design made it impossible to fully mask the treatments (heat and cold modalities, flexibility exercises). Further, the participants in the

heat wrap groups received more interventions than did the control group and participants who received the cold pack therapy. Previous researchers discussed the importance of balancing intervention times among treatment groups in prospective randomized clinical trials, but admitted that deliberately balancing intervention times may not be pragmatic or clinically relevant.<sup>33</sup> Research with blinded treatment group assignment and equal intervention times among groups would be useful to clarify the mechanisms underlying the efficacy of low-level heat wrap therapy found in this study. Finally, an important limitation of the study is that DOMS was intentionally induced, which may or may not be an accurate representation of clinical DOMS-related acute LBP. The experimental nature of the DOMS that we assessed reduces its generalizability to clinical practice.

### Future Study

To investigate the clinical relevance of our findings, larger, fully randomized trials with enhanced control groups and with heterogeneous samples in different settings would be useful. Suggestions for control groups include: no intervention, unheated wrap, light resistance exercise, low back flexibility exercise, and cryotherapy in which the participant can remain active during application. Research that investigates the effects of combining heat wrap therapy with exercise for low back DOMS prevention and treatment would also be valuable.

### CONCLUSIONS

In this small study, continuous low-level heat wrap therapy provided some significant benefits in the prevention of symptoms and deficits in self-reported physical function related to exercise-induced low back DOMS. It provided superior pain relief and similar improvements in self-reported physical function in the early phase treatment of low back DOMS, compared with cold pack therapy. Research with enhanced control groups is needed to fully assess the efficacy of continuous low-level heat wrap therapy in the prevention and treatment of low back DOMS.

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#### Suppliers

- a. MedX, 4820 Newberry Rd, Ocala, FL 32607.
- b. Procter & Gamble Co, Procter & Gamble Plz, Cincinnati, OH 45202.
- c. Chattanooga Group, 4717 Adams Rd, Hixson, TN 37343.