Paraspinal Musculature and Skin Temperature Changes: Comparing the ThermaCare HeatWrap, the Johnson & Johnson Back Plaster, and the ABC Warme-Pflaster

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Study Design: Prospective, randomized, crossover design.
Objectives: To compare the effectiveness of the Johnson & Johnson Back Plaster, the ABC Warme-Pflaster, and the ThermaCare HeatWrap on skin and paraspinal muscle temperature. Also, to compare the subjects' heat perception for the 3 products.
Background: Heat therapy is a common treatment for low back pain and disability. There are a number of products on the market that are suggested to relieve low back pain by providing warmth to the back; however, their effectiveness for increasing tissue temperature compared with heat sensation has not been tested.
Methods and Measures: To measure paraspinal muscle temperature, 1 thermocouple monofilament was inserted into the paraspinal muscle 2 cm from the skin surface at the L3 level using a 20-gauge 1.25-in (3.15-cm) sterile catheter. To measure skin interface temperature, 2 thermocouples were placed on the skin at distances of 5 cm and 7 cm from the insertion site. The Isothermex was used to record temperatures to the nearest 0.1°C for 120 minutes. The subjects also rated heat perception using a 10-cm visual analog scale at 0, 30, 60, 90, and 120 minutes. Analysis of covariance models were used for statistical analysis.
Results: There was a significant product × time interaction ($F_{14,231} = 3.77$, $P < .0001$) at the intramuscular site, but there was not a significant product × time interaction ($F_{14,231} = 1.03$, $P = .4228$) at the skin site. Both the main effects for product ($F_{2,33} = 41.59$, $P < .0001$) and time ($F_{3,51} = 19.02$, $P < .0001$) were significant for the visual analog scale data. The ThermaCare HeatWrap produced significant increases in both skin and intramuscular temperatures with less heat sensation. The Johnson & Johnson Back Plaster and the ABC Warme-Pflaster increased temperature at the skin surface and provided the greatest heat sensations, but they did not provide intramuscular heat.
Conclusions: The ThermaCare HeatWrap is more effective at increasing temperature at a 2-cm depth with less perceived heat compared to the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster. The latter 2 products provide a sensation of heat but do not actually provide a muscle temperature change at a depth of 2 cm. *J Orthop Sports Phys Ther 2004;34:549-558.*

Key Words: *heat, low back, physical agents, temperature*

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Nearly 80% of all people will suffer from low back pain or disability at some point in their lives.[20] In an effort to decrease the amount of back pain and disability, individuals with a back injury and clinicians often use thermotherapy because it decreases pain and promotes soft tissue healing.[3,4,16]

Heat can increase local blood flow,[2,3,8] increase metabolism,[2,3] increase extensibility of collagen fibers,[3,13,19] promote relaxation of soft tissue,[3,13] and reduce pain and muscle spasm.[3,5,9,11] Hypalgesia, however, is perhaps the most frequent indication for use of heat in a therapeutic setting.[4] Experimental research on patients with low back pain has demonstrated that low-level, continuous, topical heat wraps provided greater pain relief and resulted in lower disability for 24 hours after thermotherapy application when compared to no treatment.[18] Similar effects were also shown in the treatment of trapezius myalgia with low-level topical heat.[17] One of the suspected mechanisms for the hypalgesic and muscle relaxant effects of topical heat therapy is increased blood flow. Erasala et al[8] used Doppler ultrasound to demonstrate increased blood flow in the trapezius muscle following topical thermotherapy. In addition to increased blood flow, heating is also believed to cause a counterirritant effect through stimulation of cutaneous nerves, specifically thermoreceptors.[3] It is suggested that as a result of thermoreceptor activity, both sedation and relaxation are facilitated, which often leads to pain modulation.[3,4] Although the mechanisms underlying these phenomena are not completely understood, both the gate control theory and a decrease in the gamma efferent firing rate have been proposed as possible mechanisms for the decreased pain and muscle relaxation that occurs with the application of thermotherapy.[3,4,12]

Mild heating is often used to increase blood flow, decrease muscle spasm, reduce pain, and resolve tissue inflammation.[10] Mild heating is achieved by increasing tissue temperature to less than 40°C.[10,12] However, for benefits including increased tissue metabolism and softening of the connective tissue, vigorous heating is indicated.[10,12] Lehmann and deLateur[12] suggest that to achieve vigorous heating, the intramuscular temperature should be raised to between 40°C and 45°C, or at least 3°C to 4°C above baseline temperature. Both mild and vigorous heating are possible in the therapeutic setting with modalities such as silicate gel hot packs,[6] whirlpools,[1] ultrasound,[6] or diathermy.[7] However, these modalities are not readily available to individuals outside of the clinical setting.[16]

The Back Plaster (Johnson & Johnson, Skillman, NJ), the ABC Warme-Pflaster N (Beieserdorf, Germany), and the ThermaCare HeatWrap (Procter & Gamble, Cincinnati, OH) are currently 3 products that are all convenient, portable, easy to store, inexpensive, and readily available to the public. According to manufacturers' claims, these products may be helpful to relieve low back pain by providing warmth.

To date there have been no published studies on these products. We felt that it was important to test these heating modalities' ability to produce heat in the paraspinal muscles and overlying skin and to monitor the subject's heat perception during application at rest. Therefore, the purpose of this study was to compare the effectiveness of the Johnson & Johnson Back Plaster, the ABC Warme-Pflaster, and the ThermaCare HeatWrap at increasing skin interface and paraspinal muscle temperatures. Subject's heat perception was also compared for the 3 products.

METHODS

Design

This was a prospective, randomized, crossover design study. Skin and intramuscular temperature changes from baseline, skin and intramuscular maximum temperature, and heat perception changes from baseline were measured for 3 heating products (ThermaCare HeatWrap, Johnson & Johnson Back Plaster, ABC Warme-Pflaster) applied over the lumbar region for 2 hours. All subjects (with 1 exception) were treated with all 3 products, each product applied on a different day.

Subjects

Eighteen (10 males and 8 females) college-age subjects (mean age ± SD, 22.0 ± 2.5 years; mean height ± SD, 175.3 ± 10.6 cm; mean mass ± SD, 71.4 ± 12.9 kg) volunteered for this study. Those with current injury to the lumbosacral area, skin infection, previous back surgery or hypersensitivity to heat, needle injection, or derivatives of the capsicum plant were excluded. Brigham Young University Institutional Review Board approval was obtained and all subjects gave informed consent.

Instruments

A 16-channel Isothermex (Isothermex, Columbus, OH) was used to record intramuscular and skin interface temperature to the nearest ±0.1°C every minute for 120 minutes. Prior to all data collection, the Isothermex was factory calibrated over a range of −20°C to 80°C, as well as custom calibrated using a 3-temperature procedure (center point, 37°C). The Isothermex was interfaced to a desktop computer and temperatures were sampled and recorded at 1-minute intervals throughout the 2-hour session. An intramuscular-implantable thermocouple (Type IT-21 [diameter, .41 mm]; Physitemp Instruments, Clifton, NJ) sensor was used to measure temperature 2 cm deep in the lumbar area (L3) of each subject and 2 type-T, Cooper-Constantan thermocouple sensors (PT-6; Physitemp Instruments, Clifton, NJ) were used to measure skin interface temperature at 5 cm and 7 cm lateral to the intramuscular insertion site

(Figure 1). Throughout the experiment, room temperature was also monitored using a type-T Copper Constantan thermocouple interfaced with the Isothermex.

Before each use, all intramuscular-implantable thermocouples were sterilized in Wavicide (Medical Chemical Corporation, Torrance, CA) for at least 24 hours. Prior to sterilization, the intramuscular-implantable thermocouples were marked at 5 cm from the tip of the sensor so depth of placement could be accurately measured.

Perceived temperature in the lumbar area was measured using a 10-cm visual analog scale (VAS) (Figure 2). Subjects filled out separate VAS forms at 0, 30, 60, 90, and 120 minutes. VASs have been established as valid and reliable in a range of clinical and research applications when measuring multiple subjective variables.[14]

Three superficial heating modalities were used for the study (Figure 3). The Johnson & Johnson Back Plaster is a 26.7 × 14.4-cm disposable adhesive plaster made with a heavy cotton backing that contains oleoresin of Capsicum, which is a mixture of oil and resin extracted from various plants in the Capsicum genus (common pepper plant). The ABC Warme-Pflaster is a 22 × 14-cm disposable adhesive plaster made with a heavy cotton backing that contains capsaicin. Capsaicin is a colorless, pungent crystalline compound derived directly from the cayenne pepper plant. The primary ingredients of both the ABC Warme-Pflaster and the Johnson & Johnson Back Plaster are counterirritants to the skin. The ThermaCare HeatWrap is a cloth wrap with multiple disks made of iron powder, activated charcoal, sodium chloride, and water. These disks are spaced throughout the 34.4 × 13.8-cm cloth wrap's application surface. On average there is a 5-mm superior-inferior distance and a 10-mm medial-lateral distance between disks. When the wrap is removed from its sealed pouch and exposed to oxygen, the disks oxidize, producing an exothermic reaction.

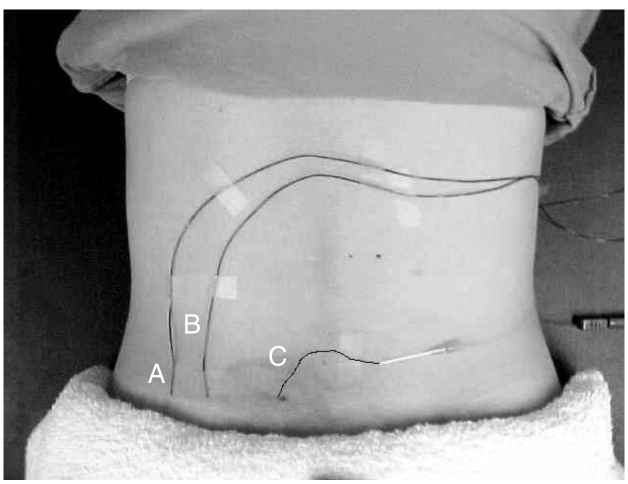

FIGURE 1. Intramuscular and skin interface thermocouple placement: (A) skin thermocouple 7 cm lateral to intramuscular thermocouple; (B) skin thermocouple 5 cm lateral to intramuscular thermocouple; (C) intramuscular thermocouple.

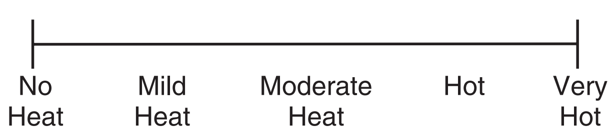

FIGURE 2. 10-cm visual analog scale used to assess perceived temperature.

Procedures

Subjects reported to the university research laboratory on 3 separate occasions for a 2-hour session separated by a minimum of 2 days and a maximum of 18 days (mean, 7.7 days). Subjects received all 3 products and a balanced Latin-square table was used to determine treatment order.

On the first visit to the lab, a single researcher took lumbosacral skinfolds to verify that the 2-cm-deep intramuscular thermocouple would be within the paraspinal muscles. Three skinfolds were measured at the L3 level at a width corresponding to the posterior superior iliac spines. Skin and subcutaneous fat thickness was determined using the method established by Merrick et al.[15] The mean lumbar skinfold was less than 2 cm for all subjects; hence, the placement of the intramuscular thermocouple was within the paraspinal muscle when positioned 2 cm below the skin's surface.

Subjects then assumed a prone position on a standard therapeutic table. After 5 minutes, the subjects filled out their baseline VAS measurement and were prepared for thermocouple insertion. The intramuscular thermocouple insertion site was determined by anatomical palpation. The left posterior superior iliac spine and iliac crest were located and a pen mark was made cranially to the posterior superior iliac spine at the level of the L3 spinous process. A 3 × 3-cm area surrounding the marked insertion site was cleansed with Proviodine-Iodine Prep Pads (Medline Industries, Mundelein, IL).

The intramuscular thermocouple was inserted perpendicular to the skin surface to a depth of 2 cm via a 20-gauge 1.25-in (3.15-cm) sterile intravenous catheter (Model 21-4056; Johnson & Johnson Medical, Arlington, TX). After insertion of the catheter and needle into the lumbar region, the needle was removed and the implantable thermocouple was threaded through the catheter tube into the paraspinal muscle. Threading the thermocouple into the catheter until the 5-cm mark on the thermocouple reached the top of the catheter controlled the initial insertion depth. The catheter was then removed and the distance between the skin surface and the 5-cm mark on the thermocouple was measured.

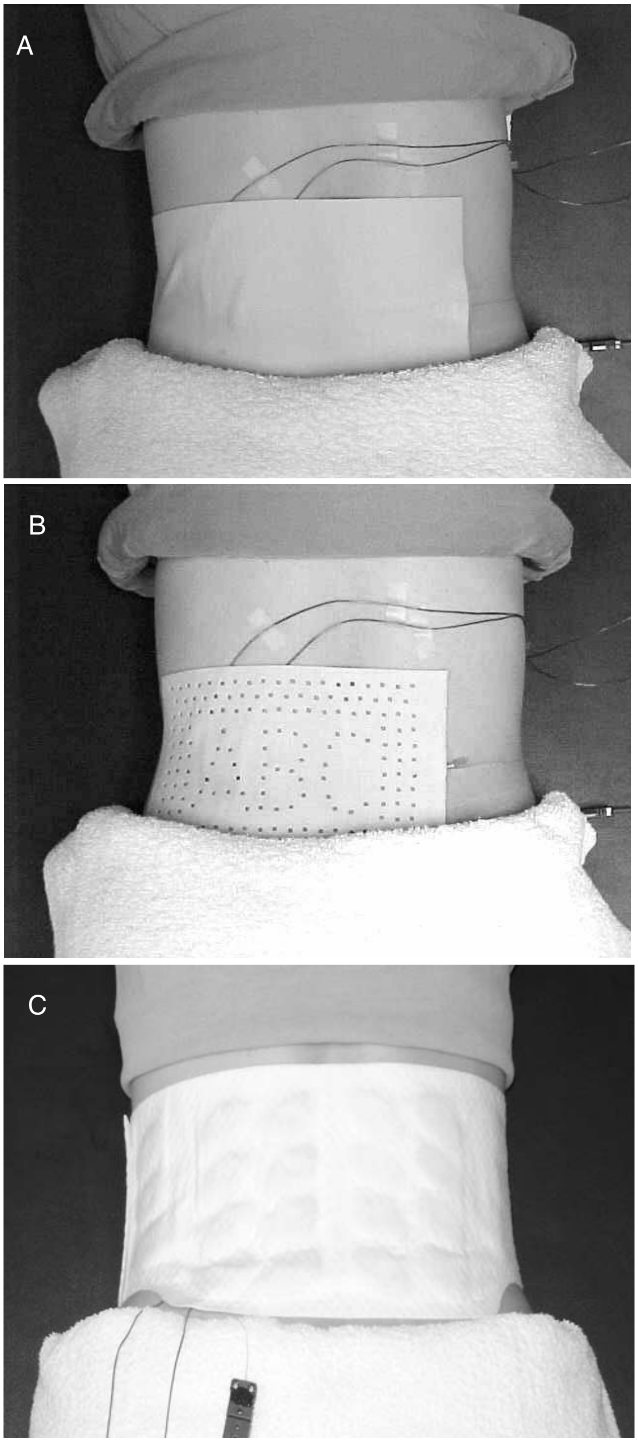

FIGURE 3. Heat products: (A) Johnson & Johnson Back Plaster; (B) ABC Warme-Pflaster; (C) ThermaCare HeatWrap.

Because the thermocouples were intentionally inserted deeper than necessary, they were withdrawn until the mark was 3 cm above the skin surface. Transpore clear tape (3M Healthcare, St Paul, MN) was used near the insertion site to secure the thermocouple and to prevent extraction of the thermocouple during the experiment. Next, the Cooper-Constantan thermocouple sensors were attached to the skin surface with Transpore clear tape at 5 cm and 7 cm from the insertion site (Figure 1). All thermocouples were connected to the Isothermex and the connections were verified through real-time temperature measurement.

Prior to product application, the baseline pretreatment temperatures were recorded. For this study, baseline was reached when the intramuscular and skin temperatures did not change more than 0.5°C over 3 consecutive 1-minute readings. Immediately following the baseline measurement, one of the 3 heat products was applied to the lumbosacral region according to the manufacturer's guidelines. The Johnson & Johnson Back Plaster and the ABC Warme-Pflaster were removed from their packaging and the adhesive backing was placed so that the back plaster covered the intramuscular and both skin interface thermocouples. ThermaCare HeatWrap was exposed to air for 10 minutes prior to application as recommended by the manufacturer. The wrap was positioned so that an iron disk was over the intramuscular insertion site. Another disk was positioned over the 5-cm skin interface thermocouple and a cloth space between disks was positioned over the 7-cm skin interface thermocouple. Using its own Velcro fasteners, the cloth wrap was fastened snuggly around the waist of the subject allowing only 1 finger to slide between the skin and cloth wrap. Application of the back plasters or heat wrap was accomplished in less than 2 minutes.

The subjects were positioned and remained in either a prone (n = 16) or sidelying (n = 2) position throughout the 120-minute session to maintain product and thermocouple placement. Subjects studied or watched television during the treatment period. At 30-minute intervals each subject filled out a separate VAS as a measure of their perceived warmth in the lumbosacral area at that time. At the end of the 120-minute treatment session, the product, the skin interface thermocouples, and the intramuscular thermocouple were all removed. The skin was cleansed with Proviodine-Iodine Prep Pads and an adhesive bandage (Johnson & Johnson, Skillman, NJ) was placed over the insertion site. Each subject was given instructions on monitoring the area for potential infection and was told to report to the university health center immediately if any signs or symptoms appeared. No problems were reported as a result of intramuscular thermocouple insertion. The same protocol was repeated on 2 additional occasions using a different heat product.

Data Analysis

Temperature was recorded every minute; however, the temperature measurements of primary interest were taken at 0 (baseline), 15, 30, 45, 60, 75, 90, 105, and 120 minutes. For analysis, temperature data from

TABLE 1. Baseline (mean ±SD) temperatures (°C) at the intramuscular and skin sites and baseline perceived heat (cm) based on a 10-cm visual analog scale.*

	Intramuscular	Skin	Perceived Heat
Johnson & Johnson Back Plaster	37.10 ± 0.13	31.37 ± 0.34	0.57 ± 0.15
ABC Warme-Pflaster	36.97 ± 0.12	31.43 ± 0.33	0.36 ± 0.15
ThermaCare HeatWrap	36.97 ± 0.12	31.67 ± 0.33	0.24 ± 0.15

* No significant differences across the 3 products for any of the variables (P>.05).

TABLE 2. Temperature changes (°C) across time for the 3 products at the skin site (mean ±SD).

Product	Temperature Change
Johnson & Johnson Back Plaster	1.4 ± 0.4
ABC Warme-Pflaster	2.1 ± 0.4*
ThermaCare HeatWrap	5.0 ± 0.4†

* Significantly different than Johnson & Johnson Back Plaster (P<.0001).
† Significantly different than other 2 products (P<.0001).

the Isothermex were entered into a customized software program which determined the differences from baseline at 15, 30, 45, 60, 75, 90, 105, 120 minutes and the time required to reach maximum temperature. A 1-way analysis of variance was used to detect differences between products for time to maximum temperature. We used 2 separate 3 × 8 repeated-measures analyses of covariance to analyze temperature changes at the intramuscular site and the 7-cm skin interface site. The first factor was product and the second factor was time. Baseline intramuscular and baseline skin temperatures (°C) were used as covariates, for their respective analyses. The 5-cm skin interface site was not used for analysis because an iron disk was positioned over this site during the ThermaCare Heat Wrap sessions. The purpose of this site was to record the temperature increase at the iron disk/skin interface so its heating properties could be measured.

Visual analog scale (VAS) data for heat perception were recorded at 0, 30, 60, 90, and 120 minutes and differences from baseline (0 minutes) were calculated and analyzed using a 3 × 4 repeated-measures analysis of covariance. The first factor was product and the second factor was time. Baseline heat perception (cm) was the covariate.

Post hoc Duncan's tests of the least-square means were used to determine product, time, and product × time differences.

We analyzed data for 18 subjects for the ThermaCare HeatWrap and ABC Warme-Pflaster and 17 subjects for the Johnson & Johnson Back Plaster. One subject only completed 2 treatment sessions before voluntarily withdrawing because of low back discomfort due to thermocouple insertion and training for the university cycling team.

RESULTS

Baseline Temperature and Perceived Heat

Across the 3 products, baseline temperature was not significantly different between subjects (Table 1) at either the intramuscular site (P = .699) or the skin site (P = .782). Baseline perceived heat, measured by VAS, was also not different (P = .3007) across the 3 products (Table 1).

Intramuscular Temperature

There was a significant product × time interaction ($F_{14,231}$ = 3.77, P<.0001) at the intramuscular site. Duncan's post hoc analyses (Figure 4) of the interaction verified that at each 15-minute interval the positive temperature changes produced by the ThermaCare HeatWrap were significantly different than the negative changes produced by the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster (P<.01). Post hoc tests also indicated that only the Johnson & Johnson Back Plaster and the ThermaCare HeatWrap had differences across time (Figure 4). The 15-minute interval for the Johnson & Johnson Back Plaster was significantly different from its 90-minute interval (P = .0358) and its 105-minute interval (P = .0213). The 15-minute interval for the ThermaCare HeatWrap was significantly different from all its other time intervals (P<.013) and the 30-minute interval was significantly different from the 75, 90, 105, 120 minute intervals (P<.0242).

Skin Temperature

There was not a significant product × time interaction ($F_{14,231}$ = 1.03, P = .4228) at the skin site. Both the main effects for product ($F_{2,33}$ = 391.74, P<.0001) and time ($F_{7,119}$ = 9.69, P<.0001) were significant (Figure 5). The average skin temperature changes across time for the 3 products are presented in Table 2.

Time to Maximum Temperature

The average times (minutes) for subjects to reach maximum paraspinal and skin temperature were calculated from all 120-minute readings and are shown in Figure 6. There was no significant product

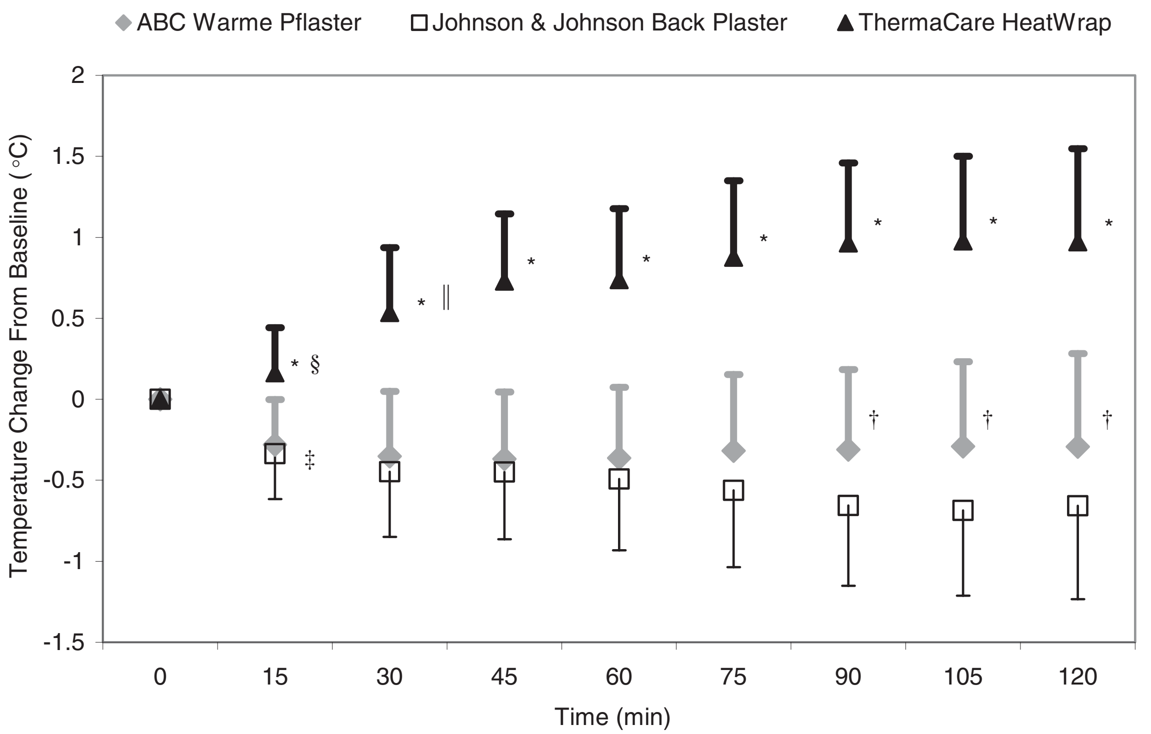

FIGURE 4. Mean intramuscular temperature changes (°C) from baseline at 15-minute intervals. Error bars represent 1 standard deviation and are drawn in only 1 direction.
* ThermaCare HeatWrap significantly different than the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster for each corresponding time interval ($P<.01$).
† ABC Warme-Pflaster was significantly different than the Johnson & Johnson Back Plaster at 90, 105, and 120 minutes ($P<.05$).
‡ Value at 15 minutes for the Johnson & Johnson Back Plaster significantly different than at 90 ($P = .0358$) and 105 ($P = .0213$) minutes for the same product.
§ Value at 15 minutes for the ThermaCare HeatWrap significantly different than at 30 minutes ($P = .0139$) and at all other time intervals for same product ($P<.0002$).
‖ Value at 30 minutes for the ThermaCare HeatWrap significantly different than at 75, 90, 105, and 120 minutes ($P<.05$) for the same product.

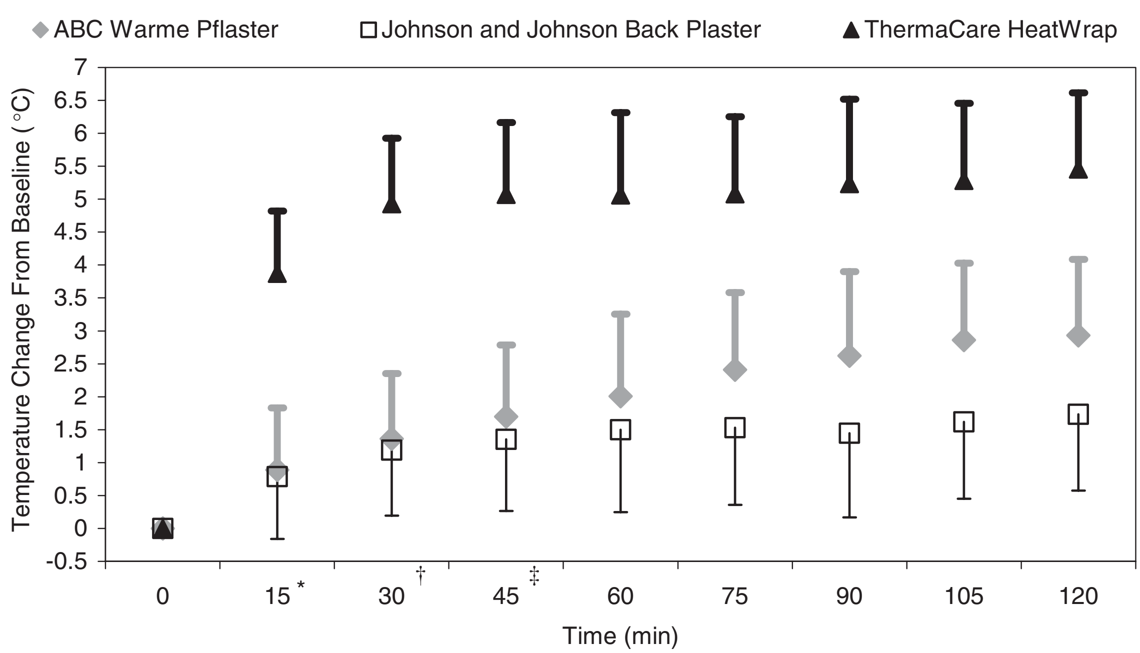

FIGURE 5. Mean skin temperature changes (°C) from baseline at 15-minute intervals. Change in temperature across time was significantly different for the 3 products ($P<.0001$). Error bars represent 1 standard deviation and are drawn in only 1 direction.
* Across products, temperature change at 15 minutes was significantly less than at all other time intervals ($P<.0044$).
† Across products, temperature change at 30 minutes was significantly less than at 75, 90, 105, and 120 minutes ($P<.05$).
‡ Across products, temperature change at 45 minutes was significantly less than at 105 ($P = .0153$) and 120 minutes ($P = .0033$).

effect for the time to maximum temperature at the skin ($F_{2,49}$ = 1.16, P = .3230). The time data were skewed so the standard deviations do exceed 120 minutes.

Data for the intramuscular site indicated that only the ThermaCare HeatWrap caused an intramuscular temperature increase (Figure 6). Therefore, only data for the ThermaCare HeatWrap are shown for the intramuscular site, and no statistical comparison was performed.

Heat Perception

There was not a significant product × time interaction ($F_{6,99}$ = 1.85, P = .0968) for the VAS data (Figure 7). Both the main effects for product ($F_{2,33}$ = 41.59, $P<.0001$) and time ($F_{3,51}$ = 19.02, $P<.0001$) were significant. Duncan post hoc tests of product indicated that across time the subjects perceived that the ABC Warme-Pflaster was warmer than both the Johnson & Johnson Back Plaster (P = .0015) and the ThermaCare HeatWrap ($P<.0001$). Post hoc tests also indicated that the Johnson & Johnson Back Plaster was perceived to be warmer than the ThermaCare HeatWrap ($P<.0001$). Across all products, the 30-minute interval had the least perceived heat (Figure 7).

DISCUSSION

Our study was designed to specifically test the heating effectiveness of commercial heating products for the lumbosacral region. This study provides evidence that throughout a 120-minute treatment performed at rest, the ThermaCare HeatWrap was the only product to produce an increase in intramuscular temperatures above baseline, whereas the use of the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster resulted in a decrease in intramuscular temperature (Figure 4). We believe there are 2 possible explanations for the intramuscular temperature decrease for the Johnson & Johnson Back Plaster and ABC Warme-Pflaster. First, as the subjects rested for 2 hours on the treatment tables their intramuscular temperatures declined; however, the Johnson & Johnson Back Plaster and ABC Warme-Pflaster did not produce enough heat to counteract this decline, resulting in a net temperature reduction. Second, blood flow may have been diverted from the muscle to the skin as a result of the counterirritant effect of these 2 plasters, thereby decreasing the intramuscular temperature. On the other hand, the ThermaCare HeatWrap was able to provide heat to the paraspinal muscle.

All the heat products produced increases in lumbosacral skin interface temperatures, but the ThermaCare HeatWrap produced the greatest increases when compared to the Johnson & Johnson and the ABC back plasters (Figure 5). However, the ABC produced more heat at the skin interface than the Johnson & Johnson Back Plaster.

The paraspinal temperature increases produced by the ThermaCare HeatWrap fall within the mild heating range (temperature increase up to 40°C) proposed by Lehmann and deLateur,[12] whereas the skin temperature increases fall within the vigorous heating range (temperature increases between 40°C and 45°C). The skin temperature increases produced by Johnson & Johnson Back Plaster and the ABC Warme-Pflaster fall within the mild heating ranges proposed by Lehmann and deLateur.[12] Previous research has shown that mild heating may allow for pain reduction,[3,5,11] improved circulation,[2,8] and reduction of muscle spasm.[9] However, the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster did not produce paraspinal muscle temperature increases. Without any temperature increases and the associated therapeutic effects, like pain reduction and improved circulation, these wraps may have limited therapeutic effects at the paraspinal level. Therefore, it is possible that only the ThermaCare HeatWrap provides for pain reduction, improved circulation, and reduction of muscle spasm within the paraspinal muscles.

All 3 products did produce temperature increases at the skin. The Johnson & Johnson Back Plaster and ABC Warme-Pflaster produced temperature increases within the mild heating range and the ThermaCare HeatWrap produced a temperature increase within the vigorous heating range. These findings suggest that the Johnson & Johnson Back Plaster and ABC Warme-Pflaster may have the ability to improve circulation and provide pain and spasm reduction through neural stimulation at the skin surface.[12] However, the ThermaCare HeatWrap may have the additive benefit of providing for an increased extensibility of collagen tissue[13,19] and increased metabolism[2] within the skin and underlying collagen tissue. Therefore, if the intent is to heat the muscle and the skin to within a therapeutic range, then the ThermaCare HeatWrap is the superior choice.

We believe that the differing temperature results at the intramuscular site were related to the type of product and the method of heat production. The ThermaCare HeatWrap uses the oxidation of iron disks to produce heat through exothermic reactions, whereas the Johnson & Johnson and the ABC Warme-Pflaster use plant derivatives from the Capsicum genus. The pepper plant derivatives produced a counterirritation to the skin, which raised skin temperature as a response to the stimulation of chemoreceptors. However, the iron disks of the ThermaCare actually produced heat at the skin interface. The mean temperature increase for an iron disk obtained from the thermocouple located 5 cm from the insertion site was 8.44°C ± 0.45°C. The greater

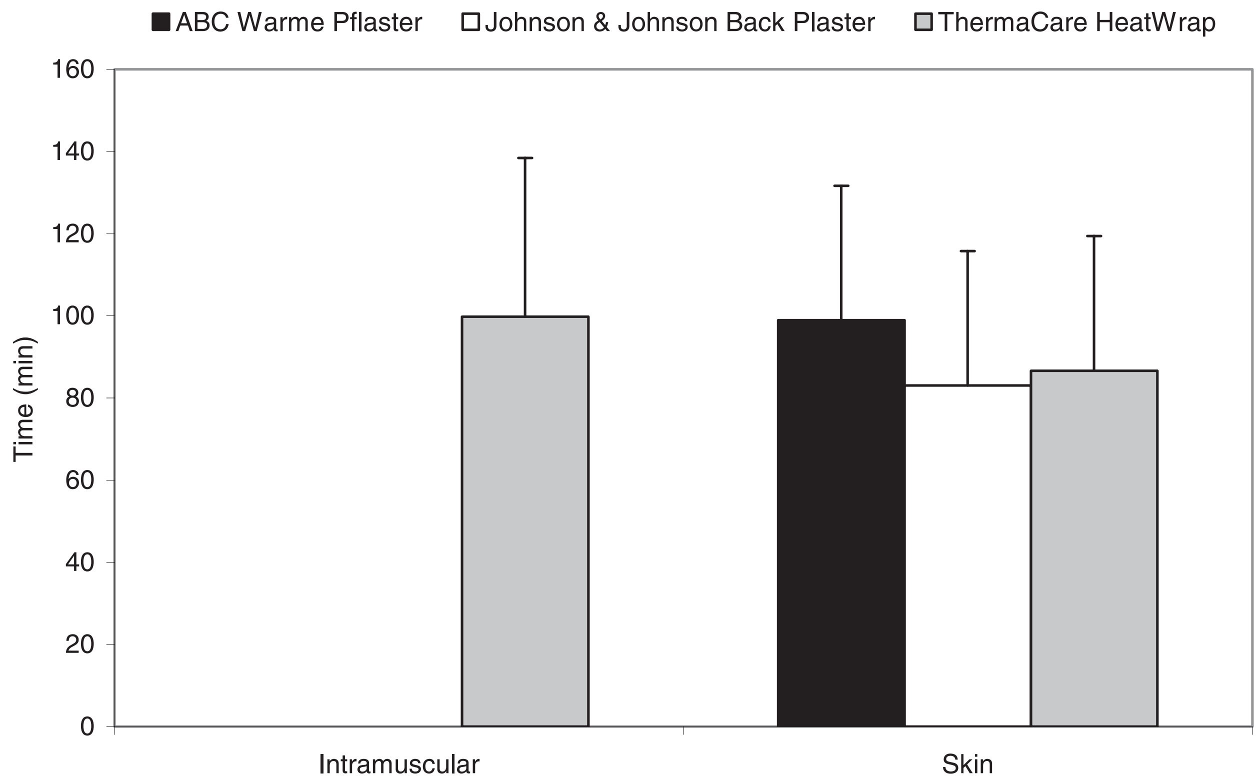

FIGURE 6. Mean time (minutes) to maximum temperature increase for heat products at the intramuscular and skin sites. Only the ThermaCare HeatWrap increased intramuscular temperature. No significant timing difference was measured across products for time to reach maximum skin temperature ($P>.05$). Error bars represent 1 standard deviation.

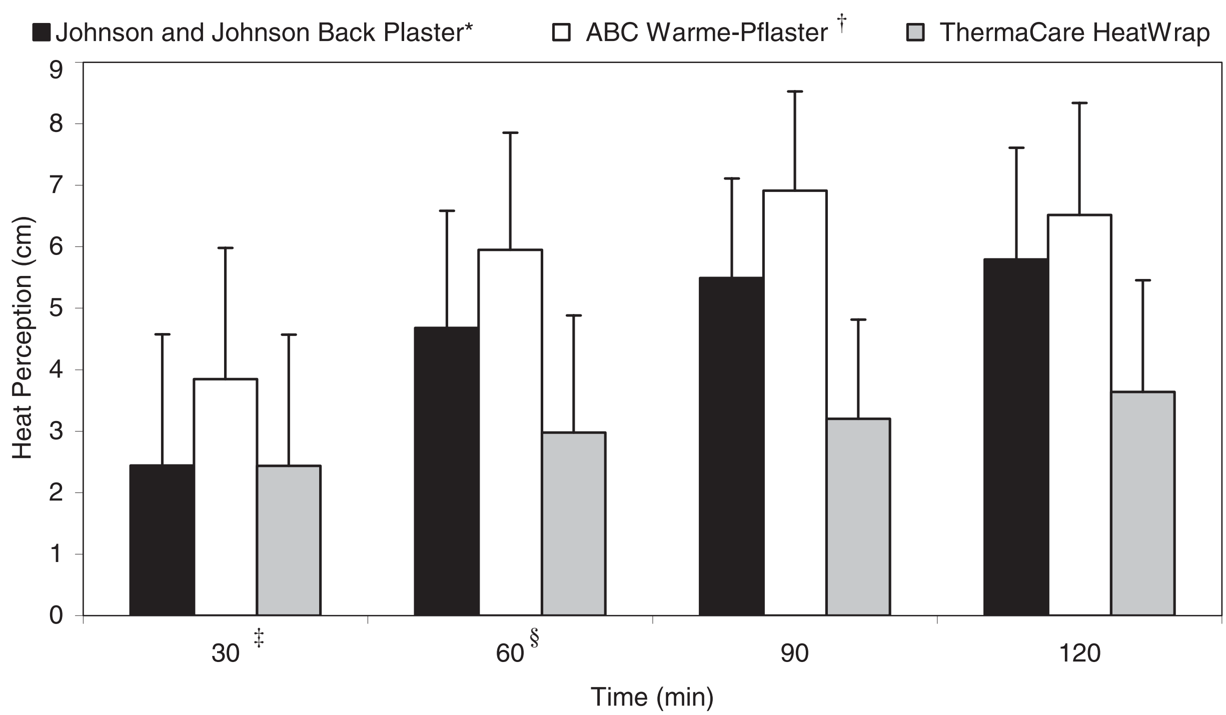

FIGURE 7. Heat perception (cm) at 30-minute time intervals. Error bars represent 1 standard deviation.
* Across time, Johnson & Johnson Back Plaster was perceived to be significantly warmer than the ThermaCare HeatWrap ($P<.0001$).
† Across time, ABC Warme-Pflaster was perceived to be significantly warmer than the Johnson & Johnson Back Plaster ($P = .0015$) and ThermaCare HeatWrap ($P<.0001$).
‡ Across product, perceived heat at 30 minutes was significantly less than at 60, 90, and 120 minutes ($P<.0001$).
§ Across product, perceived heat at 60 minutes was significantly less than at 120 minutes ($P = .0347$).

thermal gradient produced by the ThermaCare allowed for a greater conduction of heat through the skin and into the deeper tissue. The increase in intramuscular temperature for the ThermaCare HeatWrap compared to no intramuscular heating for both plasters might be explained by the temperature gradients between the products and the skin, because the conduction of heat is directly proportionate to the temperature gradient between the skin and the heating agent.[3] It is possible that the counterirritants from the oleoresin of Capsicum and the capsaicin, which are the primary mechanisms for heat production in the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster, produced sensations of heat rather than actual thermal energy. Therefore, the skin temperature increases may have been from the skin's superficial reaction to the counterirritant, such as increased blood flow, and the lack of temperature increase within the muscle may have been because there was not a sufficient temperature gradient.

Further evidence that the sensations of heat produced by the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster were the result of the counterirritation of the skin, rather than thermal energy, comes from our results from the time to maximum temperature at the skin site (Figure 6) and the perception of heat results from the VAS scale (Figure 7). Because the average time to maximum skin temperature and the time at which the peak perceived temperature occurred are similar (Figures 6 and 7), we believe the sensations of heat produced by the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster were a result of the counterirritation of the skin rather than thermal energy production. We also believe that the purer capsaicin on the ABC Warme-Pflaster was a better counterirritant because the ABC Warme-Pflaster produced a higher mean peak skin temperature increase (2.9°C) than the Johnson & Johnson Back Plaster (1.7°C) at 120 minutes. On the other hand, the ThermaCare HeatWrap had the greatest skin temperature increase (5.0°C) and produced its maximum sensations of heat at a time similar to the time to maximum skin and intramuscular temperatures; therefore, it is likely the ThermaCare HeatWrap was producing and conducting thermal energy throughout the treatment (Figures 6 and 7).

As of this date, no other studies on back plasters have reported perception of heat, intramuscular temperature, and skin temperature. Heating of the muscle is important for tissue healing and regeneration.[7,11] However, the perception of heat is also important because a patient's sensation can be an integral part of effective treatment.[10] Even though our study did not explore pain reduction, it did demonstrate that all 3 products produced moderate to very hot heat sensations. Through extensions of the gate control theory of pain, one can deduce that the perceived feeling of heat may help control pain.[3,4] All the manufacturers claim that these heat products are able to reduce pain in addition to providing warmth.

However, only the ThermaCare HeatWrap produced both intramuscular and skin temperature increases. Therefore, the Johnson & Johnson Back Plaster and the ABC Warme-Pflaster may only be effective for therapeutic pain reduction and not for heating the tissue beneath the skin surface. So the ThermaCare HeatWrap may be the better choice when therapeutic intervention for low-back disability includes both the modulation of pain and the physiological repair of damaged tissue through factors like increased collagen elasticity, reduced muscle spasm, increased metabolism, or increased blood flow.

Limitations to this study include the treatment time, patient activity level, and patient population. Only college-age healthy subjects were used; no specific conclusions can be made in regards to the effectiveness of these products in the relief of pain in a symptomatic patient. A population of individuals with back pain could provide further insight into the effectiveness of these convenient and portable heat modalities on reducing pain. In addition, this study only evaluated treatment for 2 hours, so the effects of these products after 2 hours are not known. All 3 products are marketed to be long-lasting treatments for low back pain, the ThermaCare HeatWrap even suggests an 8-hour application time. Finally, all subjects were in a resting position for the entire treatment. Activity while wearing one of these products might create further increase in muscle and skin temperature, which could result in better patient outcomes. Therefore, further studies are needed to assess the effectiveness of these products over periods longer than 2 hours and during activity.

CONCLUSIONS

The Johnson & Johnson Back Plaster and the ABC Warme-Pflaster provide a sensation of heat and a small increase in the temperature at the skin surface, but do not provide intramuscular heat. The ThermaCare HeatWrap produced significant increases in both skin and intramuscular temperatures with less heat sensation. Because the ThermaCare HeatWrap was able to increase both skin and muscle temperature it seems to be a more effective thermal modality than both the Johnson & Johnson Back Plaster and ABC Warme-Pflaster.

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