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ORIGINAL ARTICLE

Pilot Study of the Effects of a Heat-Retaining Knee Sleeve on Joint Pain, Stiffness, and Function in Patients With Knee Osteoarthritis

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Objective. **To identify changes in joint pain, stiffness, and functional ability in patients with knee osteoarthritis (OA) after use of a knee sleeve that prevents loss of body heat by the joint.**

Methods. **Subjects with symptomatic knee OA (n = 52) were randomized to 2 treatment groups: verum sleeve (specially fabricated to retain body heat) or placebo sleeve (standard cotton/elastane sleeve). Subjects wore the sleeve over the more painful OA knee for at least 12 hours daily for 4 weeks. Pain, stiffness, and functional impairment (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC]) in the index knee were measured at baseline and after 4 weeks of wear, after which sleeve use was discontinued. Telephone followup interviews were conducted 2 and 4 weeks later.**

Results. **After 4 weeks of sleeve wear, subjects in the active treatment group reported a 16% decrease in mean WOMAC pain score relative to baseline ($P = 0.001$). Those who wore the placebo sleeve reported a 9.7% decrease from baseline ($P = 0.002$). The difference between treatment groups was not statistically significant ($P = 0.12$). However, it was found that the 12 subjects who believed correctly that they had received the verum sleeve reported a highly significant decrease in WOMAC pain score (–27.5% relative to baseline, $P = 0.0001$). In comparison, subjects who received the verum sleeve but believed they had received the placebo sleeve exhibited only a marginally significant improvement in pain (–13.0% relative to baseline, $P = 0.07$). In the placebo group, the modest improvement in pain scores appeared unrelated to the subject's impression of the type of sleeve worn.**

Conclusion. **This pilot study was insufficiently powered to be a definitive trial of the heat-retaining sleeve. Given the magnitude of changes in knee pain in the active treatment group, heat retention merits further scientific investigation as a treatment modality for patients with knee OA.**

KEY WORDS. Osteoarthritis; Heat therapy; Nonpharmacologic treatment.

INTRODUCTION

The pain associated with osteoarthritis (OA) may be due to stretching of the joint capsule, microfractures of subchondral bone, medullary hypertension, synovitis, muscle spasm, or other forms of soft-tissue rheumatism (e.g., bursitis, tendinitis) (1). Nonpharmacologic measures, which typically include education of the patient in principles of joint protection, exercise, weight reduction (if the patient is obese), orthotics, ambulatory assistive devices, and thermal modalities (e.g., a heating pad or ice pack), are the keystone of symptomatic therapy for patients with knee OA (2,3). Pharmacologic agents, such as analgesics and nonsteroidal antiinflammatory drugs (NSAIDs), augment the benefits of the nonpharmacologic modalities.

The efficacy of thermal modalities in treatment of OA pain is supported, in large part, by clinical trials of effective multifocal self-care interventions for OA patients that have included guidelines for heat and cold application among an array of nonpharmacologic treatment modalities (4–6). A recent placebo-controlled trial has shown that an elastic wrap for the lumbar region, made of infrared-reflective material that prevents loss of body heat, reduced complaints of low back pain (7). Other researchers have found

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that regular use (>8 hours/day) of a wrap with similar heat-retaining properties was associated with >25% decrease in chronic back pain (8,9). Whether a similar approach to reduction of chronic musculoskeletal pain is effective in patients with knee OA, however, is unknown.

Controlled studies of isolated thermal modalities in knee OA are rare. Recent reviews of the literature on thermal modalities in arthritis (10–12) indicate that although there is some evidence that an increase in the temperature of the joint may provide short-term relief of joint pain, the few published studies in this area suffer serious methodologic limitations—notably the ability to distinguish treatment effects from placebo effects. Accordingly, we have conducted a 4-week randomized, placebo-controlled pilot study of the effects on joint pain, stiffness, and functional ability in patients with knee OA of an elastic, infrared-reflective knee sleeve fabricated of the same materials as those used in previous studies of chronic low-back pain (8,9). This pilot study was intended to provide useful estimates of the magnitude, variability, and duration of the effects of the knee sleeve that would inform the design of a definitive trial of this thermal modality.

METHODS

Design. This was a double-blind, randomized controlled trial of the effects of a heat-retaining knee sleeve on joint pain, stiffness, and function in patients with knee OA. Fifty-two patients with symptomatic knee OA were allocated in blocks of 4 to treatment for 4 weeks with either the verum (heat-retaining) sleeve or a placebo sleeve that was of comparable weight and provided a comparable area of contact to control for proprioceptive effects. Randomization in blocks of 4 (2 verum, 2 placebo) was employed to ensure that the treatment groups would be affected equally by seasonal variations in atmospheric temperature. Following the double-blind phase, the sleeve was withdrawn and the durability of the effect on pain was ascertained 2 and 4 weeks later.

Eligibility criteria. All subjects had radiographic evidence of knee OA and knee pain of moderate or greater severity. Specific eligibility criteria were grade 2 or higher Kellgren and Lawrence (K/L) radiographic severity of tibiofemoral OA in the standing anteroposterior view and a total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score ≥8 (possible range 5–25) (13,14). Thirty-eight subjects (73%) had radiographic evidence of bilateral knee OA. An index knee was identified as the more painful OA knee at baseline.

Description of the device. The verum knee sleeve was fabricated of cotton and elastane (Lycra) with a heat-retaining polyester substrate microscopically coated with aluminum and a metalized entangled fiber matrix (total aluminum content ≤5 μg per sleeve) (15). Quantitatively, the composition of the sleeve was 60% cotton, 34% polyester/polyamide, 6% elastane, and <<<1% aluminum. Placebo sleeves were of similar cotton/elastane construction, but did not contain the aluminum-coated substrate and fiber matrix. Positioning and fit of both types of sleeves were facilitated by a hook-and-loop cinch located above the kneecap (Figure 1).

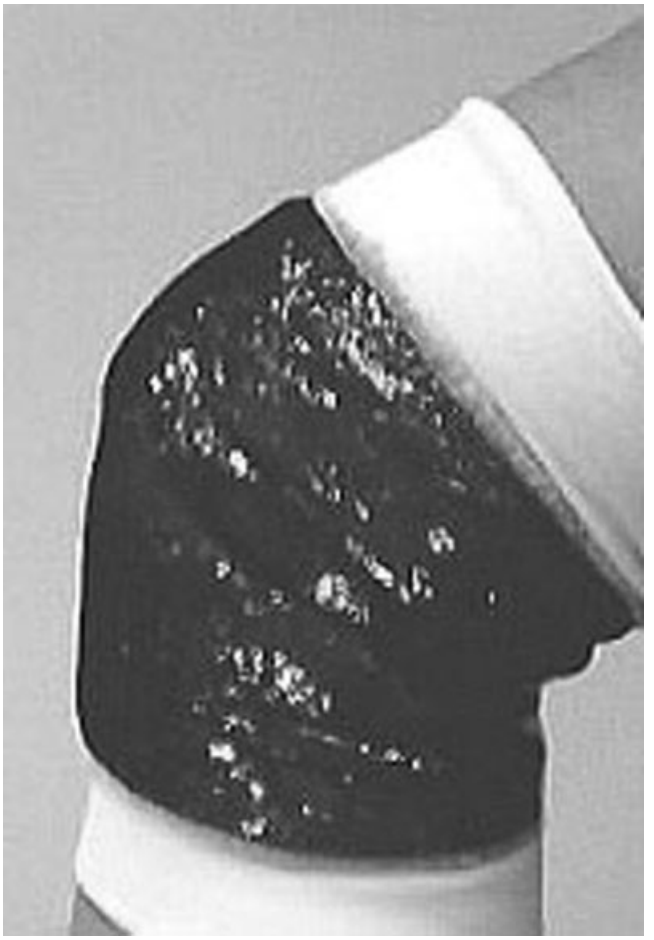

Figure 1. Adjustable heat-retaining knee sleeve used in the present study. In the photograph, the device is being worn inside-out to illustrate the infra-red reflective materials. The hook and loop cinch above the patella is not visible.

Procedures. Patients were shown at the baseline visit how to position the sleeve over the knee. To fit the verum and placebo sleeve, the circumference of the index knee was measured and the measurement was used to determine the size of the sleeve to be dispensed (small, medium, large, or extra large). The patient was cautioned not to tighten the cinch excessively, to avoid constriction of the skin. To preserve the experimental blind, sleeves were dispensed to subjects in plain unmarked boxes. Subjects were instructed to begin wearing the sleeve on the index knee after leaving the clinical research unit, to wear the sleeve at least 12 hours each day, and to continue taking their usual OA pain medication(s). Subjects were contacted by telephone 2 weeks after the sleeve was dispensed to measure adherence with the treatment protocol, identify the occurrence of any adverse events, and encourage continued participation in the trial. After 28 days of treatment, the subject returned the sleeve in its original box.

The baseline assessment consisted of the pain, stiffness,

Table 1. Characteristics of subjects*

Age, mean ± SD years	62.7 ± 11.2
Sex, % female	77
Race, % white	67
Education, % with ≥12 years	85
Radiographic severity of OA, index knee	
% Kellgren/Lawrence grade 2	50
% Kellgren/Lawrence grade 3	42
% Kellgren/Lawrence grade 4	8
WOMAC score, mean ± SD†	
Pain, possible range: 5–25	14.9 ± 3.7
Stiffness, possible range: 2–10	6.5 ± 1.4
Function, possible range: 17–85	51.8 ± 11.8

* OA = osteoarthritis.
† Greater Western Ontario and McMaster Universities Osteorthritis Index (WOMAC) scale scores indicate greater pain, stiffness, or functional limitation.

and function scales of the WOMAC (14). Assessments of joint pain and stiffness focused on the index knee. When reporting functional limitations, the patient considered both knees collectively. Assessments performed at the end of the double-blind phase included the level of adherence to the protocol (i.e., days during which the sleeve was worn for at least 12 hours), adverse events, and the WOMAC scores. Subjects were contacted by telephone 2 weeks and 4 weeks after the sleeves had been returned for assessment with the WOMAC pain scale. Administration of WOMAC scales by telephone has been validated against face-to-face administration (16).

Statistical analysis. Chi-square and Student's *t*-tests were used, as appropriate, to verify the baseline equivalence of the treatment groups with respect to age, sex, ethnicity, years of formal education, and WOMAC scale scores. The significance of differences within and between treatment groups with respect to effects of the knee sleeve on pain, stiffness, and function were evaluated, as appropriate, using Student's *t*-test.

RESULTS

The mean age of the sample (± SD) was 62.7 ± 11.2 years (Table 1). Most subjects were women (77%) with ≥12 years of formal education (85%). Subjects from minority groups comprised one-third of the sample. Index knees of 50% of the subjects (n = 26) exhibited only marginal osteophytes (i.e., K/L grade 2 radiographic severity of OA); mild-to-moderate joint space narrowing (K/L grade 3) was apparent in radiographs of the index knees of 22 subjects; the remainder (4 subjects) had index knees showing complete loss of medial joint space in the tibiofemoral compartment (K/L grade 4). The typical subject reported moderate levels of knee pain, stiffness, and functional impairment (Table 1). Both treatment groups were similar with respect to these demographic characteristics and radiographic and symptomatic severity of knee OA.

No adverse events were reported. One subject from the placebo group withdrew consent to participate in the trial before the 4-week outcome assessment for personal reasons unrelated to treatment. Two subjects (1 verum sleeve, 1 placebo) who completed the 4-week double-blind phase were lost to followup by telephone for the 6- and 8-week assessment of duration of symptomatic relief. In addition, 2 placebo subjects could not be reached by telephone at week 6, but participated in the week-8 assessment of the duration of the effects.

Outcomes after 28 days of treatment in the double-blind phase are presented in Table 2. Adherence with the treatment protocol was high in both groups; the mean number of days during which the study sleeve was worn for ≥12 hours was 26.5 in the verum sleeve group and 27.6 in the placebo group (P = not significant). After wearing the verum sleeve for 4 weeks, subjects reported a 2.5-point decrease in mean WOMAC pain score (i.e., 16% decrease relative to baseline, $P = 0.001$), whereas the placebo group reported a 9.7% decrease. The improvement, relative to baseline, in the placebo group was also statistically significant, ($P = 0.002$) but the difference between treatment groups was not significant ($P = 0.12$). The differences

Table 2. Effects after 4 weeks of treatment with verum and placebo sleeves

	Type of sleeve		
	Verum (n = 26)	Placebo (n = 25)	*P**
Adherence, days sleeve worn ≥12 hours; possible range 0–28; mean ± SD	26.5 ± 3.0	27.6 ± 1.1	0.11
Change in WOMAC scores, baseline-followup†			
Pain, mean ± SD	−2.5 ± 3.2‡	−1.4 ± 1.8‡	0.12
Stiffness, mean ± SD	−0.5 ± 1.8	−0.9 ± 1.5	0.41
Function, mean ± SD	−3.2 ± 7.8	−4.2 ± 9.5	0.68
Change in WOMAC scores (% of baseline)†			
Pain, mean ± SD	−16.0 ± 22.4	−9.7 ± 13.2	0.22
Stiffness, mean ± SD	−5.2 ± 30.1	−13.8 ± 22.7	0.26
Function, mean ± SD	−6.7 ± 17.1	−7.7 ± 16.9	0.84

* *P* values are for between-group differences
† A negative value indicates a decrease in pain, stiffness or functional limitation. WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.
‡ $P < 0.005$ to reject the hypothesis that mean WOMAC change score = 0 (paired *t*-test).

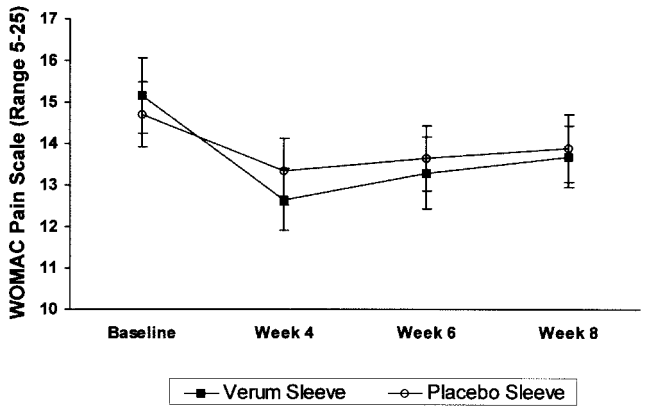

Figure 2. Mean pain score (± SE) for subjects randomized to treatment groups before and after withdrawal of verum and placebo knee sleeves at week 4. WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

between treatment groups with respect to changes in stiffness and function were not significant. Outcomes in the 2 treatment groups were similar with respect to effects among women and men, among subjects with more or less than 12 years of formal education, and in subjects with moderate versus severe knee pain at baseline.

The durability of the effect on pain in both treatment groups is shown in Figure 2. Mean WOMAC pain scores in both groups increased consistently (i.e., knee pain worsened) over the 4 weeks following withdrawal of the sleeves. The moderate, albeit statistically insignificant, difference between treatment groups with respect to WOMAC pain scores observed at the end of the 4-week double-blind phase diminished by ~50% between week 4 and week 6. By week 8, mean pain scores in the verum and placebo groups were nearly identical (13.7 and 13.9, respectively).

Notably, when asked at the end of the double-blind phase whether they thought they had worn the verum or placebo sleeve, 50% of the 26 subjects randomized to the active treatment group indicated that they believed they had received the verum sleeve. In contrast, only 4 (17%) of the 24 subjects in the placebo group believed they had received the verum sleeve ($P = 0.02$). Table 3 presents changes in WOMAC pain score in the 2 treatment groups in relation to the judgment of the subjects at the conclusion of the period of sleeve wear with respect to whether they believed they had received a verum sleeve or placebo sleeve. In the placebo group, changes in mean pain scores were small (–6.2% and –9.4%, respectively, relative to baseline), not statistically significant, and appeared unrelated to the belief of the subject regarding the type of sleeve worn.

In comparison, although based on small numbers of observations, the results in the active treatment group were intriguing: the 12 subjects who received the verum sleeve and believed they had received the verum sleeve reported a highly significant decrease in WOMAC pain score (–27.5%) relative to baseline ($P = 0.0001$). The decrease in pain scores among these patients was significantly greater than that in the subset of 4 patients in the placebo group (–6.2%) who similarly believed that they had been wearing the verum sleeve ($P = 0.003$). Eight subjects in the active treatment group believed at closeout that they had received a placebo sleeve—presumably because their level of pain relief did not meet their expectations for effective therapy. Nonetheless, these subjects exhibited a marginally significant improvement in knee pain relative to baseline (13.0%; $P = 0.07$). However, it was not significantly greater than that seen in controls who similarly believed that they had worn a placebo sleeve ($P = 0.37$).

DISCUSSION

Many patients with knee OA find that their joint pain is aggravated by cold and damp and that even warm clothing may not alleviate their discomfort (17,18). It has been shown that infrared heat escapes naturally through clothes, accounts for as much at 70% of total heat loss from the body, and changes dramatically with temperature. The loss is proportional to the temperature gradient raised to the power of 4, according to Stefan's law (19). Exposure to cold, on the other hand, causes muscle spasm and reduces circulation through vasoconstriction. Furthermore, the induced muscle spasm may cause pain. Warming reverses these effects (20,21). In addition, ligaments and tendons that are anatomically related to the knee joint (collateral ligaments, hamstring tendons, patellar tendon, iliotibial band) lie close to the skin, where they are exposed to external temperatures that may cause changes in their mechanical properties. Such changes could possibly influence joint stressors and affect nociceptors. Walker et al (22) found a significant decrease in the elastic modulus of tendon with an increase in ambient temperature, i.e., the tendon became less stiff as temperature increased. Similarly, Woo et al (23) found that the magnitude of the tensile

Table 3. Change in WOMAC pain score (baseline-followup) related to the type of sleeve subjects believed they wore*

Type of sleeve subject believed was worn	Change in mean WOMAC pain score						
	Verum sleeve group			Placebo group			
	n	Mean ± SD	Change from baseline, %	n	Mean ± SD	Change from baseline, %	*P*
Verum	12	−3.8 ± 2.3	−27.5	4	−1.0 ± 0.8	−6.2	0.003
Placebo	8	−2.6 ± 3.5	−13.0	15	−1.4 ± 1.8	−9.4	0.37
Uncertain	6	0.3 ± 0.3	+3.0	5	−1.2 ± 2.4	−10.0	0.37

* WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

load required to produce a predetermined strain in the canine medial collateral ligament decreased as the temperature increased, i.e., less stress was required to stretch the ligament at higher temperatures than at lower temperatures (24). Consistent with the above, Warren et al (25) found that rat tail tendon elongated with increasing temperature.

Patients who wore the heat-retaining sleeve reported a 16% decrease in mean WOMAC pain scores relative to baseline at the 4-week evaluation. This level of pain relief was larger than that observed by Hassan et al (6–11%) in a study of the effects of a common elastic bandage (with no extraordinary heat-retention properties) in patients with knee OA (26). This pain relief is also comparable to that seen in the active treatment group of several clinical trials of NSAIDs, in which the improvement in pain, relative to baseline, is typically ~20% and the difference between NSAID and placebo ~15–20% (27–30), although some studies have shown improvement of somewhat greater magnitude (31,32).

It is well documented that patients with knee OA exhibit an impairment in position sense (static) proprioception (33). As mentioned above, Hassan et al (26) have shown that use of a elastic bandage wrapped loosely around the OA knee produces a small decrease in knee pain; however, such a device had no effect on static proprioception. Hewitt et al (34) found that the ability to perceive movement (i.e., kinesthesia) is also diminished in patients with knee OA and that use of a common elastic bandage did not improve detection of movement. Although neither position sense nor movement detection were evaluated in the present study, the skin surface area covered by the placebo sleeve was comparable to that covered by the verum sleeve and both were applied with a comparable degree of light pressure without constriction. Presumably, the chief differences in outcomes between subjects who wore the verum sleeve and placebo sleeve were due to differences in retention of body heat, rather than to effects on proprioception.

Based on the variability in knee pain exhibited by subjects who wore verum and placebo knee sleeves (pooled SD of change in WOMAC pain scores = 2.6), this pilot study had only 30% power to conclude that the difference in knee pain observed between treatment groups (1.1 scale points) was statistically significant ($\alpha = 0.05$). Nonetheless, given the magnitude of the change in knee pain in the active treatment group, compared to the recognizable placebo response in the controls, we conclude that a heat-retaining knee sleeve merits further study for symptomatic treatment of patients with knee OA. Based on the data from this pilot study, to achieve 80% power to detect a significant difference in knee pain between treatment groups in an intent-to-treat analysis after 4 weeks of treatment, at least 91 subjects per treatment group would need to be included in a randomized controlled trial. Because the 4-week change in knee pain was significant in both groups in this pilot study, incorporation of a placebo group into the design of a larger clinical trial of this thermal modality would be advisable.

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