

BREAKING NEWS: SCIENTIFIC MEETING OF AMERICAN PAIN SOCIETY

NEW OSTEOARTHRITIS RESEARCH STUDY FINDS CONTINUOUS LOW-LEVEL HEAT WRAP THERAPY PROVIDES SIGNIFICANT PAIN RELIEF AND IMPROVED FLEXIBILITY AT THE KNEE

Boston, MA (March 30, 2005) - Results of a new study released today suggest that continuous low-level heat wrap therapy may be an effective option to manage pain and stiffness associated with osteoarthritis of the knee. According to researchers, patients treated with a continuous low-level heat wrap for eight hours reported significant benefits in pain reduction and improved flexibility of the knee, as compared to placebo and common oral pain medications such as acetaminophen and ibuprofen. The findings were presented at the 24th Annual Scientific Meeting of the American Pain Society (APS) in Boston, MA.

"With the recent warnings about the potential dangers of chronic use of oral pain medications, physicians and patients have been looking for alternative treatment options without compromising efficacy," said the study's lead author Bill McCarberg, MD, FABPM, Founder of Chronic Pain Management Program for Kaiser Permanente, San Diego, CA. "For the first time, we have clinical evidence that heat wrap therapy can significantly reduce osteoarthritis pain. The data also indicates improved range of motion a measure of knee flexibility."

The study, which consisted of 110 patients with osteoarthritis of the knee, assessed pain relief on a 5-point scale (0 = no relief and 5 = complete relief). Patients treated with the heat wrap reported a pain relief score of 2.20 ± 0.17 compared to patients who took acetaminophen and reported a score of 1.58 ± 0.25 . With respect to range-of-motion, measured using a goniometer (180 degree = fully extended knee), patients treated with the heat wrap were able to extend their knee 17 to 21 degrees as compared to patients who took ibuprofen who experienced only an 8 to 15 degree improvement.

About Osteoarthritis

Osteoarthritis (OA) affects an estimated 20.7 million Americans who are mostly female and over the age of 45¹. It is characterized by the breakdown of the joint's cartilage, the part of the joint that cushions the ends of bones. Cartilage breakdown causes bones to rub against each other, causing pain and loss of movement. The knee, which bears most of the body's weight, is the most common site of OA. Treatments for OA typically range from behavioral modifications (weight loss and exercise), heat/cold therapy to oral and intravenous medicines to reduce pain and inflammation.

About the Study

The randomized, multi-site, single blind (investigator), active, placebo-controlled, parallel design study enrolled 110 individuals with radiographic evidence of OA of the knee with at least moderate or greater pain intensity. The participants were randomized to one of five groups: Group 1 (n=44) participants wore a 104 degrees F (40°C) knee wrap (ThermaCare[®] Heat Wrap, The Procter & Gamble Company, Cincinnati, OH, **NYSE: PG**) for 8 hours continuously; Group 2 (n=21) participants were given two oral placebos; Group 3 (n=20) participants were given two 500mg tablets of acetaminophen four times a day; Group 4 (n=21) participants were given two 200mg tablets of ibuprofen three times a day; and Group 5 (n=4) participants were given an unheated knee wrap.

The primary outcome measurement was pain relief assessed during the three day treatment period with a 5-point rating scale. The secondary measurements included knee joint stiffness (rated by a NRS-101 scale), walking rate (rated by a 50ft distance) on a flat surface, a repeated sit to stand time, range of motion (rated by goniometer) and quality of life (rated by a WOMAC Osteoarthritis Index). Complete study results are available on <http://www.ampainsoc.org/abstract/2005/data/781/index.html> or upon request at 212-891-0491.

About ThermaCare®

ThermaCare is an air-activated heat wrap designed to deliver eight hours of continuous low-level heat directly to the site of pain. Each wrap contains small discs made of natural, heat-generating ingredients (iron, charcoal, table salt and water) that heat up to 104 degrees F (40°C) when exposed to oxygen in the air. ThermaCare HeatWraps(R) are available in the pain relief aisle of local retailers nationwide. P&G is currently offering a money-back guarantee to encourage consumers to experience the remarkable benefits of ThermaCare in place of their standard pain relief regimen. This heat therapy should not be used on conditions where heat may potentially damage tissue, such as in patients with diabetes, poor circulation to the hand, wrist, low back and knee or diminished sensation to pain and temperature in the hand, wrist, low back and knee. It is recommended to ask your doctor whether ThermaCare is right for you if you have diabetes, poor circulation, rheumatoid arthritis, or if you are pregnant. For more information about ThermaCare HeatWraps, visit <http://www.thermacare.com/> .

About Procter & Gamble

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¹ The Arthritis Foundation <<http://www.arthritis.org/conditions/DiseaseCenter/oa.asp>> 2005.