

# CLINICAL STUDIES

Hologenix has organized nine completed clinical studies to date, with more underway. Initially the focus was to prove that Celliant increased tissue oxygen levels by measuring transcutaneous oxygen levels (TCPO2), a practice commonly used for people suffering from hypoxia, peripheral vascular disease or any other condition that inhibits blood flow. Dr. Lawrence Lavery and Dr. Graham McClue commissioned two studies in 2003 and 2005 respectively. Both tests measured oxygen levels first among subjects with previous vascular conditions then among healthy subjects. In 2008, Hologenix commissioned a dual study with Dr. Ian Gordon measuring TCPO2 levels in healthy subjects and also a study designed to measure Celliant's effect on pain levels in subjects suffering from chronic foot pain. In 2009, a pilot study began measuring the effects of Celliant on subjects with significant sleep trouble. To further the research of the impact Celliant has on athletes we conducted a study at the University of Calgary which has been accepted for publication, a small overview is located below until publication is finalized.

## **Celliant (formerly Holofiber) Blood Flow Studies, Dr. Lawrence Lavery (2003)**

**OVERVIEW:** Celliant is a specially formulated technology that is designed to enhance oxygen levels in the body. Products with Celliant have been clinically proven to relieve pain, increase comfort and aid in healing by increasing oxygen levels and helping to regulate body temperature. Below is a summary of the results of a double blind study completed in 2003 and designed to measure the ability of Celliant to increase oxygen levels in the skin.

**STUDY BACKGROUND:** The study was conducted by Lawrence A. Lavery, DPM, MPH, an Associate Professor in the Department of Orthopedic Surgery and Rehabilitation at Loyola University Medical Center and Hines Veterans Administration Hospital in Chicago. Dr. Lavery compared 50% Celliant socks and 100% Celliant gloves to placebo products on the hands and feet of 20 diabetic patients. He measured changes in transcutaneous oxygen, a measure of oxygen in the body. The study was double blind, meaning that neither the participants nor Dr. Lavery knew which products contained Celliant until after the measurements were taken.

**RESULTS:** After less than an hour, patients wearing products with Celliant showed a statistically significant increase in transcutaneous oxygen. As shown in the figures below, this increase was observed at every ten-minute testing interval. According to Dr. Lavery, "This study provides objective evidence to support what many of us have observed or heard from people that have worn products enhanced with Celliant. It shows a significant increase in blood flow in the skin when study subjects wore the garments."

With regard to the benefits of the product, Dr. Lavery further states "An 8 to 14% improvement in oxygenation could increase circulation enough to improve wound-healing or eliminate leg pain caused by atherosclerosis or other blood flow obstructions. The significant changes observed are very compelling."

## **Celliant (formerly Holofiber) Study of Thirteen (13) Healthy Subjects, Dr. Graham McClue (2005)**

**OVERVIEW:** Celliant is a specially formulated material that is designed to enhance oxygen levels in the body. Products with Celliant have been clinically proven to relieve pain, increase comfort and aid in healing by increasing oxygen levels and helping to regulate body temperature. Below is a summary of the results of a double blind study completed in 2005 and designed to measure the ability of Celliant to increase oxygen levels in the skin (TCPO2).

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**STUDY BACKGROUND:** The study was conducted by Graham M. McClue, Ph.D., a researcher with Hyperbaric Treatment & Training Services Ltd., an independent research facility in Houston, Texas. Dr. McClue compared 50% Celliant socks and 100% Celliant gloves to placebo products on the hands and feet of 13 healthy subjects. He measured changes in transcutaneous oxygen, a measure of oxygen in the body, over a period of one hour. The study was double blind, meaning that neither the participants nor Dr. McClue knew which products contained Celliant until after measurements were taken.

**RESULTS:** The study successfully showed that patients wearing products with Celliant showed a statistically significant increase in transcutaneous oxygen. As shown in figures below, this increase was significant (10% to 24%). According to Dr. McClue, “Celliant does, in fact, increase oxygen profusion levels by 10% to 24% in a healthy non-compromised population.”

With regard to the benefits of the product, Dr. McClue further states, “Increased oxygen profusion has been shown to aid in the increase of energy. Energy produced at the cellular level will accelerate muscle tissue recovery from exercise, which is known to induce lactic acid increases, rebuild strength in muscles damaged by exercise, and also reduce the incidence of cramping, edema, and muscle fatigue post strenuous exercise in athletic conditioning.”

## **Effect of Optically Modified Polyethylene Terephthalate Fiber Socks on Chronic Foot Pain Study, Dr. Ian Gordon (2008)**

**OVERVIEW:** Celliant is a specially formulated material that is knit, woven or added to products to enhance oxygen levels in the body. Products with Celliant have been clinically proven to to enhance oxygen levels in the body. Products with Celliant have been clinically proven to relieve pain, increase comfort and aid in healing by increasing oxygen levels and helping to regulate body temperature. Below is a summary of the results of a recently completed double blind study designed to measure the ability of Celliant to reduce pain and increase comfort.

**STUDY BACKGROUND:** The study was conducted by Dr. Ian Gordon, M.D., Ph.D. at University of California Medical Center. Dr. Gordon is the Director of the University of California Wound Clinic, an Associate Clinical Professor of Surgery at the University of California, Irvine and Chief of the Vascular Surgery Section at the VA Long Beach Healthcare System as well as a member of the attending staff at the University of California Irvine Medical Center. The study was a single-center, prospective, double blind, randomized trial approved by the institutional review board. Fifty-five (55) subjects in total were enrolled, 26 with diabetic neuropathy and 29 with other causes of foot pain; 38 men and 17 women were enrolled, with an average age of 59.7 years. To be included in the study participants had to be older than 21 years of age and have persistent foot pain for at least six months prior to the study. The study has been published in the Journal of Alternative & Complimentary Medicine.

Participants in the study were asked to fill out McGill Short Form Pain Surveys—an industry accepted scale for measuring pain relief that is used in FDA trials for pain relief medications—for two consecutive weeks to measure pain and quality of life. In questions assessing pain, subjects were instructed to answer questions based solely on subjective foot pain. After completing the questionnaire the second week, subjects were given three pairs of socks in a closed container and asked to wear them exclusively for the next two weeks. One week (Week 3) and two weeks (Week 4) later they returned to again fill out the same ques-

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tionnaires. The control group received socks made from standard Comfortrel XP® polyester fiber, while the Celliant group received socks in which the bottom of the sock was modified by having Celliant incorporated into the yarn. Subjects and study personnel were blinded to the randomization, and study personnel never saw the socks given to the subjects.

**RESULTS:** All participants exhibited similar pain scores upon entry into the study. The changes between scores recorded before and after wearing socks showed improvements in both the control and Celliant groups. The fact that the control group demonstrated reduction in pain is consistent with the placebo effect often seen in studies like this one. However, significantly more reduction in pain was observed in the responses from the Celliant group than controls, based on comparisons of the median reduction in pain before and after starting treatment. Figures 1 and 2 below show 2.7x greater reduction in pain for participants wearing products enhanced with Celliant than those wearing placebo products.

## **Effect of Shirt with 42% Celliant Fiber on TCPO2 Levels and Grip Strength in Healthy Subjects, Dr. Ian Gordon (2009-2011)**

**OVERVIEW:** Celliant is a specially formulated material that is knit, woven or added to products to enhance oxygen levels in the body. Products with Celliant have been clinically proven to relieve pain, increase comfort and aid in healing by increasing oxygen levels and helping to regulate body temperature. Below is a summary of the results of a recently completed study designed to measure the ability of Celliant to increase skin oxygen levels (TCPO2).

**STUDY BACKGROUND:** The study was conducted by Dr. Ian Gordon, M.D., Ph.D. at University of California Medical Center. Dr. Gordon is the Director of the University of California Wound Clinic, an Associate Clinical Professor of Surgery at the University of California, Irvine and Chief of the Vascular Surgery Section at the VA Long Beach Healthcare System as well as a member of the attending staff at the University of California Irvine Medical Center. The study was a single-center, prospective, double blind, randomized trial approved by the institution review board. Twenty-four (51) healthy subjects were enrolled. To be included in the study, participants had to be at least 18 years of age and be in good health. The subjects wore standard polyester shirts for 90 minutes indoors in a constant temperature and indoor light environment and were asked to sit quietly in a chair. After a short rest, the procedure was continued for another 90 minutes with the subjects wearing 42% Celliant/58% polyester shirts. TCPO2 measurements were measured by standard Clarke electrodes placed on skin heated to 44°C to eliminate an increase in localized skin temperature as a possible source of increased oxygen. 17 participants had one electrode placed on their chests, 7 participants had three electrodes (two on the abdomen, one on the chest) and 27 participants had two electrodes placed on their abdomen and bicep). The TCPO2 measurements were taken at 10-minute intervals.

**RESULTS:** There was a statistically significant increase in mean TCPO2 levels associated with wearing the Celliant shirts observed at 30, 60 and 90 minute intervals, with the greatest increase, at 90 minutes, reflecting an approximate 7% overall average increase in skin oxygen levels. The increases in TCPO2 levels associated with the Celliant shirt corroborated earlier findings performed in the limbs that oxygen levels increase when socks or gloves made from Celliant fibers are worn. Given that in both trials, the transcutaneous oxygen probes were heated to 44°C and skin temperature levels did not significantly vary between the two garments, it is unlikely that the effect observed was due to increases in skin temperature causing secondary effects on skin blood flow.

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## **Pilot Sleep Study, Dr. Marcel Hungs (2009-2010)**

**OVERVIEW:** Celliant is a specially formulated material that is knit, woven or added to products to enhance oxygen levels in the body. Products with Celliant have been clinically proven to enhance oxygen levels in the body. Products with Celliant have been clinically proven to relieve pain, increase comfort and aid in healing by increasing oxygen levels and helping to regulate body temperature. Below is a summary of the results of a recently completed study designed to measure the ability of Celliant to increase skin oxygen levels (TCPO<sub>2</sub>).

**STUDY BACKGROUND:** The study began in 2009 and the trial was conducted by Dr. Marcel Hungs at the University of California, Irvine Medical Center. Dr. Hungs is the director for the Center of Sleep Medicine, an Attending Staff Physician at the VA Medical Center in Long Beach, CA, an Attending Staff Physician at the University of Irvine Medical Center. The study was a single-center, placebo controlled, double blind, cross-over pilot trial approved by the institution review board. Six (6) healthy subjects were enrolled who were suffering from chronic lower back pain causing sleep disturbances. Subjects were required to fill out studies for pain, sleep quality and additional clinical global impression scales for pain and sleep. After a two-week period of baseline readings each subject was given either a mattress cover with Celliant or a placebo mattress cover to use for the next two weeks. Then a washout period lasting one week and a second two-week period using either the Celliant or placebo mattress (whichever was not used during the first test) were administered.

**RESULTS:** Median time spent awake at night after falling asleep was reduced by 18.3 minutes. Individuals spent an average of 42 minutes less time sleeping suggesting that the sleep they received was more restful. Median sleep efficiency improved by 2.6%. Three of the six participants reported a subjective improvement of their sleep with the use of the active garment mattress cover as measured in the Clinical Global Impression scale. Two participants also reported that nocturnal back pain was better with the use of the active garment as measured in the Clinical Global Impression scale for pain. These results were encouraging and therefore the study was expanded to an additional 12 patients who will begin testing in late 2010.

## **Effect of FIR athletic apparel on oxygen consumption during exercise, Dr. Darren Stefanyshyn and Dr. Jay Worobets (2011)**

**OVERVIEW:** Far infrared (FIR) radiation ( $\approx 3-100 \mu\text{m}$ ) is considered a promising treatment modality for certain medical conditions. FIR emitting ceramic nanoparticles can be impregnated into fibers, then woven into fabrics and made into apparel. If such apparel are capable of inducing positive physiological effects, then there may be important implications when worn by athletes during exercise and/or competition. The purpose of this study was to examine whether FIR radiating athletic apparel had an effect on oxygen consumption during cycling at submaximal intensities.

## **Impacts of Subjects Socks with Application of Celliant Technical Fibers on Transcutaneous Oxygen Pressure, Dr. Li Shaojing (2012)**

**OVERVIEW:** The Test Report on the Impacts of Subject Socks with the Application of Celliant® Technical Fibers on Transcutaneous Oxygen Pressure on a Man's Foot

**STUDY BACKGROUND:** To do the preliminary study of the effects of socks that use Celliant® technical fibers provided by Qingdao ReY.S International Co., Ltd. on local transcutaneous

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Oxygen Pressure on human the foot dorsum through the clinical research before and after the wearing of the socks in a randomized, double-blind, and controlled way and on improving human body's

**RESULTS:** The participants wear subjects socks and then researchers monitor the local transcutaneous oxygen partial pressure at foot dorsum for 45 minutes. The result is (73.28ffl14.93)mmHg. The participants wear control socks and then researchers monitor the local transcutaneous oxygen partial pressure at foot dorsum for 45 minutes. The result is 62.60ffl15.69 mmHg (Table 1). Homogeneity of variance of local transcutaneous oxygen partial pressure at foot dorsum of two kinds of socks is shown (Table 2). Further variance analysis shows that compared with control socks, subjects socks' impacts on local transcutaneous oxygen partial pressure at foot dorsum has significant difference (P 0.01, Table 3). This demonstrates that compared with control socks, subjects socks within the monitoring period, can better improve the local transcutaneous oxygen partial pressure at foot dorsum.