

WHITE PAPER FORMAT

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INTRODUCTION:

The purpose of this paper is to discuss the use of capsaicin impregnated compression socks. These multipurpose socks are designed to alleviate two common lower extremity problems: foot pain and leg swelling. The socks decrease foot and ankle pain through the use of active embedded ingredients and decrease lower leg and foot edema through graduated compression.

BACKGROUND:

Compression therapy has been used for decades to ensure the proper flow of the circulatory system. Compression works by countering the negative outcomes of edema: venous return of blood and lymphatic drainage of fluid to the heart. In the lower extremity circulatory system, veins carry blood from the feet and deliver the blood to the heart. In order for blood to flow against gravity, veins have one-way valves. As we age, blood has a difficult time flow from the feet upstream towards the heart causing a delay in circulation. Heredity, weight gain, pregnancy, hormones, trauma, and other risk factors will cause a loss of function valves. Instead of blood flowing upwards towards the heart, the blood pools in the lower leg. The blood pooling leads to swelling which causes tired, aching and heaviness in the legs.

One other way fluid is carried out of the legs and returned centrally is through the lymphatic system. Lymph nodes act as reservoirs for fluid waste that is collected throughout the body. This liquid byproduct moves upwards along the lymphatic system. Surgery, trauma, and disease states can cause the lymph nodes to poorly function and the fluid begins to collect. Because we stand and walk, the gravitational force of the liquid will be towards the ground. When the lymph nodes are not functioning, fluid collects in the lower legs and feet. Compression therapy has helped ensure a one-way flow of the fluid by assisting to “milk” the fluid back up to the visceral system. Graduated compression allows a more evenly distribution of fluid flow.

Pain is a physiologic entity that is a result of an underlying alteration in homeostasis. With a disruption in anatomy or physiology in the body, there is a response called pain. There are endless conditions that lead to pain. One component of pain is nerve pain. Nerves can be affected by trauma, side effects of medication, disease states such as diabetes, spine and back problems, genetic abnormalities, alcoholism, and many other conditions. The damaged nerve endings cause neuropathy, a loss of function of the nerves. This is a painful condition leading to burning, stabbing, shooting pains. Traditional treatment options include topical ointments, oral medications, physical therapy, spinal cord injection therapy, and nerve decompressions. One common topical agent that aids to calm the painful nerve process is capsaicin. Capsaicin is a by-product of the chili pepper. When capsaicin comes in contact with human tissue it causes a

burning sensation which in turn initiates the process of defunctionalization of the nerve stimulus that caused the pain sensation in the first place. Topical capsaicin has been widely used in painful foot nerve conditions such as diabetic neuropathy.

In an effort to support the stated objectives of Nufabrx Compression Socks with Capsaicin the author conducted a single-center, active control, prospective trial. The objective was to identify qualified subjects who would meet the criteria for inclusion and provide feedback regarding the use of Nufabrx Compression Socks. It was hypothesized that the use of Nufabrx Compression Socks with Capsaicin would decrease Foot and Ankle Pain Analog Scales and Improve Quality of Life Scores thus allowing people to improve their healthy, active lifestyle. Primary objectives included a decrease in the amount of lower leg and foot edema and a decrease in foot pain due to heel pain, neuropathy, tendonitis, and arthritis. With a successful and positive primary objective, a secondary objective was established. The secondary goal was to see how easy it is to just wear a sock instead of having to apply daily topical medication or take oral medication for their pain and swelling. A garment is easy to apply and there are fewer potential side effects. Typically, people applying a topical medication tend to be proactive when it is first prescribed but when it is actively incorporated into their daily routine the use of medication becomes inconsistent.

The criteria for inclusion was defined as a patient who has edema and foot pain. Edema will be evaluated on a Grading Edema Scale of 0-4. Pain will be through a foot and ankle pain analog scale. Any person meeting inclusion/ exclusion criteria that were interested in the study and could commit to the follow-up and completion of the study were eligible for enrollment.

Patients 20-75 years of age that have a foot and ankle disability index of at least 55 (Based on the majority of people having Moderate Difficulty in weight-bearing living) and have a clinical significance of foot pain as evaluated by the principal investigator creating a standard analysis.

- Enrollment Period of 3 months to include advertising for prospects and recommending the study to existing patient base/ new patients.
- Enrollment Paperwork and Inclusion criteria and clinical examination
- Enrollment of patients through internal patient stream and local newspaper advertisement (if needed)

Specific exclusions were considered for individuals being treated for cancer, skin infections on the foot or lower leg, unhealed or acute foot fractures, pregnant or breastfeeding patients, patients starting a new pain management regimen for pain anywhere in the body and patients on an acute steroid pack.

Twenty subjects were included in this study. This provides a good evaluation for

1. Evaluate the efficacy of Nufabrx Compression Sock with Capsaicin to aid in pain relief.
2. Evaluate the improvement in quality of life by the use of Nufabrx Compression Sock with Capsaicin.

3. Use 20 patients as an initial quantitative sample of the total population in the statistical analysis.

DISCUSSION:

Overall the findings and feedback from the subjects were positive. During the enrollment period, 20 subjects were enrolled. Of the 20 subjects enrolled 16 of them completed the study. The first subject developed a contact dermatitis that resolved immediately. The second individual dropped out after two weeks stating that she could not meet the study criteria of wearing the socks at least three days a week for eight hours a day. The third subject had to stop the study as she needed leg surgery. The fourth subject discontinued the study as it was too hot over the summer and she did not want to participate.

Subjects were dispensed the socks with complete instructions. In order to enter the study subjects must wear the socks at least 8 hours a day for a minimum of three days per week. Subjects were also required to fill out two questionnaires to evaluate the benefit of the socks and support the hypothesis.

The Foot and Ankle Orthopedic Quality of Life Scale (FAOQ) is used to determine if the subject has had an improvement in their quality of life in regards to activity level and pain levels. Pre-study FAOQ scores were 56.125 and post-study scores were 50.8125 with an average decrease in score of 5.3125 points showing an improvement of the quality of life.

The Foot and Ankle Disability Index Score (FADI) is used to evaluate the functional limitations of people with various foot and ankle conditions. This is a questionnaire completed by the study subjects and was taken before enrollment, two weeks after enrollment, six weeks and twelve weeks after enrollment. The pre-FADI score was 70.6875 and the post-FADI average score was 77.375 with an improvement of 6.69 points and an overall decrease in functional limitations of subjects.

Overall there was an extremely positive response from the subjects who wore the socks and felt relief. Direct feedback included the following:

One woman experienced relief from her neuropathy pain and swelling and stated, "since wearing the socks I have felt less foot pain and pressure allowing me to be more active."

Another subject indicated that she far preferred putting on a pair of socks which was much easier and cleaner than having to apply a topical cream. "The medicine ended up sitting on my nightstand but having the medication built into the sock made it much easier and cleaner." She also stated that she felt more aware of the benefits of Capsaicin by having it directly built into the socks.

A subject stated that she could walk more during the day and did not experience the amount of pain she would normally feel by the end of the day.

Another subject who is a chef and stands on his feet for ten hours a day said, “ I can definitely stand longer and have less pain and fatigue while working.”

Finally, one gentleman who works on his feet as an emcee stated “they give a feeling of support, almost a tightness that has helped eliminate the cramping that I get in my feet. It feels like I’m walking with a cradle on each foot.”

CONCLUSION:

Nufabrx socks for compression and pain therapy works on two physiological components of edema and pain. The data from the study supported this claim and the findings by having an overall improvement of pain scale scores and a decrease in the disability index scores showing that WEARING NUFABRX SOCKS CAN HELP TO DECREASE EDEMA AND PAIN THROUGH THEIR PATENTED TECHNOLOGY OF COMPRESSION AND CAPSAICIN. Nufabrx Compression Socks with Capsaicin are designed to allow a lower leg compression garment while providing pain relief through the built-in medication technology. These findings were supported by the patients who had the benefits of wearing them during the trial.

REFERENCES:

1. <https://www.ncbi.nlm.nih.gov/pubmed/?term=capsaicin+neuropathy>
2. Martin, R. L., R. G. Burdett, and J. J. Irrgang. “Development of the foot and ankle disability index (FADI).” *J Orthop Sports Phys Ther* 29.1 (1999): A32-A33.
3. Hale, Sheri A., and Jay Hertel. “Reliability and sensitivity of the Foot and Ankle Disability Index in subjects with chronic ankle instability.” *Journal of Athletic training* 40.1 (2005): 35.
4. Dekker, Travis J., et al. “The Value of Motion: Patient-Reported Outcome Measures Are Correlated With Range of Motion in Total Ankle Replacement.” *Foot & ankle specialist* (2017): 1938640017750258.

“Nufabrx is a proprietary biomaterial platform that embeds active ingredients into fabrics, and these active ingredients can be programmed to respond to the body for predictable, effective, and long-lasting dermal release. “

