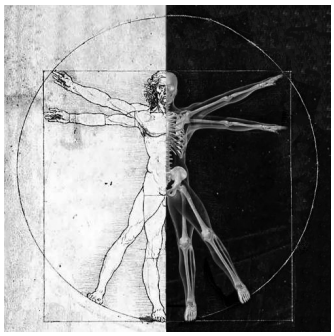

CENTER FOR CLINICAL BIOMECHANICS

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White Paper of FS6 for ING Source, Inc.

Background

Many foot problems produce inflammation and swelling (edema) related to increased fluid in the area that leads to discomfort and pain. People who suffer from Plantar Fasciitis and other problems often experience pain on rising, after prolonged rest, such as in the morning. There are very few non-pharmacological treatments for the edema causing the pain and those that are currently available are often bulky and cumbersome to wear. The FS6 Compression Foot Sleeve addresses this need by incorporating FDA approved technology, creating 6 varying levels of medical grade compression around the foot and ankle in a lightweight comfortable support sleeve.

Product Concept and Innovation

Using the same manufacturing process for medical compression stockings, six different zones with varying levels of compression were designed into this Foot Sleeve to strengthen and support the natural foot structures. The end garment zones on most tight compression garments are the most troublesome due to the sudden and abrupt increase in pressure causing an "edge" effect that leads to increased edema where the garment stops. The FS6 zones 1 and 6 are flat and smooth allowing for gradual gentle compression. Zone 1 stops just short of the ball of the foot allowing for expansion of the toes. Zone 2 corresponds to the area where the arch begins to rise and produces a graduated moderate compression as the arch takes shape. Zone 3 corresponds to the arch area producing a firm compression allowing for stabilization and slight lift & stretch to the structure of the arch. Zone 4 has a graduated return to moderate compression with a change in material composition allowing for the anatomical curves of the heel as the foot changes to the ankle. Material composition changes again at zone 5 returning to firm compression for the structures around the lower ankle/Achilles. The FS6 is designed to be worn comfortably under socks while active to provide extra support or at night while sleeping. Many runners wear them with minimalist style shoes to provide needed support while leaving the toes open.

Key Research Supported Findings

The FS6 has been fully lab tested to industry standards using specifications for graduated compression hosiery documenting the graduated compression zones and garment stiffness. (BS 6612:1985.). Garments are tested on a CMD100 Compression Tester for compliance to US FDA standards. This test equipment is calibrated to the British Standard for medical stockings.

In addition human subject research was conducted with each subject ambulating at normal walking speeds while wearing an electronic pressure sensitive film under the FS6 garment and a standard sock as control. (F-Scan, MA) Dynamically in the FS6 hose zone 2 had a 12(±4) % more compression than the control hose, while zone 3 had 33(±15) % more compression than the standard hose. Zone 4 had similar results to zone 2 with 8(±4) % more compression than the control. Zones 1 and 6 did not produce enough pressure to be measurable with this system and zone 5 proved too difficult to measure due to the transition of the foot to the ankle. The center of pressure trace was more curvilinear in the FS6 hose than the standard suggesting a more normal gait pattern.

Current research into external braces systems is beginning to focus on the role of neuromuscular adaptation. Neuromuscular adaptation is often described as the role that stimulation (compression in this case) of the nerve fibers in the joint and ligaments has on sensation and function of the muscles involved with the joint segment. This research suggests that wearing devices such as the FS6 produces a heightened neurological stimulation that provides a feedback mechanism to the muscles allowing them to adapt more efficiently near their optimal functioning position. With proper function of the muscles, the joint segments would function at a level reducing any excessive forces across the tissues allowing for normal healing. (Ref) Figure 1.

Summary

The FS6 compression foot sleeve provides graduated compression across the arch, foot and ankle at a level to reduce edema and the pain associated with conditions such as Plantar Fasciitis, Heel Spurs, and other related conditions. In addition the dynamic gait adaptation seen with the FS6 sleeves suggests that it may be producing a neuromuscular adaptation to improve foot function.

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