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The Validation of an Innovative Hallux Valgus Sock for Hallux Valgus Deformities

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Abstract

Introduction: The purpose of the present study is to test the hypothesis that an innovative Hallux Valgus [HAV] sock reduces HAV angle and restores a more normal foot function in persons living with Hallux Valgus.

Methodology: A prospective, same-subject, pre-post experimental study was conducted on twelve participants presenting with HAV. Laboratory tests utilizing electromyography in order to investigate foot function during gait with and without wearing the HV sock, lab tests utilizing foot pressure mapping in order to investigate plantar pressure distribution during gait with and without wearing the HV sock and laboratory photographic measurement of hallux valgus angle were taken.

Results: The innovative hallux valgus sock reduced the peak plantar pressure on most anatomical landmarks, including the first toe/hallux, first metatarsal head, second to fourth metatarsal head, however, no significant difference in pressure was noted on the fifth metatarsal head in both right and left foot. Hallux valgus angle reduction was evident in both left and right angle for all subjects. Finally, EMG results show that 50% of the patients showed an increase in the muscle function during walking.

Conclusion: The innovative hallux valgus sock reduced the peak plantar pressure on most anatomical landmarks, it reduced the hallux valgus angle and muscle function during walking was also increased. Apart from being user-friendly and low-cost, this sock is especially designed to be easy to use and unobtrusive to ensure patients daily compliance. The HAV sock is innovative in nature, since no other sock with such properties exist to date. This offers a novel alternative to clinicians and patients in the management of HAV.

Keywords: Hallux valgus; medical devices; conservative treatment; hallux valgus sock

Introduction

Hallux valgus (HV) is a progressive forefoot deformity, with the great toe deviating laterally at the metatarsophalangeal (MTP) joint. This condition may as well cause the prominence of the first metatarsal head along with overlapping of the first and second toes (Sarwark, 2010; Kim et al 2013).

Currently, available treatments for HV can be either invasive or conservative. To date no consensus has been reached on the best conservative treatment for HAV (Ying et al 2021). With the need for an alternative method to surgery in the treatment of hallux valgus, coinciding with the lack of unified support within literature of non-invasive treatments, an inexpensive, accessible new method of treating HV is necessary.

The Hallux Valgus Sock [Figure 1], designed by the researcher to manage HAV, and which was laboratory tested in this study, contains an extra elastane fiber towards the direction of the abductor hallucis longus muscle. This is a highly advanced technical fabric with a soft and natural feel. It can be used for each patient separately, because it takes the form of the foot and its thickness is 0,3 mm so very easily to be fitted in any shoes. It aims to strengthen the abductor hallucis muscle, reducing hallux angle and improving foot function in HAV patients.

The purpose of the present study is to test the hypothesis that an innovative HAV sock reduces HAV angle and restores a more normal foot function in persons living with Hallux Valgus. The results from this study could provide further insights into the effects of HAV on foot function, pain relief and quality of life and could provide persons living with HAV with a viable alternative to potentially unwanted surgical interventions.

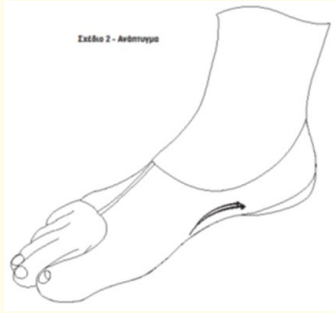

Figure 1: Innovative HAV Sock.

Methodology

A prospective, same-subject, pre-post experimental study aimed to investigate the effect of wearing/not-wearing the hallux valgus sock was conducted. This research was divided into 3 separate, pilot laboratory-based studies, held at the Clinical Biomechanics Laboratory, Faculty of Health Sciences, at a local university, in order to investigate the physiological effects while wearing the innovative HV sock. These studies comprised:

1. lab tests utilizing electromyography in order to investigate foot function during gait with and without wearing the HV sock.
2. lab tests utilizing foot pressure mapping in order to investigate plantar pressure distribution during gait with and without wearing the HV sock.
3. Laboratory photographic measurement of hallux valgus angle.

Twelve healthy, adult participants, having no systemic, musculoskeletal or neurological conditions and able to walk unaided were recruited. Participants presenting with Hallux valgus and able to walk unaided were included. Participants presenting with systemic or musculoskeletal conditions which could alter kinetics and kinematics during gait, such as neuropathy, Parkinsons, cerebral palsy amongst others were excluded. Participants who walked with an aid, had a history of hallux valgus surgery, sustained any major or minor amputation and had angiopathy were excluded. Participants who fitted the inclusion/exclusion criteria were recruited after giving informed consent. A Participant assessment sheet was devised to document all the necessary demographic, biomechanical examination results and anthropometric measurements.

All participants were biomechanically tested with the following examinations to check if there was any biomechanical restriction within the foot and angle: Ankle Range of motion (Purcell et al, 2009; Shi et al, 2023), midtarsal joint, subtalar joint, Jack's test, Hubsher maneuvre (Halstead & Redmond, 2006), hallux 1st MPJ, 1st ray, Manchester scale (Menz et al, 2010) and Foot Posture Index (Morrison & Ferrari, 2006) were performed to the patients before the laboratory testing.

Laboratory photographic measurement of hallux valgus angle

A digital photograph was taken for each participant of the Hallux valgus angle whilst wearing and not wearing the hallux valgus sock. Any differences in angles changes were recorded [Figure 2].

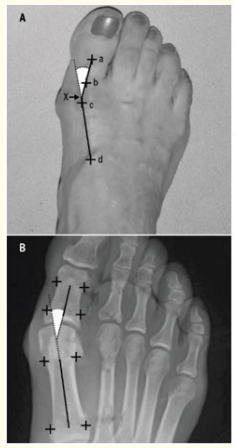

Figure 2: Hallux valgus angle.

Lab tests utilizing foot pressure mapping in order to investigate plantar pressure distribution during gait with and without wearing the HV sock.

Participants were instructed to walk barefoot with and without the hallux sock at a self-selected speed using the two-step method (Chevalier et al, 2010; van der Leeden et al, 2004; McPoil et al, 1999) over the Tekscan HR Mat system (Tekscan Inc, Boston, USA), where a period of acclimatization was advised so as to practice placing one foot completely on the mat without targeting. This was followed by recording five trials. Plantar pressure analysis was performed using a pressure mapping platform, where pressure time integral data were obtained. Each foot in every trial was masked and divided into four anatomical landmarks, including the first toe, first metatarsal head, second to fourth metatarsal head and the fifth metatarsal head as per standard protocol. The analysed plantar pressure results from the five correct trials were averaged and recorded on Microsoft Excel.

EMG Sensors

A Delsys wireless EMG system was utilized to capture muscle activation levels of the abductor hallucis longus muscle. Participants were instructed to walk barefoot with and without the sock on a 7-meter corridor utilizing electromyography in order to investigate the activation of the abductor hallucis longus and the hallux valgus angles changes during walking [Figure 3]. After proper skin preparation using 70% alcohol, electrode EMG sensors were also placed according to SENIAM guidelines (www.seniam.org) on the muscle belly of abductor hallucis longus, adductor hallucis longus, flexor hallucis brevis and extensor hallucis longus muscles. by recording the muscle activity during gait, initially with each subject not wearing the hallux valgus sock, then with the hallux valgus sock on. For analysis purposes, 4 trials were done for each condition, making a total of 8 trials per subject. This would allow for any aberrant data to be discarded and would also allow for a mean activation value per instance to be taken. EMG data was recorded in Vicon Nexus software, then exported to Microsoft Exel whereby the activation levels both pre- and post-intervention were plotted for each foot.

Figure 3: Delsys miniature EMG sensor.

Results

Demographic Data

All 12 subjects (10 female, 2 male) (mean 55 years, 72.4 kg and 159 cm) voluntarily took part in the study. The severity of hallux valgus varied from mild to severe hallux valgus. Five patients presented with a grade B hallux valgus on the Manchester Scale, 5 participants presented with a grade C, 1 participant presented with a grade A and 1 participant presented with a grade D score on the right foot according to the Manchester scale. Seven participants had a grade B hallux valgus, 3 grade C, 1 grade A and 1 grade D score on the left foot according to the Manchester scale.

The Foot Posture Index [FPI] on the right foot was recorded as neutral for all participants and slightly pronated for the left foot respectively.

Most of the participants [n= 11] were found to be dorsiflexed on ankle range of motion on both feet and only one participant had sight limitation.

The range of motion of the midtarsal joint for most of participants was normal (8 participants for both feet) and 4 participants were hypermobile on both feet.

The range of motion of the subtalar joint was normal for the 11 participants for both feet and one participant was hypermobile on both feet. Jack test was normal for the 11 participants and restricted for only one participants for both feet. The Hubscher Manoeuvre test showed that eight participants were normal, four restricted on the right foot, seven participants were normal and five restricted on the left foot. The range of motion of the 1st MPJ was 9 participants normal, 3 limited on the right foot, 11 normal and 1 limited on the left foot.

Finally, the range of motion of the 1st ray was normal for the 9 participants on the right foot and 3 participants were limited on the left foot.

Statistical Analysis

Plantar Pressure Measurements

In order to analyze distribution of data for peak plantar pressure under the hallux before (pre-) and after (post-) use of the Hallux Valgus Sock, the Shapiro-Wilk test was employed. Since data was found to be parametric the paired sample T-Test was employed. Results showed a reduction in peak plantar pressure upon use of the sock in most of the subjects at both left and right hallux as shown below in figure 4 [p-value <0.05]. The mean pressure of 142.71 was reduced to 95.5083KPa upon using the HAV Sock. Furthermore, a p-value <0.001, with significant reduction in mean pressures of 151.2658 reduced to 103.1033KPa upon using the HAV Sock.

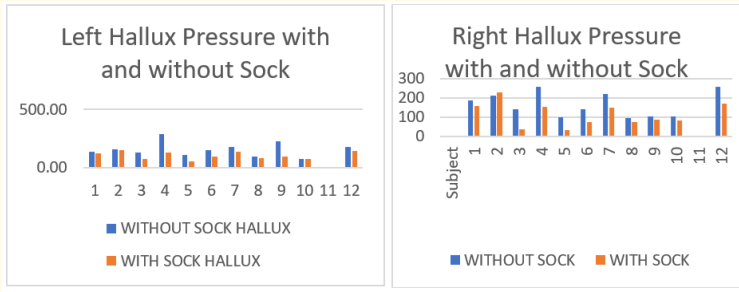

Figure 4: Denotes pressure at the right and left hallux before and after the use of sock, clearly depicting the reduction in peak plantar pressure upon use of the sock in most of the subjects.

Results also showed a reduction in peak plantar pressure upon use of the sock in most of the subjects at both left and right first MPJ as shown in figure 5, since the mean pressure of 69.3167 was reduced to 53,783KPa upon using the HAV Sock (left) and the mean pressure of 87.657 was reduced to 57.998KPa upon using the HAV Sock (right), resulting in a p-value <0.05.

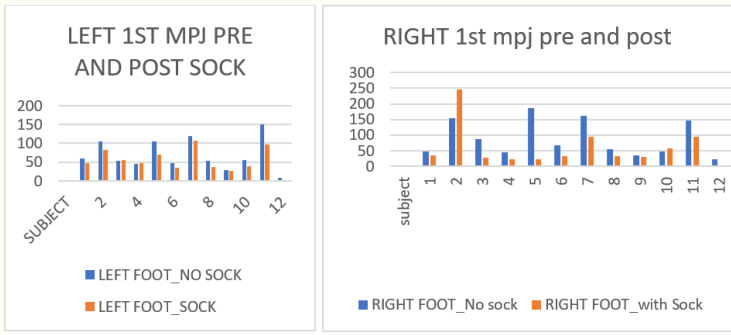

Figure 5: Denotes pressure at left and right 1st MPJ before and after the use of sock, clearly depicting the reduction in peak plantar pressure upon use of the sock in most of the subjects.

The paired-sample T-test for left 2-4th MPJ resulted in significant reduction since the mean pressure of 93.7121 was reduced to 76.5642KPa upon using the HAV Sock. Similar were the results for right 2-4th MPJ, which resulted in significant reduction, since the mean pressure of 92.9800 was reduced to 75.1133 KPa upon using the HAV Sock. [Figure 6].

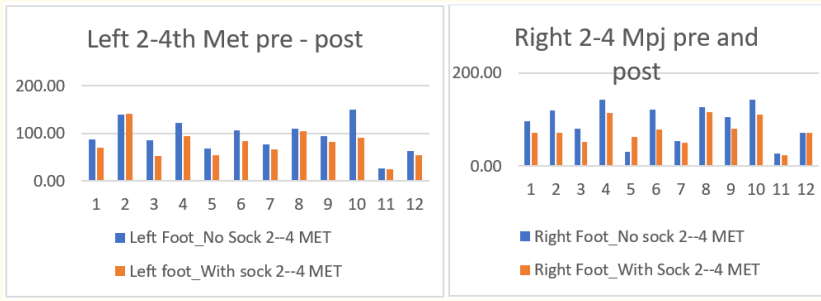

Figure 6: Denotes pressure at Left and right 2-4th met before and after the use of sock, clearly depicting the reduction in peak plantar pressure upon use of the sock in most of the subjects.

Paired-sample T-test resulted in a p-value of 0.479, which signifies a non-significant difference in peak plantar pressure at both 5th MPJ's. However, the non-significant result could be due to the small sample size since a difference in mean pressures was noted - there was a mean difference from 60 KPa (without the sock) reduced to 46KPa (with the sock) in the left foot. [Figure 7].

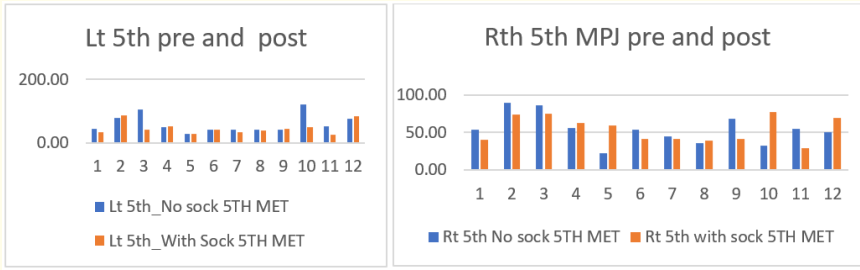

Figure 7: Denotes pressure at left and right 5st MPJ before and after the use of sock.

Angle measurements using photography

Another hypothesis for this study was that the innovative corrective sock would alter the angle of the hallux from the forefoot. As seen below the results regarding angle measurements showed a mean decrease in angle of 4.19. This reduction was evident in both left and right angle for all subjects [Figure 8].

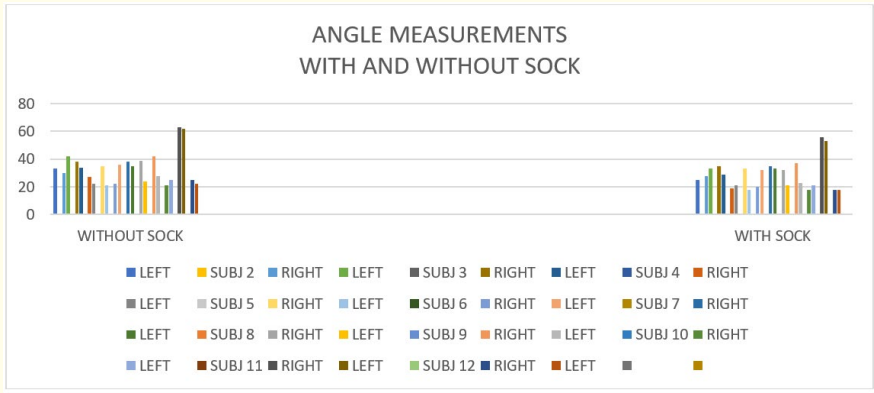

Figure 8: Angle changes of the hallux valgus with and without the hallux valgus sock using photography.

EMG Data results

Another hypothesis was that the corrective sock would increase the abductor hallucis function. Preliminary results show that the hallux valgus sock increased the movement of the abductor halluces longus muscle in 50% of the feet studied. In the other 50%, activation of this muscle remained constant. At this stage, it is being hypothesized that the hallux valgus sock can have a beneficial increase in muscle activation, however this needs to be researched carefully. The hypothesis is that the hallux valgus sock strengthens the abductor halluces muscle in some patients, thus controlling the movement of the 1st ray and reducing the displacement of the hallux laterally. The results shows that a minimum of 50% of the patients showed an increase in the muscle function observing the EMG data during walking. Figure 9 clearly demonstrates the typical increase in muscle activation whilst subject was wearing the hallux valgus sock.

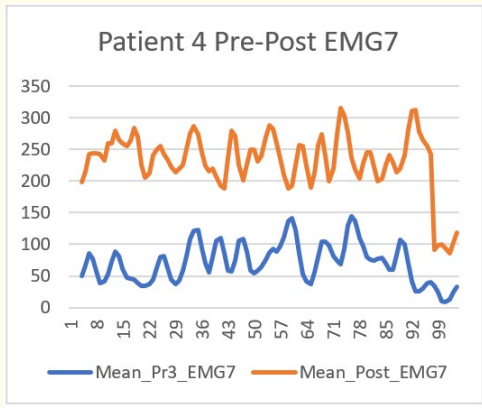

Figure 9: Sample EMG Data, showing increased activation whilst wearing the hallux valgus sock.

Discussion

The purpose of the present study was to test the hypothesis that an innovative HAV sock reduces HAV angle, reduces the maximum pressure on various anatomical landmarks of the foot and strengthens the abductor halluces longus muscle.

The laboratory studies showed a significant difference in pressure reduction at the 1st Hallux, 1st MPJ and on 2-4th MPJ's on the foot; however, no significant difference was found on the 5th MPJ by wearing the hallux valgus sock. The hallux sock was designed to reduce pressure mostly on these joints, since it controls the 1st ray movement so that the maximum pressure is transferred equally to the whole plantar area of the foot. Thus, this could have been the reason for no changes of pressure on the 5th MPJ. The value when using the hallux valgus sock is that it helps to adduct the 1st MPJ so the maximum pressure is transferred equally to the lateral side of the foot. To date, up to the knowledge of the author no other study has been conducted, which has evaluated with great detail a specific treatment for hallux valgus and evaluated its reduction in pressure on specific areas in the foot.

The second hypothesis of this study was that the hallux valgus sock would alter the angle of the hallux valgus. In order to determine this, a photo of the foot was taken with and without the hallux sock. An iOS application (angle meter 360 by Alexey Kozlov) was used to measure the hallux angle from the photo. This application was validated by measuring the angle with the application and with a protractor and the angle was exactly the same by using both ways. Results from this study found that the angle was reduced in most of the participants while wearing the hallux valgus sock. The reason behind this finding could be the fact that the sock was designed to strengthen the abductor halluces longus muscle to reduce the HV. Kim et al. (2015) showed that strengthening of the muscle reduces the hallux valgus angle, supporting the rationale behind the sock.

The third hypothesis was that the Hallux valgus sock could increase the function of the abductor hallucis longus, which it did in 50% of the subjects studied. According to the results of the study, it may be stated that the use of the hallux valgus sock can be effective to control the function of the 1st ray and reduce the display hallux laterally.

Our results are congruent to the study conducted by Abdalbary (2018) who reported further improvement in all measurements for patients treated with 3 months of foot mobilization and exercise along with a toe separator, when compared to those who did not receive any intervention, who experienced less improvement in outcome measures. Additional research also confirms improvement of the hallux function by exercises and taping (Bayar et al, 2011; Schmitt et al 2019). Formosa et al. (2017) conducted a time series, quasi-experimental, same-subject design study, the aim of which was to determine the effect of a taping technique on the quality of life in patients presenting with hallux abducto valgus deformity, where the authors reported an improvement in managing hallux abducto valgus resulting in a better quality of life experienced by participants.

Although study results are similar to each other, the present study was different in that the measurements were taken using objective measurements with an EMG and other laboratory technologies and tests. The measurements of the EMG would show the improvement of the muscle function of the Abductor halluces longus by using the hallux valgus sock. Results from our study demonstrated that 50% of the participants had an increase in muscle activation when using the hallux valgus sock. Our laboratory studies also confirm the value of wearing the hallux valgus sock, which may help to increase muscle activation and control the 1st ray during walking. In those subjects where no increase in muscle activation was noted, the data will be further analysed as this could have been affected by a number of factors, such as incorrect placement of the EMG sensors and rigidity of the hallux in the transverse plane, which could have prevented such muscle activation. The area of EMG studies of the abductor hallucis longus in itself will open up new possibilities for additional research to be conducted in this area, in which scientific literature is lacking.

Conclusion

Apart from being user-friendly and low-cost, this medical device is especially designed to be easy to use and unobtrusive to ensure patients daily compliance. The HAV sock is innovative in nature since no other sock with such properties exist to date. This offers a novel alternative to clinicians and patients in the management of HAV.

Statements and Declarations

The authors have nothing to declare. All authors contributed to the study conception and design. Material preparation was performed by E. Arvanitakis. The first draft of the manuscript was written by E. Arvanitakis and all authors commented on previous ver-

sions of the manuscript. All authors read and approved the final manuscript.

Competing Interests and Funding

No competing interests and no funding was received.

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